Human Fertilisation & Embryology Authority

Authority meeting - agenda

09 May 2018, Church House, Deans Yard, Westminster, London, SW1P 3NZ

Agenda item	Time
1. Welcome, apologies and declaration of interests	1.00pm
2. Minutes of 14 March 2018 **HFEA (09/05/18) 877** For decision	1.05pm
3. Chair's report (verbal)	1.10pm
4. Chief Executive's report (verbal)	1.20pm
5. Committee chairs' reports (verbal) Statutory Approvals Committee PGD Explanatory Note **HFEA (09/05/18) 878** For decision	1.30pm
6. Performance report **HFEA (09/05/18) 879** For information	1.45pm
7. Strategic risk register **HFEA (09/05/18) 880** For information	2.15pm
8. Treatment add ons (presentation) For information	2.35pm
Break	**2.55pm**
9. Code of practice **HFEA (09/05/18) 881** For information	3.05pm
10. Patient survey (presentation) For information	3.20pm
11. Any other business	3.50pm
12. Close	3.55pm

Minutes of Authority meeting 14 March 2018

Strategic delivery:	☐ Safe, ethical effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (09/05/18) 877
Meeting date	9 May 2018
Author	Helen Crutcher – Risk and Business Planning Manager
Output:	
For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	☒ Low ☐ Medium ☐ High
Annexes	

Minutes of the Authority meeting on 14 March 2018 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire (Chair until item 10) Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore (Chair for items 11-13) Bobbie Farsides Ruth Wilde
Apologies	Anita Bharucha	Andy Greenfield
Observers	Kim Hayes (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Nick Jones Richard Sydee Clare Ettinghausen Catherine Drennan Paula Robinson	Caylin Joski-Jethi Helen Crutcher Yuba Bessaoud Niamh Marren Chris Hall

Members

There were 9 members at the meeting, 5 lay members and 4 professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the second meeting of 2018. As with previous meetings, it was audio-recorded and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.

1.2. Apologies were received from Andy Greenfield and Anita Bharucha.

1.3. Declarations of interest were made by:

- Anthony Rutherford (Clinician at a licensed centre)
- Yacoub Khalaf (Clinician and Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 24 January 2018

2.1. Members agreed the minutes of the meeting held on 24 January 2018, subject to a minor amendment to be submitted by the member after the meeting, for signature by the Chair of the meeting.

3. Chair's report

3.1. The Chair said that the Annual Conference would take place the next day. It would mark two important medical anniversaries: 2018 was 40 years since the birth of the first IVF baby, Louise Brown and 70 years since the establishment of the NHS. The Chair noted that more information about the annual conference would be provided by the Director of Strategy and Corporate Affairs under the Performance Report later in the meeting.

3.2. The Chair provided members with a summary of events that she attended since the last Authority meeting in January:

- On 29 January 2018 the Chair attended the HFEA All Staff Away Day which was a useful opportunity to meet staff outside of the office and to commend them on the great work they do.
- On 5 February the Chair attended the SCAAC meeting. Three key items were discussed:
    - Regulation of embryo culture media
    - Review of novel process applications
    - Prioritisation of issues identified during the horizon scanning process
- On 20 February, the Chair and Chief Executive met with Parliamentary Under-Secretary (Department of Health and Social Care), Jackie Doyle Price. This was a useful opportunity to discuss the shape of the fertility sector in general, and in particular:
    - Patient safety.
    - Recent service development.
    - Working with the NHS: improving commissioning.
    - Research and innovation with an emphasis on mitochondrial donation and genome editing.

4. Chief Executive's report

4.1. The Chief Executive reported on the All Staff Away Day on 29 January. This was an opportunity for staff to consider the results of a recent staff survey and agree how they wished to develop as an organisation. Feedback suggested that the day was well received and a number of important commitments were made on:

- finding more time for learning and development
- finding ways to better recognise staff contributions within very tight public-sector wage constraints
- starting work on HFEA culture, which was particularly important given a significant proportion of staff were relatively new.

4.2. The Chief Executive noted that the Authority would receive updates on progress towards these goals, including increased reporting on HR data to the Audit and Governance Committee.

4.3. The Chief Executive reported that in February, he took part in two of the four Code of Practice workshops that were run across the country. The Director of Strategy and Corporate Affairs would provide an overview of the workshops later in the meeting. The Chief Executive recorded his thanks to all the staff that participated and noted the positive feedback from conversations

with clinic staff who attended, all of whom thought the HFEA had become much more open as an organisation over the past few years.

4.4. On 6 March the Chief Executive attended the Audit and Governance Committee meeting.

Press coverage

Trends report

4.5. The Chief Executive noted that the Fertility Trends and Figures report had been published that morning and simultaneously released to the press. A further item was included later in the meeting to discuss this in detail.

Ovarian Hyperstimulation Syndrome (OHSS)

4.6. The Chief Executive noted that that there had been some sporadic interest in the OHSS issue which was initially raised in 2017. A recent Guardian article had covered the issue again, reporting that some in the sector were arguing that clinics should compensate the NHS for OHSS admissions.

4.7. The HFEA position on this was clear: investigations had revealed no evidence of under-reporting of OHSS by clinics, and the evidence to date pointed to it being largely a reporting issue in hospitals, where OHSS was often the default coding option for fertility-related admissions.

4.8. The Chief Executive stressed that the HFEA took any risk of harm to patients very seriously, and continued to work with the BFS, RCOG and others to consider ways to provide clearer guidance to clinics in both handling and reporting OHSS.

Genome editing public dialogues

4.9. Members were informed that several studies had been published on public attitudes to genome editing. These had not yet involved the HFEA directly. A number of these had been picked up in the press.

4.10. Following a 2017 Progress Educational Trust and Genetic Alliance study, and ahead of a Nuffield report, the Royal Society had published a review into public attitudes. This had been based on a number of focus group sessions and an online survey of around 2,000 people. The results were reported in the press and included some interesting findings, such as a majority of people being in favour of using such treatments for the eradication of illness, but not for human enhancement.

4.11. The Chief Executive stressed that genome editing is currently illegal in treatment in the UK, though allowable in research, but this debate showed no signs of going away.

4.12. The Chair commented that it was important for the HFEA to undertake further work to understand the issues around OHSS and this was something that the organisation cared about and would continue to focus on.

5. Committee Chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 25 January and 22 February. At the January meeting it considered six preimplantation genetic diagnosis (PGD) applications and two mitochondrial donation patient applications. The minutes for the mitochondrial donation patient applications had not yet been published. All of the PGD conditions were approved. The reason for the delay to mitochondrial donation minutes concerned

the need to balance the interests of the patient, and the need to protect their confidentiality, with the requirement to publish sufficient information to demonstrate good decision making. At the February meeting, the committee considered one mitochondrial donation application, one PGD application and one request for Special Directions. The PGD condition was approved. The minutes for the mitochondrial donation application have not been published. The application for Special Directions was also approved.

5.2. Members asked for information about the deliberations of the committee. The Chair of SAC indicated that items could sometimes take up to two hours each. Specialist and legal advisors were present in the room for each meeting and the Committee follow a decision tree for each item.

5.3. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met four times since the Authority last met; on 22 January, 2 February, 16 February and 2 March. The panel considered fifteen items; six renewals, including one which was adjourned; two interims, both of which saw the licence continued; four variations and three executive updates, one of which was adjourned. The Licensing Officer also approved one licence variation and two voluntary revocations.

5.4. The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) advised members that the committee met on 5 February. The committee discussed:

- the regulation of embryo culture media. There was some evidence that culture media could impact birth weight of babies and the Committee were joined by a Senior Clinical Advisor at the Medicines and Healthcare Products Regulatory Agency (MHRA), who gave an overview about the regulatory processes for bringing medical devices to the market.
- a review of two novel processes; intrauterine culture and gamete activation using calcium ionophore. On the former the Committee were concerned that data was insufficient and more information would be needed from the centre to make a judgment on the safety of the process. On the latter, the Committee received evidence from two centres and agreed that there was no evidence to suggest it was unsafe and that it should remain on the list until new evidence suggested otherwise.
- horizon scanning to decide the Committee's workplan for the year. The following four high priority areas were identified:
    - mitochondrial donation
    - synthetic human entities with embryo-like features (SHEEFs)
    - impacts of stress on fertility treatment outcomes
    - the impact of microbiome on fertility and fertility treatment.

5.5. The Chair of the meeting noted that the minutes of SCAAC meetings were available for the public.

5.6. Members discussed culture media. The Chair noted that although this is not in the HFEA jurisdiction, it was important for this to stay on the SCAAC agenda so that the Authority could understand it as fully as possible. Members were interested in the MHRA's approach to regulation and the Director of Compliance and Information noted that further joint working was planned and that the MHRA understood the need for more and better research.

5.7. A member noted that the Nuffield Council on Bioethics had SHEEFs on their agenda for future consideration and it would be positive to work with them on this.

5.8. A member noted that stress and its effect on treatment success and infertility was a topic of research. The Chair of SCAAC agreed and said that the committee would continue to track progress, although there had not been significant changes in research in this area.

5.9. The Deputy Chair of the Audit and Governance Committee (AGC) advised members that the committee met on 6 March and, in addition to the usual standing items and updates from internal and external audit, the committee received reports on:

- Finance and Resources Update
- Impact of Brexit
- Digital Programme Update
- Resilience, Business Continuity Management and Cyber Security
- Strategic Risk Register
- GDPR (General Data Protection Regulation)
- Whistle blowing and Fraud
- Contracts and procurement
- Review of AGC activities & effectiveness, terms of reference

5.10. The Deputy Chair of AGC noted the committee's appreciation of the frank discussion with the Executive on the digital programme update, more on which would be reported later in the meeting. Further reports on GDPR progress would be provided to AGC before its next meeting.

5.11. The Deputy Chair of the Licence Committee advised members that the committee met on 11 January and the 8 March. In January the committee considered, one treatment renewal, one research renewal, one research variation and one research revocation. It approved all four items. It also noted one treatment interim.

5.12. In March, the committee considered one research licence renewal, one treatment licence renewal and one executive update. The minutes were not yet available.

5.13. Members discussed developments in the area of research by clinics. They agreed that it would be helpful to understand the trends in this area over the coming months. The Chief Executive agreed to take this forward. Members agreed that it was important for the HFEA to encourage centres to report findings and demonstrate the value of research data. A member noted that it would be helpful for the Authority to publish some of the results of the research. The Chief Executive reported that this was available on the website but he acknowledged that this could be done in a more accessible way.

5.14. A member asked about how GDPR (general data protection regulation) would impact the Register and Authority and whether patients could ask to remove their data from the Register. The Chief Executive noted that the Register was not affected by this legislation – there was no way for patients to opt out of the Register due to the HFE Act. The report on progress and the impact of the GDPR would be shared with the Authority.

5.15. The executive agreed to circulate the report on compliance with the GDPR to Authority as well as AGC and to provide further information to clinics in Clinic Focus about the GDPR

6. Performance report

6.1. The Chief Executive introduced this item, which reported on both organisational performance and progress against our strategy. The Chief Executive reflected that performance was generally positive and the organisation was in a good position at the end of the financial year. He highlighted the trend in turnover, especially establishment leavers, and reflected that this was largely as a result of a period of organisational change. Turnover had exceeded tolerance in March 2016 and not returned to the target range since then. However, the picture was now improving and viewed in a wider context of other HR indicators, the Chief Executive was of the view that this would improve going forward.

6.2. The Chief Executive reflected on the fact that better metrics to AGC on HR matters would be helpful. Some turnover was natural as people wish to progress their careers, but pay was a factor for a number of staff. Work on organisational culture and learning and development would help to embed new staff and maintain the positive culture and opportunities for staff.

6.3. The Director of Finance and Resources reported on the latest budget outturns and income figures, these were in line with what had been previously reported. He explained that the income forecasting model, which the Authority agreed in January, seemed to be borne out by recent trends, which suggested that the model was accurate. Internal audit had concluded that financial governance processes were effective, which reflected the consistency of implementation of these processes around the organisation.

6.4. The Director of Strategy and Corporate Affairs reported on activity and performance within her directorate. The annual conference preparation was taking place the following day and over 300 delegates were expected. She thanked the communications team for their hard work on this and thanked the Authority members for agreeing to chair sessions throughout the day.

6.5. The Director of Strategy and Corporate Affairs noted that the Fertility Trends publication which was launched that morning had already received some press coverage and this was likely to increase. More would be reported on this later, but it represented the first in a new style of reports, written with the patient in mind. As noted by the Chief Executive, four workshops to consult on changes to the Code of Practice had been held around the country and feedback on the proposed changes had been very positive. The outlined proposals were on the right track and feedback would be consolidated before the formal consultation took place from April.

6.6. The Director of Compliance and Information summarised activity and performance within his directorate. He noted that the end to end figure for licensing was at an all-time low, which reflected the hard work across the board. Training and development was vital, to ensure that the balance was right between work and the development of staff.

6.7. The Director noted that the end to end PGD target was being missed and although this was only by a small number of days, it was still important to aim for this. These missed targets reflected the complexity of items. Members discussed the worsening trends and the reasons for this and noted that it was importance to remember the patient at the end of the process. The Chair of SAC noted that the quality of papers had improved. The Chief Executive agreed that they would prepare some statistical material to enable this discussion to continue outside of the meeting and agree appropriate actions.

6.8. The Director of Compliance and Information also reported on the remaining elements of the Information for Quality programme, being delivered as the data submission project. He gave an overview of the work and the branding of the submission system, which would be called PRISM (patient registration information system). The plan had been for a two-stage implementation; however, 3rd party suppliers and clinics using PRISM directly would now be brought onboard at the same time, in October 2018. The system would be demonstrated at the annual conference. He described the remaining timelines for implementation of the work.

6.9. The Director of Compliance and Information gave an overview of the financial situation of the project and HFEA IT generally, including updating other systems. Additional capital cover would be needed for the next year to deliver on our IT ambitions and the Department of Health and Social Care had been notified of this. Because this approval was not a given, progress would be at risk at the start of the next financial year. Further work was underway to establish firm figures for this. This situation had been reported to AGC at its last meeting and discussed in great detail.

6.10. Members welcomed this report and approved the ongoing approach to finalising and agreeing the financials of the project, particularly in relation to capital cover.

Decision

6.11. Following discussion, members noted the latest performance report.

7. Business Plan

7.1. The Head of Planning and Governance presented the draft 2018/19 business plan. Members noted that this business plan would deliver the second phase of the three-year strategy for 2017-2020. The Head of Planning and Governance noted that the activities section had not changed greatly since consideration in November.

7.2. The Head of Planning and Governance gave members an overview of how the HFEA planned to meet its strategic ambitions. Members heard that the new business year would start with a new set of tools and capabilities in place, including an intelligence strategy, to capitalise on the work done through the Information for Quality Programme and the organisational restructuring completed in 2017/18. This would enable better use of the data held – to assist clinics towards better performance, make targeted regulatory interventions when this is merited, and provide a range of improved information for patients and other stakeholders. Delivery of the 2018-20 People Strategy would also help ensure that the right Capability and Capacity was in place to deliver on the strategic aims.

7.3. The Head of Planning and Governance noted that the mid-year assessment of delivery of the new business plan (at the end of quarter two) would mark the mid-point of the current strategy, and it would be a good time to take stock of progress towards the organisation's vision. In the second half of the business year, the process for developing a new strategy from 2020 onwards would be considered.

7.4. Members noted that the highlights of the 2018/19 business plan would be:

- Standards
- Leadership culture
- New Code of Practice

- Expanded information about access to treatment and donation
- Success rates
- Intelligence strategy
- using our data for quality
- more patient feedback
- Targeted regulatory interventions

7.5. The Head of Planning and Governance discussed the work underway to agree the detailed budget. Discussions were ongoing with the Department of Health and Social Care. As mentioned under the Performance Report item, in 2018/19 greater capital cover would be required. Members received the summary budget figures and heard that the overall revenue budget was £6.3m, including Grant in Aid; and a proposed £500k capital budget. This included £80k for upkeep of the IT estate, and the rest for IfQ related completion, of which the larger component (£230K) would be to finish the new data submission system.

7.6. Members were reminded that further discussion about the annual finance allocation was required with the Department, although sign-off of the business plan and the associated budget was anticipated by the end of April, after which the business plan would be published on the HFEA website.

7.7. Members gave feedback on the business plan, including some drafting notes to be followed up after the meeting. A member noted whether more could be made of the high level of engagement with the sector in 2017/18.

7.8. The Department of Health and Social Care representative noted that these had been no issues from the Department's perspective other than the ongoing question of capital cover.

Decision

7.9. The Authority agreed to approve the near-final business plan for 2018/19, and noted that year-end information would be added in April before publication.

8. Movement of gametes and embryos across borders

8.1. The. Regulatory Policy Manager and Director of Compliance and Information gave an overview of the requirements set out in the two EU directives, on coding and import, how these differed from existing HFEA requirements, and the work that had been undertaken to implement them, including the communication that would go out to clinics in April.

8.2. A member asked how the Authority would verify that centres had effectively tested the suitability of third party suppliers. Because this was about quality and safety, inspectors would be taking it very seriously and checking this on inspection.

8.3. Another member asked whether this legislation would affect arrangements for Special Directions. The Head of Legal responded that the certification of 3rd country suppliers would happen in parallel with Special Directions. If the clinic could import under General Directions then as long as they had applied for certification for the 3rd country supplier then they would be able to import as per the General Directions. Certification would be needed before movements either under Special Directions or General Directions. The Head of Legal noted that there were transitional

arrangements for gametes and embryos already in storage and clinics would need to check whether they met those criteria.

Decision

8.4. The Authority:

- Noted and approved the arrangements for implementing the two Directives.
- Noted that the arrangements for amending General Direction 0006 in relation to importing that will be brought forward in April 2018 and agreed to delegate the approval of the General Directions and accompanying letter to the Chair.
- Approved the amendments to General Direction 0006 in relation to the application of the Single European Code

9. Choose a fertility clinic – evaluation of patient rating trial

9.1. The Media and Stakeholder Relations Manager gave an overview of the patient ratings system, the decisions previously taken by the Authority in March 2017 and presented the activities and findings of the six-month trial of patient ratings on the website.

9.2. Members heard that the ratings system had made slow but steady progress in numerical terms with, to date, over 1,200 ratings. The free text system had received more responses the previous feedback system, which meant much more data was available to HFEA inspectors. Medium sized clinics seemed to be buying into the system most eagerly, large clinics less so. Periods of intense promotion by the HFEA such as November 2017, for fertility awareness week, coincided with spike in responses, suggesting promotion could make an impact.

9.3. Members heard that the trial had raised questions about the engagement of some, particularly larger, clinics. It had also identified security issues after a large number of automated ratings had been submitted by a spambot. There were also questions about how to further increase patient and clinic engagement with the system. Members heard that there were a number of improvements that could be made and were asked for their views on these.

9.4. Members discussed how best to ensure that there was an increase in patient responses and that clinics did this appropriately. One member noted that an increase in direct marketing should be done. Another option raised was the use of cards for marketing materials. It was important to note that some clinics thought that treatment has been completed at embryo transfer, however this was not the patient experience.

9.5. The Deputy Chair of AGC noted that AGC had discussed the security issue in detail. The Director of Compliance and Information reported that the 'CAPTCHA' security system was previously much more complex and therefore at the time of launching the system a decision had been taken not to implement this. This was now much simpler and it had been implemented following the security incident. It was unclear whether the cause was a malicious attack – there was no evidence of this.

9.6. One member noted that the trial did not investigate whether patient feedback was useful for other prospective patients when choosing a clinic. Members also discussed the average rating of 4.5 and whether this was an accurate reflection of what patients thought about a given clinic. There

were a number of variables that might be affecting this. One member noted how useful the cost information would be for patients.

9.7. Another member raised concerns that non-patients may be submitting ratings. They suggested that a token system should be provided to patients undergoing treatment to ensure that they were actual patients. However, members agreed that when there were more ratings submitted then the impact of any potential gaming would be minimised.

9.8. The Director of Strategy and Corporate Affairs reported that there were tangible actions arising from the project and these would be discussed further with the communications team. Three pieces of work, on patient ratings, patient support and a new project on a national patient survey (or similar) would enable the Authority to seek greater feedback in the future. A regular survey could include specific questions related to particular pieces of work.

Decision

9.9. The Authority agreed to:

- continue the patient rating scheme and the free text mechanism for providing views to inform inspection activity.
- further work to develop best-practice guidance for the promotion of the scheme by clinic staff, and what is acceptable practice in terms of encouraging completion of the ratings scheme in-house.
- further discussion with large UK clinics to understand why take-up of the scheme has been slower, and to encourage greater participation.

10. Beyond fertility trends: the role of intelligence

10.1. The Head of Intelligence presented an overview of the key findings of the 'Fertility treatment 2014 -2016 - trends and figures' report (the trends report), noted their potential impact on HFEA policy and set out plans to use the new IT systems and intelligence team to create more in depth and better focused reports for clinics and patients.

10.2. The Head of Intelligence explained that a communications and stakeholder engagement plan had been developed for the report. Members were given an overview of key findings on multiple births, egg freezing and donor egg treatment.

10.3. Members heard that the new perspective on HFEA-held data opened up additional possibilities for policy, such as decisions on what to do next on multiple births, clinical commissioning of IVF and how to approach communications of changes in treatment trends, such as increased egg freezing.

10.4. Members heard that a new reporting structure was proposed to enable more frequent and regular reporting. Lessons had been learnt from the report this year and these would be taken on board in future reports.

10.5. Members commented on the findings and proposed future reporting approaches. A member noted the fact that NICE guidance around the age of women undertaking treatment was based on a complex health economic model and applied solely to IVF. Donor egg treatment was a separate issue as the cost was greater for donor eggs and therefore the cost effectiveness of the

treatment was different. Members discussed the data available on male fertility and noted that more information should be included on this in the future.

10.6. A member queried the data in some of the charts in the report. The Head of Intelligence agreed to consider this (NB: a response was given at the end of the meeting under AOB).

10.7. Members asked whether it was possible to include more up to date data than 2016, while recognising there was an inevitable nine-month delay for birth data, they hoped that more recent pregnancy data could be included. Clinics themselves were able to provide more recent data. The executive noted this for investigation in future.

10.8. Members were enthusiastic about the new approach. They discussed how the Authority might be able to discuss data and input into future reporting. The Chief Executive noted that the Chair and the executive would discuss ways to enable this in the future.

10.9. In responding to the finding that in Scotland there had been an increase in NHS funded treatments, the Chair commended the Scottish Authorities for their evident adoption of the NICE guidelines.

Decision

10.10. The Authority noted the key outcomes of the Fertility Trends and Figures 2018 report and commended the Intelligence team for their hard work.

10.11. Following the conclusion of this item, the Chair noted that she needed to leave the meeting to attend a press interview and handed over to the Deputy Chair of the Authority.

11. Effective governance

11.1. The Head of Planning and Governance summarised proposed changes to Standing Orders and the results of the annual review of committee effectiveness. Members were informed of the need to formally vote on the proposed Standing Orders. This was a simple majority vote, requiring two thirds of members (8) to be present.

11.2. The proposed changes to Standing Orders were minimal, although one proposed change, that the Executive Licensing Panel no longer varied or revoked licences was described in more detail. Variations and revocations would be handled by the Licence Committee.

11.3. Members noted that the proposed changes to Standing Orders had not been tracked in the Authority papers, however, the changes were clear in the paper. The Head of Planning and Governance agreed to follow up on this.

11.4. Members heard that the annual review of committee effectiveness showed that most committees were working well overall with robust decision-making taking place. Terms of reference and membership were appropriate.

11.5. Members heard that several suggestions for improvement had been made and the executive would take forward actions on these. These related particularly to:

- Knowledge management (member turnover).
- Balancing committee workloads and item scheduling.
- Training and induction suggestions.

- Management of adviser conflicts of interest.
- Servicing and meeting-running improvements.
- Securing the right adviser expertise.

11.6. Members noted that the Audit and Governance Committee had made the following points which were not included in the paper:

- Consider having a Board member with overall responsibility for whistleblowing.
- Suggestions on risk assurance mapping.
- Regular bilateral meetings with internal and external auditors, for the Chair.

Decision

11.7. Members unanimously voted to approve the revised Standing Orders

11.8. Members noted the summary of the annual reviews of committee effectiveness.

12. Information provision

12.1. The Interim Head of Information presented an overview of work that had been undertaken to improve information provision and implement the new information policy that had originally been presented and agreed by Authority in 2017. Much of this related to the new data submission system that would launch later in 2018.

12.2. Members heard that two changes were proposed in relation to the information submission policy; one was some small amendments to General Direction 0005, and the other was more clarity on the arrangements for clinics to confirm the quality of their data before HFEA published it, for example on Choose a Fertility Clinic. This meant a new information bargain with the sector, where in return for easier submission, HFEA would expect more timely data, of a higher quality, from clinics. The Authority in turn would commit to making more data publicly available. These expectations would be more transparent in the future.

12.3. Members heard the proposal to formally notify third party suppliers. There had already been considerable engagement with the suppliers so this should come as no surprise, but it would formalise the existing informal arrangement with them. This was necessary, as the clinics, not the Authority, have the contractual agreements with the suppliers. Clinics would be notified of the need to do this by way of a Chair's letter.

12.4. A Member raised the issue of the cost to clinics of any updates to third-party systems. The Interim Head of Information noted that the costs would depend upon the contractual arrangements clinics had with suppliers. Suppliers would continually have to update their systems already and the expectation would usually be for suppliers to ensure that their systems were fit for purpose. A member noted that it was important to have a clear message to clinics. The Chief Executive stated that this had been discussed by the Authority previously and the changes would be no surprise to clinics or to the suppliers and would represent an improvement for all. In addition, the HFEA system would be available to any clinics whose third-party suppliers were unable to comply.

Decision

12.5. Members agreed to formally advise clinics with third party patient record systems that their suppliers should be given six-months' notice of changes to be made to enable data submission to the HFEA, by way of a Chair's Letter.

12.6. Members agreed the proposed changes to General Direction 0005 and the arrangements for data confirmation.

13. Any other business

13.1. Following up on an issue raised under item 10, the Director of Strategy and Corporate Affairs noted that the electronic version of the trends report clearly showed per cycle figures in the graphs, but this was not clear in the printed format of the report. This would be investigated further and this issue resolved for future reports.

13.2. The Chair of the meeting confirmed that the next meeting will be held on Wednesday 9 May at Church House, London, SW1P 3NZ. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

14. Chair's signature

I confirm this is a true and accurate record of the meeting.

Signature

Chair

Date

PGD Explanatory Note – minor revisions

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	5		
Paper number	HFEA (09/05/2018) 878		
Meeting date	9 May 2018		
Author	Paula Robinson, Head of Planning and Governance		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to agree minor revisions to the PGD explanatory note used by the Statutory Approvals Committee		
Resource implications			
Implementation date	10 May 2018		
Communication(s)	For incorporation into the standard licensing pack and the PGD decision tree.		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex 1: Revised PGD Explanatory Note		

1. Introduction

1.1. The Statutory Approvals Committee (SAC) uses an explanatory note to assist in its consideration of applications to have new conditions added to the PGD list. Following recent discussions, the committee agreed that some minor changes would be helpful.

1.2. The proposed changes are for clarity only, and do not involve any changes to the Authority's existing policy on PGD.

2. Summary of the changes

2.1. The text refers to Licence Committee, since the original document predates the formation of SAC. Therefore we should take this opportunity to update these Committee references.

2.2. Paragraph 2.1 of the explanatory note refers to decisions being made 'without reference to the particular circumstances of any individual or family'. This wording could be interpreted to mean that the Committee is not allowed to take into account any input submitted by patients suffering from the condition.

2.3. It has been custom and practice for some time for the HFEA to actively seek out input from patients when applications for new conditions are received. Such feedback is occasionally received, and included in the papers for SAC's meetings. It is a welcome and useful addition to the application, peer review, and other materials that make up the set of papers for each item.

2.4. Therefore, minor changes are proposed to paragraphs 2.1 and 2.3 to ensure that the wording does not inadvertently rule this out (or could be interpreted to rule it out).

3. Recommendation

3.1. The Authority is asked to approve the proposed revisions to the PGD explanatory note (Annex A), for use at all subsequent SAC meetings.

Annex A

Human Fertilisation and Embryology Authority
Pre-Implantation Diagnostic Testing ("PGD")
Explanatory Note For Statutory Approvals Committee

1. Preamble

The Statutory Approvals Committee of the Human Fertilisation and Embryology Authority has produced this explanatory note to set out its approach to the statutory criteria of "risk" and "seriousness" which it is required to assess when considering applications to undertake PGD. This explanatory note should be read in conjunction with the PGD Decision Tree.

The approach set out in this explanatory note was first approved by the Authority on 8 September 2010 and the explanatory note was adopted by the Chair of the Licence Committee on 28 October 2010.

This explanatory note is effective from 9 May 2018.

2. Introduction

2.1 The Authority has delegated the function of considering PGD applications to the Statutory Approvals Committee. The Authority has adopted a condition based approach to the approval of applications which means that the Statutory Approvals Committee will usually consider applications to perform PGD for an abnormality ~~without reference~~ based on the condition rather than ~~to~~ the particular circumstances of any individual or family.

2.2 Once the Statutory Approvals Committee has approved an application to perform PGD for a particular abnormality, any licensed PGD centre in the UK can offer PGD for that abnormality. However, centres will still need to assess, on an individual family basis, whether a particular request for PGD is appropriate. The Code of Practice provides guidance on how such decisions should be made.

2.3 When considering PGD applications, the Statutory Approvals Committee will take into account material provided with the application, including evidence from the applicant, peer reviewers and, where available, from patients and patient groups.

3. The Statutory Requirements

3.1 Paragraph 1ZA of Schedule 2 (Annex A) sets out the statutory criteria which the Statutory Approvals Committee must consider before deciding whether or not a PGD application should be granted.

3.2 These criteria include the requirements that:

a) there should be a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality; and

b) there should be a significant risk that the person with abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

4. Particular Risk

4.1 When considering whether or not there is a particular risk that an embryo may have an abnormality, the Statutory Approvals Committee will take into account whether or not the abnormality is heritable and if so, what the mode of inheritance is.

4.2 This is an objectively measurable criterion. For example, if a genetic abnormality is “autosomal dominant”, there will be a one in two chance of an embryo carrying the abnormality. However, if the abnormality is “autosomal recessive”, there will be a one in four chance of an embryo carrying that abnormality.

5. Significant Risk and Seriousness

5.1 When considering the significance of the risk, the Statutory Approvals Committee will take into account the penetrance of the condition.

5.2 The penetrance of a condition is an estimate, in percentage terms, of the likelihood that someone with the abnormality would develop the condition in question. Penetrance is a population based statistic which represents the accumulation of available studies of the incidence of that abnormality in populations of people who carry the relevant gene mutation.

The options are:

- full penetrance (100% - i.e. it is a certainty that a person with the abnormality will develop the condition in question), or

- incomplete penetrance, which is usually presented as a range of percentages (e.g. 40 – 60%) i.e. only a subset of people with the abnormality will develop the condition.

5.3 When assessing the seriousness of the disability, illness or condition, the Statutory Approvals Committee will take into account the following factors:

.

a) Age of onset.
Is the condition congenital or does it manifest later in life? If it does manifest later, at what stage (childhood, early adulthood, later)?

b) Symptoms of the disease.
What are the symptoms of the condition and is it fatal, life threatening or life limiting?

c) Whether the condition is treatable

d) What type of treatment is available for those conditions that can be treated
What is the extent of the treatment available? How invasive is the treatment or likely treatment?

e) *Effect of the condition on quality of life*
This will include any evidence about the speed of degeneration in progressive disorders and the extent of any physical and /or intellectual impairment.

f) Variability of symptoms
Symptoms associated with the same condition can vary from family to family (and from individual to individual), and can range from the mild to the severe.

5.4 Where the condition has variable symptoms, the Statutory Approvals Committee will take account of:

- what the range of variability is; and
- whether the range suggests that some forms of the condition are so mild that they might not meet the 'serious' test.

5.5 Where a condition has a range of penetrance (e.g. 40-60%), the Statutory Approvals Committee will base its decision on the highest penetrance figure.

5.6 Where a condition has variable symptoms, the Statutory Approvals Committee will base its determination of how serious the disability, illness or condition is, on the worst possible symptoms.

6. Reasons

6.1 The Statutory Approvals Committee will give reasons for the decisions it makes. The reasons will set out clearly the matters that the Statutory Approvals Committee took into account in deciding whether or not to grant the application to perform PGD.

ANNEX A

1ZA

(1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes--

(a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

(c) in a case where there is a particular risk that any resulting child will have or develop--

(i) a gender-related serious physical or mental disability,

(ii) a gender-related serious illness, or

(iii) any other gender-related serious medical condition,

establishing the sex of the embryo,

(d) in a case where a person ("the sibling") who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and

(e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

(2) A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied--

(a) in relation to the abnormality of which there is a particular risk, and

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),

that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

(3) For the purposes of sub-paragraph (1)(c), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that--

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

(4) In sub-paragraph (1)(d) the reference to "other tissue" of the resulting child does not include a reference to any whole organ of the child.

Performance report

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	6		
Paper number	HFEA (09/05/2018) 879		
Meeting date	09 May 2018		
Author	Helen Crutcher, Risk and Business Planning Manager		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest performance report.		
Resource implications	In budget		
Implementation date	Ongoing		
Communication(s)	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper). The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Performance report		

1. Introduction

1.1. The attached paper summarises our performance up to the end of March 2018.

1.2. The Corporate Management Group decided in March 2018 to stop holding separate performance meetings. Directors discuss performance with their Heads and the overall performance report is now discussed in monthly Senior Management Team (SMT) meetings. The report is circulated to CMG and feedback from SMT meetings is discussed with Heads. All other performance reporting remains unchanged.

2. Reviewing performance

2.1. SMT reviewed the January – March performance data at its April 23 meeting.

2.2. Overall performance is good. Three indicators are currently classified as red. There is a full discussion of these in the performance report, provided in the annex to this paper.

3. Recommendation

3.1. The Authority is asked to note the latest performance report.

HFEA performance scorecard

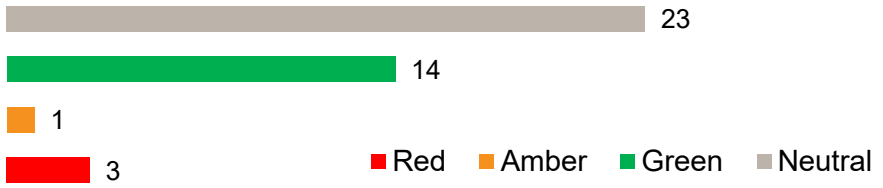
Dashboard – March data

People – capacity

Establishment leavers per month
(% turnover for the year).
KPI: 5 - 15% establishment turnover

⇩
Leavers: 0
(19.4%)

Overall performance – RAG status (all indicators)



Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month
(baseline to be established once the website has been active for a year)

⇧
57,620
sessions

Licensing end-to-end

Length of the whole inspection and licensing process
KPI: ≤ 70 working days

★
57 working days

Money – budget

Summary Financial Position - March 2018

	Year to Date		
	Actual £'000	Budget £'000	Variance £'000
Income	**6,307**	**6,230**	**76**
Expenditure	**5,850**	**6,064**	**214**
TOTAL Surplus / (Deficit)	**456**	**166**	**290**

Commentary

The table above shows our year end financial position, a surplus of £456k, which is £290k higher than budgeted for.
Increased income in relation to the recharge of seconded staff time has contributed to this surplus, as have a number of underspends in particular within our legal budget.

Overall performance – March 2018

We reviewed the overall performance picture at the SMT meeting on 23 April. There were 3 red indicators.

Overall, March performance is generally good and represents a positive position as at year end.

The 3 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

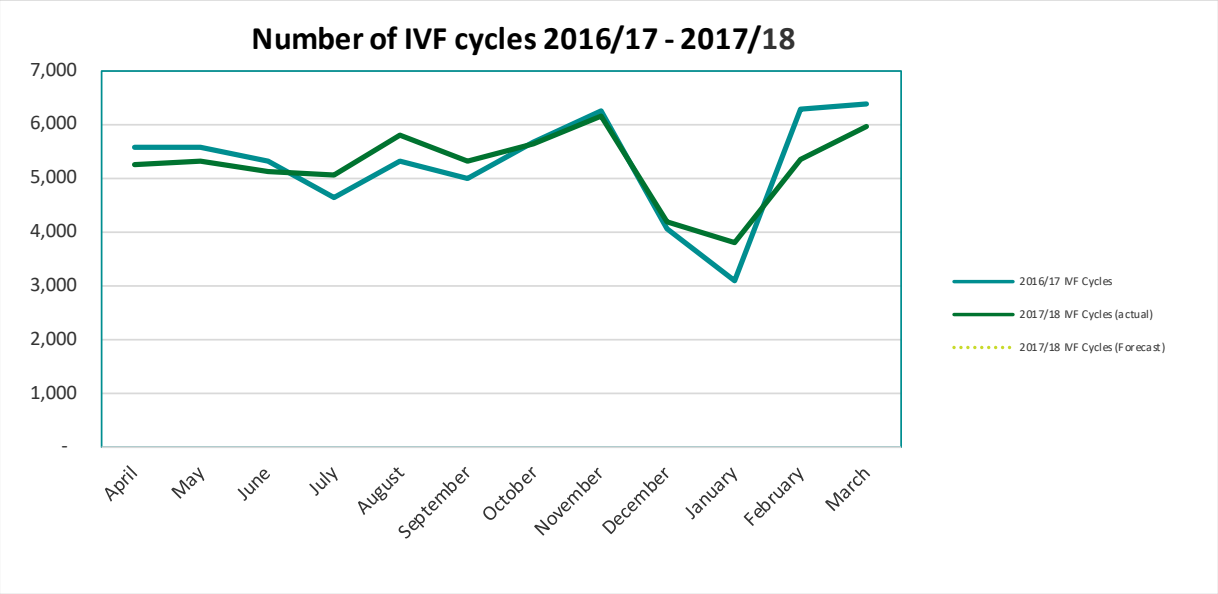
- Outstanding errors - 12 month running total. Our target is to decrease this number. If the number increases by more than 5%, we rate this indicator as red. Current performance is an increase of 14% in March to 2,501 errors that are 2-14 months old. It is worth noting however that the overall number of errors is less than the total errors as at December and the rise in outstanding errors from February was due to just two centres which had technical issues so didn't submit for a time. These technical issues have been resolved, but when the centres did submit their data these had errors which have taken some time to address.
- Percentage of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests responded to within statutory deadlines. We missed one deadline for a FOI response in March due to administrative failure. The systems are now being reviewed to hopefully avoid this happening in the future.
- Average number of working days from day of inspection to the day the draft report is sent to the PR. Our target is for 90% of reports to be sent within 20 working days of inspection. In March, performance was 60% in 20 working days, this was based on five reports. Of these, three were within the KPI and two were not. The two reports which missed the KPI did so for differing reasons. One was by two days and the other was by 15. The report that was 15 days overdue was due to various causes, including bereavement absence of a key clinic staff member at the time of inspection and sickness absence of the lead inspector post-inspection.

Amber indicator

- 'Unplanned' leavers. Our target is to remain within 5 - 15% headcount turnover for the year. Performance in March was 19.4%. (down from 21.1 in December) This is still above target but it has reduced and the overall planned and unplanned leavers for the year has also dropped to 27.5%. March was the first in many months where there were no leavers at all. Authority will recall a number of discussions about this indicator during the extended period of organisational change. As it is now decreasing and indications are that the picture is improving, we have classed this as amber rather than red.

Overall, performance around PGD processing has improved, with all PGD indicators receiving a green rating this month. A piece of work is underway, led by the Head of Planning and Governance to understand the factors affecting PGD performance and analyse whether there are any process improvements that can be made. Early indications are that myriad factors impact this KPI from one month to the next. We are approaching a pinch point for applications where items may need to be deferred to later meetings due to lack of agenda space in May and June, and this will have a knock-on impact on meeting the KPIs. The compliance and licensing teams are actively managing this issue and will consider any mitigating actions.

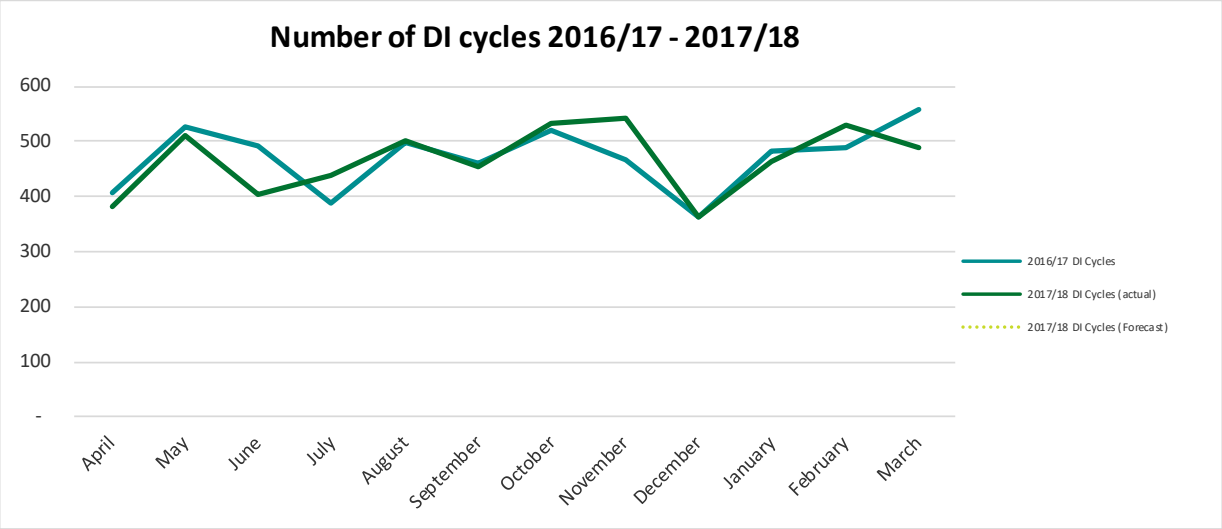
2017/18 Income



IVF Cycles

	YTD Volume	YTD £
2016/17 IVF Cycles	63,111	5,048,854
2017/18 IVF Cycles	62,969	5,037,520
Variance	142	11,334

The last two months of the year saw significantly lower sector activity than for the same period in 2016/17, this has offset the increased activity during the middle of the year resulting in overall activity being broadly aligned to last year. It is worth noting that there is sometimes a lag in reporting so the the final figures for the year may show an increase.



DI Cycles

	YTD Volume	YTD £
2016/17 DI Cycles	5,651	211,913
2017/18 DI Cycles	5,607	210,263
Variance	44	1,650

The year end has seen a minor decrease in cycles compared to 2016/17, resulting in reduced income of £2k.

HFEA Income & Expenditure Mar-2018

	Year to Date		
	Actual £'000	Budget £'000	Variance £'000
Income			
Grant-in-aid	933	938	(5)
Licence Fees	5,305	5,286	19
Other Income	6	6	(0)
Seconded Salary reimbursed	63	-	63
Total Income	**6,307**	**6,230**	**76**
Revenue Costs			
Salaries (excluding Authority)	4,050	3,778	(272)
Staff Travel & Subsistence	169	200	31
Other Staff Costs	109	151	42
Authority & Other Committees costs	248	303	55
Facilities Costs incl non-cash	633	690	58
IT costs	115	125	10
Legal / Professional Fees	329	637	308
Other Costs	197	180	(16)
Total Revenue Costs	**5,850**	**6,064**	**214**
TOTAL Surplus / (Deficit)	**456**	**166**	**290**

Management commentary

Income.

At the end of the financial year, our Treatment and Licence fee income exceeded our budget by 0.4%. This is slightly less than we were forecasting at quarters 2 and 3 and is due to a decline in volumes over the last two months of the year, (although as moted above, a lag in reporting may see an improved revision to income). Overall our income does exceed budget by 1.2% aided by income from seconded staff.

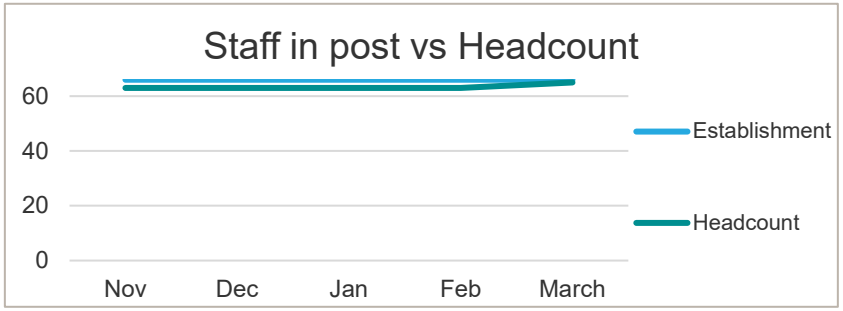
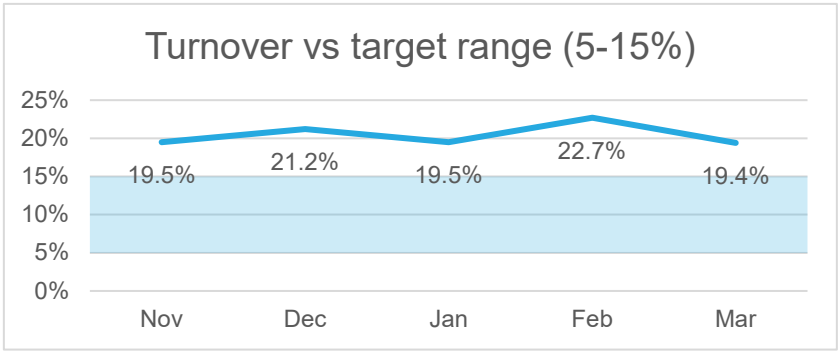
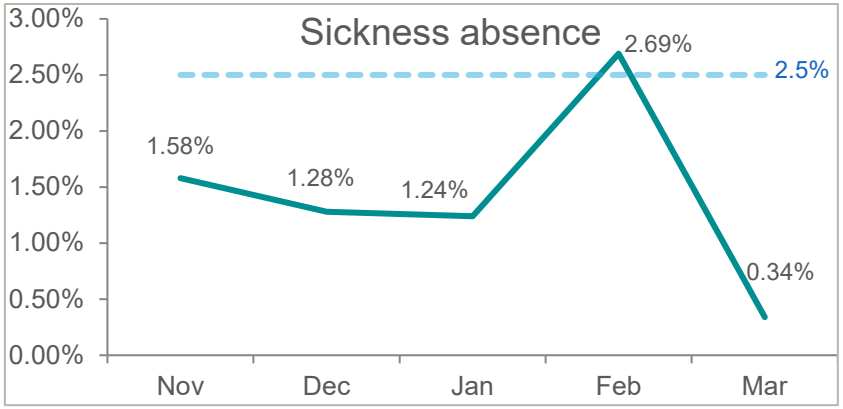
Expenditure.

The final position on expenditure at 31 March is an underspend of £214k (3.5%) against budget. This was achieved despite the overspends in the following areas which are markers for the 2018/19 budget:
- Increased costs relating to a significant number of agency and temporary staff providing backfill for vacancies
- Significant overspend in relation to stakeholders events on the Annual Conference and Code of Practice workshops which were not budgeted for.

Outturn.

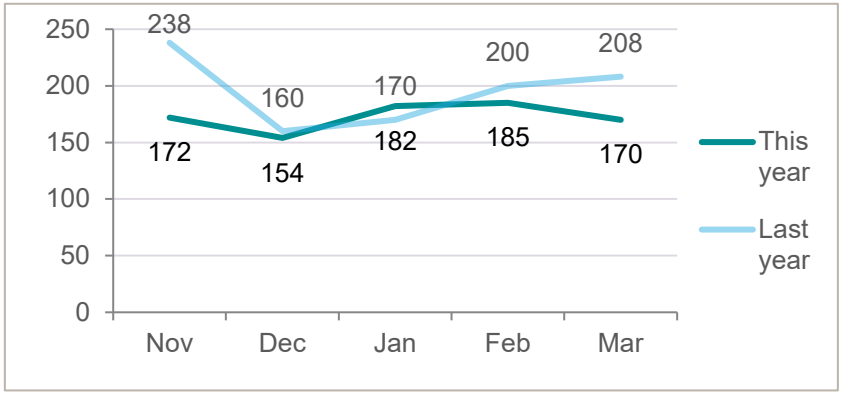
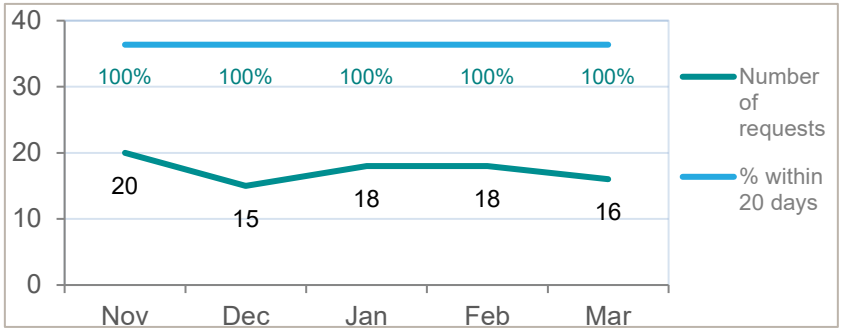
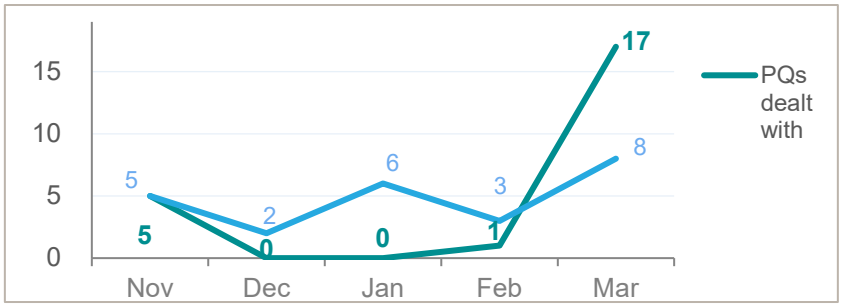
Our initial outturn, before finalisation of our accounts, is an underspend against budget of **£290k (5%).** This reflects the overspends highlighted above, offset by significant underspends in our legal budget, facilities and committee and travel costs.

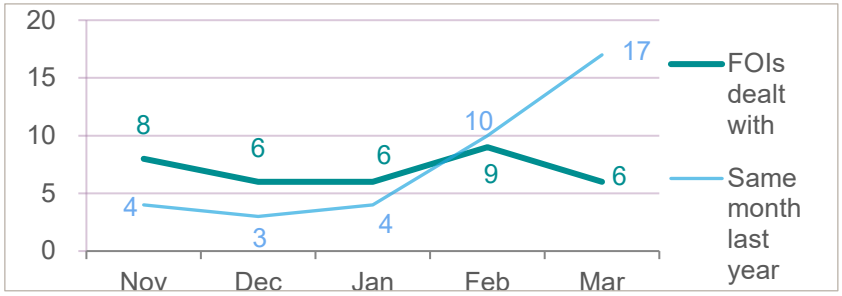
People – key performance and volume indicators

Indicator	Score	RAG	Recent trend[1]	Notes
Current headcount by month Staff in post/headcount	65/66	⇧		Overall volume (capacity) indicator. The Senior Governance Manager and Programme Support Officer joined in March.
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	19.4%	⇩		KPI range: 5-15% turnover for the rolling year The public-sector average is 10.9% (Xpert HR 2017) which therefore forms the basis of our target.
Staff sickness absence rate (%) per month.	0.34%	★		KPI: Absence rate of ≤ 2.5%. Average rate of public sector sickness absence is 2.9% versus 1.7% for the private sector. (Source: ONS data 2016) Although this looks like a steep decrease, the rate is comparable to last year.

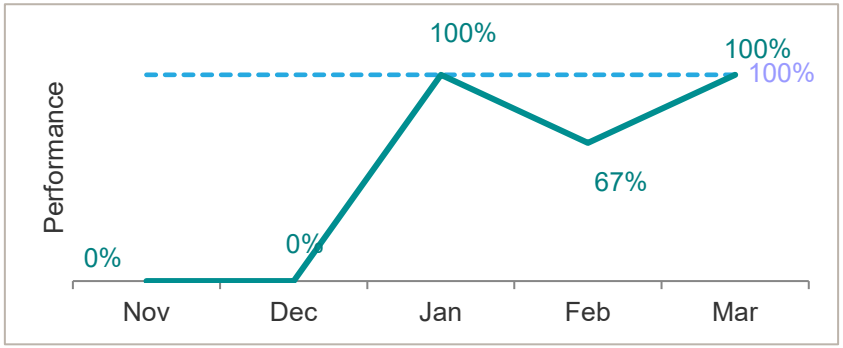
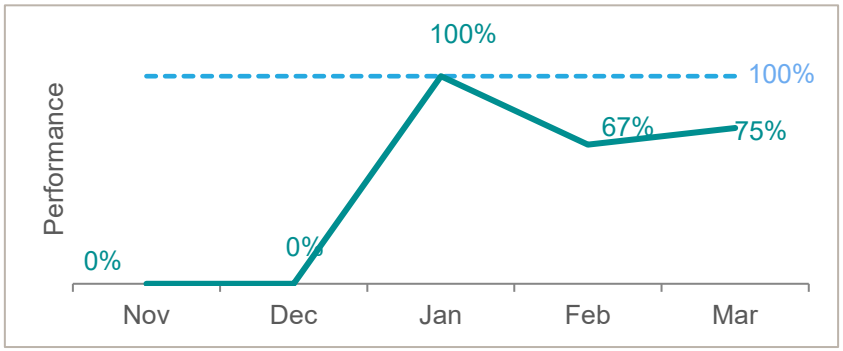
[1] KPIs, where applicable, are show as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Information – key performance and volume indicators

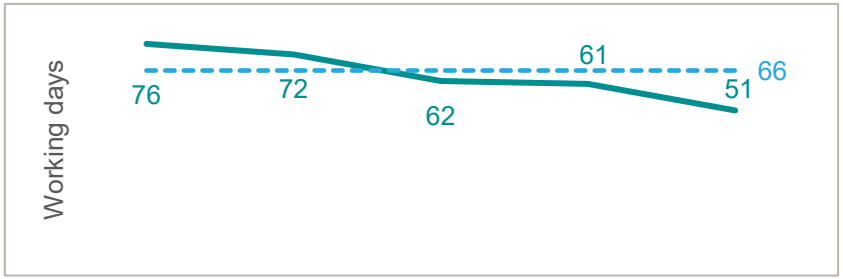
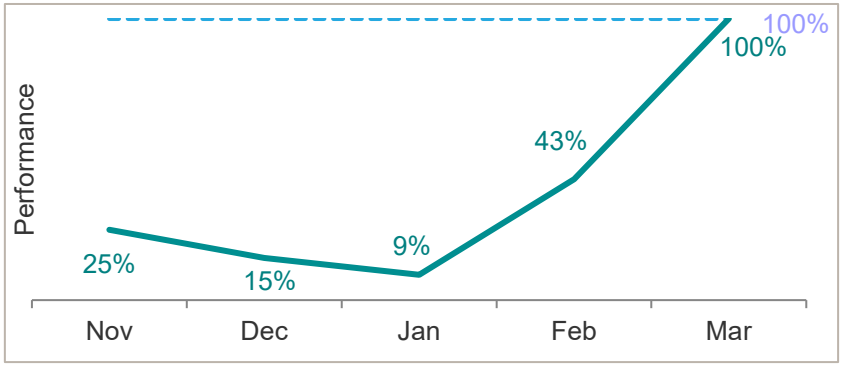
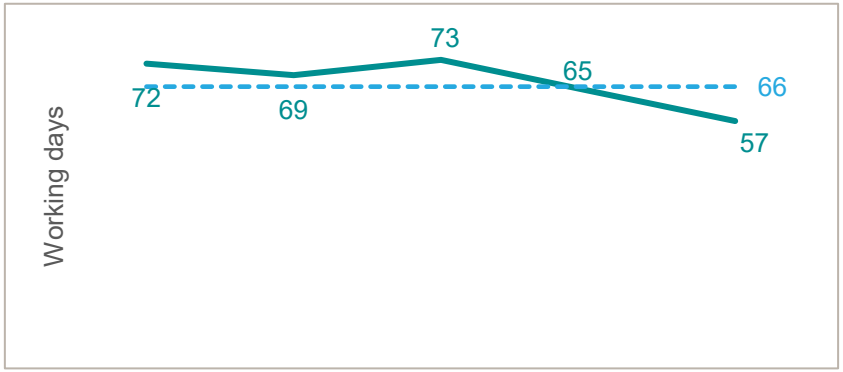
Indicator	Score	RAG	Recent trend	Notes
Number of emailed public enquiries received (compared with same month last year)	170	⇩		Volume indicator. We are now tracking telephone enquiries as well as those via email. These are reported to SMT in more detail. We are in the process of integrating the enquiries team with website development, to ensure it meets user needs.
Percentage of Opening the Register requests responded to within 20 working days	100%	★		KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)
Number of requests for contributions to Parliamentary questions	17	⇧		Volume indicator. All 17 PQs were related to the number of eggs collected in IVF cycles and were submitted on the same day by the same MP. This is likely due to increased parliamentary interest in OHSS and possible overstimulation during IVF treatment.

Indicator	Score	RAG	Recent trend	Notes
Number of Freedom of Information (FOI) requests	6	⇩		Volume indicator.

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend[2]	Notes
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair)	57	★		KPI: Less than or equal to 70 working days.
Monthly percentage of PGD applications processed within three months (66 working days).	100% (3/3)	★		KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.

[2] KPIs, where applicable, are show as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Indicator	Score	RAG	Recent trend[2]	Notes
Average number of working days taken (in the month).	51 (average for 4 reports)	★		
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	100% (7/7)	★		KPI: As above. We are reporting against a three-month rolling average rather than an annualised average, since this will allow us to see trends, without being affected by negative performance from a year ago which has been addressed.
Average number of working days taken (cumulative 3 month picture).	57	★		

Strategic risk register

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	7		
Paper number	HFEA (09/05/2018) 880		
Meeting date	09 May 2018		
Author	Helen Crutcher, Risk and Business Planning Manager		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.		
Resource implications	In budget		
Implementation date	Ongoing		
Communication(s)	The risk register is reviewed monthly by the Senior Management Team (SMT), and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 6 March, and will review it again at its meeting on 12 June.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Risk management developments

1.1. During its annual review in February, the Corporate Management Group (CMG) discussed how it addresses risk management through quarterly risk meetings. In March, CMG decided to cease holding this separate quarterly risk meeting and agreed to defer detailed reviews of the strategic risk register to the Senior Management Team (SMT). This allows Directors to formally consider the register at more frequent, monthly intervals and for Heads to focus upon the operational handling of risks and identifying emerging risk sources.

1.2. Heads are still involved in revising the strategic risk register, giving updates on actions and Directors engage with their management teams on both operational and strategic risk on a regular basis.

1.3. We are in the process of formally revising the risk policy and processes to reflect these changes, along with including changes relevant to the General Data Protection Regulations. These changes will be signed off by CMG and the risk policy will go to the Audit and Governance Committee for their information in October.

2. Latest reviews

2.1. SMT reviewed all risks, controls and scores in the strategic risk register at its meeting on 16 April. As agreed by the Authority in November, SMT considered that it was now the correct time to remove the organisational change risk, since the change programme is now complete, save for a single ongoing recruitment, this is no longer a strategic risk in its own right. Any remaining risk sources related to organisational change have now been included under the remaining risks. None of the six risks were above tolerance.

2.2. The finance risk has been considered by the Director of Finance following the SMT meeting, in the light of the most recent developments relating to Department of Health and Social Care budget approvals. A verbal update will be provided at the Authority meeting.

2.3. The risk register was discussed at AGC on 6 March. No changes were made to the risk scores at that time. Any comments from the Authority will be fed into the Committee's next review on 12 June.

2.4. SMT and AGC's comments are summarised on page 22 of the risk register, at Annex A.

3. Recommendation

3.1. The Authority is asked to note and comment on the latest edition of the strategic risk register.

Latest review date – 30/04/2018

Human Fertilisation & Embryology Authority

Strategic risk register 2017/18

Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
C1: Capability	Generic risk – whole strategy	**12 – High**	At tolerance	⇔⇔⇔⇩
LC1: Legal challenge	Generic risk – whole strategy	**12 – High**	At tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**6 – Medium**	At tolerance	⇔⇔⇔⇔
RE1: Regulatory effectiveness	Improving standards through intelligence	**6 – Medium**	At tolerance	⇔⇔⇔⇔
ME1: Effective communications	Safe, ethical effective treatment Consistent outcomes and support	**6 – Medium**	At tolerance	⇔⇔⇔⇔
FV1: Financial viability	Generic risk – whole strategy	**6 – Medium**	Below tolerance	⇔⇩⇔⇔

* Strategic objectives 2017-2020:

Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment

Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add ons and feel prepared

Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics

Consistent outcomes and support: Improve access to treatment

Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients

Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce

** This column tracks the four most recent reviews by AGC, CMG, SMT or the Authority (eg,⇧⇔⇩⇔).
Note: as of April, SMT review the strategic risk register rather than CMG. It is circulated to CMG afterwards. Recent review points are: AGC 5 December ⇨ CMG 7 February⇨ AGC 6 March⇨SMT 16 April

FV1: There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 - High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**9 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Financial viability FV1: Income and expenditure	Richard Sydee, Director of Finance and Resources	Whole strategy	⇔⇔⇔⇩

Commentary
Below tolerance. In February CMG reduced this risk, owing to the newly implemented forecasting model and the near certain likelihood of a surplus, this brought it below tolerance. Shortly afterwards, it became clear that developments in the digital projects would require an increase in capital spending in the 2018/19 budget. As at April 2018 we have not yet had confirmation from DHSC of our additional capital allocation. We have sufficient capital cover to sustain activities to the end of the first quarter. We expect confirmation before the end of Q1 but should cover not be confirmed this would be a discussion for CMG, with escalation to AGC and Authority as required.

Causes / sources	Mitigations	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.	CMG see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We have established a model for forecasting treatment fee income and this reduces the risk of significant variance, by utilising historic data and future population projections. As at March 2018, the current receipts are within 1% of the model's forecast. We will refresh this quarterly internally and review at least annually with AGC.	Quarterly, ongoing, with AGC model review at least annually - Richard Sydee

Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles.	Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. If clinics were not able to submit data and could not be invoiced for more than three months we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted.	Ongoing – Richard Sydee In place – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flags any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee
Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.	Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations. The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.	In place and ongoing - Richard Sydee Quarterly meetings (on-going) – Morounke Akingbola
Project scope creep leads to increases in costs beyond the levels that have been approved.	Finance staff present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance.	Ongoing – Richard Sydee or Morounke Akingbola
	Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time-critical.	Monthly (on-going) – Morounke Akingbola
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance leads to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Continuous - Richard Sydee Annually and as required – Morounke Akingbola
Failure to secure capital cover for the remaining IfQ spend in 2018/19	There are no mitigations available for this risk. If it were to arise, careful consideration would be needed to assess available actions and impacts.	Nick Jones/Richard Sydee

Risk interdependencies (ALBs / DHSC)	Control arrangements	Owner
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola As at April 2018 there is one litigation matter on the horizon (scheduled to be held in the high court in Autumn 2018).
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model.	Accountability quarterly meetings (on-going) – Richard Sydee
	Annual budget agreed with DHSC Finance team alongside draft business plan submission. GIA funding has been provisionally agreed through to 2020.	December/January annually – Richard Sydee
	We will be undertaking a review of budgets for 2018/19 as part of our business planning process.	Planned for Q4 2017/18 – Morounke Akingbola

C1: There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Capability C1: Knowledge and capability	Peter Thompson, Chief Executive	Whole strategy	⇔⇔⇔⇩

Commentary
At tolerance This risk and the controls are focused on business as usual capability, rather than capacity, though there are obviously some linkages between capability and capacity. Since we are a small organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level. After a period of high turnover and internal churn, in part caused by the organisational change programme, the organisation is entering a period of greater stability. As at April 2018, a number of developments have taken place. Some recruitment is ongoing, including the developer role, which has proved more difficult to recruit for, however alternate solutions are being considered and there is currently temporary developer resource in place to cover some of this capability gap. Recruitment of another analyst in the intelligence team, ongoing in April, will boost to ability to deliver the intelligence-related aspects of the strategy. Work has started to improve the offer to staff, including the establishment of a staff-led employee recognition group which has undertaken a review of the potential benefits available. A learning and development calendar has been generated with a range of training available to all staff and some tailored to more senior managers. CMG agreed in April to an increase in the training budget for 2018/19, to recognise the importance of staff development in retaining staff and increasing capability in areas of business need. Improving this offer should increase the likelihood of staff staying in post and developing at the HFEA, rather than leaving, although we are naturally limited by wider government pay constraints.

Causes / sources	Mitigations	Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We plan to put in place corporate guidance for all staff for handovers. A checklist for handovers has been written and this will be circulated to managers when staff leave. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist written – to be used from Q1 when staff leave – Yvonne Akinmodun

	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention. CMG and managers prioritise work appropriately when workload peaks arise.	In place – Yvonne Akinmodun In place – Peter Thompson
Poor morale could lead to decreased effectiveness and performance failures.	Engagement by managers through team and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Staff survey results for 2017/18 informed the development of the people strategy. The all staff awayday in January 2018 gave staff a chance to feedback in further detail. The strategy was launched in April 2018. Work has been underway to review the benefits offered to staff. An employee recognition group meets to consider options to improve the offer, including a new buying and selling of annual leave policy.	Annual survey and staff conferences – Yvonne Akinmodun/ Peter Thompson
Increased workload either because work takes longer than expected or reactive diversions arise.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources at monthly meetings.	In place – Paula Robinson
	Oversight of projects by both the monthly Programme Board and CMG meetings, to ensure that projects end through due process (or closed, if necessary).	In place – Paula Robinson
	Learning from Agile methodology to ensure we always have a clear 'definition of done' in place, and that we record when products/outputs have met the 'done' criteria and are deemed complete. Agile approach to be brought into project processes under new project governance framework.	Partially in place – further work to be done by early 2018/19 - Paula Robinson
	Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery. Requirement for this to be in place for each business year.	In place – Paula Robinson
	Planning and prioritising data submission project delivery, and therefore strategy delivery, within our limited resources.	In place until project ends in Autumn 2018 – Dan Howard
Possible future increase in capacity and capability needed	Licensing processes for mitochondrial donation are in place (decision trees etc).	Issue for further

to process and assess licensing activity including mitochondrial donation applications. As at April 2018, the initial mitochondrial donation applications have taken up a significant amount of resource at Statutory Approvals committee and for the executive in preparing papers and minutes. There have also been some issues with finding suitably experienced peer reviewers.	An external review of the HFEA licensing processes has been carried out to assess current capabilities and processes and make changes for the future. This will be considered and where relevant implemented May – July 2018. To mitigate the present capacity and capability issues, the executive has signed up more experienced mitochondria peer reviewers and have received feedback on the process to address any capability concerns. As at April, improvements to the application form are being made in order to ensure all of the right information is elicited, to prevent additional administration and/or unnecessary adjournments.	consideration – Clare Ettinghausen
Loss of knowledge in the Policy team given high-turnover of key individuals, including the Head during Q3/4 2017/18. This will have a knock-on impact on other teams primarily Legal.	As above, knowledge transfer has been prioritised. The team has been at complement since February 2018 and new starters have been thoroughly inducted, although it takes some time for new staff to get up to speed. Policy work has been reprioritised with a focus on the Code of Practice October 2018 revision and key SMT/CE have been involved as and when needed.	In place - Clare Ettinghausen
Bedding down the new organisational structure to maximise organisational capability will necessarily involve some team building time, developing new processes, staff away days to discuss new ways of working, etc. This will be challenging given small organisational capacity and ongoing delivery of business as usual.	Continuing programme of leadership development for Heads and SMT. Organisational development activity has continued, including summer awayday (10 July 2017), to support new ways of working development. A leadership awayday (November 2017) and another all staff awayday happened in January 2018 with a focus on building an HFEA culture following the organisational changes	Leadership development programme planned for Q1 and Q2 2018/19 Ongoing – Yvonne Akinmodun
Following organisational change implementation, a number of staff are simultaneously new in post. This carries a higher than normal risk of internal incidents and timeline slippages while people learn and teams adapt.	Recognition that a settling in period where staff are inducted and learn, and teams develop new ways of working is necessary. Formal training and development are provided where required. Knowledge management via records management and documentation and Yvonne Akinmodun is reviewing onboarding methods as part of ongoing HR work.	In progress, – Peter Thompson Underway Q1 2018/19 – Yvonne Akinmodun
The new organisational model may not achieve the desired benefits for organisational capability	The model will be kept under review following implementation to ensure it yields the intended benefits.	A review of the new model will be presented to AGC in June 2018 – Peter Thompson
Risk interdependencies	**Control arrangements**	**Owner**

(ALBs / DHSC)		
Government/DHSC: The government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	We were proactive in reducing headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review and Triennial Review).	In place – Peter Thompson

CS1: There is a risk that the HFEA has unsuspected system vulnerabilities that could be exploited, jeopardising sensitive information and involving significant cost to resolve.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**3**	**2**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Cyber security CS1: Security and infrastructure weaknesses	Nick Jones, Director of Compliance and Information	Whole strategy	⇔⇔⇔⇔

Commentary
At tolerance. As at April 2018 the review of all IT policies is ongoing, to ensure that these remain fit for purpose. All new development has been done with cyber security in mind and this is especially true of the Register migration which will not be completed until we receive adequate external assurance of data security. This external assurance has been ongoing throughout the migration planning process. Penetration testing of the submission system is underway in April and May and this should provide further assurance that the system can withstand a cyber security attack. In recent months the national cyber security risk has heightened and this is something the Chief Information Officer, his team and the SIRO have been acutely aware of. Staff have been updated on the developing situation and we have responded to DHSC requests for assurance on cyber attacks to reassure them that our systems are fit for purpose. Following a recent automated attack to the patient rating feature on CaFC, we have added additional cyber security measures.

Causes / sources	Mitigations	Timescale / owner
Insufficient governance or board oversight of cyber security risks (relating to awareness of exposure, capability and resource, independent review and testing, incident preparedness, external linkages to learn from others).	AGC receives reports at each meeting on cyber-security and associated internal audit reports. Internal audit report on data loss (October 2017) gave a 'moderate' rating, and recommendations are being actioned and reported at each CMG Risk and AGC meeting. Detailed information on our security arrangements is available in other documents. A business continuity plan is in place.	Ongoing regular reporting - Nick Jones/Dan Howard

Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	The website and Clinic Portal are secure and we have been assured of this. The focus now is on obtaining similar assurance through penetration testing report to the SIRO in relation to the remaining data submission deliverables.	Penetration testing underway in April-May 2018 - Nick Jones/Dan Howard
There is a risk that IT demand could outstrip supply and so IT support doesn't meet the business requirements of the organisation and so we cannot identify or resolve problems in a timely fashion.	We continually refine the IT support functional model in line with industry standards (ie, ITIL). We are actively improving our controls by investigating additional support delivered by a third party. This includes partnering with similar organisations such as the HTA, or entering into a separate agreement with an infrastructure support provider (it is likely that desktop support would remain unaffected by such an arrangement).	Approved per the ongoing business plan and budget agreement process – Dan Howard Short term arrangement should be finalised in May. A longer-term support arrangement will be in place c. Autumn 2018 – Dan Howard
Confidentiality breach of Register or other sensitive data by HFEA staff.	Staff are made aware on induction of the legal requirements relating to Register data. All staff have annual compulsory security training to guard against breaches of confidentiality. Relevant and current policies to support staff in ensuring high standards of information security. There are secure working arrangements for the Register team and other relevant staff both in the office and when working at home (end to end data encryption via the internet, hardware encryption) Further to these mitigations, any malicious actions would be a criminal act.	In place – Peter Thompson As at April 2018, we are continuing to review and update key existing policies. To be completed by end Q1 2018/19 – Dan Howard
There is a risk that technical or system weaknesses lead to loss of, or inability to access, sensitive data, including the Register.	Back-ups of the data held in the warehouse in place to minimise the risk of data loss. Regular monitoring takes place to ensure our data backup regime and controls are effective. We are ensuring that a thorough investigation takes place prior, during, and after moving the Register to the Cloud. This involves the use of third party experts to design and implement the configuration of new architecture, with security and reliability factors considered.	In place – Dan Howard Results of penetration testing to be available in April. The new Register will be in use from

		Autumn 2018 – Dan Howard
Business continuity issue (whether caused by cyber-attack, internal malicious damage to infrastructure or an event affecting access to Spring Gardens).	Business continuity plan and staff site in place. Improved testing of the BCP information cascade to all staff was undertaken in September 2017 as well as a tabletop test and testing with Authority members. Existing controls are through secure off-site back-ups via third party supplier. A cloud backup environment has been set up to provide a further secure point of recovery for data which would be held by the organisation. As at April final testing is underway.	BCP in place, regularly tested and reviewed annually – Nick Jones Undertaken monthly – Dan Howard The new Register cloud backup environment will come into use in the Autumn - Dan Howard
The corporate records management system (TRIM) is unsupported and unstable and we are carrying an increased risk of it failing. Alongside this, there is the risk of poor records management by staff. The organisation may be at risk of poor records management until the new system is functioning and records successfully transferred.	A comprehensive review of our records management practices and document management system (TRIM) has started including the formation of a working group. A formal project will be initiated in July 2018 once initial scoping has been completed.	Project to be delivered within 2018/19 business year – Peter Thompson
Cloud-related risks.	Detailed controls set out in 2017 internal audit report on this area. We have in place remote access for users, appropriate security controls, supply chain security measures, appropriate terms and conditions with Microsoft Azure, Microsoft ISO 27018 certification for cloud privacy, GCloud certification compliance by Azure, a permission matrix and password policy, a web configuration limiting the service to 20 requests at any one time, good physical and logical security in Azure, good back-up options for SQL databases on Azure, and other measures.	In place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

LC1: There is a risk that the HFEA is legally challenged in such a way that resources are significantly diverted from strategic delivery.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	5	25 – Very high	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Legal challenge LC 1: Resource diversion	Peter Thompson, Chief Executive	Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment	⇔⇔⇔⇔

Commentary
At tolerance. As at April 2018, planning is underway for the CaFC appeal hearing in the autumn. The Chief Executive continues to engage with the appellant with a view to settling the case, but it is not yet possible to say whether a settlement is achievable. The number of legal parenthood cases has reduced since the initial flood of cases in 2015. Although the number of cases going through the courts is much reduced, there is nevertheless a small chance that a particularly difficult or complex case might still give rise to wider criticism. There has been an increase in the number of storage consent cases coming to the HFEA from clinics that have failed to comply with the applicable statutory provisions on extension of storage. Whilst the facts and circumstances of some cases mean that it is possible to find a way forward, it is possible that one of these cases will end up in court which would cause significant resource diversion. We have therefore added this new risk source below.

Causes / sources	Mitigations	Timescale / owner
Assisted reproduction is complex and controversial and the Act and regulations are not beyond interpretation. This may result in challenges to the way the HFEA has interpreted and applied the law.	Evidence-based and transparent policy-making and horizon scanning processes. Horizon scanning meetings occur with the Scientific and Clinical Advances Advisory Committee on an annual basis.	In place – Laura Riley with appropriate input from Catherine Drennan
	Through constructive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges or minimise the impact of them. Where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to	Ongoing – Catherine Drennan In place – Peter Thompson

	put the HFEA in the best possible position to defend any challenge.	
	Case by case decisions on the strategic handling of contentious issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	In place – Catherine Drennan and Peter Thompson
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or JRs. **Note**: Inspection rating on CaFC may mean that more clinics make representations against licensing decisions.	Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision making processes. From Spring 2018 the Head of Legal has been working with the panel to ensure consistency of advice between the legal advisors from different firms. These include: • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop • SharePoint site for sharing questions, information and experiences	In place – Peter Thompson Ongoing – including the annual workshop with advisors – Catherine Drennan
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. to ensure we take decisions well. Consistent decision making at licence committees supported by effective tools for committees. Standard licensing pack distributed to members/advisers (refreshed in April 2018). As of April 2018, the final report of the licensing review is complete. We now need to review this to assess which changes will be implemented and how, to make the licensing process more efficient and robust.	In place, licensing SOPs have been refreshed in Q4 2017/18 and this will be further informed by the licensing review, expected to be discussed and implemented May-July 2018 – Paula Robinson
	Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible.	In place – Sharon Fensome-Rimmer
Involvement of the Head of Legal in an increased number of complex Compliance management reviews and related advice impacts other legal work.	The Compliance team stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for effective planning of work. The Compliance management team will monitor the number and complexity of management reviews to ensure that the Head of Legal is only involved as appropriate.	In place – Sharon Fensome Rimmer, Nick Jones

Moving to a bolder strategic stance, eg, on add ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers. Any changes could be perceived as a threat – not necessarily ultimately resulting in legal action, but still entailing diversion of effort.	Risks considered whenever a new approach or policy is being developed. Business impact target assessments carried out whenever a regulatory change is likely to have a cost consequence for clinics. Stakeholder involvement and communications in place to ensure that clinics can feed in views before decisions are taken, and that there is awareness and buy-in in advance of any changes. Major changes are consulted on widely.	In place – Clare Ettinghausen
The Courts approach matters on a case by case basis and therefore outcomes can't always be predicted. So, the extent of costs and other resource demands resulting from a case can't necessarily be anticipated.	Scenario planning is undertaken with input from legal advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly.	In place – Peter Thompson
Legal proceedings can be lengthy and resource draining, and divert the in-house legal function away from business as usual.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.	In place – Peter Thompson
Adverse judgments require us to alter or intensify our processes, sometimes more than once.	Licensing SOPs being improved and updated, committee decision trees in place.	In progress (to complete in Q1 of 2018/19) and in place – Paula Robinson
HFEA process failings could create or contribute to legal challenges, or weaken cases that are otherwise sound,	Licensing SOPs being improved and updated, committee decision trees in place. Advice sought through the Licensing review on specific legal points, so that improvements can be identified and implemented.	In progress (to complete in Q1 of 2018/19) and in place – Paula Robinson To be discussed and implemented May-July 2018 – Paula Robinson
	Up to date compliance and enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes.	In place but review now due now – Nick Jones / Sharon

		Fensome-Rimmer
Storage consent failings at clinics are leading to a significant diversion of legal resource and additional costs for external legal advice.	We will be taking advice from a leading barrister on the possible options for a standard approach for similar cases. The Head of Legal made significant amendments to guidance in the Code of Practice dealing with consent to storage and extension of storage. This guidance should mean that clinics are clearer about their statutory responsibilities.	In Q1 2018/19 – Catherine Drennan This version of the Code comes into force October 2018 –Laura Riley
GDPR requirements require a large number of changes to practice. If we fail to comply with the requirements, this could open the HFEA up to legal challenge and possible fines from the Information commissioner's office.	GDPR work has been handled proactively, with a joint HFEA and HTA project team. The GDPR project has been sponsored directly by the Director of Finance and Resources to ensure senior oversight. AGC have regular updates on progress.	Project ongoing until October 2018 - Richard Sydee
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: HFEA could face unexpected high legal costs or damages which it could not fund.	If this risk was to become an issue then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson
DHSC: Legislative interdependency.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget. The Department are aware of the complexity of our Act and the fact that aspects of it are open to interpretation, sometimes leading to challenge. Sign-off for key documents such as the Code of Practice in place.	In place – Peter Thompson

RE1: There is a risk that planned enhancements to our regulatory effectiveness are not realised, in the event that we are unable to make use of our improved data and intelligence to ensure high quality care.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 - High	**2**	**3**	**6 – Medium**
Tolerance threshold:					**6 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Regulatory effective-ness RE 1: Inability to translate data into quality	Nick Jones, Director of Compliance and Information	Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce	⇔⇔⇔⇔

Commentary
At tolerance. As at April 2018 the overall number of Register errors is decreasing, thanks mainly to the ongoing work of the Register team. One centre is responsible for a high number of errors. Data submission work continues at a good pace. The background development work is on course to be completed in Spring 2018 and clinics will be using the new system by Autumn. The work of the Intelligence team is well underway and the latest edition of Fertility Trends successfully launched in March 2018. The team's work focuses on improving the use of our existing data and making the most of the new Register post-migration.

Causes / sources	Mitigations	Timescale / owner
IfQ has taken longer than planned, and there will be some ongoing development work needed leading to delays in accessing the benefits.	The data submission project is well planned and under way after initial delays. Data Submission development work is now largely complete, with clinic implementation and access to it following by Autumn 2018. Oversight and prioritisation of any remaining development work will be through the IT development programme board.	Completion of data submission project Autumn 2018 – Nick Jones
Risks associated with data migration to new structure, compromises record accuracy and data integrity.	Migration of the Register is highly complex. IfQ programme groundwork focused on current state of Register. There is substantial high-level oversight including an agreed migration strategy which is being followed. The migration will not go ahead until agreed data quality thresholds are met.	Autumn 2018 with regular reporting on progress prior to this – Nick

	Work on the migration is going to plan as at April 2018.	Jones/Dan Howard
We could later discover a barrier to meeting a new reporting need, or find that an unanticipated level of accuracy is required, involving data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible, through engagement with stakeholders to anticipate future needs and build these into the design. Further scoping work would occur periodically to review whether any additions were needed. The structure of the new Register makes adding additional fields more straightforward than at present.	In place regular reviews to occur once the Register goes live – Nick Jones
Risk that existing infrastructure systems – (eg, Register, EDI, network, backups) which will be used to access the improved data and intelligence are unreliable.	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery. In March 2018 CMG agreed to a new approach, including some outsourcing of technical second and third line support, this will provide greater resilience against unforeseen issues or incidents. The IT systems manager is actively investigating a medium-term solution with an outsourced IT services provider.	In place with work underway to improve arrangements in Spring 2018 – Dan Howard
Insufficient capability and capacity in the Compliance team to enable them to act promptly in response to the additional data that will be available.	Largely experienced inspection team. Business support and the inspection teams are at full complement. Although not all systems are in place in relation to providing data to inspectors eg, patient feedback, workarounds are in place which are being monitored for their effectiveness.	In place – Nick Jones
Failure to integrate the new data and intelligence systems into Compliance activities due to cultural silos.	Work is underway in 2018 to further define and bed in HFEA culture in the light of organisational changes. The people strategy was launched in April 2018.	Ongoing, Q1 and 2 2018/19 - Yvonne Akinmodun
Regulatory monitoring may be disrupted if Electronic Patient Record System (EPRS) providers are not able to submit data to the new register structure until their software has been updated.	Earlier agreements to extend part of 'IfQ' delivery help to address this risk by extending the release date for the data submission project. The Compliance management team are considering how to manage any centres with EPRS systems who are not ready to provide Register data in the required timeframe. This may include regulatory sanctions. Early engagement with EPRS providers means the risk of non-compliance is slim.	Plan in place to deal with any inability to supply data - Nick Jones
Data migration efforts are being privileged over data quality	The Register team uses a triage system to deal with clinic queries systematically, addressing the most critical errors first.	In place – Nick Jones

leading to an increase in outstanding errors		
	We undertake an audit programme to check information provision and accuracy.	In place – Nick Jones
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them although they are very reliant on a small number of individuals. We have systems for checking consistency of answers.	In place – Clare Ettinghausen / Caylin Joski-Jethi
Risk that we do not get enough patient feedback to be useful / usable as soft intelligence for use in regulatory and other processes, or to give feedback of value to clinics.	During the patient feedback trial a communications strategy was in place, including considering ways to encourage more patient feedback. The intelligence strategy focuses in part on making best use of the information gleaned from patients, and converting our mix of soft and hard data into real outcomes and improvements. This includes a new patient survey to be piloted in 2018 to give us qualitative and quantitative data on patient's experience of fertility treatment in the UK.	In place for the trial however, a plan to be developed post March 2018 with input from the Authority – Clare Ettinghausen /Caylin Joski-Jethi/Jo Triggs
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None	-	-

ME1: There is a risk that patients and our other stakeholders do not receive the right information and guidance.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Effective communications ME1: Messaging, engagement and information provision	Clare Ettinghausen Director of Strategy and Corporate Affairs	Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add ons and feel prepared Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics. Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.	⇔⇔⇔⇔

Commentary
At tolerance. The status of this risk in April is generally positive. In March 2018 we released the latest edition of Fertility Trends which has made birth data from 2016 available to patients and the wider public and stakeholders. The website was reviewed to ensure that all statistics were current. Work is underway on a new publication and engagement strategy which will ensure that we publish information regularly and align this to other wider events. A review of FOI processes and training will occur in 2018 to ensure that any further mitigations are identified and we strengthen our expertise. We do not therefore believe that this risk has risen at this point in time.

Causes / sources	Mitigations	Timescale / owner
Some of our strategy relies on persuading clinics to do things better. This is harder to put across effectively, or to achieve firm outcomes from.	Communications strategy in place, including social media and other channels as well as making full use of our new website. Stakeholder meetings with the sector in place to help us to underline key campaign messages. The Communications team cannot do this in isolation and a good deal of communication with clinics occurs through the inspectorate. When there are messages that need to be conveyed to clinics through the inspection team, Policy or	In place – Jo Triggs In place - Sharon Fensome-Rimmer,

	Communications work with the team so that a co-ordinated approach is achieved. Equally, the inspection team keep abreast of all communications with the sector through Clinic Focus, Chairs letters etc. When there are new or important issues or risks that may impact patient safety, alerts are produced collaboratively by the Inspection, Policy and Communications teams to quickly ensure that.	Laura Riley, and Jo Triggs
Patients and other stakeholders do not receive the correct guidance or information.	Policy team ensures guidance is created with appropriate stakeholder engagement and is developed and implemented carefully to ensure it is correct. Ongoing user testing and feedback about the information on the website allows us to properly understand user needs. We have internal processes in place which meet the Information Standard.	In place – Laura Riley, Jo Triggs
We are not able to reach the right people with the right message at the right time.	We have an ongoing partnership with NHS Choices to get information to patients early in their fertility journey. Planning for campaigns and projects includes consideration of communications channels. When developing policies, we ensure that we have strong communication plans in place to reach the appropriate stakeholders. Extended use of social media to get to the right audiences. The communications team analyse the effectiveness of our communications channels in order to ensure that they continue to meet our user needs. The new intelligence strategy has enabled the communications team to develop a further engagement strategy based around the reports that the intelligence team will be producing in 2018/19.	In place and developing – Jo Triggs In place and ongoing – Jo Triggs In place - Laura Riley, Jo Triggs In place– Jo Triggs Ongoing through Digital Communications Board meetings – Jo Triggs
Risk that incorrect information is provided in PQs or FOIs and this may lead to misinformation and misunderstanding by patients, journalists and others. As at April 2018, a number of people who are involved in FOIs are not trained in FOI practices and procedures, which means this risk is increased.	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. However, as at April 2018, formal organisational training is required in relation to FOIs. We have systems for checking consistency of answers and a member of SMT must sign off every PQ response before submission. A future review of the FOI processes and procedures in the organisations This will include a review of general staff understanding of FOIs.	Training to be planned for later in 2018 - Clare Ettinghausen Clare Ettinghausen /SMT - In place Clare Ettinghausen – being

		planned, to occur Spring/Summer 2018
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	
There is a risk that we provide inaccurate data on our website.	The Communications team ensure that public information reflects the latest knowledge from intelligence and Policy. Intelligence and Policy teams take all steps to ensure that accurate information is provided to Communications. The Communications team work quickly to amend any factual inaccuracies identified. The Communications publication schedule includes a review of the website, to update relevant statistics when more current information is available.	In place - Caylin Joski-Jethi, Laura Riley, and Jo Triggs In place – Jo Triggs In place – Jo Triggs
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
NHS Choices site and our site contain links to one another.	We maintain a relationship with the NHS Choices team.	

Reviews and revisions

SMT review – April 2018 meeting (16/04/2018)

- SMT considered the finance risk and agreed that by the time of the Authority meeting it would be clearer what risk remained in relation to finances and whether the risk score should be changed.
- SMT agreed to remove the organisational change risk as agreed with the Authority. Elements of the risk were moved to other risk sources as appropriate.
- SMT agreed that it now felt appropriate to reduce the score of the capability risk to at tolerance. Particular capability issues, such as that created by turnover in policy team were being addressed and though the developer role had proved more difficult to recruit for, temporary developer resource was in place to cover some of this capability gap. SMT agreed that the improvements that were underway to increase the learning, development and recognition offer would help boost organisational capability and address the risk of further loss of staff.

AGC review – March 2018 meeting (06/03/2018)

AGC reviewed the register and made the following comments:

- The finance risk had been reduced when it was reviewed at CMG however, changes in relation to the budget of the remaining digital work, as reported at the meeting, made AGC consider that this could be premature. The Chief Executive confirmed that this was due to the timing of the review of the register by the Committee which had been before the changes relating to the digital projects spend had been known.
- An update was needed to the section addressing mitochondrial applications.
- AGC asked about the cyber (CS1) risk The Chief Executive stated that, despite the recent patient feedback incident on the website, he felt reassured that the residual risk rating for cyber security remains correct.

CMG review – February 2018 meeting (20/02/2018)

CMG reviewed the strategic risk register and made the following points in discussion:

- CMG discussed the capability risk at length and considered whether the additional mitigations put in place to bring this risk back to within tolerance had been effective. CMG discussed the fact that the organisational changes were nearly complete and this would have some effect on this risk, however, it was clear that the outstanding position, the developer role, was of some concern to members. Changes in the Policy team would also lead to a loss of capability while new staff came up to speed. This would impact the Compliance and Legal teams. In the light of discussion, CMG considered that the additional mitigations had not yet materially improved the position and the risk was still above tolerance, however it agreed that the Chief Executive and Head of HR would meet to review the mitigations in detail and consider other actions available.
- On reviewing the mitigations and actions underway at a further meeting between the Chief Executive and Head of HR were minded to lower the risk to an at tolerance score of 12, to reflect the view that the actions that we put in place to reduce this risk have been partially effective and this, and the overall organisational context, reduced the residual likelihood of this risk. However, on balance they decided to retain the higher score for now as this bedding in process will take time.
- When discussing the Cyber security risk, CMG discussed whether the business continuity side of this risk belonged alongside the cyber risks or whether these should be split out. CMG agreed to consider whether there was a place for a more general information risk to be included on the register, but were mindful not to proliferate risk areas where this was not necessary.
- In relation to legal risks, CMG noted that there are no upcoming cases on the near horizon, however, this risk encompasses all legal activity and resources were stretched owing to increased demands from

Policy (from project work) and Compliance (management reviews). CMG discussed the score and considered whether it was appropriate to lower the risk likelihood. Given the new sources of this risk relating to skills gaps, CMG felt that it was more appropriate to leave the risk score the same, in spite of the reduced likelihood of litigation in the near future.

- CMG discussed whether there were any other strategic risks missing from the register. One member queried whether some of the risks listed in the operational report may in fact have strategic consequences and so should be reflected in the strategic register. No new risks were added, but CMG agreed to continue to consider this in future.

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Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.

Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in rank order according to the severity of the current residual risk score.

Risk trend

The risk trend shows whether the threat has increased or decreased recently. The direction of the arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

Likelihood:	1=Very unlikely	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Insignificant	2=Minor	3=Moderate	4=Major	5=Catastrophic

Risk scoring matrix

Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
	Likelihood				

Risk Score = Impact x Likelihood

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HFEA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlike to change, unless the organisation's role or environment changes dramatically.

Risk tolerance on the other hand is the willingness of the HFEA to accept and deal with risk in relation to specific goals or outcomes. Risk tolerance will vary according to the perceived importance of particular risks and the timing (it may be more open to risk at different points in time). The HFEA may be prepared to tolerate comparatively large risks in some areas and little in others. Tolerance thresholds are set for each risk and they are considered with all other aspects of the risk each time the risk register is reviewed

Assessing inherent risk

Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'. This can be taken to mean 'if no controls at all are in place'. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

'the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.'

System-wide risk interdependencies

As of April 2017, we explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. A distinct section to record any such interdependencies beneath each risk has been added to the risk register, so as to be sure we identify and manage risk interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DHSC or auditors as required.

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.

Code of Practice update

Strategic delivery:	☒ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (09/05/2018) 881		
Meeting date	9 May 2018		
Author	Erin Barton, Policy Manager		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note the launch of a consultation on the revised draft Code of Practice.		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex A: Consultation on the revised Code of Practice Annex B: Draft 9th edition of the Code of Practice		

1. Introduction

1.1. The Authority is required to publish a Code of Practice to provide licensed clinics and research establishments with guidance on how they should carry out licensed activities in line with legislation. The Code of Practice is reviewed regularly to update existing, or incorporate new, requirements. Although we call it a Code of Practice update, the policy decisions involved can lead to other regulatory tools such as General Directions, consent forms and best practice guidance, being updated too.

1.2. A new edition of the Code is in preparation containing some wide-ranging revisions. This paper provides a summary of recent engagement with stakeholders and the revisions to the Code currently out for public consultation.

2. Stakeholder engagement

2.1. In January, the Authority were made aware that we had established a working group comprising a range of clinic and laboratory staff, including nurses, embryologists, quality managers, doctors, counsellors and administrators. The function of the group was to advise the Executive in developing the next edition of the Code of Practice, to comment on draft sections of the Code, and to provide feedback and suggestions on the format, structure and usability. The working group met in December and January, and much of the revised Code has been directly informed by their initial feedback.

2.2. In February, we held workshops in London, Edinburgh, Manchester and Bristol where we heard the views of over 100 stakeholders on the various areas of guidance under review. One of the striking outcomes of the workshops was the commonality of themes and often quite strong consensus on the proposed direction of travel that arose.

3. Public consultation

3.1. The consultation is open for six weeks from 23 April – 1 June 2018 and stakeholders can comment via an online survey or by completing the PDF version (attached in Annex A). We have also circulated a draft version of the full Code for context, with significant changes clearly highlighted in yellow (attached in Annex B). The following areas of guidance have been reviewed as part of this update:

- Leadership
- Patient support
- Information provision to patients
- Extension of storage
- Consent
- Egg sharing
- Ovarian hyperstimulation syndrome (OHSS)
- Surrogacy
- Data Protection

- Import and export of gametes and embryos
- Single European Code
- Donor screening and quarantine
- Data submission
- QMS
- Minor consent form changes

3.2. The draft Code and consultation was sent to clinic staff in a special edition of Clinic Focus, and to members of our advisory groups; the Association of Fertility Patient Organisations (AFPO), the Licensed Centres Panel (LCP) and Professional Organisations Stakeholder Group (PSG). The consultation was also sent to various other key stakeholders as well as regional workshop attendees and members of the Code of Practice working group. The consultation will continue to be available both on the website and Clinic Portal until 1 June.

4. Next steps

4.1. After analysing consultation responses and revising any guidance as necessary, the final draft Code of Practice will be presented to Authority in June for approval. Subject to sign off by the Secretary of State the new version of the Code will be in effect from in October 2018.

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

Chief Executive's introduction

Dear colleagues,

We want to hear your views on the changes we are making to the HFEA Code of Practice. The purpose of the new edition is to provide all staff at licensed clinics with a clear and up-to-date reference point about the HFEA's expectations in relation to interpreting the law that governs all our work.

We published the last edition of the code in 2009 and have been producing regular updates since then. This new edition includes some wide-ranging revisions, particularly in the areas of support for patients and leadership in relation to patient care and clinic activities. It also brings the code up to date to in light of EU Directives coming into force in Spring 2018 and anticipating the Department of Health and Social Care's intention to update the law in relation to surrogacy and applications for parental orders. The new edition also incorporates all the directions given by Chair's and Chief Executive's letters and Clinic focus articles since we last incorporated them comprehensively in 2015.

The focus on leadership that runs throughout the new edition is applicable to staff at licensed clinics in all roles and we look forward to continuing to support leadership in teams to reflect their multidisciplinary needs more widely. We are beginning with planning a new programme of engagement with persons responsible across 2018. We will be inviting all PRs to attend a new meeting for the sector for topical discussion with us, continuing professional development and networking, which we hope will become an annual event helping PRs to share their good practice with their peers and to continue their work to drive up standards across the sector as a whole.

Revising the current code has offered a welcome opportunity for us to engage with all those involved in delivering fertility treatment and other stakeholders to develop a shared understanding of what these changes will mean to clinical and research practice. Staff from licensed centres across the UK have shared examples of their good practice in raising the overall standards of care and support that all patients can expect, for which we thank them.

Given the new EU Directives that came into force in April 2018, several months earlier than the Government had expected, some of the elements referred to in the draft code will already be in force at the time of consultation and our detailed guidance on these will have been given separately in a Chair's letter. We have included the new guidance here for information only. We will, of course, seek feedback on how effective that guidance has been in future consultations on the code once clinics have had time to work with the new requirements.

We also ask whether there are any other important areas that we could provide guidance on that are not included in this new edition, which we can then address in future.

Thank you to those people who have already given us your views and to those who took part in the workshops to inform the changes set out in this consultation. The consultation period runs for six weeks until 1 June 2018. We hope you will respond as your feedback is important.

Yours sincerely,

Peter Thompson
Chief Executive, HFEA

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

Background to the consultation on the Code of Practice 2018

We produce the Code of Practice to help clinics comply with the legal requirements set out in the Human Fertilisation and Embryology Act.

To help inform the development of this draft code, we convened a Code of Practice review working group made up of clinicians, embryologists, counsellors and nurses and other key stakeholders delivering licensed fertility services to patients. From the outset of this work in December 2017, this group have met to represent to us the views of the core professional audience for this new edition of the Code of Practice.

We have further engaged directly with relevant professional and regulatory bodies, patient groups and licensed clinic representatives on relevant areas of the draft code.

We also commissioned specific legal advice on particular issues and have discussed the relevant policy principles and issues at Authority meetings with our board members and Chair, Sally Cheshire, who also outlined some of this work at our recent annual conference.

One of the most valuable approaches to us in the development of this draft code has been the open workshops we held in early 2018. At these workshops in London, Edinburgh, Manchester and Bristol, we sat down to talk through these proposed changes with over 100 attendees gathered from all disciplines and working at all levels of clinical care and research practice. The discussions that arose were incredibly valuable to us and directly informed the revised drafting in the code presented here for consultation, changes to the relevant Directions, and our policy thinking. Thank you to all who attended those.

One of the striking outcomes of the workshops was the commonality of themes and often quite strong consensus on the proposed direction of travel that arose. While we will take account of all views, and this consultation forms an important part of doing that openly, we hope that the support we have heard thus far at the workshops for principles in the new code around patient support, leadership and information provision, including around treatment add ons, for example, reflect our ongoing efforts to build a two-way, listening regulatory relationship, engaging with the sector well in advance of and outside of the set points for formal public consultation.

We hope that the sections of the code that we are consulting on here set out the standards that we expect licensed centres to meet. We welcome your comments on whether we have expressed these standards clearly, and whether the proposed regulatory approach will allow centres to follow our guidance.

The new code will look similar to previous codes in format and we hope that licensed centres will continue to find the familiar format easy to use. For improved ease of use of the code online, we will be taking steps to help centres with searching the code via our website and Clinic Portal.

The consultation runs from 23 April to 1 June and is available to comment online at www.surveymonkey.com/ or in pdf formathere xxxx

To contact us about the consultation, or any other aspect of our work, please email enquiriesteam@hfea.gov.uk.

HFEA Code of Practice 9th edition

General questions

This survey will guide you through several areas of guidance that have been reviewed as part of this new edition. We have included excerpts of the draft code throughout to enable you to answer questions and comment. Highlighted text draws your attention to an area of the guidance that has been amended or added. Where extracts from the code are not highlighted, this is all new text.

The areas of guidance we are amending are:

- leadership
- patient support
- information provision to patients
- extension of storage
- consent
- screening
- egg sharing
- ovarian hyperstimulation syndrome
- surrogacy
- general data protection regulation.

For information:

- import and export of gametes and embryos
- single European code
- other amendments including:
    - data submission
    - QMS
    - minor consent form changes
- format and usability.

You do not have to complete every question. There is space for any other comments at the end of each section.

*** 1. Personal details**

Name	
Job title	
Organisation	

Leadership

Good leadership improves patient care. It therefore follows that if we are to ensure that all fertility patients receive high quality care, we need to set a regulatory framework which encourages good leadership. The proposed changes to the code below are designed to do just that, but they will not alone bring about the general improvement in leadership in the sector that we wish to see. We will also be looking at the training and support we can provide to persons responsible (PRs) in particular.

Guidance notes 1 and 2 set out our policy requirements of the PR, the Licence Holder (LH) and staff within centres. In previous editions of the code those requirements have been fairly narrowly focussed on the relationship between the PR and the LH (see HFEA guidance note 1: 1.1 and 1.2 below), the qualifications of the PR (1.3 and 1.4 below), the awareness and understanding of the legal obligations involved (1.6(a) below), and the need to participate in the various regulatory processes in place (1.6(b) and (c)). Requirements relating to the management of staff, their professional registration, training and other matters is set out in guidance note 2.

We want to be more ambitious in respect of the expectations we place on PRs and other staff within centres because we believe that improving leadership will continue to improve patient care. We propose a number of changes to guidance note 1 to include explicit reference to leadership capability.

Being a leader can be a lonely role and we want to see evidence that the PR will have the necessary authority and autonomy to carry out the role to the best of his/her abilities. This is particularly important where the PR is not the sole owner of the clinic. We propose amending 1.4 to place a requirement on the LH to provide evidence that any proposed PR will have that authority.

In a fast-moving field like fertility treatment, it is vital that PRs have an up-to-date understanding of their policy and legal obligations. To date, we have only assessed that understanding when the PR is first appointed. We propose amending 1.5(a) to refer to the need for all PRs to complete the PREP (person responsible entry programme) assessment; work is underway on revising PREP so that it is suitable for periodic refresher training and we will consult with the sector on the appropriate frequency and scope of any such reassessment.

A well-led clinic is one where staff are involved at all levels and in future we wish to see evidence that PRs have systems in place to ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. We have introduced 1.6 (a), (b) and (c), and a new requirement in guidance note 2 at 2.3, to that effect.

A high performing clinic is one where roles and accountabilities are clear and risks are well managed,

and where the PR is responsive to feedback whether positive or negative. We propose making explicit those obligations by introducing a new section to guidance note at 1.7 below.

The licence holder and the person responsible

1.1 The licence holder and the person responsible should be separate individuals. Clinics operating within a hospital or other healthcare organisation may find it advantageous for a senior hospital manager to hold the post of licence holder.

1.2 It is the responsibility of the licence holder to inform the HFEA if the person responsible is unable to perform their duties. Where the centre no longer has a person responsible, the licence holder should seek the advice of the HFEA as soon as possible on continuing to provide licensable activities. Either the person responsible or the licence holder may apply for a licence or for its variation or revocation. However, only the licence holder may apply to a licence committee to vary a licence in order to designate another individual to be the person responsible.

Qualifications for the role of the person responsible

1.3 The person responsible should have enough understanding of the scientific, medical, legal, social, ethical and other aspects of the centre's work to be able to supervise its activities properly. It is also important that the person responsible possesses integrity and leadership capability.

1.4 When applying to vary a licence in order to appoint a new person responsible, the licence holder must provide evidence that the proposed individual has the managerial authority and capability necessary to perform their duties.

1.5 The HFEA expects the person responsible to take any necessary specialist advice to allow them to run the centre professionally.

Responsibilities of the person responsible

Interpretation of mandatory requirements 1B

The person responsible is ultimately responsible for ensuring that all licensed activities are conducted with proper regard for the regulatory framework that governs treatment and research involving gametes or embryos.

1.6 The role of the person responsible should include:

(a) maintaining an up-to-date awareness and understanding of legal obligations
(b) responding promptly to requests for information and documents from the HFEA
(c) co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement, regulation or healthcare, and
(d) informing the HFEA of any change to their professional registration

1.7 The person responsible should ensure that:

(a) all staff maintain an up-to-date awareness and understanding of legal obligations
(b) all staff possess the competencies necessary for their role, and have access to learning and professional development
(c) all staff are encouraged, as appropriate, to contribute to discussions and decisions about improving patient care.

1.8 The person responsible is accountable for the overall performance of the centre and to that end should ensure that:

(a) there are clear responsibilities, roles and systems of accountability to support good governance
(b) appropriate action is taken following feedback from the HFEA, staff and patients, including through the outcomes of inspections, audits, patient complaints and feedback.

Centre staff

2.3 All staff should maintain an up-to-date awareness and understanding of legal obligations, and should support the person responsible in monitoring and improving the performance of the centre.

2. Do you think these new requirements clearly set out the expectations of a person responsible?

- ◯ Yes
- ◯ No
- ◯ Unsure

3. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

Patient support

Undertaking fertility treatment can be a distressing and anxious time for patients and their partners and we want to reduce the emotional burden. We know that emotional support for patients during their treatment is very important to their overall experience at clinics. Our aim is to improve the emotional experience for patients and donors and there partners, where applicable, before, during and after treatment or donation. We want to see a cultural shift in clinics to place a greater emphasis on the emotional aspect of patient treatment.

We think it is right to set clear expectations in the Code of Practice for clinics regarding the support they provide to patients. We recognise that many clinics do an excellent job in supporting their patients, but this is not universal. We hope to raise the standard of patient care across all clinics by proposing that every clinic sets out a policy on patient care outlining how it will ensure patients, donors and their partners receive appropriate psychosocial support from all staff they encounter before, during and after treatment. We also plan to guide and help clinics to improve their patient support in the coming months, which may include organising training workshops and publishing a patient support pathway and guidelines to support clinics in implementing their patient support policy.

New addition to guidance note 3: counselling

Patient support

3.17 The centre should develop a 'patient support policy', to outline how the centre ensures that patients, donors and their partners (where applicable) receive appropriate psychosocial support from all staff they encounter before, during and after treatment. Psychosocial support is delivered by all members of staff and includes, but is not limited to, access to counselling. All patients, donors and their partners (where applicable) should be treated with sensitivity and respect, and supported through all aspects of their treatment and, in particular, if they are suffering distress at any stage.

3.18 The policy should include:

a) a definition of patient-centred care and how this will be delivered at the centre

b) a statement regarding each individual staff member's responsibility for supporting patients and managing their expectations

c) a list of written and online information to be provided and how patients will be able to access this

d) what the centre will provide in terms of

   i) support groups
   ii) forums for patients to engage with each other
   iii) signposting to external groups and forums
   iv) other events/groups/open evenings etc

e) the expectations about how all staff will communicate with patients, donors and their partners

f) an outline of customised support interventions at different stages of treatment and for different types of patients

g) the annual programme of training that will be provided to staff on different aspects of patient support, including skills training, adapted as appropriate to reflect staff members' role within the clinic

h) feedback mechanisms for collecting data on the patient/donor experience, and

i) quality indicators for systematically monitoring and evaluating the centre's provision of patient support and patient care as contained in this policy.

3.19 Clinics should also refer to the HFEA's guidelines on patient support for further guidance on best practice.

4. Is the proposed guidance clear about what should be included in the patient support policy?

- ◯ Yes
- ◯ No
- ◯ Unsure

5. Can you foresee any difficulties in implementing a patient support policy in your clinic?

- ◯ Yes
- ◯ No
- ◯ Unsure

Amendments to guidance note 23: Quality management system

Quality policy and quality objectives

23.6 The quality policy is defined as:

'the overall intentions and direction of an organisation related to quality as formally expressed by centre management. A quality policy statement defines or describes an organisation's intentions and commitment to quality and provides a framework for setting quality objectives and planning.' (International Organization for Standardization)

23.7 Centre management should ensure the quality policy includes a commitment to:

(a) providing a service that meets its users' needs and requirements. This should include ensuring that all staff who come into contact with patients, donors and their partners (where applicable) provide the good quality supportive care before, during and after treatment, as outlined in the centre's patient support policy
(b) meeting the provisions of this Code of Practice and statutory provisions and standard licence conditions
(c) continually improving the effectiveness of the quality management system
(d) upholding good professional practice, and
(e) ensuring the health, safety and welfare of all staff and visitors to the centre.

23.8 The quality policy should be:

(a) signed and issued by the person responsible
(b) communicated, understood and available throughout the centre, and
(c) reviewed for continuing suitability.

23.9 Centre management should establish documented quality objectives. These should:

(a) include objectives needed to meet users' needs and requirements, including their need for supportive care and treatment, from clinic staff, before, during and after treatment or donation (see GN 3 paragraph 3.14)
(b) be measurable and consistent with the quality policy, and
(c) be reviewed regularly.

Quality indicators

23.16 The centre should establish quality indicators for systematically monitoring and evaluating the centre's provision of emotional support and patient care generally.

Assessing user satisfaction

23.17 The centre should assess whether or not the service has met users' needs and requirements, including the extent to which they felt supported before, during and after their treatment or donation. It should keep records of the information it collects and the actions it takes. Methods should include user surveys for all aspects of the service.

6. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

Information provision to patients

We want to ensure that patients receive good quality, unbiased information before they give consent to treatment and/or storage. We also want to ensure that patients receive the same standard of information for emerging or unproven treatment add ons as they do for established treatments such as IVF.

During Summer 2017 we ran a patient survey to find out how patients feel about the information they receive before giving consent. We explored the findings from this survey during a clinic workshop held in November 2017.

We have redrafted guidance note 4 - Information to be provided prior to consent - with the following key changes:

- a new structure breaking down requirements into focused subheadings
- explicit requirements for information relating to treatment add ons
- requirements for centres to provide information about the effectiveness of treatments and treatment add ons
- strengthened guidance relating to OHSS
- encouragement for centres to display their success rates 'per embryo transferred'.

The guidance relating to information for transgender patients in guidance note 4 has not been amended as part of this exercise so is not included in this consultation.

Information specific to the centre

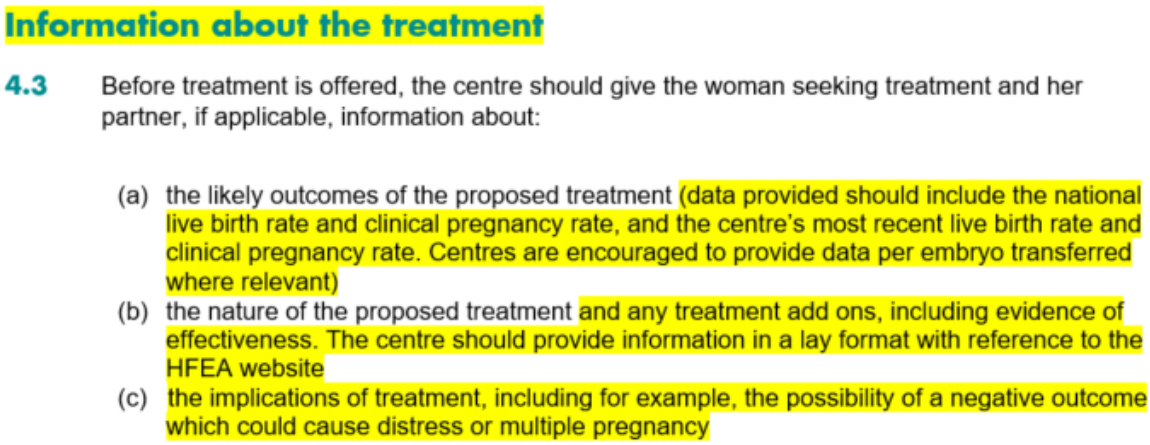
4.2 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the centre's policy on selecting patients
(b) the centre's statutory duty to take account of the welfare of any resulting or affected child
(c) the expected waiting time for treatment
(d) fertility treatments available, including any treatment add ons which may be offered and the evidence supporting their use. Any information should explain that treatment add ons refers to the technologies and treatments listed on the treatment add ons page of the HFEA website (https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/)
(e) the availability of facilities for freezing and storing eggs, sperm and embryos
(f) where patients freeze and store eggs, sperm or embryos the centre should provide information about future use including information about consent to posthumous use
(g) the importance of informing the treatment centre about the eventual outcome of the treatment (including if no live birth results)
(h) the centre's complaints procedure.

7. Do you think that guidance in 4.2 includes all the relevant information that should be provided to patients about the centre?

- ◯ Yes
- ◯ No
- ◯ Unsure

We want patients to receive clear and unbiased information about the nature of any treatments or treatment add ons which they are offered. We also want patients to receive information about the likely effectiveness of any proposed treatments or treatment add ons so they can make an informed decision about their treatment options.



Information about the treatment

4.3 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the likely outcomes of the proposed treatment (data provided should include the national live birth rate and clinical pregnancy rate, and the centre's most recent live birth rate and clinical pregnancy rate. Centres are encouraged to provide data per embryo transferred where relevant)
(b) the nature of the proposed treatment and any treatment add ons, including evidence of effectiveness. The centre should provide information in a lay format with reference to the HFEA website
(c) the implications of treatment, including for example, the possibility of a negative outcome which could cause distress or multiple pregnancy

8. Do you think that the requirements set out above in 4.3 (b) will be effective in ensuring that patients receive sufficient unbiased, evidence-based information about the nature and effectiveness of any treatment or treatment add on which they may be offered?

- ◯ Yes
- ◯ No
- ◯ Unsure

We want to ensure that patients are informed of what to do and who to contact if they experience symptoms of OHSS. In the draft guidance we have focussed on the outcome rather than setting out exactly how clinics should go about informing their patients.

Information about the risks of treatment

4.4 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the potential immediate and longer-term risks of the treatment and any treatment add ons used, including the risk to the patient and of any children conceived having developmental and birth defects
(b) the nature and potential risks of any alternative treatment options available so the patient can make an informed decision about their treatment
(c) the possible side effects and risks to the woman being treated and any resulting child
(d) the possibility of developing ovarian hyperstimulation syndrome (OHSS). Any information provided should include the possible symptoms of OHSS, what the woman being treated should do and who to contact if experiencing symptoms of OHSS
(e) the nature and potential risks (immediate and longer-term) of using emerging or unproven treatments, including reference to the clinic's experience and wider evidence base
(f) the potential risk of emotional distress associated with negative outcomes both during and after treatment.

9. Do you think the requirements set out in 4.4 (d) will be effective in ensuring that patients are informed of what to do and who they should contact if experiencing symptoms of OHSS?

- ◯ Yes
- ◯ No
- ◯ Unsure

Any other comments

In 2016 the Authority decided to display HFEA birth rate statistics per embryo transferred. In this update to the Code of Practice we encourage centres to display their success rates in the same way.

Information about success rates

4.5 In line with the Advertising Standards Authority's Code, the centre should ensure that the information provided on its website complies with the following guidance. This also applies to other relevant marketing communications of the centre and associated satellite and transport centres.

(a) The information should include the most recent data available from the past three years.
(b) Centres are encouraged to display live birth rate data per embryo transferred where relevant and this may be displayed alongside other success rate measures. The information should not highlight a high success rate that is not statistically significant where it applies only to a small, selected group of patients.
(c) The data should show split by maternal age and, if appropriate, by treatment type.
(d) The information should provide raw numbers rather than just percentages.
(e) The website should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.).
(f) The centre's published success-rate data should refer to the HFEA as the source of national information through its Choose a Fertility Clinic function.
(g) The information must state clearly that information on success rates is of limited value in comparing centres and choosing where to seek treatment. It should include a link to the HFEA's advice on choosing a clinic: https://www.hfea.gov.uk/choose-a-clinic/learn-about-choosing-a-clinic/
(h) If the information refers to comparative costs, it should indicate the likely total cost for a typical cycle, based on the actual costs for recent patients, not individual items in tariffs.

10. Do you think that the guidance provided in section 4.5 is sufficiently clear that clinics can understand what is expected of them in terms of success rates displayed on their website or any other material they produce?

- ◯ Yes
- ◯ No
- ◯ Unsure

11. Any comments

Human Fertilisation & Embryology Authority

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Extension of storage of gametes and embryos

The guidance around storage of gametes and embryos is being amended to provide more clarity in respect of:

- when written consent is needed from a gamete provider

- the requirement for a medical opinion for extension of storage
- when to obtain patient's consent for extension of storage, and
- what is not considered premature infertility.

The changes are highlighted below in yellow.

Interpretation of mandatory requirements 17C

The law requires the centre to obtain written informed consent from a person before it stores their gametes or embryos created with their gametes.

The law allows gametes to be stored without consent if the conditions met in paragraph 9 or 10, and 11 of Schedule 3 of the HFE Act 1990 (as amended) are met.

Gametes stored following the application of these paragraphs may be used only if the person from whom they were collected gives written effective consent to their use (and has sufficient capacity and competence to do so).

In certain limited circumstances involving premature infertility, gametes and embryos can be stored beyond the statutory maximum storage period.

Gametes first placed in storage before 1 August 1991

Any gametes currently in storage which were originally placed into storage prior to 1 August 1991 i.e. prior to statutory regulation, can only continue to be stored if the original 10-year storage period was properly extended under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 (the 1991 Regulations) and has not expired. Any gametes in storage as at 31 July 2001 (10 years after the storage period was deemed to commence) and which were not eligible for extension of storage under the 1991 Regulations should have been allowed to perish. The Schedule to the 1991 Regulations sets out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period must be calculated from 1 August 1991.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage between 1 August 1991 and 1 October 2009

Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period ~~without the written consent of the gamete provider~~ if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied. The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period begins on the date that the gametes were stored. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

Embryos first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period but only if both people whose gametes were used to bring about the creation of the embryo confirm in writing that they have no objection to the extension (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are satisfied). The Schedule to these Regulations set out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage after 1 October 2009

Gametes or embryos first placed in storage after 1 October 2009 may continue to be stored beyond the statutory maximum storage period, to a maximum of 55 years, but only with the written consent of the gamete provider or the people whose gametes were used to bring about the creation of the embryo (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 Regulations') are satisfied). Gametes and embryos first stored earlier than 1 October 2009 may be stored for an extended period under the 2009 Regulations but only where the gametes or embryos are either still within the statutory storage period, or are being stored subject to a lawfully extended period under the 1991 or 1996 Regulations respectively.

For guidance about steps to take when consent is not required, see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.

Extension of storage

Interpretation of mandatory requirements 17D

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 Regulations') allow gametes or embryos to be stored for longer than the

10-year standard storage period, up to a maximum of 55 years, provided that the conditions set out in those Regulations have been met.

There are two criteria that must be met; the first is that the relevant person(s) have provided written consent to the gametes or embryos being stored for longer than 10 years; and the second is that on any day within the relevant period a registered medical practitioner has given a written opinion that the person who provided the gametes, or in the case of embryos, one of the persons whose gametes were used to create the embryos, or the person to be treated, is prematurely infertile or likely to become prematurely infertile.

To meet the statutory requirements, the written consent to storage for a period of more than 10 years must be given before expiry of the original 10-year statutory storage period or, in the case of gametes or embryos which have already been stored pursuant to an extended period under the 2009 Regulations, before expiry of that extended period.

The written opinion on premature infertility must be provided by a medical practitioner who is registered with the General Medical Council and must be provided within 10 years from the date that the gametes or embryos were first placed in storage or, in the case of gametes or embryos which are being stored pursuant to an extended period under the 2009 Regulations, within 10 years of the date of the most recent medical opinion.

The statement from the medical practitioner must be renewed for every 10-year storage period beyond the initial statutory period.

17.16 The centre should inform patients wishing to store gametes or embryos for more than 10 years of criteria set out in the 2009 Regulations and how these must be satisfied. It is important that, in the case of patients who wish to store gametes or embryos for more than 10 years, centres take steps to satisfy the requirements of the 2009 Regulations before expiry of the patient's current storage period.

17.17 To satisfy the Regulations for extended storage periods, the centre should seek a written medical opinion to certify that one of the gamete providers, the woman who is to be treated with the gametes, or the person who the gametes or embryos have been allocated to, is prematurely infertile or likely to become prematurely infertile. This medical opinion should be obtained before expiry of the current storage period and needs to come from a medical practitioner registered with the General Medical Council (GMC). A medical opinion from an overseas medical practitioner who is not registered with the GMC does not satisfy the requirements of the 2009 Regulations.

17.18 The centre should seek the written medical opinion on premature infertility whilst the gamete provider is alive. However, if the gamete provider (who has provided consent to extended storage) dies before a medical opinion is in place, the medical opinion may be sought after death based on evidence that the person would have satisfied the premature infertility criteria when they were alive. Although the medical opinion may be provided after the gamete provider's death, it must nevertheless be provided within the relevant period; that is within the 10-year statutory storage period, or in the case of gametes or embryos that are being stored pursuant to an extended period under the 2009 Regulations, within ten years of the most recent medical opinion.

17.19 Whether a person is or is likely to become prematurely infertile is a clinical judgment taking into account all relevant considerations and information known to the clinician at the time. A woman who has reached menopausal age will not however be considered prematurely infertile and similarly, a same-sex couple will not be considered prematurely infertile.

17.20 Provided the provisions of the 2009 Regulations have been met, the centre can store the gametes and embryos for a further 10 years from the date the criteria are met. The centre can extend the storage period by further 10-year periods (up to the maximum of 55 years) if it is shown at any time within each extended storage period that the criteria continue to be met.

End of storage

Interpretation of mandatory requirements 17F

No centre may keep embryos or store gametes after the expiry of the statutory storage period, or after the end of any shorter period specified by the gamete provider(s). Storing embryos or gametes beyond the relevant period is a criminal offence, punishable by a prison sentence, fine or both.

17.23 The centre should make efforts to stay in contact with patients who have gametes or embryos in storage for their own treatment, and with any woman to be treated with stored gametes or embryos (where she is not a gamete provider.) The centre should also explain to gamete providers and current patients the importance of informing the centre of any change in their contact details, including that their gametes or embryos may be removed from storage if they do not keep their contact details up to date.

17.24 The centre should establish and use documented procedures to contact patients who have gametes or embryos in storage for their own treatment when the end of the permitted storage period is approaching but long enough in advance to allow the centre and patient to take any steps necessary to comply with the 2009 Regulations where extension of storage is an option for the patients. The centre should use all contact details available to them, including at least one written form of contact. Patients should be provided with information about the options available to them as the end of their permitted storage period approaches. They should be given enough notice to enable them to consider those options and to access appropriate advice. Options could include the donation of the gametes or embryos for research, training or for the treatment of others. If contact with the patient is not possible, the centre should record the steps it has taken in the patient's medical records.

12. Do you think that the changes to guidance note 17 are sufficient to provide clarity about these legal obligations?

- ◯ Yes
- ◯ No
- ◯ Unsure

13. Any comments

Human Fertilisation & Embryology Authority

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Consent

It is important that when a patient gives consent that the clinic can assure themselves that the consent is informed and given by the right person. We think there should be more guidance in the Code

for clinics to have processes in place to ensure consent is taken properly and is witnessed.

We propose to add an additional step to guidance note 5.11 ensure consent is taken properly:

Procedure for obtaining consent

5.11 The centre should ensure that consent is:

(a) given voluntarily (without pressure to accept treatment or agree to donation)
(b) given by a person who has capacity to do so
(c) taken by a person authorised by the centre to do so, and
(d) given at the clinic (with both parties if a couple is being treated) where possible, clinics should record why a patient is not able to sign at the clinic and should have a documented process for ensuring consent forms being signed outside the clinic are signed by the correct person

14. Is this addition feasible for clinics to carry out to ensure consent is given by the correct individual?

- ◯ Yes
- ◯ No
- ◯ Unsure

Our aim is to ensure that clinics have processes in place to ensure consent is taken properly and is witnessed appropriately, and that consent is informed and given by the right person.

Clinics also need to be able to satisfy themselves of the evidence of legal relationships such as marriage or civil partnership between a couple who are seeking treatment together. Clinics need a clear understanding of such patients' legal relationships to each other to be able to discuss consent with them appropriately, given the implications for legal parenthood.

5.13 Treatment centres should take all reasonable steps to verify the identity of anyone accepted for treatment, including partners who may not visit the centre during treatment. The centre should establish the relationship between a patient and their partner and a record of this should be retained in the patients' notes. If a patient's identity is in doubt or if a centre has reason to question whether the person is who they claim to be, the centre should verify their identity, including examining photographic evidence such as a passport or a photocard driving licence. The centre should record this evidence in the patient's medical records. Centres should have a process in place to verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment, to ensure the patient and their partner are the same people they treated initially. The clinic should establish whether the patient and their partner's personal circumstances have changed in the period since their last treatment, for example, whether the couple has divorced or separated since their previous treatment and give consideration to whether any changes in their personal circumstances impact on consent.

In paragraph 5.15 of the Code of Practice, the guidance requires that where the partner of a patient has not visited the clinic or does not return for subsequent treatment, the clinic should take reasonable steps to find out if they still consent to treatment. We propose to make an addition that says treatment should not commence until the clinic is satisfied that the partner consents to the treatment.

15. Do you think that these additions will be effective in allowing clinics to be given evidence of the legal relationships between patients seeking treatment together as a couple in a marriage or civil partnership?

- ◯ Yes
- ◯ No
- ◯ Unsure

5.15 To avoid the possibility of misrepresentation or mistake, the centre should check the identities of patients (and their partners, if applicable) against identifying information in the medical records. This should be done at each consultation, examination, treatment or donation. If the partner of a patient who is having treatment has not visited the clinic throughout the treatment, or does not return with the patient for subsequent treatment, centres should take reasonable steps to find out whether the patient's partner still consents to the treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is still valid. The centre should not commence treatment until it is satisfied that the partner in fact consents to the treatment.

16. Do you think that this guidance will be effective in ensuring that the clinic can avoid carrying out potentially unlawful treatment when a partner of a patient no longer consents to treatment?

- ◯ Yes
- ◯ No
- ◯ Unsure

17. Any comments

Human Fertilisation & Embryology Authority

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Egg sharing

The guidance on egg sharing has been reviewed to address an overly informal culture in some clinics on the provision of information to patients in relation to donation treatment and the special nature of both egg donation and egg sharing.

When the Code of Practice was updated in April 2017, our guidance on egg sharing was changed to explicitly rule out 'egg giving'. However, at 12.5 the guidance does make a provision for “exceptional circumstances” where deferring treatment to the egg provider is appropriate. We asked our working

group and attendees at our regional workshops whether there are enough examples of what could constitute "exceptional circumstances" for this to be useful, or whether making this provision is confusing and could be harmfully misinterpreted.

Clinic staff felt that there are no "exceptional circumstances" where the egg provider should donate all the eggs collected in the initial cycle. If deferring treatment to the egg provider is appropriate, egg freezing should be offered where possible. In the very rare event that this is not possible, the centre can contact their inspector. This is reflected in the updated guidance below.

NB: Although we are proposing removing reference in 12.5 to the situation where the number of eggs collected is lower than is needed for a benefits in kind arrangement, this is already mentioned in 12.20 – "If too few eggs are collected for use in a benefits in kind agreement, the woman should be given the option of using or storing all the eggs for her own treatment, at the agreed discount."

Benefits

12.4 Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for fertility treatment or mitochondrial donation.

12.5 If benefits in the form of licensed services are offered to an egg provider (including a mitochondrial donor), they should be given in connection with the cycle in which eggs are supplied for a recipient's treatment unless providing treatment to the egg provider at this stage could be harmful, or there is a clinical reason(s) to defer treatment to the egg provider.

In the exceptional circumstance where deferring treatment to the egg provider is appropriate, ~~the egg provider may choose to donate all the eggs collected in the initial cycle and receive the benefits in a subsequent cycle. This excludes cases where the number of eggs collected is lower than is needed for a benefits in kind arrangement. In this event, and where possible,~~ egg or embryo freezing should be offered where possible.

18. Do you think that this deletion is a feasible requirement?

- ○ Yes
- ○ No
- ○ Unsure

Inspection findings have suggested that we should introduce guidance on the distribution of eggs in an egg sharing arrangement. We have introduced a requirement for centres to distribute eggs evenly between the provider and the recipient(s) and to be clear about who will receive the additional egg if an odd number is collected. This updated guidance can be found in 12.6, 12.22 and 12.30.

Benefits

12.6 In an egg sharing arrangement, centres should ensure that, where the minimum number of eggs required for the arrangement are collected, eggs are distributed equally between the egg provider and the recipient(s). Where an odd number of eggs is collected, the benefits in kind agreements should clearly set out who will receive the additional egg.

Agreement between a licensed centre and a gamete provider

12.22 The agreement should include full details of the proposed arrangements for distributing the eggs or sperm between the provider and recipient(s), including:

(a) the minimum number of eggs required for a benefits in kind arrangement
(b) the number of recipients among whom the eggs or sperm will be shared (which for eggs should be no more than two, excluding the egg provider), and
(c) who will receive the additional egg where an odd number is collected.

Agreement between a licensed centre and a recipient

12.30 The agreement should set out the proposed arrangements for distributing the eggs between the provider and recipient(s), including:

(a) the minimum number of eggs required for the benefits in kind arrangement
(b) the number of recipients among whom the eggs or sperm will be shared (which for eggs should be no more than two, excluding the egg provider), and
(c) who will receive the additional egg where an odd number is collected.

19. Do you think that this addition is a feasible requirement?

- ◯ Yes
- ◯ No
- ◯ Unsure

We propose that, should the gamete provider choose not to have counselling, clinics should record the reason for refusal and discuss the implications of donation with the gamete provider. In addition, an agreement between the clinic and the gamete provider, and between the clinic and recipient, should confirm that the gamete provider and the recipient have received information about the treatment and donation.

This updated guidance can be found in 12.10, 12.19(e) and 12.27(e).

Consent

12.10 Centres should ensure that where a gamete provider elects not to have counselling, the implications of donation are discussed with the gamete provider. Centres should record that the implications of donation have been discussed and why the gamete provider has elected not to have counselling. The gamete provider should be given enough time to consider the implications of donating, before giving consent.

Agreement between a licensed centre and a gamete provider

12.19 The agreement should include a statement from the egg or sperm provider confirming that they have:

(a) had an opportunity to talk with a member of staff qualified to explain the procedures involved in providing gametes as part of a benefits in kind arrangement
(b) received verbal and written information about the treatment
(c) received all the appropriate information listed in the relevant parts of this Code of Practice
(d) been offered counselling
(e) received information about the implications of the treatment and donation, and
(f) been made aware of the screening that will be done before treatment begins.

Agreement between a licensed centre and a recipient

12.27 The agreement should include a statement from the recipient confirming that she has:

(a) had an opportunity to discuss with an experienced member of the centre's staff the procedures involved in receiving eggs or sperm as part of a benefits in kind arrangement
(b) received verbal and written information about her treatment
(c) received all the appropriate information listed in the relevant parts of this Code of Practice (written information should be attached to the agreement)
(d) been offered counselling
(e) received information about the implications of the treatment and using donated gametes, and
(f) been informed about the screening that the egg or sperm provider has undergone and the limitations of that screening in avoiding transmissible conditions.

20. Do you think that this proposal will be effective in ensuring prospective gamete providers and recipients in a benefits in kind arrangement receive appropriate information prior to consent?

- ○ Yes
- ○ No
- ○ Unsure

21. Any comments

Human Fertilisation & Embryology Authority

Ovarian hyperstimulation syndrome (OHSS)

Ovarian hyperstimulation syndrome (OHSS) is a potentially serious side effect which some patients develop in reaction to the drug treatment necessary for IVF.

To support improvements to the care and follow up of patients affected by OHSS, changes to the Code of Practice in guidance notes 4, 15, 27 and Directions 0011 are proposed to clarify our expectations on this issue.

These changes aim to better inform patients about OHSS, support OHSS prevention, improve accuracy of reporting around OHSS and to highlight the part that information sharing with local NHS hospitals could play in this reporting.

To improve accuracy of reporting around OHSS:

All 'severe' and 'critical' cases of OHSS must be reported to the HFEA, irrespective of whether or not the patient's case has involved a hospital admission. This will bring our reporting requirements into line with the criteria for assessing and classifying the severity of OHSS, as set out in the relevant RCOG Green top guideline. Hospital admission and the length of time spent in hospital are not part of the RCOG's classification system and are not in themselves an indicator of severity.

To do this, we propose to remove the text 'requires a hospital admission and' from 27.1 of the Code of Practice, (which defines an 'adverse incident') and also 4 a) and 4 d) of Directions 0011 which make the same specification.

We will also provide a new form to help to simplify OHSS reporting to us, for use from October 2018, when the new edition of the Code of Practice comes into force. We propose that guidance note 27.8 will mention a requirement for centres to complete this reporting form for OHSS incidents (where there is a severity grading of 'severe' or 'critical'), within 25 working days.

Definitions

27.1 An 'adverse incident' is any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre. This includes serious adverse events, serious adverse reactions, breaches of confidentiality, anomalies or deficiencies in the obtaining or recording of consent, and ovarian hyperstimulation syndrome (OHSS) which ~~requires a hospital admission and~~ has a severity grading of severe or critical.

Reporting and timescales

27.8 When reporting cases of OHSS with a severity grading of severe or critical the centre must complete the OHSS form within 25 working days.

To help support good practice in OHSS management and prevention

Where appropriate, clinics' OHSS documented procedures should cover establishing if any patients have experienced OHSS as part of the routine follow up of patients. We propose that procedures should also be in place to cover prevention of OHSS. This would be in addition to the current requirement for documented procedures around the management of OHSS (where appropriate).

To do this, we will add the requirement to specifically include 'establishing if any patients have experienced OHSS', to 15.1 (h) of the Code of Practice under 'follow up after treatment'. Furthermore, at 15.1 (i) we propose to add 'prevention' to the existing wording, that requires documented procedures for the management of OHSS.

To support awareness around management of OHSS, and in determining of the severity of OHSS using the grading of 'severe' or 'critical', we will add a link to the Code of Practice (under 'Professional Guidelines') to the relevant 2016 RCOG guidelines: 'Ovarian Hyperstimulation Syndrome, Management (Green-top Guideline No. 5)', in guidance note 27.

To support awareness around prevention of OHSS, we will add a link to the Code of Practice (under 'Professional Guidelines') to the relevant 2014 BFS paper: 'British Fertility Society Policy and Practice Committee: Prevention of Ovarian Hyperstimulation Syndrome, 2014', in guidance note 15.

Clinicians have told us that good quality information giving about OHSS might be able to play a part in encouraging patients to self-report (suspected) OHSS to clinics. Our expectations in relation to informing patients about OHSS are currently set out at guidance note 4.4.(d) of the Code of Practice.

This states that "before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about: (d) ovarian hyperstimulation syndrome (OHSS). Any information provided should include what the woman being treated should do and who to contact if experiencing symptoms of OHSS."

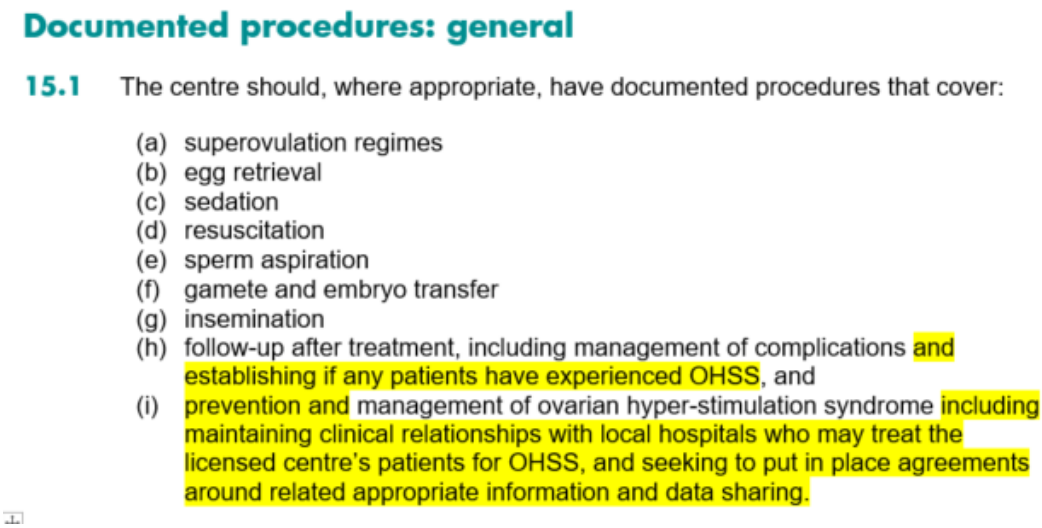
While we do not propose to alter this wording at this stage, we note feedback from clinics that they would welcome the sharing of good practice around appropriate information giving. In particular, more specific guidance around how they should inform patients 'what to do and who to contact', or what should be included in this information. We will carry out further work in this area, with a view to clarifying expectations in future.

To help support appropriate clinical information sharing about the care of patients with OHSS

Within the broader aim of improving patient care, we note that accurate reporting of OHSS to the HFEA may be improved via fertility clinics and their local hospitals establishing and maintaining close clinical liaison. Such a relationship could help to raise awareness among local hospital staff that patients from the local clinic may present with OHSS. Fertility clinics could also seek to establish and maintain information and data sharing relationships with these centres.

Clinics should have in place procedures for maintaining clinical liaison with local hospitals around OHSS, including seeking to put in place written information and data sharing agreements. Where implemented, we would expect that these would provide that if a treating NHS team becomes aware that a fertility clinic's patient has been admitted with OHSS, the NHS team can share appropriate information about that episode with the fertility clinic in a timely way. (We do appreciate that a patient may not always attend their own local hospital, or the hospital nearest their fertility clinic, if they need to seek help in the event of OHSS, however.)

To work towards this outcome, guidance note 15.1 (i), already requires licensed centres to have documented procedures covering the prevention and management of ovarian hyperstimulation syndrome where appropriate. We propose to add "including maintaining clinical relationships with local hospitals who may treat the licensed centre's patients for OHSS, and seeking to put in place agreements around related appropriate information and data sharing".



Documented procedures: general

15.1 The centre should, where appropriate, have documented procedures that cover:

(a) superovulation regimes
(b) egg retrieval
(c) sedation
(d) resuscitation
(e) sperm aspiration
(f) gamete and embryo transfer
(g) insemination
(h) follow-up after treatment, including management of complications and establishing if any patients have experienced OHSS, and
(i) prevention and management of ovarian hyper-stimulation syndrome including maintaining clinical relationships with local hospitals who may treat the licensed centre's patients for OHSS, and seeking to put in place agreements around related appropriate information and data sharing.

22. Do you think that taken together, these proposed changes will be effective in supporting improvements to the care and follow up of patients affected by OHSS?

- ◯ Yes
- ◯ No
- ◯ Unsure

23. Do you think that taken together, these proposed changes will be feasible for clinics to implement?

- ◯ Yes
- ◯ No
- ◯ Unsure

24. Any comments

HFEA Code of Practice 9th edition

Surrogacy

With surrogacy becoming more prevalent, we want to make sure that our guidance clearly sets out what clinics should consider when treating people entering into such arrangements. We want to ensure that both the surrogate and intended parents understand the arrangement and its implications for them, that they are suitable candidates to enter into a surrogacy arrangement and are offered appropriate emotional support throughout the process.

Some of the changes have been made to guidance on surrogacy in guidance notes 3, 8, 14 and 30.

We have added some new points to guidance note 3, which aim to ensure that all intended parents and surrogates receive implications counselling before entering into a surrogacy arrangement. Implications counselling should take place three times: for the surrogate (with the intended parents not present), for the intended parents (with the surrogate not present) and in a joint session for both the intended parents and the surrogate.

New subheading and requirements in guidance note 3: counselling

Implications counselling for surrogacy arrangements

3.7 The centre should ensure that any person intending to begin treatment as a surrogate has implications counselling (depending on their wishes, alone, or with a partner, if the surrogate has one). The implications counselling should be provided by a qualified counsellor. The intended parents should not attend this appointment and where practicable this appointment should take place on a date separate to any appointment to be attended by or with the intended parent(s). This appointment should address potential risks and implications of surrogacy (including, but not limited to, risks to the surrogate's physical and mental health, legal implications, practical and financial matters and emotional impact on the surrogate and the surrogate's partner and/or family. This appointment should allow full opportunity for the intended surrogate to ask questions and discuss any concerns.

3.8 The centre should ensure that any person intending to enter a surrogacy arrangement as an intended parent has implications counselling provided by a qualified counsellor. The surrogate should not attend this appointment and where practicable this appointment should take place on a date separate to any appointment to be attended by or with the surrogate This appointment should address potential risks and implications of surrogacy, including, relevant risks outlined in 3.7 and the risk of the surrogate not wishing to agree to the parental order being made once a child is born. This appointment should allow full opportunity for the intended surrogate to ask questions and discuss any concerns.

3.9 In addition to the separate implications counselling referred to at 3.7 and 3.8, the surrogate and intended parent(s) should attend a joint implications counselling session with a qualified counsellor. This should cover any relevant risks/considerations mentioned in 3.7 and 3.8. Both the intended surrogate and the intended parent(s) should have full opportunity to ask questions and discuss any concerns.

25. Do you think that the requirements set out above in 3.7- 3.9 will be effective in ensuring that surrogates, intended parents, and their partners, where applicable, fully understand the implications of entering into a surrogacy arrangement and have a sufficient opportunity to ask any questions and voice any concerns?

- ◯ Yes
- ◯ No
- ◯ Unsure

26. Are guidance notes 3.7-3.9 sufficiently clear about what a clinic needs to provide in terms of implications counselling for surrogacy arrangements?

- ◯ Yes
- ◯ No
- ◯ Unsure

We want both surrogates and intended parents considering a surrogacy arrangement to give careful consideration to the medical, emotional, legal and practical issues involved in surrogacy, and to the implications of surrendering the child at birth.

In addition, we have added into guidance note 8 the following guidance which more explicitly emphasises the responsibility of the clinic to be satisfied that a surrogate is a safe and suitable candidate for surrogacy.

We want clinics to weigh up all the evidence before deciding whether to treat individuals seeking a surrogacy arrangement and seek out further information when there is any doubt over suitability.

The welfare of the child assessment process for surrogacy arrangements

8.4 If the child is not to be raised by the carrying mother (ie, in a surrogacy arrangement), the centre should assess both those commissioning the surrogacy arrangement and the surrogate (and the surrogate's partner, if she has one, to ensure the welfare of the child in the event of a breakdown in the surrogacy arrangement leading to the surrogate keeping the child). A Welfare of the Child form should be completed by the surrogate in conversation with the treating clinician at the centre.

8.5 The centre should satisfy itself that the information given on the Welfare of the Child form is complete and correct so that any decisions relating to the treatment provided to the surrogate are fully informed and take account of all relevant considerations. The centre should obtain any relevant medical records from the surrogate's GP and any other relevant organisations and use that information to verify the information provided in the Welfare of the Child form. Any omission, discrepancy or other concern which raises questions about the woman's suitability for surrogacy or which might impact on decisions relating to her treatment should be investigated by the centre and discussed with the surrogate.

8.6 The centre should use evidence it has gathered from the GP, surrogate and any other relevant sources to satisfy itself that the woman is suitable to act as a surrogate, taking into account all relevant factors (including, but not limited to, the surrogate's age, medical history, previous obstetric history, mental health, Body Mass Index etc.) Further information should be sought where required so that the treating clinician can make decisions having been fully informed of all relevant considerations.

27. Does the new text above offer appropriate guidance to help clinics ensure that a surrogate and intended parent are suitable to enter into an appropriate and medically safe surrogacy arrangement?

- ◯ Yes
- ◯ No
- ◯ Unsure

We have also added a new requirement for clinics to have in place a standard operating procedure (SOP) for surrogacy arrangements, alongside a written protocol for decision making for deciding or refusing treatment in the case of a surrogacy arrangement.

8.7 Centres should have a Standard Operating Procedure in place for managing treatments involving surrogacy. Whilst acknowledging that the decision to proceed with treatment involving a surrogate should be made on a case by case basis, the SOP must detail its processes and policies in relation to (but not limited to) the following aspects of a surrogacy arrangement:

(a) Legal parenthood in surrogacy
(b) Surrogacy agreements
(c) Counselling requirements
(d) Confidentiality and arrangements for sharing information, in particular, between the intended parents and the surrogate
(e) Assessment of the surrogate and procedure for when a surrogate is deemed unsuitable for treatment
(f) Ensuring provisions are made for the surrogate to be seen alone by a healthcare professional
(g) The handover of care of the surrogate, once a viable pregnancy has been confirmed

8.8 The SOP must include a written decision-making protocol setting out the range of factors that may be taken into account when assessing the surrogate's suitability. The protocol should require the treating clinician to document the evidence that he or she relied on when reaching a decision as to the surrogate's suitability or unsuitability and should detail how the decision should be communicated to the surrogate and the commissioning couple. The decision-making protocol should be used in every case of a proposed surrogacy arrangement and a record made of the decision-making process and outcome for each individual intended surrogacy arrangement.

28. Is the new guidance sufficiently clear about what is needed from a surrogacy SOP?

- ◯ Yes
- ◯ No
- ◯ Unsure

Guidance note 14 relates exclusively to surrogacy arrangements. We have added in some more detail to the guidance. We want to emphasise the special status of surrogacy arrangements due to the particular legal risks, the emotional pressure the surrogate may feel and the number of lives which may be affected by a surrogacy arrangement which breaks down.

Offer of counselling to those considering surrogacy

14.7 The centre should ensure that all those involved in a surrogacy arrangement receive proper counselling about the implications of the steps they are considering. The counselling requirements are outlined in guidance note 3.

14.8 The centre should encourage those involved in a surrogacy arrangement to reflect on their decisions before it obtains their consent. The centre should provide detailed information, advice and guidance and encourage questions. The centre should be satisfied that all parties fully understand all aspects of the surrogacy arrangement and are entering into the arrangement freely and voluntarily, before obtaining their consent. This should include testing the understanding of both the intended surrogate and intended parents and ensuring that information is provided clearly and at an appropriate level of complexity tailored to an individual's capacity to understand it.

14. 9 The centre should exercise particular caution and sensitivity when discussing and taking consents for surrogacy arrangements and be aware of the vulnerable positions of both the intended surrogate and intended parents and serious implications for all concerned of a surrogacy arrangement breaking down. The centre should be alert to any sign of coercion. The centre's role should be to protect both parties from entering into a surrogacy arrangement which it suspects may be unsuitable or unethical for any reason.

29. Does this guidance do enough to protect the interests and wellbeing of surrogates and intended parents?

- ◯ Yes
- ◯ No
- ◯ Unsure

30. Any comments

HFEA Code of Practice 9th edition

Data protection

Data protection law is changing on 25 May 2018, when the General Data Protection Regulation (GDPR) will come in to force. This is the biggest reform of data protection law for decades and strengthens and upgrades the current data protection rules.

While the GDPR is EU law, the UK Government has confirmed that the UK will be implementing the GDPR in full and no immediate changes are expected post-Brexit.

The GDPR sets a higher standard for consent to process personal data and introduces much more severe penalties for organisations that get it wrong than under existing provisions, with fines of up to 20million Euros or 4% of worldwide turnover.

GDPR applies to all licensed centres (both NHS and private). All centres will need to make the necessary changes to bring practices and procedures in line with the new requirements of the GDPR.

GDPR is not part of our regulatory remit, but we want to make sure that clinics are alert to the upcoming changes and know where to go for more detailed advice on what they need to do to ensure they are complying with the new legislation.

We are proposing some amendments to the current Code of Practice. These include small changes to guidance notes 4, 5, 11, 25, but mainly affect guidance note 30 (confidentiality). In guidance note 30 we have added in text to inform clinics about the new GDPR legislation and what it means for them, to emphasise the new stricter financial penalties for getting it wrong and to to signpost them to the guidance published by the Information Commissioner’s Office (ICO), the UK's independent body set up to uphold information rights.

We have added the following to guidance note 30: confidentiality and privacy

The General Data Protection Regulation (EU) 2016/679 (GDPR)

30.14 The General Data Protection Regulation will be implemented in the UK on 25 May 2018. On that date a new Data Protection Act also entered into force, repealing and replacing the existing Data Protection Act 1998. Many of the requirements of the GDPR are similar to those in the Data Protection Act 1998 (DPA 1998) therefore, if centres are compliant with the DPA 1998, they are likely to be compliant with the GDPR. However, GDPR does introduce some new requirements and significant enhancements to existing requirements. GDPR introduces much more severe financial penalties for organisations that get it wrong. Each centre is responsible for ensuring that it complies with the new legislation.

30.15 GDPR introduces some new rights for individuals and enhances other rights, but in general an individual's rights under GDPR are not absolute and will only apply in certain circumstances. For example, although GDPR introduces a right for individuals to have personal data erased, that right does not apply if the processing of the individual's personal data is necessary to comply with a legal obligation. In other words, centres will not need to comply with a patient's request for erasure of their IVF treatment records given that it is a legal requirement, by virtue of General Direction 0012, that the centre retains those records for at least 30 years. Matters which raise questions about the application of GDPR and the HFE Act 1990 should be considered on a case by case basis and centres should consult the Information Commissioner's website for guidance and take their own legal advice where necessary.

30.16 GDPR applies to both NHS and private centres and all centres are expected to do an audit of their current Data Protection arrangements as against the new requirements of the GDPR to determine whether they are fully compliant, and where indicated, make the necessary changes to bring practices and procedures in line with the new requirements of the GDPR.

The audit should assess amongst other things, what and when personal data is collected, the legal basis for the processing of personal data (for example to fulfil legal obligations to report certain personal data, including data about treatment, to the HFEA or for employment purposes), where data is stored and what measures are in place to protect it, whether it is shared with third parties and why it is shared.

30.17 Centres should also review practices to ensure that all individuals (this includes patients and their partners, donors and members of staff) are provided with sufficient information about what the centre does with their personal data. Where indicated by the audit, centres should revise processes and procedures to ensure that they are fully compliant with all the individual rights set out in GDPR.

30.18 GDPR introduces a duty to report certain types of personal data breaches to the Information Commissioner. Centres must report notifiable breaches to the ICO within 72 hours of becoming aware of the breach, where feasible.

If the breach is likely to result in a high risk of adversely affecting individuals' rights and freedoms, centres must also inform the affected individuals without undue delay.

30.19 Centres should ensure that they have robust procedures for detecting and investigating any data breaches. This should include a clear procedure for staff to alert the PR of any personal data breaches and a procedure for notifying the ICO of reportable breaches. A record should be kept of any personal data breaches regardless of whether the centre is required to report the breach.

31. Is the new guidance sufficiently clear?

- ◯ Yes
- ◯ No

32. Any comments

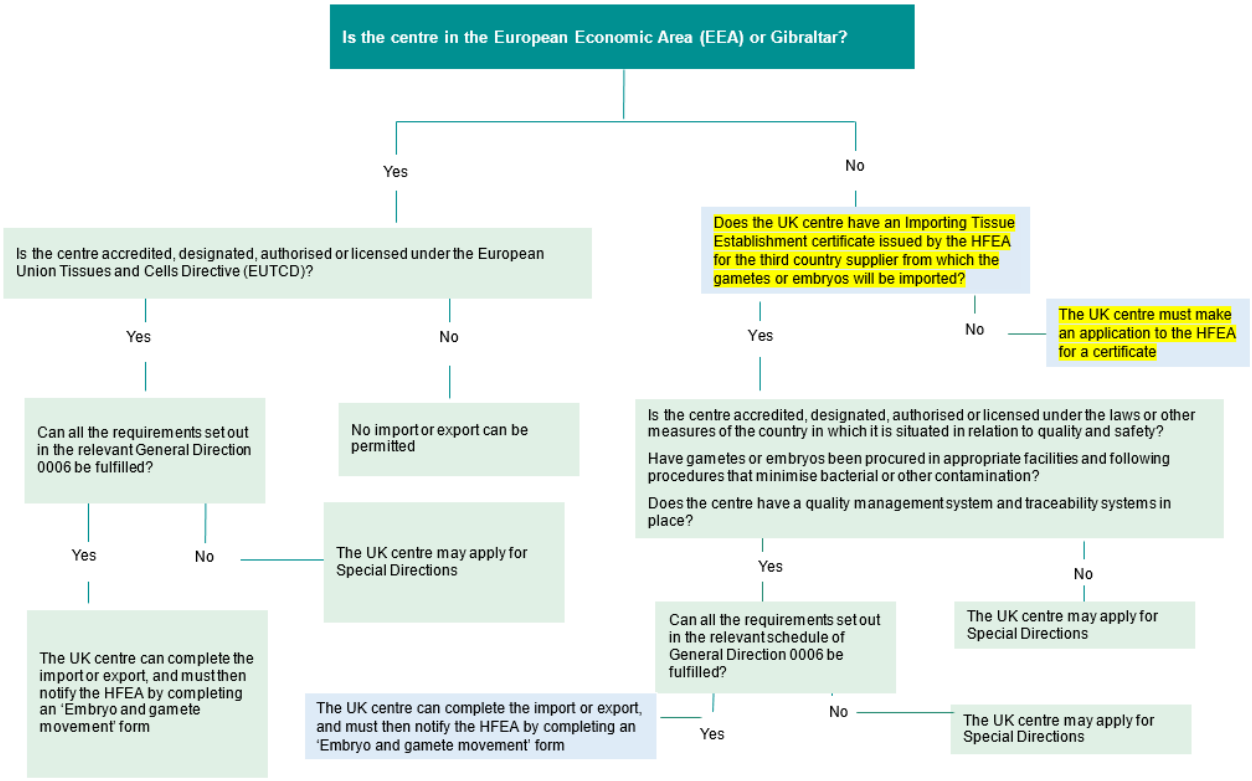
HFEA Code of Practice 9th edition

For information: EU Directives on the import and export of gametes

The guidance on the import and export of gametes (guidance note 16) has been amended to include the changes brought in by the new EU Directive on import. The Human Fertilisation and Embryology Act 1990 (as amended) now incorporates the requirements further to the passing of regulations through Parliament in February 2018 (The Human Fertilisation and Embryology (Amendment) Regulations 2018). Clinics are required to comply with the requirements for importing from outside of the EU, EEA and Gibraltar.

We have included the new guidance here for information only. We will, of course, seek feedback on how effective that guidance has been in further consultations on the code once clinics have had time to work with the new requirements.

Updated decision tree



Updated interpretation of mandatory requirements

General Directions: evidence of compliance

Interpretation of mandatory requirements 16B

(a) Within the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from another EEA state or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that the receiving or sending centre is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD).

(b) Outside the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from a country outside the EEA or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that:

(i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety

(ii) the centre has appropriate quality management and traceability systems, and

(iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination.

Where a centre wants to import from a third country supplier, the person responsible at the UK clinic must:

(i) ensure that, before undertaking any import from a third country supplier, the UK clinic has an Importing Tissue Establishment Certificate issued by the HFEA for the third country supplier it proposes to import from has a certificate

(ii) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety

(iii) provide the HFEA with the information specified in the relevant schedule to General Direction 0006 for ongoing imports

(iv) provide the HFEA with the documents specified in the relevant schedule to General Direction 0006 for one-off imports

(v) make available for inspection any documents specified in General Direction 0006

(vi) establish a written agreement with any proposed third country supplier that complies with the requirements set out in General Direction 0006.

When a certificate is issued to the Importing Tissue Establishment, the Person Responsible must:

(i) Seek written approval from the HFEA for any planned substantial changes to their import activities (i.e if it has previously only imported sperm and now wishes to import oocytes a written approval from the HFEA will be needed).

(ii) Inform the HFEA of their decision to cease their import activities in part or in full.

(iii) Inform the HFEA of any suspected or actual serious adverse events or reaction, reported to them by the third country supplier and which may influence the quality and safety of the tissues and cells they import.

(iv) Notify the HFEA of any revocation or suspension of a third country supplier's authorisation to export tissues and cells

(v) Notify the HFEA of any decision taken for reasons of non-compliance by the competent authority of the country that the third country supplier is based in where the quality and safety of imported tissues and cells are affected.

(vi) Notify the HFEA if a further import is anticipated for a couple on whose behalf a one-off import has previously been made whether by your clinic or any other clinic in the UK

In each case, a copy of the information retained must be provided to the Authority on request.

In all cases, all the remaining requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met.

No import of eggs or embryos that have undergone maternal spindle transfer (MST) or pronuclear transfer (PNT) is permitted to the UK.

33. Any comments

HFEA Code of Practice 9th edition

For information: the Single European Code

Guidance note 15 has been amended to include some guidance on the Single European Code (SEC). The Human Fertilisation and Embryology Act 1990 (as amended) now incorporates the requirements further to the passing of Regulations through Parliament in February 2018 (The Human Fertilisation and Embryology (Amendment) Regulations 2018). Clinics are required to comply with the requirements.

Guidance note 19 has one minor addition that you should refer to guidance note 15 for details on the Single European Code.

Single European Code (SEC)

15.21 The EU Commission Directive 2004/23/EC sets out standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application. It also sets out that to facilitate traceability it is necessary to establish a unique identifier applied to tissues and cells (including reproductive cells) distributed in the EU (by way of a SEC) providing information on the main characteristics and properties of those tissues and cells.

15.22 The SEC is applied to the movement of donor gametes and embryos between licensed clinics (or tissue establishments) within and outside the UK. Movement of 'partner' embryos and gametes are exempt from the requirements.

15.23 A further exemption relates to where gametes and embryos are imported from a tissue establishment and not distributed thereafter (that is for use in that clinic). The SEC need not be applied in such cases.

15.24 The SEC is the unique identifier for tissues and cells distributed in the EU. It is made up of the following (six) features.

Donation identification sequence			**Product identification sequence**		
ISO Country code	Tissue Establishment code	Unique Donation Number	Product code	Split number	Expiry date
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
GB	**000123** HFEA Licensed Centre number	**00000000XX456** Clinic's donor registration 'number' – submitted to the HFEA currently in	**E0000059** 1 of 5 for reproductive cells (EUTC system) -Embryos (56)	**001** If sperm, for example, is distribute	**20181231** Date of expiry of consent, for example, 31 December 2018

		registering the donor, with zeros added	-Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	d to more than one TE	
SEC GB00012300000000XX456 E000005900120181231					

15.25 There are three coding platforms permitted by the EU (and HFEA) one of which must be accessed to identify a product code.

1. The EU coding platform: https://webgate.ec.europa.eu/eucoding.
2. to ICCBBA ISBT128 https://www.iccbba.org (International Council for Commonality in Blood Banking Automation).
3. Eurocode international blood labelling system (IBLS) http://www.eurocode.org/.

15.26 Each coding platform provides tools to create a SEC. The EU coding platform contains detailed information on all Tissue Establishments in Europe in the Tissue Establishment compendium. If your clinic distributes embryos or gametes to a licensed clinic or tissue establishment, or similarly receives them, then you must access the EU coding platform to access the compendium.

15.27 The HFEA has a responsibility for ensuring the details of all UK HFEA licensed clinics on the compendium are current. We will do so further to changes we make to the Register of licensed clinics as part of our usual licensing activity.

15.28 We will check compliance at inspection, by sampling donor gamete and embryo movements into and out of the clinic to ensure the SEC has been applied appropriately.

15.29 Clinics identifying an error or change in relation to its details held on the EU Tissue Establishment compendium must notify their HFEA inspector as soon as practicable.

15.30 Clinics receiving gametes or embryos from a licensed clinic or tissue establishment without a SEC must note this is a serious adverse incident, and report it to the HFEA using the current incident reporting channel.

34. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

For information: Screening requirements

Our changes to guidance on screening requirements (Guidance note 11) will focus on requirements relating to Nucleic Acid Technique (NAT) testing. Licence condition T53 currently states that quarantine

of donor sperm is not required when NAT testing is used in addition to serology. However, the Code of Practice also states that donors of gametes and embryos should be screened in accordance with current professional body guidance which recommends that the quarantine period should still be observed when NAT testing is used in addition to serology.

In order to provide some clarity on this matter, we held a meeting with representatives from the relevant professional bodies and the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), which advises UK ministers and health departments of the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion or transplantation.

SaBTO has recently released a blood, tissue and cell donor selection criteria report and at the meeting we held it was decided that SaBTO would produce an addendum to this report with recommendations for gamete donor screening when NAT testing is used in addition to serology.

SaBTO is considering its recommendations and these will be incorporated into the HFEA Code of Practice and licence conditions. It is anticipated that these recommendations will include requirements for a shorter quarantine period for donated sperm when NAT testing is used in addition to serology, and recommendations for NAT testing of egg donors.

The exact details of SaBTO's recommendations will be added to this guidance note once they are available. Licence condition T53 will also be amended accordingly.

35. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

For information: Other amendments

Consent forms

We are proposing some minor changes to our consent forms including:

- Wording will be added to section 3.1 of the 'Your consent to the storage of your eggs or sperm' form (GS form) informing clinics that the 'Your consent to the use of your sperm in artificial insemination' (MGI form) will need to be completed along with the GS form if patients want to consent for their partner to use their sperm in IUI or GIFT in the event of their death or incapacity.
- The introductory page of the 'Stating your spouse or civil partner's lack of consent' form (LC form) will contain a bullet point explaining that patients should make sure they have been told that the purpose of the form is to record, in their view, that their spouse and partner does not consent to their treatment, but it does not guarantee that their spouse or partner will not be the second legal parent.
- The 'Record of information before consent' will have a row for the 'Your consent to being registered as the legal parent in the event of your death' form' (PBR form).

36. Any comments

Quality management system

We have made some changes to our guidance on the quality management system guidance (guidance note 23) to facilitate a more cohesive understanding of incident and audit investigations in addition to the management of risks within centres.

Monitoring, evaluation and improvement

23.26 The centre's processes for monitoring, evaluation and improvement should:

(a) show that procedures and outcomes are satisfactory when judged against relevant professional standards
(b) show that the assisted conception processes are followed in a way that meets users' needs and requirements
(c) ensure conformity of the quality management system, and
(d) continually improve the effectiveness of the quality management system.

23.27 The centre should establish a documented procedure to identify and manage nonconformities and incident findings. These findings should be appropriately investigated and documented to include the following actions taken:

(a) remedial or immediate actions
(b) root cause analysis to determine the causes of nonconformities
(c) evaluating the need for action to ensure nonconformities do not recur
(d) promptly determining and implementing action needed
(e) recording the results of corrective action taken
(f) reviewing the corrective action taken and its effectiveness, and
(g) risk based thinking (preventive actions).

NOTE Action taken at the time of the nonconformity to mitigate its immediate effects is considered remedial or immediate action. Only action taken to remove the root cause of the nonconformities is considered corrective action. This is a reactive process.

23.28 The centre should establish a documented procedure to take risk based thinking (preventive action) to eliminate the causes of potential nonconformities and so prevent them happening. It should include:

(a) determining potential nonconformities and their causes
(b) evaluating the need for action to prevent nonconformities happening
(c) promptly determining and implementing action needed
(d) recording the results of preventive action taken, and
(e) reviewing any risk based thinking (preventive action) taken.

NOTE Risk based thinking (preventive action) is a way of actively identifying opportunities for improvement rather than reacting to problems or complaints when they happen. This is a proactive process as opposed to reactive.

37. Any comments

Data submission

Following the launch of our new submission system, we will have a new set of expectations and arrangements relating to good quality and timely data submission by clinics. We want to provide a transparent framework for clinics (and for the HFEA) about those expectations.

We seek to do this first by the rules of the proposed new General Direction, backed up by modest changes to the Code of Practice in its October 2018 update.

General Direction 0005 sets out mandatory requirements for clinics on collecting, recording and submitting information. The main changes to this version of the Direction are:

- To reflect the changes in the new submission system, we no longer refer to ‘forms’. Instead we refer to ‘information types’ detailed in the data dictionary, the purpose of each information type, and the deadline for submission.
- A reduction in the period allowed for correction of submission errors from two months to four weeks.
- Subtle changes in tone with more use of the word "must".
- A standardisation of submission deadlines so that they are always expressed in weeks.
- We no longer refer to the person responsible signing off a hard copy of their Choose a Fertility Clinic (CaFC) data before publication as we expect that this will be done electronically via Clinic Portal.

Guidance note 32 sets out obligations and reporting requirements of centres (along with presenting mandatory requirements from licence conditions and the act). It will be amended to reflect the changes in the new submission system - that we no longer refer to ‘forms’; and the process by which PRs will verify their data ahead of publication on CaFC.

38. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

For information: format and usability

We are using the opportunity of the 9th edition to make sure that the code is fit for purpose in today’s

clinic or laboratory, by gathering feedback on its format, structure and usability. We held user testing with our code working group and gathered further feedback on proposals in a survey and at the regional workshops.

Clinics' main frustration is with the search function on the website and Clinic Portal. We have now fixed the broken search function on Clinic Portal and are working towards improving the searchability of the entire code.

Overall, clinic staff wanted to keep the familiar format of the code with a few changes:

- making the link to Clinic Portal more prominent to encourage clinic staff onto the 'knowledge base' where they can find all guidance and news
- getting rid of the grouping of guidance notes to make them easier and quicker to find
- adding in abbreviations to aid searching the code eg, for professional bodies and other organisations
- reviewing our user guide to the code which explains the different types of guidance (currently in the PDF version of the code) and including it on the portal and website versions of the code
- providing more flowcharts to make it easier to explain particularly difficult guidance notes
- making the Chair's and Chief Executive's letters searchable by topic instead of by year
- marking Chair's and Chief Executive's letters as active or archived
- fixing all broken links.

39. Any comments or suggestions

Human Fertilisation & Embryology Authority

Code of practice

9th Edition

Edition 9.0
To be published October 2018

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Code of Practice

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Contents

Version 1.0

User guide

Version 1.0

What is the purpose of the Code of Practice?

The Human Fertilisation and Embryology Act 1990 ('the Act') covers the use and storage of sperm, eggs and embryos for human application, as well as all research involving the use of live human and admixed embryos.

One of the ways we help licensed centres comply with the Act is by publishing the Code of Practice. This is because we have a duty under the Act to maintain a document that gives guidance about licensed activities and the people who carry them out. The Code of Practice contains regulatory principles for licensed centres, and guidance notes which provides guidance to help clinics deliver safe, effective and legally compliant treatment and research.

Guidance in the Code of Practice also serves as a useful reference for patients, donors, donor-conceived people, researchers and those working in the fertility sector.

Regulatory principles for licensed centres

The Act requires us to maintain a statement of the general principles that we consider should be followed in carrying out licensed activities covered by the Act. The principles inform every part of this Code of Practice and provide:

- a summary of the key behaviours and outcomes we expect licensed centres to demonstrate, and
- a means of communicating the areas of compliance we regard as key.

Guidance notes

Each of the 33 guidance notes in the Code of Practice cover one subject area, to make it easier for users to find what they are looking for. Guidance notes are made up of the following sections:

- **Mandatory requirements**

  These sections include relevant extracts from the Act, licence conditions, and references to General Directions. The person responsible is expected to be familiar with and comply with all mandatory requirements that apply to their centre.

  Important: The Code of Practice does not provide a complete guide to the Act and other mandatory requirements. Nor is it a substitute for reading the Act.

- **Interpretation of mandatory requirements**

  We have provided an interpretation of the law where we feel centres may find it helpful, especially where the law is very complex.

  Important: Our interpretations are intended only to aid understanding and are not definitive.

- **Guidance**

  This guidance is intended to help centres comply with mandatory requirements.

- **Other legislation, professional guidelines and information**

  This section lists other useful external information, including links to relevant websites.

Compliance and enforcement

We have a duty to promote compliance with the Act and the Code of Practice. If we become aware that a centre has not complied with the legislation or the Code of Practice, we may take action in line with the Compliance and Enforcement Policy.

We will consider a centre's failure to observe any provision in the Code of Practice in the circumstances set out in section 25(6)(a) and (b) of the Act.

Regulatory principles for licensed centres

Version 1.0

The regulatory principles are a high-level statement that underpin our key regulatory priorities from the Human Fertilisation and Embryology Act 1990. They provide:

- a summary of the key behaviours and outcomes we expect licensed centres to demonstrate, and
- a means of communicating the areas of compliance we regard as key, to the Person Responsible and staff at licensed centres, patients, donors, donor-conceived people and the public.

The regulatory principles inform every part of this Code of Practice and should be read in conjunction with each of its guidance notes.

Regulatory principles

We expect the person responsible to ensure that their licensed centre demonstrates adherence to the following principles when carrying out activities licensed under the Human Fertilisation and Embryology Act 1990.

Licensed centres must:

1. treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way
2. have respect for the privacy, confidentiality, dignity, comfort and well-being of prospective and current patients and donors
3. have respect for the special status of the embryo when conducting licensed activities
4. take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
5. give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
6. ensure that patients and donors have provided all relevant consents before carrying out any licensed activity
7. conduct all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
8. ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
9. ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice

10. maintain accurate records and information about all licensed activities
11. report all adverse incidents (including serious adverse events and reactions) to us, investigate all complaints properly, and share lessons learned appropriately
12. ensure that all licensed research by the centre meets ethical standards, and is done only where there is both a clear scientific justification and no viable alternative to the use of embryos, and
13. conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including:
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from us, and
    - cooperating fully with inspections and investigations by us or other agencies responsible for law enforcement or regulation of healthcare.

1. Person Responsible

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure -

(a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,

(b) that proper equipment is used,

(c) that proper arrangements are made for the keeping of gametes, embryos and human admixed embryos and for the disposal of gametes, embryos or human admixed embryos that have been allowed to perish,

(d) that suitable practices are used in the course of the activities,

(e) that the conditions of the licence are complied with,

(f) that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and

(g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

(2) References in this Act to the persons to whom a licence applies are to -

(a) the person responsible,

(b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person responsible, as a person to whom the licence applies, and

(c) any person acting under the direction of the person responsible or of any person so designated.

16 Grant of licence

(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.

(2) The requirements mentioned in subsection (1) above are -

(a) that the application is for a licence designating an individual as the person under whose supervision the activities to be authorised by the licence are to be carried on,

(b) that either that individual is the applicant or -

(i) the application is made with the consent of that individual, and

(ii) the Authority is satisfied that the applicant is a suitable person to hold a licence,

(c) in relation to a licence under paragraph 1 or 1A of Schedule 2 or a licence under paragraph 2 of that Schedule authorising the storage of gametes or embryos intended for human application, that the individual -

(i) possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications in the field of nursing, and

(ii) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence,

(ca) in relation to a licence under paragraph 2 of Schedule 2 authorising storage of gametes, embryos or human admixed embryos not intended for human application or a licence under paragraph 3 of that Schedule, that the Authority is satisfied that the qualifications and experience of that individual are such as are required for the supervision of the activities,

(cb) that the Authority is satisfied that the character of that individual is such as is required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act,

(d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities, and

(e) that all the other requirements of this Act in relation to the granting of the licence are satisfied.

Licence conditions

T7 Where the PR is unable to carry out their duties for any reason the holder of the licence must inform the Authority immediately and apply to the Authority for a licence variation to nominate a substitute PR. This nominated substitute PR must not commence their post unless and until the Authority decides that they are suitable.

T9 The PR must have responsibility for:

a. ensuring the requirements imposed by section 31ZD of the Human Fertilisation and Embryology Act 1990 (as amended), in relation to the provision of information to donors about resulting children, are complied with

b. ensuring that the activities are carried out on suitable premises

c. ensuring the centre's staff co-operate fully with inspections and investigations by the Authority or other agencies responsible for law enforcement or regulation of healthcare

d. ensuring fees are paid to the Authority within the timescale specified in Directions or in writing

e. ensuring data provided to the Authority about activities and data, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing

f. ensuring requests for information and/or documents from the Authority are responded to promptly, and

g. notifying the Authority immediately if s/he becomes aware of any decision or proposal to

close their centre.

T10 In the event of termination of activities, for whatever reason, the PR must ensure that all stored gametes, embryos or admixed embryos are transferred to another licensed centre or centres. The PR must ensure that all relevant information including traceability data and information concerning the quality and safety of gametes and embryos, is transferred with any stored gametes, embryos or admixed embryos, or that records containing this information are made accessible as required.

Directions

0008 – Information to be submitted to the HFEA as part of the licensing process

HFEA guidance

Appointing the person responsible

Interpretation of mandatory requirements 1A

The law requires licensable activity to take place only under the supervision of the 'person responsible', as named on the centre's licence.

An individual can be appointed as the person responsible only with the approval of the HFEA. That person must complete the Persons Responsible Entry Programme (PREP) assessment before the HFEA can consider whether or not to approve them.

The licence holder and the person responsible

1.1 The licence holder and the person responsible should be separate individuals. Clinics operating within a hospital or other healthcare organisation may find it advantageous for a senior hospital manager to hold the post of licence holder.

1.2 It is the responsibility of the licence holder to inform the HFEA if the person responsible is unable to perform their duties. Where the centre no longer has a person responsible, the licence holder should seek the advice of the HFEA as soon as possible on continuing to provide licensable activities. Either the person responsible or the licence holder may apply for a licence or for its variation or revocation. However, only the licence holder may apply to a licence committee to vary a licence in order to designate another individual to be the person responsible.

Qualifications for the role of the person responsible

1.3 The person responsible should have enough understanding of the scientific, medical, legal, social, ethical and other aspects of the centre's work to be able to supervise its activities properly. It is also important that the person responsible possesses integrity and leadership capability.

1.4 When applying to vary a licence in order to appoint a new person responsible, the licence holder must provide evidence that the proposed individual has the managerial authority and capability necessary to perform their duties.

1.5 The HFEA expects the person responsible to take any necessary specialist advice to allow them to run the centre professionally.

Responsibilities of the person responsible

Interpretation of mandatory requirements 1B

The person responsible is ultimately responsible for ensuring that all licensed activities are conducted with proper regard for the regulatory framework that governs treatment and research involving gametes or embryos.

1.6 The role of the person responsible should include:

(a) maintaining an up-to-date awareness and understanding of legal obligations
(b) responding promptly to requests for information and documents from the HFEA
(c) co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement, regulation or healthcare, and
(d) informing the HFEA of any change to their professional registration.

1.7 The person responsible should ensure that:

(a) all staff maintain an up-to-date awareness and understanding of legal obligations
(b) all staff possess the competencies necessary for their role, and have access to learning and professional development
(c) all staff are encouraged, as appropriate, to contribute to discussions and decisions about improving patient care.

1.8 The person responsible is accountable for the overall performance of the centre and to that end should ensure that:

(a) there are clear responsibilities, roles and systems of accountability to support good governance
(b) appropriate action is taken following feedback from the HFEA, staff and patients, including through the outcomes of inspections, audits, patient complaints and feedback.

2. Staff

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure -

(a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,

Schedule 3A Supplementary Licence Conditions: Human Application

Requirements for procurement of gametes and embryos

5. Licence conditions shall require all persons to whom a licence applies who are authorised to procure gametes or embryos, or both, to comply with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

Licence conditions

T11 The centre must have an organisational chart which clearly defines accountability and reporting relationships.

T12 Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals.

T13 All personnel must have job descriptions that accurately reflect their tasks, and responsibilities.

T14 Personnel carrying out licensed activities or other activities carried out for the purposes of providing treatment services that do not require a licence must, where appropriate, be registered in accordance with the appropriate professional and/or statutory bodies, (eg, General Medical Council, Health & Care Professions Council, Nursing and Midwifery Council).

T15 Personnel must be provided with initial/basic training. Training must be updated as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development must be provided. The training programme must ensure and document that each individual:

a. has demonstrated competence in the performance of their designated tasks

b. has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks

c. understands the organisational framework, quality system and Health & Safety rules of

	the centre in which they work, and
	d. is adequately informed of the broader ethical, legal and regulatory context of their work.
T16	The centre must have access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities.

HFEA guidance

Centre staff

2.1 The centre should establish documented procedures for staff management that ensure all staff have:

(a) initial basic training and updated training as required
(b) on-going competence assessment, with audits of this assessment
(c) an annual joint review (with their line manager)
(d) continuing education and professional development
(e) staff records, and
(f) appropriate access to meetings and communications.

2.2 Staff records should include:

(a) job description
(b) terms and conditions of employment
(c) a record of staff induction and orientation
(d) a record of health and safety training
(e) a record of education and training, including continuing professional development
(f) relevant educational and professional qualifications
(g) certificate of registration, if relevant
(h) absence record
(i) accident record
(j) a record of annual joint reviews
(k) occupational health record, and
(l) a record of any disciplinary action.

The centre should ensure that confidentiality of staff records is in line with best practice and relevant legislation.

2.3 All staff should maintain an up-to-date awareness and understanding of legal obligations, and should support the person responsible in monitoring and improving the performance of the centre.

2.4 All staff should participate in an annual joint review that examines the needs of the centre and of the individual to improve the quality of the service to users and to encourage productive working relationships. Staff performing annual reviews must receive appropriate training.

2.5 The centre should have an effective way of communicating information to, and receiving suggestions from, staff. Centre management should also ensure that the accountabilities and reporting relationships shown in the centre's organisational chart are communicated within the centre.

2.6 Centre management should ensure that staff members who are in contact with patients, donors and their partners where applicable:

(a) follow the centre's 'patient support policy',

are prepared to offer appropriate emotional support to people suffering distress at any stage before, during and after treatment

(b) understand and can explain the role of counselling, and

know when and how to refer people to the centre's qualified counsellor.

For more detailed guidance on the patient support policy, see paragraph 3.14 of GN 3 ('Patient Support and Counselling') and [link to new professional guidelines currently in development]

2.7 Centre management is responsible for delivery of the patient support policy and for using intelligence to monitor and evaluate the effectiveness of the policy. Centre management should ensure that the policy addresses the emotional support needs of patients, donors and their partners (where applicable) in order to continuously improve their experience of treatment services.

2.8 Centres should require all prospective and existing staff to report promptly all criminal convictions they have had to the person responsible. In deciding whether or not an individual shall take part in a licensed activity at the centre, the person responsible should take into account relevant previous convictions and breaches of regulations.

Medical staff

2.9 The person responsible should ensure that staff who must be registered with professional bodies are registered, their registration is up to date, and records of this are kept.

2.10 The individual with overall medical responsibility for treatment services involving in vitro fertilisation should:

(a) have completed training recognised by the Royal College of Obstetricians and Gynaecologists (or an equivalent professional body)
(b) be on the General Medical Council's Specialist Register, and
(c) participate in a recognised programme of continuing medical education and professional development.

2.11 If the centre is licensed to provide insemination services only, the individual with overall medical responsibility should:

(a) be a registered medical practitioner, and
(b) have sufficient experience in an established fertility centre to be qualified to take full charge of the centre's treatment services.

2.12 Other medical staff who take part in providing treatment services should be registered medical practitioners with sufficient experience under supervision to qualify them to do so. Medical staff who do laparoscopies should be Fellows or Members of the Royal College of Obstetricians and Gynaecologists (or an equivalent professional body). Medical staff in training should follow relevant training programmes under appropriate supervision.

Nursing staff

Interpretation of mandatory requirements 2A

All nursing staff must be appropriately qualified and registered by the Nursing and Midwifery Council.

2.13 Nurses should be:

(a) working towards competencies set nationally, locally or both, to ensure appropriate standards of clinical competence, and
(b) able to provide evidence of competence in the duties performed (for example, a certificate for a recognised qualification or a written testimonial by another person who is suitably qualified and competent in that discipline or function).

Counselling staff

2.14 Treatment centres should ensure that at least one individual is appointed to fulfil the role of counsellor. All counsellors should have specialist competence in infertility counselling and:

(a) hold a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to the level of diploma of higher education or above, and
(b) be accredited under the scheme of the British Infertility Counselling Association (or an equivalent body), or show evidence of working towards such accreditation.

2.15 It is recognised that it may be necessary to appoint a general counsellor to the role, who is not a fertility specialist. This member of staff should be able to provide evidence of being an accredited member of, or working towards accredited membership of, a recognised professional counselling body, in order to prove specialist competence in infertility counselling. The body should have with a complaints/disciplinary procedure, and the individual should have agreed to abide by this organisation's code of conduct or ethics. The appointed general counsellor should be compliant with the requirement to demonstrate specialist competence in infertility counselling within a period of two years.

2.16 Treatment centres carrying out pre-implantation genetic diagnosis or mitochondrial donation should ensure that patients have access to counsellors with appropriate knowledge and expertise in these specialisms, including a good understanding of the risks and implications for patients who have treatment involving mitochondrial donation techniques and any children that may be born following such treatment.

See also

Guidance note 3 – Counselling

Staff engaged in scientific services

2.17 Centre management should ensure that the centre has access to a nominated registered scientist to advise on and oversee scientific activities.

2.18 All healthcare scientists working in licensed centres should be registered or show evidence of working towards registration with the Health & Care Professions Council (HCPC), or other equivalent body where applicable. It is expected that all staff should be registered with the HCPC (or other equivalent body) within one year of their becoming eligible, including those eligible as international applicants after training overseas.

2.19 Healthcare scientists from overseas who are registered in their own country but working in a licensed centre as a visiting scientist, should seek temporary registration with the HCPC (or other equivalent body).

2.20 Healthcare scientists employed in roles not yet requiring state registration (eg, aspirant groups, healthcare science assistants and healthcare science practitioners) should follow an appropriate induction and training programme for the tasks performed. Each individual should maintain proper records of this training.

2.21 The individual responsible for the seminology laboratory should:

(a) possess a degree or higher national diploma in a relevant discipline
(b) have acquired sufficient experience in such a laboratory to supervise and be responsible for one, and
(c) be registered with the HCPC as a clinical scientist or biomedical scientist, or be able to demonstrate equivalent training or expertise.

See also

Association of Biomedical Andrologists: Laboratory andrology guidelines for good practice (third edition, 2012)

2.22 The individual responsible for the clinical embryology laboratory should:

(a) possess an appropriate scientific ~~or medical~~ degree
(b) have had sufficient experience in such a laboratory to be able to supervise and be responsible for one, and
(c) be registered with the HCPC (or other equivalent body) as a clinical scientist with specific expertise in clinical embryology.

See also

Association of Clinical Embryologists: Accreditation standards and guidelines for IVF laboratories (2000)

Association of Clinical Embryologists: Guidelines on good practice in clinical embryology laboratories (2012)

Competence and training of ICSI and embryo biopsy practitioners and mitochondrial donation practitioners

2.23 The person responsible should ensure that micromanipulation procedures such as ICSI, embryo biopsy and mitochondrial donation are only carried out by practitioners who have the necessary competence.

2.24 Following training, the competence of each person performing micromanipulation procedures should be evaluated at intervals specified in the quality management system. Retraining should be given when required.

2.25 In the case of mitochondrial donation, only the embryologist(s) practitioner(s) who have been designated as competent by a licence committee ('the designated embryologist(s)') and named on the clinic's licence may carry out maternal spindle transfer (MST) and/or pronuclear transfer (PNT). If the clinic wishes to change the designated embryologist or add to the list of designated embryologists, the clinic will need to apply to the Authority to vary its licence.

Staff involved in genetic testing and mitochondrial donation

2.26 A senior clinical geneticist or mitochondrial disease expert should be involved in the decision-making process when deciding whether a patient should receive treatment involving embryo testing or mitochondrial donation.

2.27 The centre should ensure that a multidisciplinary team is involved in providing the service. Where relevant the team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticist, molecular geneticists and mitochondrial disease specialists. It should maintain close contact with the primary care physician or the referring clinician.

2.28 If the centre offers an embryo testing or mitochondrial donation service, the individual responsible for this laboratory should

(a) hold an appropriate scientific or medical degree
(b) have acquired sufficient experience in an appropriately accredited medical genetics diagnostic laboratory to supervise and be responsible for one, and
(c) be registered with the HCPC (or other equivalent body) as a clinical scientist with specific expertise in clinical genetics.

2.29 If genetic testing of those seeking treatment or considering donation is offered, the centre should ensure that an individual is available who understands the:

(a) nature of the tests conducted
(b) scope and limitations of the tests
(c) accuracy and implications of the tests, and
(d) meaning of the test results.

2.30 The centre should ensure that people seeking treatment have access to clinical geneticists, mitochondrial donation specialists and genetic counsellors where relevant.

2.31 The centre should work closely with the local genetics or mitochondrial disease team of those seeking treatment.

See also

Guidance note 10 – Embryo testing and sex selection

Guidance note 33 – Mitochondrial donation

Other legislation, professional guidelines and information

Legislation

The Nursing and Midwifery Order 2001

Professional guidelines

Association of Biomedical Andrologists: Laboratory andrology guidelines for good practice (third edition, 2012)

Association of Clinical Embryologists: Accreditation standards and guidelines for IVF laboratories (2000)

Association of Clinical Embryologists: Guidelines on good practice in clinical embryology laboratories (2012)

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (third edition, 2012)

Royal College of Nursing: Representing nurses and nursing, promoting excellence in practice, and shaping health policies

Clinic Focus articles

Clinic Focus article: HCPC professional indemnity guidance (August 2013)

Clinic Focus article: Do your counsellors have the relevant qualifications? (January 2016)

3. Counselling and patient support

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

13 (6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

13 (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

13A Conditions of licences for non-medical fertility services

(3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.

Schedule 3ZA

Part 1: Kinds of treatment in relation to which counselling must be offered

1. The treatment services involve the use of the gametes of any person and that person's consent is required under paragraph 5 of Schedule 3 for the use in question.

2. The treatment services involve the use of any embryo the creation of which was brought about in vitro.

3. The treatment services involve the use of an embryo taken from a woman and the consent of the woman from whom the embryo was taken was required under paragraph 7 of Schedule 3 for the use in question.

Part 2: Events in connection with which counselling must be offered

4. A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.

5. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

6. A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.

7. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

Schedule 3

3 (1) Before a person gives consent under this Schedule -

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

Licence conditions

T60 A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

T61 A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.

HFEA guidance

The offer of counselling

Interpretation of mandatory requirements 3A

The law requires counselling to be offered when:

(a) a woman or couple seeks treatment with donated gametes or embryos (including mitochondrial donation)

(b) an individual or couple seeks treatment that will create embryos in vitro

(c) an individual or couple seeks to store their gametes or embryos (for exceptions see Schedule 3 of the HFE Act 1990 (as amended), paragraphs 9 or 10)

(d) an individual or couple seeks to donate their gametes or embryos for the treatment of others (including mitochondrial donation)

(e) an individual seeks to donate their gametes for use in non-medical fertility services

(f) an individual or couple seeks to donate their embryos for research purposes or for training people in embryo biopsy, embryo storage or other embryological purposes

(g) an individual seeks to provide their gametes or cells for the creation of embryos or human admixed embryos for research (for exceptions, see mandatory requirements outlined in guidance note 22 – research and training)

(h) a woman provides embryos (obtained by lavage) for any purpose

(i) written notice is served by a man or woman consenting to the man being treated as the legal father or parent of any child born as a result of the woman's treatment, or

(j) written notice is served by a woman, or her female partner, consenting to the partner being treated as the legal parent of any child born as a result of the woman's treatment.

3.1 The centre should provide a suitable opportunity for counselling after the individual or couple has received oral and written information about the services to be provided and before they consent to treatment, donation, or to the storage or use of gametes or embryos. Counselling should be accessible in terms of location. The timing and frequency of counselling sessions should be agreed between counsellor and the person or couple concerned, in order to meet their needs.

3.2 The centre should make patients, donors and their partners (if applicable) aware that the offer of counselling is a routine part of the treatment pathway. The offer of counselling should include written information giving the name(s) of the qualified counsellor(s), explaining their role, when they are available and how to access the service. The centre should allow enough time before treatment starts for people to consider the offer and to have counselling if they wish.

3.3 If the possibility of treatment with donated gametes or embryos arises (including mitochondrial donation), the centre should offer counselling about the implications of treatment with donated material separately from counselling about the implications of treatment in general, and before treatment with donor gametes starts. If the patient is seeking mitochondrial donation treatment, they should be able to access counsellor(s) with the relevant expertise through the centre performing the mitochondrial donation.

3.4 If the possibility of donating gametes or embryos (including mitochondrial donation) for the treatment of others, or donating embryos for research or training arises, the centre should offer counselling about the implications of donation separately from counselling about the implications of treatment before the treatment starts. If treatment has already begun, it should continue only if the potential donor and, if applicable, his or her partner have been offered counselling about the implications of donation.

3.5 The centre should provide proper counselling throughout the treatment, donation or storage processes, and afterwards if requested. Counselling should routinely be offered following adverse events and/or unsuccessful outcomes. If a person who has previously donated gametes or embryos (including mitochondrial donation), or received treatment, requests further counselling at any point, the centre should take all practicable steps to help them obtain it. Group sessions may be offered in addition to individual and couple sessions.

3.6 The centre should offer people the opportunity to have counselling either with their partner or alone, depending on what each person prefers. In the case of counselling on the implications of treatment or donation, if two people are being treated together, then we would recommend they both attend the counselling session. In the case of an intended surrogacy arrangement, please

see 3.7.

Implications counselling for surrogacy arrangements

3.7 The centre should ensure that any person intending to begin treatment as a surrogate has implications counselling (depending on their wishes, alone, or with a partner, if the surrogate has one). The implications counselling should be provided by a qualified counsellor. The intended parents should not attend this appointment and where practicable this appointment should take place on a date separate to any appointment to be attended by or with the intended parent(s). This appointment should address potential risks and implications of surrogacy (including, but not limited to, risks to the surrogate's physical and mental health, legal implications, practical and financial matters and emotional impact on the surrogate and the surrogate's partner and/or family. This appointment should allow full opportunity for the intended surrogate to ask questions and discuss any concerns.

3.8 The centre should ensure that any person intending to enter a surrogacy arrangement as an intended parent has implications counselling provided by a qualified counsellor. The surrogate should not attend this appointment and where practicable this appointment should take place on a date separate to any appointment to be attended by or with the surrogate This appointment should address potential risks and implications of surrogacy, including, relevant risks outlined in 3.7 and the risk of the surrogate not wishing to agree to the parental order being made once a child is born. This appointment should allow full opportunity for the intended surrogate to ask questions and discuss any concerns.

3.9 In addition to the separate implications counselling referred to at 3.7 and 3.8, the surrogate and intended parent(s) should attend a joint implications counselling session with a qualified counsellor. This should cover any relevant risks/considerations mentioned in 3.7 and 3.8. Both the intended surrogate and the intended parent(s) should have full opportunity to ask questions and discuss any concerns.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 6 – Legal parenthood

Guidance note 22 – Research and training

The provision of counselling

3.10 The provision of counselling should be clearly distinguished from:

(a) the assessment of a person's suitability to receive treatment, or to store or donate their gametes or embryos (including mitochondrial donation)
(b) the provision of information before obtaining consent or providing treatment, and
(c) the normal relationship between clinical staff and patients or donors.

3.11 The counselling service should comply with current professional guidance on good practice in infertility counselling. Only qualified counsellors should provide counselling.

See also

Guidance note 2 – Staff

3.12 Counselling should be available from a counsellor attached to the centre whose qualifications and experience satisfy the requirements of guidance note 2.14 to 2.16. If this is not possible or if the patient prefers to seek counselling elsewhere, the centre should provide:

(a) information on local counsellors who have specialist competence in infertility counselling and who meet the requirements of guidance note 2.14 to 2.16
(b) information on organisations that can provide specialist support.

3.13 The centre should ensure that arrangements are in place to provide, or refer people for, specialist counselling if appropriate, taking account of their duty of confidentiality under the HFE Act. This might include genetic counselling, counselling for patients undergoing treatment involving mitochondrial donation and counselling for oncology patients or others requiring the long-term storage of gametes or embryos.

3.14 The centre should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions. The centre should also consider the use of other media for counselling sessions, such as video or audio calls in order to make counselling as accessible as possible for patients and donors.

Counselling records and confidentiality

3.15 Information obtained during counselling should be confidential (although it may be disclosed in certain circumstances, for example if it gives rise to concerns about the suitability of a person to donate gametes, be a surrogate, or to receive treatment). The written records of the professional counsellor should be kept in a secure place. These written records are confidential and should not be shared with others, including clinic staff. The Centre should ensure that their policies on record keeping and data protection include information on when the counselling records form part of the patient's medical record and therefore could be disclosed to the patient on request.

3.16 The centre should keep a record that it has offered people counselling, even if they choose not to accept this offer.

Patient support

3.17 The centre should develop a 'patient support policy', to outline how the centre ensures that patients, donors and their partners (where applicable) receive appropriate psychosocial support from all staff they encounter before, during and after treatment. Psychosocial support is delivered by all members of staff and includes, but is not limited to, access to counselling. All patients, donors and their partners (where applicable) should be treated with sensitivity and respect, and supported through all aspects of their treatment and, in particular, if they are suffering distress at any stage.

3.18 The policy should include:

a) a definition of patient-centred care and how this will be delivered at the centre

b) a statement regarding each individual staff member's responsibility for supporting patients and managing their expectations

c) a list of written and online information to be provided and how patients will be able to access this

d) what the centre will provide in terms of

   i) support groups
   ii) forums for patients to engage with each other
   iii) signposting to external groups and forums
   iv) other events/groups/open evenings etc

e) the expectations about how all staff will communicate with patients, donors and their partners
f) an outline of customised support interventions at different stages of treatment and for different types of patients

g) the annual programme of training that will be provided to staff on different aspects of patient support, including skills training, adapted as appropriate to reflect staff members' role within the clinic

h) feedback mechanisms for collecting data on the patient/donor experience, and

i) quality indicators for systematically monitoring and evaluating the centre's provision of patient support and patient care as contained in this policy.

3.19 Clinics should also refer to the HFEA's guidelines on patient support for further guidance on best practice.

See also

Guidance note 30 – Confidentiality and privacy

Other legislation, professional guidelines and information

Professional guidelines

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (third edition, 2012)

4. Information to be provided prior to consent

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General Conditions

(1) The following shall be conditions of every licence granted under this Act -

…(c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with,…

13 Conditions of licences for treatment

(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

(6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

13A Conditions of licences for non-medical fertility services

(3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc.

3 (1) Before a person gives consent under this Schedule -

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

Licence conditions

T58 Prior to giving consent gamete providers must be provided with information about:

a. the nature of the treatment
b. its consequences and risks
c. any analytical tests, if they are to be performed
d. the recording and protection of personal data and confidentiality
e. the right to withdraw or vary their consent, and
f. the availability of counselling.

T59 The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.

NOTE For the mandatory requirements pertaining to consent, see guidance note 5 – consent to treatment, storage, donation, training and disclosure of information.

Directions

0005 – Collecting and recording information for the HFEA

HFEA guidance

Information to provide

Interpretation of mandatory requirements 4A

The law requires appropriate information to be provided when:

(a) a woman or couple seeks treatment with donated gametes, mitochondria or embryos (including mitochondrial donation)

(b) an individual or couple seeks treatment that will create embryos in vitro

(c) an individual or couple seeks to store their gametes or embryos (for exceptions, see Schedule 3 of the HFE Act 1990 (as amended), paragraphs 9 or 10)

(d) an individual or couple seeks to donate their gametes, mitochondria or embryos for the treatment of others (including mitochondrial donation)

(e) an individual seeks to donate their gametes for use in non-medical fertility services

(f) an individual or couple seeks to donate their embryos for research purposes, or for training people in embryo biopsy, embryo storage or other embryological techniques

(g) an individual seeks to provide their gametes or cells for the creation of embryos or human admixed embryos for research (for exceptions, see mandatory requirements outlined in guidance note 22 – research and training)

(h) a woman provides embryos (obtained by lavage) for any purpose

(i) written notice is served by a man or a woman consenting to the man being treated as the legal father of any child born as a result of the woman's treatment, or

(j) written notice is served by a woman, or her female partner, consenting to the partner being treated as the legal parent of any child born as a result of the woman's treatment.

Information must always be provided before consent is given to treatment, storage, provision or donation (cases (a) to (h) above) or treatment is provided or continued (cases (i) and (j) above). In the

case of donors wishing to donate gametes or embryos for use in mitochondrial donation and patients wishing to undergo treatment involving mitochondrial donation, the above information must be provided by a clinic licensed to offer mitochondrial donation.

Distinguishing the provision of information from the offer of counselling

4.1 The provision of information should be clearly distinguished from the offer of counselling.

See also

Guidance note 3 – Counselling

Information specific to the centre

4.2 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the centre's policy on selecting patients
(b) the centre's statutory duty to take account of the welfare of any resulting or affected child
(c) the expected waiting time for treatment
(d) fertility treatments available, including any treatment add ons which may be offered and the evidence supporting their use. Any information should explain that treatment add ons refers to the technologies and treatments listed on the treatment add ons page of the HFEA website (https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/)
(e) the availability of facilities for freezing and storing eggs, sperm and embryos
(f) where patients freeze and store eggs, sperm or embryos the centre should provide information about future use including information about consent to posthumous use
(g) the importance of informing the treatment centre about the eventual outcome of the treatment (including if no live birth results)
(h) the centre's complaints procedure.

Information about the treatment

4.3 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the likely outcomes of the proposed treatment (data provided should include the national live birth rate and clinical pregnancy rate, and the centre's most recent live birth rate and clinical pregnancy rate. Centres are encouraged to provide data per embryo transferred where relevant)
(b) the nature of the proposed treatment and any treatment add ons, including evidence of effectiveness. The centre should provide information in a lay format with reference to the HFEA website
(c) the implications of treatment, including for example, the possibility of a negative outcome which could cause distress or multiple pregnancy

Information about the risks of treatment

4.4 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the potential immediate and longer-term risks of the treatment and any treatment add ons used, including the risk to the patient and of any children conceived having developmental and birth defects
(b) the nature and potential risks of any alternative treatment options available so the patient can make an informed decision about their treatment
(c) the possible side effects and risks to the woman being treated and any resulting child
(d) the possibility of developing ovarian hyperstimulation syndrome (OHSS). Any information provided should include the possible symptoms of OHSS, what the woman being treated should do and who to contact if experiencing symptoms of OHSS
(e) the nature and potential risks (immediate and longer-term) of using emerging or unproven treatments, including reference to the clinic's experience and wider evidence base
(f) the potential risk of emotional distress associated with negative outcomes both during and after treatment.

Information about success rates

4.5 In line with the Advertising Standards Authority's Code, the centre should ensure that the information provided on its website complies with the following guidance. This also applies to other relevant marketing communications of the centre and associated satellite and transport centres.

(a) The information should include the most recent data available from the past three years.
(b) Centres are encouraged to display live birth rate data per embryo transferred where relevant and this may be displayed alongside other success rate measures. The information should not highlight a high success rate that is not statistically significant where it applies only to a small, selected group of patients.
(c) The data should show split by maternal age and, if appropriate, by treatment type.
(d) The information should provide raw numbers rather than just percentages.
(e) The website should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.).
(f) The centre's published success-rate data should refer to the HFEA as the source of national information through its Choose a Fertility Clinic function.
(g) The information must state clearly that information on success rates is of limited value in comparing centres and choosing where to seek treatment. It should include a link to the HFEA's advice on choosing a clinic: https://www.hfea.gov.uk/choose-a-clinic/learn-about-choosing-a-clinic/
(h) If the information refers to comparative costs, it should indicate the likely total cost for a typical cycle, based on the actual costs for recent patients, not individual items in tariffs.

Information about the cost of treatment

4.6 Before treatment, storage or both are offered, the centre should also give the person seeking treatment or storage, and their partner (if applicable) a personalised costed treatment plan. The plan should detail the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The centre should give patients the opportunity to discuss the plan before

treatment begins.

Further information to provide

4.7 There are different kinds of information centres should give, where appropriate, to patients, patients' partners and donors prior to obtaining consent to treatment, storage or donation. Centre staff should familiarise themselves with all the appropriate information to provide. This information is contained in the following list of guidance notes:

5 – Consent to treatment, storage, donation, and disclosure of information
6 – Legal parenthood
7 – Multiple births
8 – Welfare of the child
9 – Preimplantation genetic screening (PGS)
10 – Embryo testing and sex selection
11 – Donor recruitment, assessment and screening
12 – Egg sharing arrangements
14 – Surrogacy
15 – Procuring, processing and transporting gametes and embryos
17 – Storage of gametes and embryos
20 – Donor assisted conception
21 – Intra-cytoplasmic sperm injection (ICSI)
22 – Research and training
29 – Treating people fairly
30 – Confidentiality and privacy
33 – Mitochondrial donation

Additional information for treating trans patients

4.8 The centre should be aware that there are multiple terms used to refer to trans people and that terminology in this area is evolving. For inclusivity, this Code of Practice uses the term 'trans' to refer to all trans identities, including persons who consider themselves 'non-binary' (ie, identify as somewhere, either fixed or moveable, on the male-female continuum) and 'non-gendered' (ie, neither male, female, nor on the male-female continuum).

4.9 The centre should be aware that under the Gender Recognition Act 2004, a trans person can apply to be legally recognised as their acquired gender and must be so recognised if they have a full gender recognition certificate (GRC) that has been issued by a Gender Recognition Panel (GRP). The centre should be aware that, on occasion, a GRP may issue an interim GRC before a full GRC is issued in certain circumstances, for example where a trans person needs to end their marriage or civil partnership.

A GRP must grant a GRC if satisfied that a person meets the relevant conditions.

4.10 The centre should be aware that under equality legislation, a trans person does not need to undergo gender reassignment or obtain a GRC to have the protection from discrimination on the grounds of gender reassignment. For example, if a trans person who was male at birth subsequently identifies as a female, and chooses to live in her female identity permanently without any medical intervention, she will have the protection of the Equality Act 2010. The law recognises a person's intention without the person undergoing gender reassignment.

4.11 Before treatment or storage is offered to a trans person, the centre should (as with all patients)

consider the treatment and storage options that are available to the patient, depending on their individual circumstances. For example, if a trans person is visiting the clinic prior to gender reassignment they may be seeking options for fertility preservation (ie, storage of either testicular or ovarian tissue, or eggs or sperm depending on whether they have undergone puberty); or if a trans person is visiting the clinic after gender reassignment they may be seeking ways to use their preserved tissue, eggs or sperm in treatment with a partner and/or a surrogate, or extend their storage periods due to premature infertility.

4.12 Before treatment, storage or both are offered, the centre should inform a trans person (as with all patients) that they may need to be screened as a donor at the time of egg or sperm collection depending on the treatment options they may wish to pursue in the future, and explain the reasons why. For example, they may wish to use their eggs or sperm in treatment with a surrogate.

4.13 Before treatment, storage or both are offered to a person who is yet to undergo gender reassignment or who is not yet living in their acquired gender, the centre should inform them that should they change their identity before returning for further treatment, it will be necessary for them to provide evidence of their acquired identity and to verify that they are the person previously treated.

4.14 The centre should recognise the sensitivities of treating trans patients, and have practical ways of accommodating their needs with dignity and respect. For example, rather than making assumptions about how a trans patient would like to be addressed, centres should ask how they would prefer to be addressed. Centres may also need to explain why gender at birth may be noted in medical records, should avoid making assumptions when referring to gender (eg, if a telephone enquiry is received regarding sperm storage, avoid assuming the caller is male), and should take privacy and sensitivity into consideration.

See also

Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information

Guidance note 6 – Legal parenthood

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 17 – Storage of gametes and embryos

Guidance note 29 – Treating people fairly

Guidance note 30 – Confidentiality and privacy

Other legislation, professional guidelines and information

Legislation

Data Protection Act 1998

Equality Act 2010

Gender Recognition Act 2004

Professional guidelines

Advertising Standards Authority: UK code of non-broadcast advertising, and direct and promotional

marketing (CAP Code)

National Institute for Health and Care Excellence: Fertility problems – assessment and treatment [CG156] (2013)

5. Consent to treatment, storage, donation, training and disclosure of information

Version 10.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General Conditions

(1) The following shall be conditions of every licence granted under this Act -

…(c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with…

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc.

1 (1) A consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.

(2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability (a "person unable to sign"), and any notice under paragraph 4 by a person unable to sign varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the person unable to sign, in the presence of the person unable to sign and in the presence of at least one witness who attests the signature.

(3) In this Schedule "effective consent" means a consent under this Schedule which has not been withdrawn.

2 (1) A consent to the use of any embryo must specify one or more of the following purposes -

(a) use in providing treatment services to the person giving consent, or that person and another specified person together,

(b) use in providing treatment services to persons not including the person giving consent,

(ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or

(c) use for the purposes of any project of research,

and may specify conditions subject to which the embryo may be so used. …

(2) A consent to the storage of any gametes, any embryo or any human admixed embryo must -

(a) specify the maximum period of storage (if less than the statutory storage period),

(b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and

(c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,

and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.

(2A) A consent to the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.

(2B) In relation to Scotland, the reference in sub-paragraph (2)(b) to the person lacking capacity is to be read as a reference to the person -

(a) lacking capacity within the meaning of the Age of Legal Capacity (Scotland) Act 1991, or

(b) being incapable within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000.

(3) A consent under this Schedule must provide for such other matters as the Authority may specify in directions.

(4) A consent under this Schedule may apply -

(a) to the use or storage of a particular embryo or human admixed embryo, or

(b) in the case of a person providing gametes or human cells, to the use or storage of –

(i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and

(ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.

(5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to -

(a) a particular embryo or particular embryos, or

(b) a particular human admixed embryo or particular human admixed embryos.

Procedure for giving consent

3 (1) Before a person gives consent under this Schedule -

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

(2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 and, if relevant, paragraph 4A below.

Use of gametes for treatment of others

5 (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.

(2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.

(3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

In vitro fertilisation and subsequent use of embryo

6 (1) A person's gametes or human cells must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for one or more of the purposes mentioned in paragraph 2(1)(a), (b) and (c) above.

(2) An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the embryo to the use for one or more of the purposes mentioned in paragraph 2(1)(a), (b), (ba) and (c) above of the embryo.

(3) An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each relevant person in relation to the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents. …

(3E) For the purposes of sub-paragraphs (2), (3) and (3B) each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro (“embryo A”) -

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.

(4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

Embryos obtained by lavage, etc.

7 (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.

(2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.

(3) Sub-paragraphs (1) and (2) do not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.

(4) An embryo taken from a woman must not be used to bring about the creation of any embryo in vitro or any human admixed embryo in vitro.

Storage of gametes and embryos

8 (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.

(2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents…

(2C) For the purposes of sub-paragraphs (2) and (2A) each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A") -

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.

(3) An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent.

(4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraphs 4A(4), 16 and 20.

Cases where consent not required for storage

9 (1) The gametes of a person ("C") may be kept in storage without C's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -

(a) the treatment is likely to cause a significant impairment of C's fertility, and

(b) the storage of the gametes is in C's best interests.

(4) Condition C is that, at the time when the gametes are first stored, either -

(a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes -

(a) given consent under this Schedule to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications -

(a) for sub-paragraph (4), substitute -

"(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.", and

(b) in sub-paragraph (5), for "becoming competent to deal with the issue of consent to the storage of the gametes" substitute "acquiring such capacity".

10 (1) The gametes of a person ("P") may be kept in storage without P's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -

(a) the treatment is likely to cause a significant impairment of P's fertility,

(b) P lacks capacity to consent to the storage of the gametes,

(c) P is likely at some time to have that capacity, and

(d) the storage of the gametes is in P's best interests.

(4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.

(5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule -

(a) given consent to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.

(6) In relation to Scotland -

(a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,

(b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and

(c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.

11 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death.

Interpretation

22 …(6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

Licence conditions

T57 Gametes or embryos must not be used in the provision of treatment services (except in the use of gametes in the course of providing basic partner treatment services or non-medical fertility services) unless effective consent is in place from each gamete provider in accordance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

Directions

0006 – Import and export of gametes and embryos

0007 – Consent

HFEA guidance

Consent to use and storage of gametes and embryos

Interpretation of mandatory requirements 5A

It is unlawful to procure, store or use gametes or embryos without written, effective consent from the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created). Where the relevant legal requirements can be met prior to storage, it may be possible to store the gametes of someone who is unable to give consent to storage. The legal requirements that must be met in such casesare set out in paragraphs 9 and 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) (see 5G). It is important to note that paragraph 10 of Schedule 3 can only be relied on where the person who lacks capacity and whose gametes are to be stored, is likely at some future point to have or regain the capacity to give consent. .

Gametes from a person who has died (including cases of brain stem death) cannot be stored or used without that person's written consent. The gametes or embryos of a person who has died, can be used but only where they have given consent to posthumous use. While a patient can give consent to the posthumous storage and use of their gametes, storage and use is only possible for the duration of their consent.

The provisions of the Human Tissue Act 2004, which allow next of kin, a friend or close relative to give consent to procure, store or use organs and tissues of the deceased, do not apply to gametes. No one can give consent on behalf of a gamete provider.

Anyone who procures, stores or uses gametes without written, effective consent from the gamete provider may be committing a criminal offence.

The use of donor gametes or embryos to create more families than a donor has consented to is a breach of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

The law requires the centre to obtain written, effective consent from a person before it performs the following procedures:

(a) storing that person's gametes (exemptions are outlined in paragraphs 9 or 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended)

(b) using that person's gametes for the treatment of others or for nonmedical fertility services

(c) creating embryos in vitro with that person's gametes

(d) storing embryos created with that person's gametes

(e) using embryos created with that person's gametes for their own treatment, treatment of a partner or treatment of others

(f) using embryos created with that person's gametes for training people in embryo biopsy, embryo storage or other embryological techniques

(g) using embryos created with that person's gametes for any research project

(h) using that person's cells to create embryos for research, or

(i) creating human admixed embryos with that person's gametes or cells.

If gametes or embryos are to be transferred to a centre outside the UK, the requirements set out in General Direction 0006 must be met. These include that the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created) has given written, effective consent to the export of the gametes or embryos to the country in which the receiving centre is situated. Such consent must then be provided to the centre receiving the gametes or embryos.

If gametes or embryos are to be transferred into the UK from a centre outside the UK, the requirements set out in General Direction 0006 must be met. These include the requirement that the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created) has given written, effective consent to the transfer of the gametes or embryos to the UK, and has not withdrawn that consent.

If the provisions of General Direction 0006 cannot be met, the UK centre may need to consider applying for a Special Direction to permit the import or export.

Further requirements regarding consent to the use of gametes, cells and embryos for research (including for the creation of admixed embryos), are outlined in guidance note 22 – research and training.

Requirements regarding consent to legal parenthood are outlined in guidance note 6 – legal parenthood, and General Direction 0006.

5.1 The centre should obtain written, effective consent from a person before it carries out the following procedures:

(a) using their gametes for their own treatment or their partner's treatment, or
(b) using their gametes for research and training.

5.2 When a woman is to undergo an egg or embryo transfer, the centre should:

(a) obtain her consent to the proposed number of eggs or embryos to be transferred, and
(b) record her consent in her medical records.

5.3 The centre should establish and use documented procedures to ensure that no activity involving the handling or processing of gametes or embryos is carried out without the appropriate consent

having been given. This should include a documented assurance process to ensure that all relevant consent forms have been properly and correctly completed before treatment.

5.4 If, following treatment, the centre discovers errors in the consent provided by a patient or their partner, the centre should:

(a) take all reasonable steps to notify the affected patient at the earliest opportunity
(b) assess the error(s) and potential impact, and consider the remedial actions that should be taken
(c) take all reasonable steps to support any affected patients (and their partner(s), if relevant) and offer independent legal assistance where necessary, and
(d) report any error(s) as an adverse incident.

NOTE Consent to legal parenthood is subject to specific legal requirements. Centres should familiarise themselves with guidance note 6, which contains guidance and mandatory requirements relevant to legal parenthood.

5.5 If the centre becomes involved in a case where a partner or family member of a deceased person intends to make an emergency application to the High Court to permit harvesting of gametes without valid consent, the centre should notify the HFEA as soon as it becomes aware of this.

See also

Guidance Note 6 – Legal parenthood

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Chief Executive's letter CE(12)02: Extension of storage of gametes and embryos where one of the gamete providers is deceased

Procedure for obtaining consent

Interpretation of mandatory requirements 5B

The law requires that before a person consents to the procedures outlined in box 5A, they should be given:

(a) enough information to enable them to understand the nature, purpose and implications of their treatment or donation

(b) a suitable opportunity to receive proper counselling about the implications of the steps which they are considering taking, and

(c) information about the procedure for varying or withdrawing any consent given, and about the implications of doing so.

5.6 Centres should ensure that, before a person gives consent, they are given the information outlined in guidance note 4.

5.7 The centre should ensure that the person giving consent is able to give their consent freely. The centre should not pre-complete consent forms on behalf of the person giving consent. For example, a person giving consent to the storage of their gametes and/or embryos should be

free to choose how long to consent to store for, within what is permitted by regulations. The centre should not restrict storage consent to tie in with payment or funding arrangements. Contractual agreements covering payment or funding should be separate to consent. Further information on removing gametes and embryos within the storage period is outlined in guidance note 17.

5.8 The centre should inform anyone providing gametes that they can, if they wish, specify extra conditions for storing or using their gametes (or embryos created using them).

5.9 The centre should give anyone seeking treatment or considering donation or storage enough time to reflect on their decisions before obtaining their consent. The centre should give them an opportunity to ask questions and receive further information, advice and guidance.

5.10 If the possibility of donating gametes or embryos (including mitochondrial donation) for the treatment of others, or donating embryos for research or training purposes, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.

5.11 The centre should ensure that consent is:

(a) given voluntarily (without pressure to accept treatment or agree to donation)
(b) given by a person who has capacity to do so
(c) taken by a person authorised by the centre to do so, and
(d) given at the clinic (with both parties if a couple is being treated) where possible, clinics should record why a patient is not able to sign at the clinic and should have a documented process for ensuring consent forms being signed outside the clinic are signed by the correct person

A child under the age of 16 is only able to provide consent if it has been established that he or she is 'Gillick competent'.

5.12 The centre should ensure that anyone giving consent has been:

(a) given enough information to enable them to understand the nature, purpose and implications of the treatment or donation
(b) given a suitable opportunity to receive proper counselling about the implications of the proposed procedures
(c) given information about the procedure for varying or withdrawing consent, and
(d) given information in writing that is correct and complete.

5.13 Treatment centres should take all reasonable steps to verify the identity of anyone accepted for treatment, including partners who may not visit the centre during treatment. The centre should establish the relationship between a patient and their partner and a record of this should be retained in the patients' notes. If a patient's identity is in doubt or if a centre has reason to question whether the person is who they claim to be, the centre should verify their identity, including examining photographic evidence such as a passport or a photocard driving licence. The centre should record this evidence in the patient's medical records. Centres should have a process in place to verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment, to ensure the patient and their partner are the same people they treated initially. The clinic should establish whether the patient and their partner's personal circumstances have changed in the period since their last treatment, for example, whether the couple has divorced or separated since their previous treatment and give consideration to whether any changes in their personal circumstances impact on consent.

5.14 Where a patient has changed their name (eg, where someone has changed their name by deed poll, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation, centres should take all reasonable steps to verify the patient's identity. This is to ascertain that a patient presenting for treatment or donation is the same person the centre previously engaged with or treated.

Centres should verify a patient's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the person's medical records. This can be a sensitive issue, and centres should take care to address identity issues with consideration. As evidence of their new name, centres should ask the person to provide one of the following:

(a) a marriage certificate, or
(b) evidence of a change in name (such as via deed poll)

For trans patients:

(c) a birth or adoption certificate in an acquired gender
(d) a Gender Recognition Certificate, or
(e) a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed poll).

Centres must ensure that a patient's records are updated to accurately reflect their new identity.

5.15 To avoid the possibility of misrepresentation or mistake, the centre should check the identities of patients (and their partners, if applicable) against identifying information in the medical records. This should be done at each consultation, examination, treatment or donation. If the partner of a patient who is having treatment has not visited the clinic throughout the treatment, or does not return with the patient for subsequent treatment, centres should take reasonable steps to find out whether the patient's partner still consents to the treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is still valid. The centre should not commence treatment until it is satisfied that the partner in fact consents to the treatment.

5.16 The centre should consider the needs of people whose first language is not English and those who face other communication barriers. Where consent is obtained, the centre should record:

(a) any difficulties in communicating the implications of giving consent and providing other information to the person (eg, language barriers or hearing impairment), and
(b) an explanation of how these difficulties were overcome (eg, the use of an independent interpreter). (This guidance is based on a paragraph taken from The Human Tissue Authority's Code of Practice on Consent (2008)).

5.17 The centre should establish and follow documented procedures to obtain written informed consent.

See also

Guidance note 3 – Counselling

Guidance note 4 – Information to be provided prior to consent

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 17 – Storage of gametes and embryos

Guidance note 22 – Research and training

Guidance note 23 – The quality management system

Guidance note 29 – Treating people fairly

Guidance note 31 – Record keeping and document control

HFEA consent forms

HFEA guide to consent

Recording consent and related information

Interpretation of mandatory requirements 5C

The law requires consent, or any subsequent variation or withdrawal of consent, to be in writing and signed by the person giving consent, except in the following situation:

If the person giving consent, or varying or withdrawing consent, has the mental capacity to do so but cannot sign because of illness, injury or physical disability (for example, quadriplegia), they can direct someone to sign on their behalf, provided that:

(a) the person giving consent, or varying or withdrawing consent is present at the time, and

(b) the signature is also witnessed, and attested to by at least one other person.

5.18 The centre should keep a copy of a person's signed consent form(s) (either electronically or as a hard copy) so that a copy can be made available to them upon request.

5.19 The centre should ensure that it documents in the medical records that:

(a) relevant information, as outlined in guidance note 4, has been provided to the person, and
(b) the person has been offered counselling before giving consent.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 31 – Record keeping and document control

HFEA consent forms

Additional consent requirements for storing gametes and embryos

Interpretation of mandatory requirements 5D

Written consent to the storage of gametes, embryos or human admixed embryos must:

(a) specify the maximum period of storage (if less than the statutory storage period), and

(b) state what should be done with the gametes, embryos or human admixed embryos if the person giving the consent dies or cannot, because of mental incapacity, withdraw or vary the terms of the consent.

In relation to b), where consent is given following the application of the parental consent provisions in Schedule 3, the consent needs only to specify what is to be done with the embryo or the human admixed embryo if the person to whom the consent relates dies.

The consent may also specify conditions under which the gametes, embryos or human admixed embryos may remain in storage.

In certain limited circumstances involving premature infertility, gametes and embryos can be stored beyond the statutory maximum storage period.

Gametes first placed in storage before 1 August 1991

Any gametes currently in storage which were originally placed into storage prior to 1 August 1991 i.e. prior to statutory regulation, can only continue to be stored if the original 10-year storage period was properly extended under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 (the 1991 Regulations) and has not expired. Any gametes in storage as at 31 July 2001 (10 years after the storage period was deemed to commence) and which were not eligible for extension of storage under the 1991 Regulations should have been allowed to perish. The Schedule to the 1991 Regulations sets out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period must be calculated from 1 August 1991.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage between 1 August 1991 and 1 October 2009

Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied. The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period begins on the date that the gametes were stored. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

Embryos first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period but only if both people whose gametes were used to bring about the creation of the embryo confirm in writing that they have no objection to the extension (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are satisfied). The Schedule to these Regulations sets out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage after 1 October 2009

Gametes or embryos first placed in storage after 1 October 2009 may continue to be stored beyond the statutory maximum storage period, to a maximum of 55 years, but only with the written consent of the gamete provider or the people whose gametes were used to bring about the creation of the embryo (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 are satisfied) (the 2009 Regulations). Gametes and embryos first stored

earlier than 1 October 2009 may be stored for an extended period under the 2009 Regulations but only where the gametes or embryos are either still within the statutory storage period, or are being stored subject to a lawfully extended period under the 1991 or 1996 Regulations respectively.

5.20 The centre should ask patients to give consent to storage at the same time as consent to the use of gametes and embryos. However, the centre should accommodate anyone seeking long-term storage of gametes who may wish to consent to storage separately from consent to use. Any patient who has given consent to storage but who has not given consent to use, should be informed that their gametes cannot lawfully be used in treatment unless they have given consent to use. This scenario becomes particularly problematic in the case of patients who have died since storing their gametes and whose surviving partner or spouse wishes to use their gametes posthumously but is prevented from doing so because there is no consent to use in place.

5.21 Before the centre obtains consent from anyone wishing to store gametes or embryos for more than 10 years, it should explain that storage can only continue beyond 10 years if a medical practitioner has certified in writing that the gamete provider, their partner, or the person who the gametes or embryos have been allocated to, meet the medical criteria for premature infertility or are likely to become prematurely infertile. This medical opinion must be obtained before expiry of the statutory 10-year storage period and in the case of gametes or embryos which are subject to an extended storage period, must obtained within 10 years from the date of the previous medical opinion. The opinion must be provided in writing and be given by a medical practitioner who is registered with the General Medical Council (GMC).

5.22 The centre should have regard to their obligations to help trans patients. Trans patients, particularly those of a younger age, may be able to store their gametes beyond the statutory 10 years, depending on their individual circumstances and if they can comply with the requirements of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. This includes the need to obtain a written opinion from a registered medical practitioner certifying that they are, or are likely to become prematurely infertile. Giving consideration to whether the patient meets the criteria for extended storage will help to ensure that trans patients have viable treatment options in the future.

5.23 The centre should ensure that they discuss the possibility of posthumous use and the need for consent to posthumous use with all patients particularly those who are storing gametes prior to undergoing treatment which is likely to impair their fertility. Where patients wish to consent to posthumous use, the clinic must take particular care to ensure that all necessary consent forms are properly completed including consent to posthumous use and posthumous birth registration.

5.24 The gamete provider should be made aware that if they die or become mentally incapacitated, the gametes and embryos cannot be used in treatment unless the necessary consent has been provided and their partner has been named on the relevant consent form. It is therefore important that patients who have previously completed consent forms and not given consent to posthumous use are encouraged to keep in contact with the centre so that they can update their consent forms if their personal circumstances change and they wish to give consent to posthumous use.

See also

Guidance note 6 – Legal parenthood

Guidance note 17 – Storage of gametes and embryos

HFEA consent forms

Interpretation of mandatory requirements 5E

The law requires the centre to ensure that consent to the use of any embryo (not a human admixed embryo) must specify one or more of the following uses for the embryo:

(a) providing treatment for the person giving the consent, or, where applicable, that person and another named person together

(b) providing treatment for others

(c) training centre staff in embryo biopsy, embryo storage or other embryological techniques, or

(d) contributing to a specified research project.

In relation to human admixed embryos, the law requires that consent to their use must specify use for a research project.

The consent may also specify conditions for how the embryo may be used.

5.24 Consent to the use of gametes or embryos for the treatment of others should state the number of families that may have children using the donated gametes or embryos.

5.25 When an individual gives consent to the use of gametes for the treatment of others, the centre need not get consent from the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.

5.26 Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:

(a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
(b) referred to information on the HFEA's website on this issue, and
(c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

See also

Guidance note 20 – Donor assisted conception

Guidance note 22 – Research and training

HFEA consent forms

Additional consent requirements for those participating in a benefits in kind agreement

5.27 The person obtaining consent should ensure that a gamete provider's consent is recorded so that different conditions can be placed on:

(a) the use or storage of the gametes, and the use and storage of embryos created for the gamete provider's own treatment, and
(b) the use of eggs or sperm, and the use and storage of embryos created for the treatment of the recipient(s)

These conditions should be able to be varied independently of each other.

5.28 The person obtaining consent should tell the gamete provider and recipient(s) that the gamete provider may withdraw or vary their consent up to when the gametes or embryo(s) are:

(a) transferred to a woman
(b) used in a research project (defined as being under the control of the researchers and being cultured for use in research)
(c) used for training, or
(d) allowed to perish.

The possible consequences of this should:

(e) be made clear to the gamete provider and the recipient(s) before the treatment begins, and
(f) be set out in the written patient information included with the benefits in kind agreement.

The person obtaining consent should tell the gamete provider and recipient(s) that consent to providing gametes solely for use in mitochondrial donation treatment cannot be withdrawn or varied once the patient's nuclear DNA has been inserted into the egg or embryo.

See also

Guidance note 12 – Egg sharing arrangements

HFEA consent forms

Consent to examination and treatment

5.29 Everyone has the right to withhold or give consent to examination and treatment. Unless there are exceptional circumstances, the centre may not examine, treat or receive gametes from people without first obtaining their consent. The only exceptional circumstance likely to arise during fertility treatment is:

(a) where the procedure is necessary to save the patient's life, and
(b) the treatment cannot be postponed, and
(c) the patient is unconscious or mentally incapacitated so cannot indicate their wishes.

5.30 The centre should comply with current professional guidelines on consent.

Consent to the presence of observers

5.31 If a member of the centre's team wishes an observer to be present when a patient is being examined, treated or counselled, they should explain why beforehand and state who the

observer is. The centre should give the patient appropriate information about the proposed observation and ask them whether they consent to the observer's presence.

Consent to disclose identifying information

Interpretation of mandatory requirements 5F

Patients have the right to decide what identifying information should be disclosed and to whom. Centres should obtain a patient's written consent before disclosing information relating to their treatment (or providing gametes for a partner's treatment), or the storage of gametes or embryos.

In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or gamete/embryo storage. For example, consent would be needed from a patient's partner if they could be identified through disclosure of information about the patient's treatment.

If a child born as a result of treatment could be identified, consent must be obtained from the parent(s), unless identification is necessary in disclosing information about the patient's treatment. Once a child born as a result of treatment is considered competent to consent, then their consent (if given) will override the consent of the parent(s).

5.32 Before obtaining consent to disclose information, the centre should give the person enough information for them to make a properly informed decision, including:

(a) precisely what information is to be disclosed
(b) the terms on which it is to be disclosed
(c) the reasons for disclosure (eg, to keep the person's GP informed about the fertility treatment)
(d) the implications of disclosure, in particular the fact that, once it is disclosed, the information will be subject no longer to the special provisions of the HFE Act 1990 (as amended) but only to the general law of confidentiality, and
(e) the categories of people to whom the information is to be disclosed.

5.33 The centre should seek consent to disclosure to the following categories of people:

(a) the patient's GP or the patient's partner's GP
(b) other healthcare professionals outside the centre (so they can provide the patient or the patient's partner with the best possible medical care)
(c) auditors or administrative staff outside of the centre (so they can perform their functions in connection with the centre's licensable activities), and
(d) medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).

5.34 Under the General Data Protection Regulation (GDPR), information about gender reassignment and information relating to a person's gender history is classed as 'special category data'; a category of personal data which is more sensitive and which centres must take particular care to protect. Centres should be aware that it is an offence under the Gender Recognition Act 2004 to disclose information that centres have obtained in an official capacity about a person who has applied for a gender recognition certificate (GRC) or the gender history of someone who has obtained a GRC, unless consent has been obtained from that person.

The centre should consider circumstances where they may need to disclose a person's gender history (eg, to those within the centre who need to know of a trans patient's previous identity to

deliver safe and appropriate care) to determine whether they need to obtain the person's consent to disclosure of this information. This should be discussed in detail with the person and any consent obtained should be filed with their medical records. Centres dealing with requests for disclosure of this information may wish to seek advice from information law specialists before disclosing any information.

5.35 The centre should renew consent to disclosure if the nature of treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used instead of the patient's own, or if the patient moves from unlicensed to licensed fertility treatment).

5.36 The centre should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:

(a) the precise terms upon which it was disclosed and for which consent has been given, and
(b) that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.

See also

Guidance note 30 – Confidentiality and privacy

HFEA consent forms

Cases where consent is not required for storage

Interpretation of mandatory requirements 5G

Cases where consent not required for storage

Gametes may be stored without consent if the conditions in paragraph 9 or 10, of Schedule 3 of the HFE Act 1990 (as amended) are met.

Paragraph 9 sets out the conditions that must be met before the gametes of a person who is **under the age of 18** can be stored without their consent.

Condition A is that the gametes are lawfully taken from the person before they reach the age of 18 years.

Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the person is expected to undergo medical treatment and that in the opinion of the registered medical practitioner:

(a) the treatment is likely to cause a significant impairment of their fertility, and

(b) the storage of the gametes is in the person's best interests.

Condition C is that, at the time when the gametes are first stored, either:

(a) the person has not reached the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) the person is 16 years old but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to storage. A registered medical

practitioner must actively establish that the person is not competent to deal with the issues arising in relation to consent to the storage of their gametes.

NOTE In relation to Scotland for Condition C, the test is whether, at the time the gametes were first stored, the person has capacity within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991.

Condition D is that the person has not, since becoming competent to deal with the issue of consent to the storage of the gametes:

(a) given consent to the storage of the gametes, or

(b) given written notice to the centre that they do not wish their gametes to continue to be stored.

Paragraph 10 sets out the conditions that must be met before the gametes of a person who is **16 years or over** may be stored without their consent.

Condition A is that the gametes are lawfully taken from or provided by the person after they have reached the age of 16 years.

Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the person is expected to undergo medical treatment and that in the opinion of the registered medical practitioner:

(a) the treatment is likely to cause a significant impairment of their fertility,

(b) the person lacks capacity to consent to the storage of the gametes,

(c) the person is likely at some time to have that capacity, and

(d) the storage of the gametes is in their best interests.

Condition C is that, at the time when the gametes are first stored, the person lacks capacity to consent to their storage.

Condition D is that the person has not subsequently, at a time when he or she has capacity to give a consent:

(a) given consent to the storage of the gametes, or

(b) given written notice to the centre that they do not wish their gametes to continue to be stored.

Gametes stored in compliance with these paragraphs may be used in treatment if the person from whom they were collected gives written effective consent to their use. A person's gametes must not be kept in storage by virtue of either of paragraph 9 or 10 after the person's death.

5.37 Before a centre can store a patient's gametes without their consent, the centre must ensure that each of the conditions set out in either paragraph 9 or 10 of Schedule 3 of the 1990 Act (whichever is applicable in the circumstances) are met. The centre should ensure that it documents its decision to store the patient's gametes in the absence of consent and records the evidence relied upon to establish that each of the conditions have been met.

5.38 When assessing a patient's competence to consent, the centre should follow current guidance produced by the Department of Health, the General Medical Council and other professional bodies.

5.39 When assessing whether it is in a child's best interests to store their gametes, the centre should refer to applicable General Medical Council guidance and consider the child's short- and long-term best interests. When the child is competent to give consent, the centre should seek their consent to the continued storage of the gametes.

5.40 The centre should provide written information about the proposed procedures that children and young people can read and understand easily. This information should be given by a member of staff experienced in communicating with children.

5.41 The conditions outlined in 5G are situations where consent for storage is not required by anyone. Therefore, no one needs to sign a consent for storage on behalf the patient.

Competence

5.41 If the centre's staff doubt someone's competence to consent to a proposed procedure, or to the storage or use of gametes or embryos, they should:

(a) refer to the Mental Capacity Act 2005 (England and Wales), or the Age of Legal Capacity (Scotland) Act 1991 and the Adults with Incapacity (Scotland) Act 2000, and
(b) follow the current guidelines of professional bodies. If they remain in any doubt, the centre should seek legal advice.

Variation and withdrawal of consent

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3

Variation and withdrawal of consent

4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

(1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and "egg A" and "egg B" have the same meanings in this paragraph as in that regulation).

(1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

(2) Subject to sub-paragraph (3) to (3B), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used -

(a) in providing treatment services,

(aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or

(b) for the purposes of any project of research.

(3) Where the terms of any consent to the use of an embryo ("embryo A") include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human

admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

(3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and "embryo A" and "embryo B" have the same meanings in sub-paragraph (3B) as in that regulation).

(3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.

4A (1) This paragraph applies where -

(a) a permitted embryo, the creation of which was brought about in vitro, is in storage,

(b) it was created for use in providing treatment services,

(c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation("P") gives the person keeping the embryo notice
withdrawing P's consent to the storage of the embryo, and

(d) the embryo was not to be used in providing treatment services to P alone.

(2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P's withdrawal of consent.

(3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.

(4) Storage of the embryo remains lawful until -

(a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or

(b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.

(5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.

Interpretation of mandatory requirements 5H

The law allows consent to be varied or withdrawn at any point until gametes or embryos (other than human admixed embryos) are used to provide treatment services, or used for a research project or for training.

Consent to providing eggs, embryos or sperm solely for use in mitochondrial donation treatment cannot be withdrawn or varied once the patient's nuclear DNA has been inserted into the egg or embryo.

Consent to the use of any human admixed embryo can be varied or withdrawn until the embryo has been used for a research project.

If someone wishes to withdraw consent to the storage or use of gametes, embryos or human admixed embryos, they must do so in writing, except if they are unable to do so because of illness, injury or

incapacity. In these cases, they can direct someone to sign on their behalf, provided that the person withdrawing consent is present at the time, and that the signature is also witnessed and attested to by at least one other person.

If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment (created from their gametes), the law requires the centre to take all reasonable steps to notify the intended recipient(s).

The law allows embryos to be stored for 12 months from the date that the centre receives written withdrawal of consent, or less if the centre receives written signed consent from all intended recipients for the embryos to be destroyed.

This 12-month 'cooling off' period must not extend beyond the end of the period for which valid consent exists.

5.42 The centre should check the identity of anyone withdrawing or varying consent against identifying information held in the medical records. The centre should also ensure that the person withdrawing or varying consent has been given sufficient information to enable them to make an informed decision about doing so.

5.43 The centre should have procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment. In this situation the centre should stop treatment and notify all relevant parties. Centres should provide information about counselling or mediation services as appropriate.

See also

HFEA consent forms

HFEA guide to consent

Other legislation, professional guidelines and information

Legislation

Age of Legal Capacity (Scotland) Act 1991

Adults with Incapacity (Scotland) Act 2000

General Data Protection Regulation (GDPR)

Equality Act 2010

Gender Recognition Act 2004

Mental Capacity Act 2005

Consent to examination and treatment

Department of Health: Reference guide to consent for examination or treatment (second edition, 2009)

General Medicines Council: Consent – patients and doctors making decisions together (2008)

Human Tissue Authority: Code of Practice – 1: Consent (2014)

Office of the Public Guardian: Code of Practice – Mental Capacity Act (2013)

Royal College of Obstetrics and Gynaecologists: Obtaining valid consent [Clinical Governance Advice No.6] (third edition, 2015)

General information

Department of Health: Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health (2004)

Clinic Focus articles

Clinic Focus article: Harvesting sperm from deceased men (October 2012)

Chief Executive's letters

Chief Executive's letter CE(12)02: Extension of storage of gametes and embryos where one of the gamete providers is deceased

Chief Executive's letter CE(16)02(a): Changes to the interpretation of several regulations

6. Legal parenthood

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

PART 2: PARENTHOOD IN CASES INVOLVING ASSISTED REPRODUCTION

Meaning of "mother"

33 Meaning of "mother"

(1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.

(2) Subsection (1) does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.

(3) Subsection (1) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

Application of sections 35 to 47

34 Applications of sections 35 to 47

(1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as "W") as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.

(2) Subsection (1) has effect subject to the provisions of sections 39, 40 and 46 limiting the purposes for which a person is treated as the child's other parent by virtue of those sections.

Meaning of "father"

35 Women married [to a man] at time of treatment

(1) If -

(a) at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination, W was a party to a marriage [with a man], and

(b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage, then, subject to section 38(2) to (4), the other party to the marriage is to be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).

(2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1)(a).

36 Treatment provided to woman where agreed fatherhood conditions apply

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but -

(a) the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,

(b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed fatherhood conditions (as set out in section 37) were satisfied in relation to a man, in relation to treatment provided to W under the licence,

(c) the man remained alive at that time, and

(d) the creation of the embryo carried by W was not brought about with the man's sperm, then, subject to section 38(2) to (4), the man is to be treated as the father of the child.

37 The agreed fatherhood conditions

(1) The agreed fatherhood conditions referred to in section 36(b) are met in relation to a man ("M") in relation to treatment provided to W under a licence if, but only if, -

(a) M has given the person responsible a notice stating that he consents to being treated as the father of any child resulting from treatment provided to W under the licence,

(b) W has given the person responsible a notice stating that she consents to M being so treated,

(c) neither M nor W has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of M's or W's consent to M being so treated,

(d) W has not, since the giving of the notice under paragraph (b), given the person responsible -

(i) a further notice under that paragraph stating that she consents to another man being treated as the father of any resulting child, or

(ii) a notice under section 44(1)(b) stating that she consents to a woman being treated as a parent of any resulting child, and

(e) W and M are not within prohibited degrees of relationship in relation to each other.

(2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.

(3) A notice under subsection (1)(a), (b) or (c) by a person ("S") who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

38 Further provision relating to sections 35 and 36

(1) Where a person is to be treated as the father of the child by virtue of section 35 or 36, no other person is to be treated as the father of the child.

(2) In England and Wales and Northern Ireland, sections 35 and 36 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.

(3) In Scotland, sections 35 and 36 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.

(4) Sections 35 and 36 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the man's child.

39 Use of sperm, or transfer of embryo, after death of man providing sperm

(1) If -

(a) the child has been carried by W as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,

(b) the creation of the embryo carried by W was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in W after his death,

(c) the man consented in writing (and did not withdraw the consent) -

(i) to the use of his sperm after his death which brought about the creation of the embryo carried by W or (as the case may be) to the placing in W after his death of the embryo which was brought about using his sperm before his death, and

(ii) to being treated for the purpose mentioned in subsection (3) as the father of any resulting child,

(d) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (3) as the father of the child, and

(e) no-one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the man is to be treated for the purpose mentioned in subsection (3) as the father of the child.

(2) Subsection (1) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

(3) The purpose referred to in subsection (1) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.

(4) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

40 Embryo transferred after death of husband etc. who did not provide sperm

(1) If -

(a) the child has been carried by W as a result of the placing in her of an embryo,

(b) the embryo was created at a time when W was a party to a marriage with a man],

(c) the creation of the embryo was not brought about with the sperm of the other party to the marriage,

(d) the other party to the marriage died before the placing of the embryo in W,

(e) the other party to the marriage consented in writing (and did not withdraw the consent) -

(i) to the placing of the embryo in W after his death, and

(ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,

(f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and

(g) no-one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.

(2) If -

(a) the child has been carried by W as a result of the placing in her of an embryo,

(b) the embryo was not created at a time when W was a party to a marriage or a civil partnership but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,

(c) a man consented in writing (and did not withdraw the consent) -

(i) to the placing of the embryo in W after his death, and

(ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,

(d) the creation of the embryo was not brought about with the sperm of that man,

(e) the man died before the placing of the embryo in W,

(f) immediately before the man's death, the agreed fatherhood conditions set out in section 37 were met in relation to the man in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,

(g) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and

(h) no-one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.

(3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.

(4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.

(5) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

Cases in which woman to be other parent

42 Woman in civil partnership [or marriage to a woman] at time of treatment

(1) If at the time of the placing in her of the embryo or the sperm and eggs or of her artificial insemination, W was a party to a civil partnership [or marriage with another woman], then subject to section 45(2) to (4), the other party to the civil partnership [or marriage] is to be treated as a parent of the child unless it is shown that she did not consent to the placing in W of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).

(2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1).

43 Treatment provided to woman who agrees that second woman to be parent

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but -

(a) the embryo or the sperm and eggs were placed in W, or she was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,

(b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed female parenthood conditions (as set out in section 44) were met in relation to another woman, in relation to treatment provided to W under that licence, and

(c) the other woman remained alive at that time, then, subject to section 45(2) to (4), the other woman is to be treated as a parent of the child.

44 The agreed female parenthood conditions

(1) The agreed female parenthood conditions referred to in section 43(b) are met in relation to another woman ("P") in relation to treatment provided to W under a licence if, but only if, -

(a) P has given the person responsible a notice stating that P consents to P being treated as a parent of any child resulting from treatment provided to W under the licence,

(b) W has given the person responsible a notice stating that W agrees to P being so treated,

(c) neither W nor P has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of P's or W's consent to P being so treated,

(d) W has not, since the giving of the notice under paragraph (b), given the person responsible -

(i) a further notice under that paragraph stating that W consents to a woman other than P being treated as a parent of any resulting child, or

(ii) a notice under section 37(1)(b) stating that W consents to a man being treated as the father of any resulting child, and

(e) W and P are not within prohibited degrees of relationship in relation to each other.

(2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.

(3) A notice under subsection (1)(a), (b) or (c) by a person ("S") who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of

subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

45 Further provision relating to sections 42 and 43

(1) Where a woman is treated by virtue of section 42 or 43 as a parent of the child, no man is to be treated as the father of the child.

(2) In England and Wales and Northern Ireland, sections 42 and 43 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.

(3) In Scotland, sections 42 and 43 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.

(4) Sections 42 and 43 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.

46 Embryo transferred after death of civil partner [or wife] or intended female parent

(1) If -

(a) the child has been carried by W as the result of the placing in her of an embryo,

(b) the embryo was created at a time when W was a party to a civil partnership [or marriage with another woman],

(c) the other party to the civil partnership [or marriage] died before the placing of the embryo in the woman,

(d) the other party to the civil partnership [or marriage] consented in writing (and did not withdraw the consent) -

(i) to the placing of the embryo in W after the death of the other party, and

(ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,

(e) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other party to the civil partnership [or marriage] to be treated for the purpose mentioned in subsection (4) as the parent of the child, and

(f) no one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the other party to the civil partnership is to be treated for the purpose mentioned in subsection (4) as a parent of the child.

(2) If -

(a) the child has been carried by W as the result of the placing in her of an embryo,

(b) the embryo was not created at a time when W was a party to a marriage or a civil partnership, but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,

(c) another woman consented in writing (and did not withdraw the consent) -

(i) to the placing of the embryo in W after the death of the other woman, and

(ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,

(d) the other woman died before the placing of the embryo in W,

(e) immediately before the other woman's death, the agreed female parenthood conditions set out in section 44 were met in relation to the other woman in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,

(f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other woman to be treated for the purpose mentioned in subsection (4) as the parent of the child, and

(g) no one else is to be treated -

(i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3), or

(ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the other woman is to be treated for the purpose mentioned in subsection (4) as a parent of the child.

(3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.

(4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the deceased woman's particulars to be entered as the particulars of the child's other parent in a relevant register of births.

(5) In the application of subsections (1) and (2) to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

48 Effect of sections 33 to 47

(1) Where by virtue of section 33, 35, 36, 42 or 43 a person is to be treated as the mother, father or parent of a child, that person is to be treated in law as the mother, father or parent (as the case may be) of the child for all purposes.

(2) Where by virtue of section 33, 38, 41, 45 or 47 a person is not to be treated as a parent of the child, that person is to be treated in law as not being a parent of the child for any purpose.

(3) Where section 39(1) or 40(1) or (2) applies, the deceased man -

(a) is to be treated in law as the father of the child for the purpose mentioned in section 39(3) or 40(4), but

(b) is to be treated in law as not being the father of the child for any other purpose.

(4) Where section 46(1) or (2) applies, the deceased woman -

(a) is to be treated in law as a parent of the child for the purpose mentioned in section 46(4), but

(b) is to be treated in law as not being a parent of the child for any other purpose.

(5) Where any of subsections (1) to (4) has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.

(6) In relation to England and Wales and Northern Ireland, a child who -

(a) has a parent by virtue of section 42, or

(b) has a parent by virtue of section 43 who is at any time during the period beginning with the time mentioned in section 43(b) and ending with the time of the child's birth a party to a civil partnership with the child's mother, is the legitimate child of the child's parents.

(7) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 33(1) or sections 35 to 47, read with this section -

(a) affects the succession to any dignity or title of honour or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or

(b) affects the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.

(8) In relation to Scotland -

(a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of its holder or affect the succession to any such title, coat of arms or dignity or its devolution, and

(b) where the terms of any deed provide that any property or interest in property is to devolve along with a title, coat of arms, honour or dignity, nothing in those provisions is to prevent that property or interest from so devolving.

References to parties to marriage or civil partnership

49 Meaning of references to parties to a marriage

(1) The references in sections 35 to 47 to the parties to a marriage at any time there referred to -

(a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but

(b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.

(2) In subsection (1)(a) "judicial separation" includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

50 Meaning of references to parties to a civil partnership

(1) The references in sections 35 to 47 to the parties to a civil partnership at the time there referred to -

(a) are to the parties to a civil partnership subsisting at that time, unless a separation order was then in force, but

(b) include the parties to a void civil partnership if either or both of them reasonably believed at that time that the civil partnership was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.

(2) The reference in section 48(6)(b) to a civil partnership includes a reference to a void civil partnership if either or both of the parties reasonably believed at the time when they registered as civil partners of each other that the civil partnership was valid; and for this purpose it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.

(3) In subsection (1)(a), "separation order" means -

(a) a separation order under section 37(1)(d) or 161(1)(d) of the Civil Partnership Act 2004 (c. 33),

(b) a decree of separation under section 120(2) of that Act, or

(c) a legal separation obtained in a country outside the United Kingdom and recognised in the United Kingdom.

Further provision about registration by virtue of section 39, 40 or 46

51 Meaning of "relevant register of births"

For the purposes of this Part a "relevant register of births", in relation to a birth, is whichever of the following is relevant -

(a) a register of live-births or still-births kept under the Births and Deaths Registration Act 1953 (c. 20),

(b) a register of births or still-births kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49), or

(c) a register of live-births or still-births kept under the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I.14)).

52 Late election by mother with consent of Registrar General

(1) The requirement under section 39(1), 40(1) or (2) or 46(1) or (2) as to the making of an election (which requires an election to be made either on or before the day on which the child was born or within the period of 42 or, as the case may be, 21 days from that day) is nevertheless to be treated as satisfied if the required election is made after the end of that period but with the consent of the Registrar General under subsection (2).

(2) The Registrar General may at any time consent to the making of an election after the end of the period mentioned in subsection (1) if, on an application made to him in accordance with such requirements as he may specify, he is satisfied that there is a compelling reason for giving his consent to the making of such an election.

(3) In this section "the Registrar General" means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or (as the case may be) the Registrar General for Northern Ireland.

Interpretation of references to father etc. where woman is other parent

53 Interpretation of references to father etc.

(1) Subsections (2) and (3) have effect, subject to subsections (4) and (6), for the interpretation of any enactment, deed or any other instrument or document (whenever passed or made).

(2) Any reference (however expressed) to the father of a child who has a parent by virtue of section 42 or 43 is to be read as a reference to the woman who is a parent of the child by virtue of that section.

(3) Any reference (however expressed) to evidence of paternity is, in relation to a woman who is a parent by virtue of section 42 or 43, to be read as a reference to evidence of parentage.

(4) This section does not affect the interpretation of the enactments specified in subsection (5) (which make express provision for the case where a child has a parent by virtue of section 42 or 43).

(5) Those enactments are -

(a) the Legitimacy Act (Northern Ireland) 1928 (c. 5 (N.I.)),

(b) the Schedule to the Population (Statistics) Act 1938 (c. 12),

(c) the Births and Deaths Registration Act 1953 (c. 20),

(d) the Registration of Births, Deaths and Marriages (Special Provisions) Act 1957 (c. 58),

(e) Part 2 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49),

(f) the Congenital Disabilities (Civil Liability) Act 1976 (c. 28),

(g) the Legitimacy Act 1976 (c. 31),

(h) the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)),

(i) the British Nationality Act 1981 (c. 61),

(j) the Family Law Reform Act 1987 (c. 42),

(k) Parts 1 and 2 of the Children Act 1989 (c. 41),

(l) Part 1 of the Children (Scotland) Act 1995 (c. 36),

(m) section 1 of the Criminal Law (Consolidation) (Scotland) Act 1995 (c. 39), and

(n) Parts 2, 3 and 14 of the Children (Northern Ireland) Order 1995 (S.I. 1995/755 (N.I. 2)).

(6) This section does not affect the interpretation of references that fall to be read in accordance with section 1(2)(a) or (b) of the Family Law Reform Act 1987 or Article 155(2)(a) or (b) of the Children (Northern Ireland) Order 1995 (references to a person whose father and mother were, or were not, married to each other at the time of the person's birth).

58 Interpretation of Part 2

(2) For the purposes of this Part, two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships -

(a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and

(b) include the relationship of a child with his adoptive, or former adoptive, parents, but do not include any other adoptive relationships.

Licence conditions

T58 Prior to giving consent gamete providers must be provided with information about:

a. the nature of the treatment

b. its consequences and risks

c. any analytical tests, if they are to be performed

d. the recording and protection of personal data and confidentiality

e. the right to withdraw or vary their consent, and

f. the availability of counselling.

T59 The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.

T60 A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

T61 A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.

T62 The reference in licence conditions T60 and T61 above to the intended second parent is a reference to:

a. any man with respect to whom the agreed fatherhood conditions in Section 37 of the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61, and

b. any woman with respect to whom the agreed female parenthood conditions in Section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61.

T63 In the case of treatment services using donated gametes, or embryos created using donated gametes, the person receiving treatment and any intended second parent, must be provided with information about:

a. the importance of informing any resulting child at an early age that they were born as a result of such treatment, and

b. suitable methods of informing such a child of that fact.

T64 In cases where the nominated second parent withdraws their consent to be treated as the parent of any child born to a named woman, the PR must:

a. notify the woman in writing of the receipt of the notice from the second parent, and

b. ensure that no treatment services are provided to the named woman until she has been notified of the second parent's withdrawal of consent.

T65 If a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this.

Directions

0007 – Consent

HFEA guidance

Legal parenthood and parental responsibility

6.1 The centre should provide information to people seeking treatment about legal parenthood, or should direct those people to suitable sources of information. This information should include who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation. Nationals or residents of other countries, or individuals treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the United Kingdom. In particular, if people are seeking treatment as part of a surrogacy arrangement that involves nationals or residents of other countries, the centre should:

(a) make clear to those involved that the legal and immigration implications are complex; and
(b) advise them to seek their own legal advice.

6.2 The centre should seek to ensure that people seeking treatment understand:

(a) the difference in law between legal parenthood and parental responsibility; and
(b) the implications of this for themselves and any child born as a result of treatment.

6.3 A person recognised as the legal parent of a child may not automatically have parental responsibility. Legal parenthood gives a lifelong connection between a parent and a child, and affects things like nationality, inheritance and financial responsibility. A person with parental responsibility has the authority to decide about the care of the child while the latter is young, for example for medical treatment and education.

6.4 A woman who carries and gives birth to a child as a result of treatment will be the legal mother of that child. Where the woman is married to a man and they are seeking treatment together using the husband's sperm (or embryos created using the husband's sperm), the husband will automatically be the legal father of any resulting child. However, there are cases where the woman's partner may not automatically be the legal parent of the resulting child.

If the woman is married or in a civil partnership at the time of the treatment, her spouse or civil partner will generally be the child's legal parent. If the woman is not married or in a civil partnership with her partner, and the woman is being treated using donor sperm (or embryos created using donor sperm), the consent of both the woman and her partner is needed for the partner to be recognised as the child's legal parent.

For further details about establishing legal parenthood, see below.

6.5 A child's legal mother automatically has parental responsibility. The position of the father or other legal parent depends on factors including their marital status, what is recorded on the birth certificate, and whether the family court has made an order.

6.6 In any case in which people seeking treatment have any doubts or concerns about legal parenthood or parental responsibility for a child born as a result of treatment services, or where a centre has concerns about the understanding of the people seeking treatment, the centre should advise them to seek their own legal advice.

See also

HFEA consent forms

HFEA guide to consent

Guidance note 27 – Adverse incidents

Human Fertilisation and Embryology Act 2008 explanatory notes

General procedures for obtaining consent

6.7 The centre should record whether a person receiving treatment is married or in a civil partnership in their notes, and should explain to the person why this is relevant. If a person is having treatment with their partner, the centre should record whether they are married or in a civil partnership with one another (or with someone else). This may affect who will be the second legal parent of any child born following treatment and whether consent is required to make the partner the child's legal parent.

For more information on what to do if a woman who is married or in a civil partnership returns for subsequent treatment without her husband, wife or civil partner present, see paragraphs 6.14 and 6.18.

6.8 Where consent is required for the partner to be the child's legal parent, the centre should establish and use documented procedures to obtain written, effective consent to legal parenthood. Failure to carry out the following steps could mean that the partner is not legally recognised as the child's legal parent and it may be necessary for the partner to apply for a declaration of parentage through the Courts.

6.9 Consent to the partner being the legal parent must be obtained from **both** the woman receiving treatment and her partner.

6.10 Consent to legal parenthood must be obtained from the woman receiving treatment and her partner before sperm and egg transfer, embryo transfer, or insemination takes place.

6.11 Consent should be obtained and recorded using the correct HFEA consent forms. The woman must complete the form that pertains to her, and her partner must complete the form that pertains to them.

For more information on which consent to legal parenthood forms should be used and what you should do to make sure consent is taken properly, see the HFEA guide to consent.

6.12 The consent forms must be properly and correctly completed, signed and dated. The centre should retain the original signed consent forms and ensure that a copy is provided to those who have given consent.

6.13 The centre should ensure that there is documented evidence in the medical records that information about legal parenthood and an offer of counselling must be provided to the person giving consent before consent is obtained. The centre should ensure that there is documented evidence in the medical records that this has happened.

6.14 The centre should ensure that consent to legal parenthood is:

(a) given voluntarily
(b) given by a person who has the capacity to do so, and
(c) taken by a person authorised by the centre to do so.

If the person giving consent is unable to complete the consent form because of physical illness, injury or disability they may direct someone else to complete and sign it for them. However, if the person is consenting to being registered as the legal parent of any child born as a result of treatment after their death, only they can sign that part of the form.

6.15 The centre should ensure that any person giving consent declares that:

(a) they were given enough information to understand the nature, purpose and implications of receiving treatment (or their partner receiving treatment) following consent
(b) they were given a suitable opportunity to receive proper counselling about the implications of receiving treatment (or their partner receiving treatment) following consent
(c) they were given information about the implications and procedure for varying or withdrawing consent, and
(d) the information they have given in writing is correct and complete.

6.16 When obtaining consent to register the partner posthumously as the parent, the centre should ensure that the partner consents to their details and identifying information about treatment being disclosed to either the Registrar General for England and Wales, the Registrar General for Scotland or the Registrar for Northern Ireland, as appropriate.

6.17 If the woman receiving treatment withdraws or varies her consent to her partner being the child's legal parent, the partner must be notified of this in writing. If the woman's partner withdraws or varies their consent to being the child's legal parent, the woman must be notified of this in writing.

6.18 When anyone gives, withdraws or varies consent to legal parenthood, the centre should check their identity against identifying information held in the medical records. If there is doubt about a patient's identity, the centre should take steps to verify this, including examining photo identification such as a photocard driving licence or passport. The centre should record this evidence in the medical records.

6.19 There are very serious implications for patients, their partners and resulting children if consent to legal parenthood is not obtained properly, not recorded accurately or not recorded at all. Inaccuracies or errors on consent to legal parenthood forms may cause doubt about the parental status of the patient's partner, which may only be determined by the partner applying for a declaration of parentage in the courts.

For more information on how to avoid making mistakes when obtaining consent to legal parenthood, see the HFEA guide to consent.

6.20 In cases where a centre identifies anomalies in legal parenthood consent that may have an impact on the legal parenthood of any child born as a result of treatment, the centre should:

(a) take all reasonable steps to notify the affected patient at the earliest opportunity
(b) assess the error(s) and potential impact, and consider the remedial actions that should be taken, and
(c) take all reasonable steps to support any affected patients (and their partner(s), if relevant) and offer independent legal assistance where necessary.

The centre should also seek independent legal advice and must inform the HFEA in writing of any anomalies or deficiencies in legal parenthood consent that it discovers by sending a completed adverse incident form within the incident reporting timescales set out at guidance note 27.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information

HFEA consent forms

HFEA guide to consent

Legal parenthood when the woman has a husband

Interpretation of mandatory requirements 6A

Where a woman married to a man is seeking treatment using her husband's sperm or embryos created using her husband's sperm, the husband will automatically be the legal father of any child born as a result of the treatment, and will have parental responsibility.

Where a woman married to a man is seeking treatment using sperm other than that of her husband, or an embryo created using sperm other than that of her husband, her husband will be treated as the father of any child born as a result of that treatment (and will have parental responsibility) unless:

(a) at the time the sperm and eggs or embryos were placed in her, or she was inseminated, a judicial separation or separation order was in force, or

(b) it is shown that the husband did not consent to the placing in her of the sperm and eggs or embryos, or to her insemination.

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

6.21 When a woman who is married returns for subsequent treatment without her husband present, the centre should establish whether the couple are still seeking treatment together. They should also ensure that the original consent form completed by her husband during the first treatment is still valid and effective.

For more information on what a centre should consider when a patient returns for subsequent treatment, see the HFEA guide to consent.

6.22 If a woman married to a man is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

(a) ascertain whether the husband consents to the treatment 'as a question of fact' (see box 6B), taking into account the duty of confidentiality to the woman (it may not be appropriate to contact him if he is unaware his wife is having treatment), and
(b) obtain a written record of the husband's position. If the husband consents, he should complete the relevant consent form. If he does not consent 'as a question of fact' (see box 6B), the centre should take all practical steps to obtain evidence of this.

6.23 If the centre cannot obtain a written record of the husband's consent or lack of consent, it should record the steps taken to establish whether he consents to the treatment in the medical records.

6.24 A woman who is still married may wish to be treated with a new partner (with her new partner's sperm or with donor sperm or a donor embryo). If she wishes her new partner to be registered as the legal parent of any child born from this treatment, then evidence to show that her husband does not consent to the treatment must be obtained in order for the woman's new

partner to be the legal parent of any child born as a result of the treatment. It should not be assumed that the biological father will necessarily be the second legal parent if the patient is still married or in a civil partnership with another person.

The law relating to legal parenthood can be complex, this may mean that clinics and patients need to take independent legal advice to ensure that all necessary actions are taken to enable the new partner to be the second legal parent.

Interpretation of mandatory requirements 6B

Establishing lack of consent by the husband 'as a question of fact'

To prove that the husband of a woman undergoing treatment does not consent to this treatment, their lack of consent requires a basis in fact (for example, if the patient and her husband are separated – but there is no judicial separation or separation order in force – and the latter is unaware of the treatment). The patient's husband may be considered the legal father or parent of the child if they support the treatment in any way, for instance if they help the patient to attend appointments to receive treatment. Any form declaring their lack of consent may not by itself remove their status as the legal father or parent if they do consent 'as a question of fact'. If there is a factual basis for the husband not consenting, centres should obtain evidence of this, for instance evidence that the couple are about to start divorce proceedings.

Parenthood in these circumstances can be complex and is case-specific and any dispute is ultimately for the family court or births registrar (or both) to determine. Clinics and couples may need to seek their own independent legal advice before proceeding with treatment.

See also

HFEA consent forms

HFEA guide to consent

Legal parenthood when the woman has a civil partner or wife

Interpretation of mandatory requirements 6C

Where a woman in a civil partnership or same-sex marriage is seeking treatment using donor sperm, or embryos created using donor sperm, the woman's civil partner or wife will be treated as the legal parent of any resulting child unless, at the time of placing the embryo or sperm and eggs in the woman, or of her insemination:

(a) a judicial separation or separation order was in force, or

(b) it is shown that the civil partner or wife did not consent to the placing in her of the sperm and eggs, or embryos, or to the insemination.

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

NOTE The provisions relating to same-sex marriages are not in force in Northern Ireland.

6.25 When a woman who is married or in a civil partnership returns for subsequent treatment without her wife or civil partner present, the centre should establish whether the couple are still seeking

treatment together. They should also ensure that the original consent form completed by her wife or civil partner during the first treatment is still valid and effective.

For more information on what a centre should consider when a patient returns for subsequent treatment, see the HFEA guide to consent.

6.26 If a woman in a civil partnership or same-sex marriage is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

(a) ascertain whether the civil partner or wife consents to the treatment 'as a question of fact' (see box 6D), taking into account the duty of confidentiality to the woman seeking treatment (it may not be appropriate to contact her if she is unaware her civil partner or wife is having treatment), and
(b) obtain a written record of the civil partner or wife's position. If the civil partner or wife consents, she should complete the relevant consent form. If the civil partner or wife does not consent 'as a question of fact' (see box 6D), the centre should take all practical steps to obtain evidence of this.

6.27 If the centre cannot obtain a written record of the civil partner or wife's consent or lack of consent, it should record the steps taken to establish whether the civil partner or wife consents to the treatment in the medical records.

6.28 A woman who is still married or in a civil partnership may wish to be treated with a new partner (with donor sperm or a donor embryo). If she wishes her new partner to be registered as the legal parent of any child born from this treatment, then evidence to show that her civil partner or wife does not consent to the treatment must be obtained in order for the woman's new partner to be the legal parent of any child born as a result of the treatment. It should not be assumed that the biological father or mother will necessarily be the second legal parent if the woman being treated is still married or in a civil partnership with another person.

The law relating to legal parenthood can be complex, this may mean that clinics and patients need to take independent legal advice to ensure that all necessary actions are taken to enable the new partner to be the second legal parent.

Interpretation of mandatory requirements 6D

Establishing lack of consent by wife or civil partner 'as a question of fact'

To prove that the wife, or civil partner of a woman undergoing treatment does not consent to this treatment, their lack of consent requires a basis in fact (for example, if the patient and her wife, or civil partner are separated – but there is no judicial separation or separation order in force – and the latter is unaware of the treatment). The patient's wife, or civil partner may be considered the legal parent of the child if they support the treatment in any way, for instance if they help the patient to attend appointments to receive treatment. Any form declaring their lack of consent may not by itself remove their status as the legal parent if they do consent 'as a question of fact'. If there is a factual basis for the wife, or civil partner not consenting, centres should obtain evidence of this, for instance evidence that the couple are about to start divorce proceedings.

Parenthood in these circumstances can be complex and is case-specific and any dispute is ultimately for the family court or births registrar (or both) to determine. Clinics and couples may need to seek their own independent legal advice before proceeding with treatment.

See also

HFEA consent forms

HFEA guide to consent

Legal parenthood: unmarried male partner

Interpretation of mandatory requirements 6E

The following rules apply only if the woman having treatment:

(a) is neither married nor in a civil partnership, or

(b) is married or in a civil partnership but her husband/wife/civil partner is not a legal parent because there is a judicial separation or separation order in force, or because the husband/wife/civil partner does not consent to the treatment (see 6.17 and 6.21).

Where a woman is seeking treatment using her unmarried male partner's sperm, or embryos created using her partner's sperm, her male partner will automatically be the legal father of any child born as a result of the treatment.

Where a woman is seeking treatment using donor sperm, or embryos created with donor sperm, her male partner will be the legal father of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

(a) both the woman and the male partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the male partner being treated as the legal father

(b) neither consent was withdrawn (or superseded with a subsequent written notice) before insemination/transfer, and

(c) the patient and male partner are not close relatives (within prohibited degrees of relationship to each other, as defined in section 58(2), HFE Act 2008).

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also

HFEA consent forms

HFEA guide to consent

Legal parenthood: female partner who is not a civil partner or wife

Interpretation of mandatory requirements 6F

The following rules apply only if the woman having treatment:

(a) is neither married nor in a civil partnership, or

(b) is married or in a civil partnership but her husband/wife/civil partner is not a legal parent because there is a judicial separation or separation order in force or because the husband/wife/civil partner does not consent to the treatment (see 6.17 and 6.21).

Where a woman is being treated together with a female partner (not her civil partner or wife) using donor sperm, or embryos created with donor sperm, the female partner will be the other legal parent of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

(a) both the woman and her female partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the female partner being treated as the parent of any resulting child

(b) neither consent was withdrawn (or superseded with a subsequent written note) before insemination/transfer, and

(c) the patient and female partner are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), part 2, HFE Act 2008).

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also

HFEA consent forms

HFEA guide to consent

Parenthood after death of a man providing sperm

Interpretation of mandatory requirements 6G

A husband or male partner who has provided sperm for the treatment of their wife or female partner can be registered as the father of any child born as a result of treatment after their death, if the following conditions are met:

(a) the man had given written consent for his sperm, or embryos created using his sperm, to be used after his death in the treatment of his wife or partner

(b) the man had given written consent to being registered as the father of any resulting child

(c) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the man's details to be entered in the relevant register of births, and

(d) no-one else is to be treated as the father or parent of the child.

The treatment can involve insemination of sperm, transfer of sperm and eggs, or transfer of embryos created before or after the man's death. The centre must ensure that partners are given an opportunity to consent to this.

See also

HFEA consent forms

HFEA guide to consent

Parenthood after death of a partner who has not provided sperm

Interpretation of mandatory requirements 6H

A partner (husband, wife, civil partner or other partner) who has not provided sperm for

the treatment of their wife, civil partner or female partner can be registered as the father or parent of any child born as a result of treatment after their death, if the following conditions are met:

(a) the treatment involved the transfer to the woman of an embryo after the death of the partner

(b) the embryo was created when the partner was alive,

(c) the partner had given written consent for the embryo to be placed in the woman after their death

(d) the partner had given written consent to being registered as the father or parent of any resulting child

(e) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the partner's details to be entered in the relevant register of births, and

(f) no-one else is to be treated as the father or parent of the child.

The centre must ensure that partners are given an opportunity to consent to this.

Legal parenthood: surrogacy

Interpretation of mandatory requirements 6I

Surrogate mother

The woman who gives birth to the child (in this case the surrogate) is the legal mother when the child is born. She will also have parental responsibility.

Husband, wife or civil partner of the surrogate mother

If the surrogate is married or in a civil partnership at the time of insemination/transfer, her husband, wife or civil partner will be the legal father or parent of any child born as a result of her treatment (and will have parental responsibility), unless:

(a) there is a judicial separation or a separation order in force, or

(b) it is shown that her husband, wife or civil partner did not consent to the placing of the sperm and eggs, or embryos, in her, or to her insemination.

Establishing lack of consent 'as a question of fact'

For these purposes, lack of consent requires a basis in fact (for example, if the surrogate and her husband, wife or civil partner are separated and the latter is unaware of the treatment). The surrogate's husband, wife or civil partner will be the legal father or parent of the child if they support the surrogacy arrangement. Any consent form declaring their lack of consent may not by itself remove their status as the legal father or parent if they do consent, 'as a question of fact'. If there is a factual basis for the husband, wife or civil partner not consenting, centres should obtain evidence of this.

Parenthood in these circumstances can be complex and case-specific, and any dispute is ultimately for the family court or births registrar (or both) to determine.

Intended parents

The intended parents are those who intend to raise the child following a surrogacy arrangement.

If both the surrogate and her husband/wife/civil partner are the legal parents of the child, neither intended parent will be a legal parent when the child is born (and neither will have parental responsibility).

If the surrogate is neither married nor in a civil partnership, if she and her husband/wife/civil partner are judicially separated, or if her husband/wife/civil partner does not consent to her treatment), then one of the intended parents will be the legal parent when the child is born, and will acquire parental responsibility when registered on the birth certificate. The options for which intended parent is the legal parent at birth are as follows:

(a) if the intended father provides his sperm for the surrogacy arrangement, he will be the legal father at common law when the child is born, if no one else is nominated.

(b) an intended father who is not the biological father (ie, an intended father using donor sperm or, in a male same-sex couple, the partner of the biological father) will be the legal father when the child is born if, at the time the eggs and sperm, or embryos, are placed in the surrogate or she is inseminated, all the following conditions apply:

  (i) both the surrogate and the intended father nominated as a parent have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to him being the legal father

  (ii) neither consent has been withdrawn (or superseded by a subsequent written consent) before the insemination/transfer, and

  (iii) the surrogate and intended father nominated are not close relatives (within prohibited degrees of relationship to each other, as defined in section 58(2), HFE Act 2008).

(c) the intended female parent (or one of them if the intended parents are a female same-sex couple) will be the other legal parent when the child is born if, at the time the eggs and sperm, or embryos, are placed in the surrogate or she is inseminated, all the following conditions apply:

  (i) both the surrogate and the intended female parent have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to her being the other legal parent of any resulting child

  (ii) neither consent has been withdrawn (or superseded by a subsequent written consent) before the insemination/transfer, and

  (iii) the surrogate and intended female parent are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), HFE Act 2008).

Parental orders

The intended parents are expected to apply to the family court for a parental order after the child is born. A parental order will make both intended parents the legal parents (with parental responsibility) and permanently extinguish the surrogate's legal motherhood. It will also trigger the re-issue of the child's birth certificate, showing the intended parents as the legal parents.

To be able to apply for a parental order, one or both of the intended parents must be a gamete provider, and they must be a couple (married, civil partners or living together as partners). Other conditions also apply, and centres should advise those involved in a surrogacy arrangement to seek

their own legal advice to ensure they will be able to secure their family's legal status after the child is born.

For more information on what legal parenthood consent forms must be used in surrogacy arrangements and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also

HFEA consent forms

HFEA guide to consent

6.29 The decision tree on the following page provides a guide to some aspects of legal parenthood and surrogacy. It summarises some of the relevant legal positions but is not intended to replace advice on the individual facts of a specific surrogacy arrangement. Centre should advise people involved in surrogacy arrangements to seek their own legal advice.

Decision tree: Legal parenthood in surrogacy arrangements

Scenario 1
Is the surrogate married or in a civil partnership?

Yes → The **husband, wife** or **civil partner** will be the legal father or parent of any child born as a result of her treatment, unless:
(a) the surrogate and her husband, wife or civil partner were judicially separated at the time of the treatment, or
(b) it is shown, 'as a question of fact' (see box 6H), that her husband, wife or civil partner did not consent to her treatment.

No

Scenario 2
Has both the intended father provided sperm and the intended female parent provided eggs for the surrogacy treatment?

Yes → The **intended father** can be the legal father at common law when the child is born (if no one else has been nominated).
or
The **intended female parent** can be the legal parent when the child is born if:
(a) both she and the surrogate have given the relevant consent
(b) neither consent has been withdrawn (or superseded), and
(c) they are not within prohibited degrees of relationship to each other.

No

Scenario 3
Has donor sperm and the intended female parent's eggs been used for the surrogacy treatment?

Yes → The **intended father** can be the legal father when the child is born if:
(a) both he and the surrogate have given the relevant consent
(b) neither consent has been withdrawn (or superseded), and
(c) they are not within prohibited degrees of relationship to each other.
or
The **intended female parent** can be the legal parent when the child is born if:
(a) both she and the surrogate have given the relevant consent
(b) neither consent has been withdrawn (or superseded), and
(c) they are not within prohibited degrees of relationship to each other.

No

Scenario 4
Have donor eggs (or the surrogate's eggs) and the intended father's sperm been used for the surrogacy treatment?

Yes → The **intended father** can be the legal father at common law when the child is born (if no one else has been nominated).
or
The **intended female parent** can be the legal parent when the child is born if:
(a) both she and the surrogate have given the relevant consent
(b) neither consent has been withdrawn (or superseded), and
(c) they are not within prohibited degrees of relationship to each other.

No

Scenario 5
Is a male same-sex couple (of whom one has provided sperm) commissioning the surrogacy treatment?

Yes → The **biological intended father** can be the legal father at common law when the child is born (if no one else has been nominated).
or
The **non-biological intended father can** be the legal father when the child is born if:
(a) both he and the surrogate have given the relevant consent
(b) neither consent has been withdrawn (or superseded), and
(c) they are not within prohibited degrees of relationship to each other.

No

Scenario 6
Is a female same-sex couple (of whom one has provided eggs) commissioning the surrogacy treatment?

Yes → Either the **biological** or **non-biological intended female parent** can be the legal parent when the child is born if:
(a) both the intended female parent and the surrogate have given the relevant consents
(b) neither consent has been withdrawn (or superseded), and
(c) they are not prohibited degrees of relationship to each other.

See also

Guidance note 14 – Surrogacy

Legal parenthood: trans patients

6.30 The Gender Recognition Act 2004 sets out the circumstances in which a gender recognition certificate (GRC) will be issued and provides trans people with a formal mechanism by which they can be legally recognised in their acquired gender.

The centre should be aware that obtaining a GRC does not affect the status of the person as the mother, father or second legal parent of an existing child. What is relevant in determining legal parenthood is the gender identity of the trans patient at the time of treatment which results in the birth of a child. For example, where a woman has had a child and subsequently transitions to become a trans man, and obtains a GRC, he remains the mother of his existing child. Where for example a trans woman uses her sperm in her female partner's treatment, provided she and her partner have met relevant statutory requirements and provided the necessary consents, she will be the second legal parent of the child.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information

HFEA consent forms

HFEA guide to consent

People not to be treated as parents

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 2008

Part 2

41 Persons not to be treated as father

(1) Where the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to the 1990 Act (consent to use of gametes for purposes of treatment services or non-medical fertility services) was used for a purpose for which such consent was required, he is not to be treated as the father of the child.

(2) Where the sperm of a man, or an embryo the creation of which was brought about with his sperm, was used after his death, he is not, subject to section 39, to be treated as the father of the child.

(3) Subsection (2) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

47 Woman not to be other parent merely because of egg donation

A woman is not to be treated as the parent of a child whom she is not carrying and has not carried, except where she is so treated -

(a) by virtue of section 42 or 43, or

(b) by virtue of section 46 (for the purpose mentioned in subsection (4) of that section), or

(c) by virtue of adoption.

34 Application of sections 35 to 47

(1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as "W") as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.

54 Parental orders

(1) On an application made by two people ("the applicants"), the court may make an order providing for a child to be treated in law as the child of the applicants if -

(a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,

(b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and

(c) the conditions in subsections (2) to (8) are satisfied.

(1A) For the purposes of this section, neither of the following is to be treated as a person whose gametes were used to create an embryo ("embryo E") -

(a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;

(b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

Interpretation of mandatory requirements 6J

A sperm donor is not to be treated as the father of any child resulting from the use of his sperm in the treatment of others.

An egg donor is not to be treated as the parent of any child resulting from the use of her egg(s) unless her egg(s), or embryos created from her egg(s), are used in treating a civil partner or other female partner (subject to the requirements in sections 42, 43 or 46 of the HFE Act 2008, where relevant) or the resulting child is adopted by the egg donor.

Section 54 of the HFE Act 2008 is amended by the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 to provide that, where a child has been born following treatment involving mitochondrial donation, a person who donated the mitochondria is not eligible to apply for a parental order on the basis of that donation alone.

Information provision and counselling

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13

Conditions of licences for treatment

(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

(6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

(6B) The reference in subsection (6A) to the intended second parent is a reference to -

(a) any man as respects whom the agreed fatherhood conditions in section 37 of the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") are for the time being satisfied in relation to treatment provided to the woman being treated, and

(b) any woman as respects whom the agreed female parenthood conditions in section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman to be treated.

(6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about -

(a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and

(b) suitable methods of informing such a child of that fact.

Schedule 3ZA: Circumstances in which offer of counselling required as condition of licence for treatment

Part 2: Events in connection with which counselling must be offered

4. A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.

5. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

6. A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.

7. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

Interpretation of mandatory requirements 6K

The law states that, where a woman who has consented to her male or female partner being treated as the legal parent of any child born as a result of her treatment, and the partner has consented to being the legal parent, treatment may continue after the point at which consent is given only if the woman and her partner:

(a) have had a suitable opportunity to receive proper counselling about the implications of treatment in these circumstances, and

(b) have been given proper information.

When people seek treatment using donor gametes or embryos, they must be given information about:

(a) the importance of informing any resulting child, at an early age, that they were conceived using the gametes of a person who is not their parent, and

(b) suitable methods of telling the child this.

See also

Guidance note 3 – Counselling

Guidance note 4 – Information to be provided prior to consent

Notification of withdrawal of consent to parenthood

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13

Conditions of licences for treatment

(6D) Where the person responsible receives from a person ("X") notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of X's withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman ("W"), the person responsible -

(a) must notify W in writing of the receipt of the notice from X, and

(b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.

(6E) Where the person responsible receives from a woman ("W") who has previously given notice under section 37(1)(b) or 44(1)(b) of the 2008 Act that she consents to another

person ("X") being treated as a parent of any child resulting from the provision of treatment services to W -

(a) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of the withdrawal of W's consent, or

(b) a notice under section 37(1)(b) or 44(1)(b) of the 2008 Act in respect of a person other than X, the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b).

Interpretation of mandatory requirements 6L

If a person withdraws their consent to being treated as the legal parent of any child resulting from the treatment of their partner, the person responsible (PR) must notify the partner in writing of this. The partner must not be treated with sperm and eggs, or with embryos, or be inseminated, until she has been notified in this way.

If a woman withdraws her consent to her partner being treated as the legal parent of any child resulting from the woman's treatment, or notifies the centre that she wishes a different person to be treated as the legal parent of any child resulting from her treatment, the PR must notify the partner in writing of this.

Consent can be withdrawn only before sperm and egg or embryo transfer, or insemination.

6.31 The PR should ensure that the written notification they issue explains and refers to the relevant parts of the legislation regarding legal parenthood and withdrawal of consent.

See also

HFEA consent forms

HFEA guide to consent

Other legislation, professional guidelines and information

Legislation

Equality Act 2010

Gender Recognition Act 2004

Chief Executive's letter

Chief Executive's letter CE(14)01: Ensuring consent to legal parenthood is properly taken

Chief Executive's letter CE(14)02: Follow-up on legal parenthood audit

7. Multiple births

Version 1.0

Mandatory requirements

Directions

0003 – Multiple births

HFEA guidance

Strategy to minimise multiple births

Interpretation of mandatory requirements 7A

General Directions require centres to have a documented strategy to minimise multiple births. Its purpose is to reduce the annual rate of multiple births resulting from treatments at the centre.

The strategy must set out:

(a) how the centre aims to reduce the annual multiple birth rate following treatment at that centre, and to ensure the rate does not exceed the maximum rate specified by the Authority as set out in Directions,

(b) the circumstances in which the person responsible would consider it appropriate to recommend single embryo transfer (SET) to a patient (in setting out such circumstances, the centre should give proper consideration to relevant professional guidance), and

(c) the criteria for transferring eggs during gamete intrafallopian transfer (GIFT).

The centre must document regular audits that:

(a) assess progress in reducing its multiple birth rate, and

(b) help evaluate the effectiveness of its strategy.

If more than one embryo is transferred to a patient who fulfilled the SET criteria outlined in the centre's strategy, this should be recorded in the patient's medical records, with:

(a) an explanation of why the patient did not have SET, and

(b) evidence that the risks of a multiple pregnancy were fully discussed with the patient before the procedure.

The centre must keep a summary log of all cases where more than one embryo was transferred to a patient who met the SET criteria outlined in the centre's strategy.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation, and disclosure of information

Limits on egg and embryo transfer

Interpretation of mandatory requirements 7B

General Directions require centres to:

(a) detail in patients' medical records each time during a treatment cycle that four eggs or three embryos are placed in a woman, including the reasons, and

(b) keep a summary log of every treatment cycle that involves the placing in a woman of four eggs or three embryos.

7.1 The person responsible should ensure that the centre's annual multiple birth rate does not exceed the figure specified by Directions.

7.2 When implementing the centre's strategy to minimise multiple births, the person responsible should consider:

(a) the higher rate of multiple births from blastocyst transfers, and
(b) the finding that the live-birth rate does not increase with the transfer of three embryos but the risk of an adverse perinatal outcome does increase.

7.3 Where appropriate, the centre should have documented standard operating procedures for egg and embryo transfer.

7.4 The centre should not transfer more than three eggs or two embryos in any treatment cycle if:

(a) the woman is to receive treatment using her own eggs, or embryos created using her own eggs (fresh or cryopreserved), and
(b) the woman is aged under 40 at the time of transfer.

7.5 The centre should not transfer more than four eggs or three embryos in any treatment cycle if:

(a) the woman is to receive treatment using her own eggs, or embryos created using her own eggs (fresh or cryopreserved), and
(b) the woman is aged 40 or over at the time of transfer

7.6 If a woman is to receive treatment using donated eggs or embryos, or embryos created with donated eggs, the centre should not transfer more than three eggs or two embryos in a treatment cycle. This is regardless of the procedure used and the woman's age at the time of transfer.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation, and disclosure of information

Consent and provision of information

7.7 If the treatment involves the use of superovulatory drugs or the transfer of multiple eggs or embryos in any one cycle (whether fresh or previously cryopreserved), the centre should give people seeking treatment information about the risks of multiple pregnancy for the woman, the fetus and any resulting child(ren), including the:

(a) the higher risk of miscarriage and complications during pregnancy
(b) the higher rate of premature birth and the problems arising from low birth weight, the higher rate of still birth, and the higher rate of perinatal mortality
(c) the higher rate of disability and other health problems, plus the potential need for extended stays in hospital before and after birth, and
(d) the possible practical, financial and emotional impact on the family and any children.

7.8 The centre should give the woman the opportunity to discuss the number of eggs or embryos to be transferred before egg collection and just before embryo transfer.

7.9 If a woman is to undergo an egg or embryo transfer, the centre should:

(a) obtain her consent to the proposed number of eggs or embryos to be transferred and the reasons for this (including her acceptance of the risk of multiple births), and
(b) record her consent in her medical records.

Other legislation, professional guidelines and information

Professional guidelines

British Fertility Society and Association of Clinical Embryologists: Elective single embryo transfer – an update to UK best practice guidelines (2015)

Lawlor DA and Nelson SM. 'Effect of age on decisions about the numbers of embryos to transfer in assisted conception: a prospective study'. The Lancet (2012) 379:521-527

One at a Time: Better outcomes for fertility treatment

8. Welfare of the child

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

13 (5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.

2 (1) … "treatment services" means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

Licence conditions

T56 A woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.

HFEA guidance

Scope of the welfare of the child provision

Interpretation of mandatory requirements 8A

No treatment services regulated by the HFEA (including intrauterine insemination – IUI) may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth.

8.1 This guidance note applies to all fertility treatments regulated by the HFEA, including IUI. Centres providing treatments that are not regulated by the HFEA but that fall within the definition of 'treatment services' (see above) may also find this guidance note helpful.

The welfare of the child assessment process

8.2 The centre should have documented procedures to ensure that proper account is taken of the welfare of any child who may be born as a result of treatment services, and any other child who may be affected by the birth.

8.3 The centre should assess each patient and their partner (if they have one) before providing any treatment, and should use this assessment to decide whether there is a risk of significant harm or neglect to any child referred to in 8.2.

The welfare of the child assessment process for surrogacy arrangements

8.4 If the child is not to be raised by the carrying mother (ie, in a surrogacy arrangement), the centre should assess both those commissioning the surrogacy arrangement and the surrogate (and the surrogate's partner, if she has one, to ensure the welfare of the child in the event of a breakdown in the surrogacy arrangement leading to the surrogate keeping the child). A Welfare of the Child form should be completed by the surrogate in conversation with the treating clinician at the centre.

8.5 The centre should satisfy itself that the information given on the Welfare of the Child form is complete and correct so that any decisions relating to the treatment provided to the surrogate are fully informed and take account of all relevant considerations. The centre should obtain any relevant medical records from the surrogate's GP and any other relevant organisations and use that information to verify the information provided in the Welfare of the Child form. Any omission, discrepancy or other concern which raises questions about the woman's suitability for surrogacy or which might impact on decisions relating to her treatment should be investigated by the centre and discussed with the surrogate.

8.6 The centre should use evidence it has gathered from the GP, surrogate and any other relevant sources to satisfy itself that the woman is suitable to act as a surrogate, taking into account all relevant factors (including, but not limited to, the surrogate's age, medical history, previous obstetric history, mental health, Body Mass Index etc.) Further information should be sought where required so that the treating clinician can make decisions having been fully informed of all relevant considerations.

8.7 Centres should have a Standard Operating Procedure in place for managing treatments involving surrogacy. Whilst acknowledging that the decision to proceed with treatment involving a surrogate should be made on a case by case basis, the SOP must detail its processes and policies in relation to (but not limited to) the following aspects of a surrogacy arrangement:

(a) Legal parenthood in surrogacy
(b) Surrogacy agreements
(c) Counselling requirements
(d) Confidentiality and arrangements for sharing information, in particular, between the intended parents and the surrogate
(e) Assessment of the surrogate and procedure for when a surrogate is deemed unsuitable for treatment
(f) Ensuring provisions are made for the surrogate to be seen alone by a healthcare professional
(g) The handover of care of the surrogate, once a viable pregnancy has been confirmed

8.8 The SOP must include a written decision-making protocol setting out the range of factors that may be taken into account when assessing the surrogate's suitability. The protocol should require the treating clinician to document the evidence that he or she relied on when reaching a decision as to the surrogate's suitability or unsuitability and should detail how the decision should be communicated to the surrogate and the commissioning couple. The decision-making protocol should be used in every case of a proposed surrogacy arrangement and a record made of the decision-making process and outcome for each individual intended surrogacy arrangement.

See also

Guidance note 14 – Surrogacy

HFEA Welfare of the child patient history form

8.9 Assessments do not need to be done on gamete or embryo donors (including mitochondrial donors), or in cases where gametes are being stored for later use.

8.10 The centre should repeat the assessment if:

(a) the centre has been out of contact with the patient for two years or more
(b) the patient has a new partner
(c) a child has been born to the patient since the previous assessment, or
(d) the centre has reason to believe that the patient's medical or social circumstances have changed significantly.

8.11 Those seeking treatment are entitled to a fair assessment. The centre is expected to consider the wishes of all those involved, and the assessment must be done in a non-discriminatory way. In particular, patients should not be discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age.

See also

Guidance note 29 – Treating people fairly

8.12 If patients have referred themselves for treatment, the centre should take all reasonable steps to verify the identity of those seeking treatment with appropriate evidence (eg, passport or photocard driving licence).

8.13 The centre should take a medical and social history from each patient and their partner (if they have one). Where appropriate, the patient and their partner may be interviewed separately. The information gathered should relate to the factors in paragraphs 8.10–8.12 below.

Factors to consider during the assessment process

8.14 The centre should consider factors that are likely to cause a risk of significant harm or neglect to any child who may be born or to any existing child of the family. These factors include any aspects of the patient's or (if they have one) their partner's:

(a) past or current circumstances that may lead to any child mentioned above experiencing serious physical or psychological harm or neglect, for example:

(i) previous convictions relating to harming children
(ii) child protection measures taken regarding existing children, or
(iii) violence or serious discord in the family environment

(b) past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born, or that are already seriously impairing the care

of any existing child of the family, for example:

(i) mental or physical conditions
(ii) drug or alcohol abuse
(iii) medical history, where the medical history indicates that any child who may be born is likely to suffer from a serious medical condition, or
(iv) circumstances that the centre considers likely to cause serious harm to any child mentioned above.

8.15 When considering a child's need for supportive parenting, centres should consider the following definition:

'Supportive parenting is a commitment to the health, wellbeing and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.'

8.16 If the child will not be raised by the carrying mother, the centre should take into account the possibility of a breakdown in the surrogacy arrangement and whether this is likely to cause a risk of significant harm or neglect to any child who may be born or any existing children in the surrogate's family.

Obtaining further information during the assessment process

8.17 The centre should obtain consent from the prospective patient (and their partner if they have one) to approach any individuals, agencies or authorities for any factual information required for further investigation if:

(a) information provided by the patient (and their partner if they have one) suggests a risk of significant harm or neglect to any child
(b) the patient (and their partner if they have one) has failed to provide any of the information requested
(c) the information the patient (and their partner if they have one) has provided is inconsistent, or
(d) there is evidence of deception.

A refusal to provide consent to disclosure of information should not, in itself, be grounds for denying treatment but the centre should take this into account in deciding whether to provide treatment. The centre should discuss with the patient (and their partner if they have one) the reason for refusing to provide consent.

8.18 If information has been provided in confidence to a member of staff, the staff member should seek consent from the information provider to discuss it with other staff. If such consent is refused and the member of staff considers the matter to be crucial to a decision, they should use their discretion, based on good professional practice, in deciding whether to break that confidence. In line with professional guidance, patients should normally be informed of the decision to break confidence and the reasons for it, before the information is shared with other members of staff.

Refusing treatment

8.19 The centre should refuse treatment if it:

(a) concludes that any child who may be born or any existing child of the family is likely to be at risk of significant harm or neglect, or
(b) cannot obtain enough information to conclude that there is no significant risk.

8.20 In deciding whether to refuse treatment, the centre should:

(a) take into account the views of all staff who have been involved with caring for the patient (and their partner if they have one), and
(b) give the patient (and their partner if they have one) the opportunity to respond to the reason or reasons for refusal before the centre makes a final decision.

8.21 If treatment is refused, the centre should explain, in writing, to the patient (and their partner if they have one):

(a) why treatment has been refused
(b) any circumstances that may enable the centre to reconsider its decision
(c) any remaining options, and
(d) opportunities for obtaining appropriate counselling.

Record keeping

8.22 In all cases, the centre should record in the patient's medical records the information it has considered during the assessment. If further information has been sought or discussion has taken place, the record should reflect the views of those consulted in reaching the decision and the views of the patient (and their partner if they have one).

9. Preimplantation genetic screening (PGS)

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2

Licences for treatment

1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services–

...

(b) procuring, keeping, testing, processing or distributing embryos

…

Embryo testing

1ZA (1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes–

(a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

Licence conditions

T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:

a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and

b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

T89 With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.

HFEA guidance

Staff to be involved in PGS

9.1 The centre should ensure that a multidisciplinary team is involved in providing the embryo testing service. The team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticists and molecular geneticists.

9.2 Treatment should include patient support following embryo testing.

The use of PGS

Interpretation of mandatory requirements 9A

An embryo may be tested to establish whether it has a particular chromosomal abnormality only if:

(a) that abnormality may affect its capacity to result in a live birth, or

(b) there is a particular risk that it has that abnormality, and where the Authority is satisfied that there is a significant risk that a person with that abnormality will have or develop a serious medical condition.

An embryo may be tested for PGS and PGD where the requirements for each have been satisfied before testing is carried out. Fulfilling the requirements for PGS does not act as a gateway to carrying out PGD, and vice versa.

9.3 The centre should ensure that before people seeking treatment give consent to PGS for aneuploidy, they are given information explaining:

(a) the procedure and risks associated with the procedure
(b) that more robust clinical and laboratory trials are needed to assess whether or not PGS significantly increases live birth rates
(c) the failure and misdiagnosis rates associated with PGS for aneuploidy, including the fact that false results can be positive or negative
(d) the concept of mosaicism, and the effect that this could have on the accuracy of results
(e) that PGS techniques are capable of detecting segmental aneuploidies which may generate results where the clinical significance is not known
(f) that there is no guarantee against a miscarriage occurring, despite PGS for aneuploidy being performed, and
(g) the financial and emotional costs where treatment fails and there is no live birth following PGS for aneuploidy.

9.4 Before providing PGS, the centre should ensure that those seeking treatment have had sufficient opportunity to fully consider the possible outcomes and their implications.

9.5 Embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.

9.6 Where patients seek PGS, but do not wish to be given any additional genetic information that may be found via sophisticated genetic testing methodologies (eg, segmental aneuploidies), the centre should follow, where possible, guidelines around PGD for non-disclosure (paragraphs 10.10-10.12).

See also

Guidance note 10 – Embryo testing and sex selection

PGS and genetic consultation

9.7 Where PGS is carried out using technologies that give rise to additional genetic information, the centre should ensure that people seeking treatment are offered access to genetic counselling and, where appropriate, infertility counselling before and after treatment has occurred.

9.8 Where people seeking treatment have been referred, the centre should work closely with the clinical genetics team.

Prohibitions on embryo selection

Interpretation of mandatory requirements 9B

The law requires that the centre should not select embryos of a particular sex for social reasons.

NOTE Guidance note 10 (Embryo testing and sex selection) contains all general guidance and mandatory requirements relevant to embryo testing. Centres offering PGS should familiarise themselves with guidance note 10.

Other legislation, professional guidelines and information

Professional guidance

Association for Clinical Genetic Science: Practice guidelines for targeted next generation sequencing analysis and interpretation (2014)

British Fertility Society: Policy and practice guidelines on PGS (2009)

British Fertility Society and the Association of Clinical Embryologists: How should we choose the 'best' embryo? A commentary on behalf of the British Fertility Society and the Association of Clinical Embryologists (2015)

Royal College of Physicians, the Royal College of Pathologists and the British Society for Human Genetics: Consent and confidentiality in clinical generic practice – guidance on genetic testing and sharing genetic information (a report of the Joint Committee on Medical Genetics) (second edition, 2011)

10. Embryo testing and sex selection

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2 – Activities that may be licensed under the 1990 Act

Licences for treatment

Embryo testing

1ZA (1) A licence … cannot authorise the testing of an embryo, except for one or more of the following purposes–

(a) establishing whether the embryo has a gene, chromosome or mitochondrial abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

(c) in a case where there is a particular risk that any resulting child will have or develop–

(i) a gender-related serious physical or mental disability,

(ii) a gender-related serious illness, or

(iii) any other gender-related serious medical condition, establishing the sex of the embryo,

...

(e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

(2) A licence… cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied–

(a) in relation to the abnormality of which there is a particular risk, and

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b), that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

(3) For the purposes of sub-paragraph (1)(c), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that–

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Licence conditions

T86 Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability

b. a serious illness, or

c. any other serious medical condition, must not be preferred to those that are not known to have such an abnormality.

T87 Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:

a. a gender-related serious physical or mental disability

b. a gender-related serious illness, or

c. any other gender-related serious medical condition, must not be preferred to those that are not known to carry such a risk.

T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:

a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and

b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

T89 With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.

T91 Centres may use non-invasive procedures, for example metabolomics, to test and select for the viability of embryos. However, centres must not use these procedures to test for specific gene, chromosome or mitochondrion abnormality without prior authorisation from the Authority.

Directions

0008 – Information to be submitted to the HFEA as part of the licensing process

0012 – Retention of records

HFEA guidance

Staff to be involved in embryo testing

10.1 A senior clinical geneticist should be involved in deciding whether a particular patient should receive treatment involving embryo testing.

10.2 The centre should ensure that a multidisciplinary team is involved in providing the embryo testing service. The team should include reproductive specialists, embryologists, clinical

geneticists, genetic counsellors, cytogeneticists and molecular geneticists. It should maintain close contact with the primary care physician or the referring clinician.

10.3 Treatment should include patient support following embryo testing.

Embryo transfer using biopsied embryos

10.4 Embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.

Preimplantation genetic diagnosis for heritable conditions

Interpretation of mandatory requirements 10A

Preimplantation genetic diagnosis (PGD) can be carried out for a heritable condition only in two circumstances:

- where there is a particular risk that the embryo to be tested may have a genetic, mitochondrial or chromosomal abnormality, and the Authority is satisfied that a person with the abnormality will have or develop a serious disability, illness or medical condition, or
- where there is a particular risk that any resulting child will have or develop a gender related serious disability, illness or medical condition. A condition is gender related if the Authority is satisfied that it affects only one sex, or affects one sex significantly more than the other. In the first situation, PGD may be carried out to establish whether the embryo has the suspected abnormality; in the second, PGD may be carried out to establish the sex of the embryo.

An embryo may be tested for PGS and PGD where the requirements for each have been satisfied before testing is carried out. Fulfilling the requirements for PGS does not act as a gateway to carrying out PGD, and vice versa.

10.5 When deciding if it is appropriate to provide PGD in particular cases, the centre should consider the circumstances of those seeking treatment rather than the particular heritable condition.

10.6 The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. When deciding if it is appropriate to provide PGD in particular cases, the seriousness of the condition in that case should be discussed between the people seeking treatment and the clinical team. The perception of the level of risk for those seeking treatment will also be an important factor for the centre to consider.

10.7 In instances where a patient is undergoing PGD for a heritable condition, a centre may offer PGD for additional condition(s) that do not meet the particular risk requirements but have been deemed, by the Authority, to be of significant risk (as set out in box 10A). Patients should give consent for this which should be recorded in the patient notes.

10.8 In instances where a patient is undergoing PGD for a heritable condition, a centre may offer preimplantation genetic screening (PGS) at the same time in accordance with guidance note 9. Patients should give consent for this which should be recorded in the patient notes.

10.9 The centre should consider the following factors when deciding if PGD is appropriate in particular cases:

(a) the views of the people seeking treatment in relation to the condition to be avoided, including their previous reproductive experience
(b) the likely degree of suffering associated with the condition
(c) the availability of effective therapy, now and in the future
(d) the speed of degeneration in progressive disorders
(e) the extent of any intellectual impairment
(f) the social support available, and
(g) the family circumstances of the people seeking treatment.

10.10 Concerns have been raised about the ethical implications of directly testing embryos for a genetic condition without disclosing the test results to the patients (PGD with non-disclosure).

Where patients seek PGD, but do not wish to discover their own genetic status, centres should, where possible, only offer PGD with exclusion testing.

Where patients seek PGD, but do not wish to be given any additional genetic information that may be found via sophisticated genetic testing methodologies (eg, segmental aneuploidies), the centre should offer, where possible, PGD with exclusion testing and record this in the patient notes.

10.11 In exceptional circumstances the centre may offer PGD, but withhold the patient's test results (PGD with non-disclosure). However, this should only be offered under the following conditions:

(a) that patients are given the opportunity to receive genetic counselling on the implications prior to giving consent,
(b) that protocols are established to limit, as far as possible, the risk of unwanted disclosure to the patients. Centres should consider using a different embryology laboratory from their own, in order to minimise the number of centre staff who know the patient's genetic status, and
(c) that no dummy embryo transfers are to be performed.

10.12 The centre should document its reasons for offering PGD with non-disclosure to a patient. This record should include:

(a) written informed consent from the patient to perform PGD with non-disclosure,
(b) a statement from the people seeking treatment confirming that they have been given the opportunity to receive genetic counselling and that they have, prior to giving consent, received information:

(i) on the risks of inadvertent disclosure,
(ii) that where all embryos are suitable for transfer this is not evidence of the patient's genetic status,
(iii) that where no embryos are suitable for transfer this is not evidence of the patient's genetic status,
(iv) that therefore dummy embryo transfers are not necessary or permissible, and
(v) that treatment may go ahead which is not medically necessary in cases where the patient (or partner) does not have the genetic condition. This includes information about the potential costs and risks of any medically unnecessary treatments.

Preimplantation genetic diagnosis to establish the identity of gamete providers

Interpretation of mandatory requirements 10B

An embryo may be tested to establish whether it was brought about using the gametes of particular people, where this is uncertain.

Genetic consultation and counselling

10.13 The centre should ensure that people seeking treatment have access to clinical geneticists, genetic counsellors and, where appropriate, infertility counsellors before and after treatment.

10.14 The centre should work closely with the local genetics team of those seeking treatment.

Information for those seeking preimplantation genetic diagnosis

10.15 The centre should ensure that people seeking PGD are given the appropriate information about the treatment. This should include:

(a) the process, procedures and possible risks involved in IVF and biopsy procedures when providing a sophisticated genetic test.
(b) the experience of the centre in carrying out the procedure.
(c) that sophisticated genetic tests can reveal additional genetic information about an embryo(s) and that the clinical effect of these findings on a child born may not be known.

10.16 The centre should also provide information to those seeking treatment to help them make decisions about their treatment, including:

(a) genetic and clinical information about the condition being tested for
(b) the likely impact of the condition on those affected and their families
(c) information about treatment and social support available, and
(d) information from a relevant patient support group or the testimony of people living with the condition, if those seeking treatment have no direct experience of it themselves.

10.17 If the person seeking treatment has already been given information about the particular genetic disorder, for example from a regional genetics centre, the centre need not provide this information again. However, the centre should ensure that the information has been provided to a satisfactory standard of breadth and clarity.

10.18 Before providing PGD, the centre should ensure that those seeking treatment have had sufficient opportunity to fully consider the possible outcomes of genetic testing and their implications.

Prohibitions in connection with embryo selection

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13

(8) Subsections (9) and (10) apply in determining any of the following –

(a) the persons who are to provide gametes for use in pursuance of the licence in a case where consent is required under paragraph 5 of Schedule 3 for the use in question;

(b) the woman from whom an embryo is to be taken for use in pursuance of the licence, in a case where her consent is required under paragraph 7 of Schedule 3 for the use of the embryo;

(c) which of two or more embryos to place in a woman.

(9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop–

(a) a serious physical or mental disability,

(b) a serious illness, or

(c) any other serious medical condition, must not be preferred to those that are not known to have such an abnormality.

(10) Embryos that are known to be of a particular sex and to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop–

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

(11) For the purposes of subsection (10), a physical or mental disability, illness or other medical condition is gender-related if–

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Schedule 2 – Activities that may be licensed under the 1990 Act

Sex selection

1ZB (1) A licence under paragraph 1 cannot authorise any practice designed to secure that any resulting child will be of one sex rather than the other.

(2) Sub-paragraph (1) does not prevent the authorisation of any testing of embryos that is capable of being authorised under paragraph 1ZA.

(3) Sub-paragraph (1) does not prevent the authorisation of any other practices designed to secure that any resulting child will be of one sex rather than the other in a case where there is a particular risk that a woman will give birth to a child who will have or develop–

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition.

(4) For the purposes of sub-paragraph (3), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that–

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Licence conditions

T86 Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability

b. a serious illness, or

c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

T87 Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:

a. a gender-related serious physical or mental disability

b. a gender-related serious illness, or

c. any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:

…

b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

Interpretation of mandatory requirements 10C

The law prohibits the selection of an embryo for treatment if it is known to:

(a) have a gene, chromosome or mitochondrial abnormality involving a significant risk that the person with the abnormality will develop a serious physical or mental disability, a serious illness, or a serious medical condition, or

(b) be of a sex that carries a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness, or serious medical condition.

This applies only where there is at least one other embryo suitable for transfer that is not known to have the characteristics. Where there is no other embryo suitable for transfer, an embryo with these characteristics may be transferred.

10.19 The use of an embryo known to have an abnormality as described above should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

10.20 If a centre decides that it is appropriate to provide treatment services to a woman using an embryo known to have an abnormality as described above, it should document the reason for the use of that embryo.

NOTE An example of an embryo not suitable for transfer in this context is one that has no realistic prospect of resulting in a live birth.

See also

Guidance note 8 – Welfare of the child

Sex selection for social reasons

Interpretation of mandatory requirements 10D

The law requires that the centre should not, for social reasons:

(a) select embryos of a particular sex

(b) separate sperm samples, or use sperm samples that have been separated, for the purpose of sex selection, or

(c) participate in any other practices designed to ensure that a resulting child will be of a particular sex.

Sex selection: sperm sorting for medical reasons

10.21 If sperm is sorted for medical reasons to create (or maximise the chance of creating) embryos of a particular sex for medical reasons, patients should be given information about the process, procedures, possible risks and the experience of the clinic in doing the procedure.

10.22 Due to concerns about the reliability of the technique, sperm that has been sorted for sex selection using gradient methods should not be used for medical reasons.

Preimplantation genetic diagnosis for histocompatibility (tissue typing)

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2 – Activities that may be licensed under the 1990 Act

Licences for treatment

Embryo testing

1ZA (1) A licence … cannot authorise the testing of an embryo, except for one or more of the following purposes–

…

(d) in a case where a person (“the sibling”) who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling

…

1ZA (4) In sub-paragraph (1)(d) the reference to “other tissue” of the resulting child does not include a reference to any whole organ of the child.

Interpretation of mandatory requirements 10E

The law requires that the intended recipient of any donated tissue from a child born following tissue typing must:

(a) be a sibling of any child born as a result of treatment, and

(b) suffer from a serious medical condition that could be treated by umbilical cord blood stem cells, bone marrow or other tissue (excluding whole organs) of any resulting child.

The law also permits tissue typing if the embryo will not, in addition to the histocompatibility test, be tested for a particular genetic or mitochondrial abnormality.

10.23 Where preimplantation tissue typing is to be used with PGD for a heritable condition, the centre should follow the requirements and guidance applicable to a PGD service.

10.24 When deciding whether to use preimplantation tissue typing, the centre should consider the circumstances of each case individually, rather than the fact that the procedure is sought to provide tissue to treat a particular condition.

10.25 When deciding on the appropriateness of preimplantation tissue typing in a particular situation, the centre should consider the condition of the affected child, including:

(a) the degree of suffering associated with their condition
(b) the speed of degeneration in progressive disorders
(c) the extent of any intellectual impairment
(d) their prognosis, considering all treatment options available
(e) the availability of alternative sources of tissue for treating them, now and in the future, and
(f) the availability of effective therapy for them, now and in the future.

10.26 The centre should also consider the possible consequences for any child who may be born as a result, including:

(a) any possible risks associated with embryo biopsy
(b) the likely long-term emotional and psychological implications
(c) whether they are likely to require intrusive surgery as a result of the treatment of the affected child (and whether this is likely to be repeated), and
(d) any complications or predispositions associated with the tissue type to be selected.

10.27 The centre should also consider the family circumstances of the people seeking treatment, including:

(a) their previous reproductive experience
(b) their views and the affected child’s views of the condition
(c) the likelihood of a successful outcome, taking into account:

(i) their reproductive circumstances (ie, the number of embryos likely to be available for testing in each treatment cycle, the number likely to be suitable for transfer, whether carrier embryos may be transferred, and the likely number of cycles)

(ii) the likely outcome of treatment for the affected child

(d) the consequences of an unsuccessful outcome
(e) the demands of IVF/preimplantation testing treatment on them while caring for an affected child, and
(f) the extent of social support available.

Information for those seeking preimplantation genetic diagnosis for histocompatibility

10.28 Information given to patients considering preimplantation tissue typing should include:

(a) information about the tissue typing tests to be done
(b) an explanation of the latest evidence about any risk associated with the biopsy procedure for any child who may be born
(c) the overall likelihood of a successful outcome for the affected child, including:

(i) the likelihood of an embryo with appropriate tissue type being available for transfer following the IVF, biopsy and genetic testing
(ii) the likelihood of a child being born as a result, taking into account the circumstances of the people seeking treatment and their previous reproductive experience
(iii) the likelihood of tissue from that child providing a successful treatment
(iv) the limitations of the treatment for the affected child

(d) the likely impact of the proposed procedure on all family members involved, and
(e) information about other sources of treatment, counselling and social support available.

10.29 If information about the disorder affecting the existing child has already been provided, for example by a regional genetics centre or by the clinical team responsible for that child's care, it will not be necessary to provide this information again. However, the centre should:

(a) ensure that this information is satisfactorily broad and clear, and
(b) obtain a statement to that effect from those providing it.

Follow-up arrangements for preimplantation tissue typing

10.30 Centres offering preimplantation tissue typing should be able to demonstrate that they have arrangements for inviting patients and their families to take part in long-term follow-up studies. These should include long-term medical and psychosocial follow-up studies of children born as a result. Centres should strongly encourage patients and their families to participate in such studies.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Other legislation, professional guidelines and information

Professional guidelines

Association of Clinical Embryologists: Accreditation standards and guidelines for IVF laboratories (2000)

Association for Clinical Genetic Science: Practice guidelines for targeted next generation sequencing analysis and interpretation (2014)

Royal College of Physicians, the Royal College of Pathologists and the British Society for Human Genetics: Consent and confidentiality in clinical generic practice – guidance on genetic testing and sharing genetic information (a report of the Joint Committee on Medical Genetics) (second edition, 2011)

11. Donor recruitment, assessment and screening

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc.

Use of gametes for treatment of others

5 (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.

(2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.

(3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

31ZD Provision to donor of information about resulting children

(1) This section applies where a person ("the donor") has consented under Schedule 3 (whether before or after the coming into force of this section) to -

(a) the use of the donor's gametes, or an embryo the creation of which was brought about using the donor's gametes, for the purposes of treatment services provided under a licence, or

(b) the use of the donor's gametes for the purposes of non-medical fertility services provided under a licence.

(2) In subsection (1) -

(a) "treatment services" do not include treatment services provided to the donor, or to the donor and another person together, and

(b) "non-medical fertility services" do not include any services involving partner-donated sperm.

(3) The donor may by notice request the appropriate person to give the donor notice stating -

(a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,

(ab) the number of persons in respect of whom the donor is a mitochondrial donor,

(b) the sex of each of those persons, and

(c) the year of birth of each of those persons.

(4) Subject to subsections (5) and (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.

(5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within paragraphs (a) to (c) of subsection (3).

(6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible -

(a) has notified the donor that the information concerned is not held, or

(b) has failed to comply with the request within a reasonable period.

(7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible -

(a) has notified the donor that the information concerned is not held, or

(b) has failed to comply with the request within a reasonable period.

(8) In this section “the appropriate person” means -

(a) in the case of a donor who consented as described in paragraph (a) of subsection (1) -

(i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or

(ii) the Authority, and

(b) in the case of a donor who consented as described in paragraph (b) of subsection (1) -

(i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or

(ii) the Authority.

(9) In this section “the relevant statutory provisions” has the same meaning as in section 31ZA.

Conditions of licences for treatment

13 (9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop -

(a) a serious physical or mental disability,

(b) a serious illness, or

(c) any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Licence conditions

T52 Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely:

a. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg, superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)

b. the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:

- HIV 1 and 2: Anti-HIV – 1, 2
- Hepatitis B: HBsAg and Anti-HBc
- Hepatitis C: Anti-HCV-Ab
- Syphilis: see (d) below

c. the centre must devise a system of storage which clearly separates:

- quarantined/unscreened gametes and embryos,
- gametes and embryos which have tested negative, and
- gametes and embryos which have tested positive

d. a validated testing algorithm must be applied to exclude the presence of active infection with Treponema pallidum. The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific Treponema confirmatory test is non-reactive. The donor whose specimen test reacted on a Treponema-specific test will require a thorough risk assessment to determine eligibility for clinical use

e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)

f. This requirement has been removed.

g. HTLV-1 antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas

h. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi), and

i. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be

carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

T53 The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge,

b. blood samples must be obtained within a timeframe specified by the Authority, and

c. donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, quarantining of the gametes and re-testing of a repeat blood sample is not required. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

T55 Potential donors that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability

b. a serious illness, or

c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

Directions

0001 – Gametes and embryo donation

0005 – Collecting and recording information for the HFEA

HFEA guidance

Advertising

11.1 Advertising and publicity materials should be designed and written with regard to the sensitive issues involved in recruiting donors.

See also

Guidance note 13 – Payments for donors

Age of prospective donors

11.2 Centres should refer to the relevant professional guidelines on age limits before accepting gametes for the treatment of others.

NOTE Current professional guidelines state that eggs should not be taken from donors aged 36 or over, and sperm should not be taken from donors aged 41 or over.

11.3 For donated eggs, the relevant age limit should be observed unless there are exceptional reasons not to do so. The centre should record any such reasons in the patient's medical records.

11.4 For donated sperm, the relevant age limit should normally be observed. However, due to less substantial evidence on age limits for sperm donors, centres should assess the possible effect of the donor's age on a case-by-case basis. The centre should record in the patient's medical records the reasons for using a donor above the recommended age limit.

11.5 For donated embryos, the guidance above applies to both gamete providers.

11.6 Gametes for the treatment of others should not be taken from anyone under the age of 18.

General enquiries to be made

11.7 The recruiting centre should take reasonable steps to verify the identity of the prospective donor by asking for appropriate identification (eg, passport or photocard driving licence). Failure to obtain satisfactory evidence of identity should be taken into account in deciding whether to accept their gametes or embryos for treatment.

11.8 Where a donor has changed their name (eg, where someone has changed their name by deed poll, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation, centres should take all reasonable steps to verify the donor's identity. This is to ascertain that a donor presenting for donation is the same person the centre previously engaged with or treated.

Centres should verify a donor's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the donor's medical records. This can be a sensitive issue for donors and centres should take care to address identity issues with consideration. As evidence of their new name, centres should ask donors to provide one of the following:

(a) a marriage certificate, or
(b) evidence of a change in name (such as via deed poll)

For trans donors:

(c) a birth or adoption certificate in their acquired gender
(d) a Gender Recognition Certificate, or
(e) a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed poll).

Centres must ensure that a donor's records are updated to accurately reflect their new identity.

11.9 When obtaining gametes or embryos for the treatment of others (whether directly from a donor, from another licensed centre or from a foreign supplier), the centre should take appropriate steps to discover whether gametes from that donor have been obtained for use in licensed treatment before and, if so:

(a) establish which centre is the primary centre for that donor
(b) notify that centre that it proposes to use that donor's gametes
(c) seek authorisation to do so, if appropriate, and
(d) ensure that the limit of 10 families per donor will not be exceeded.

Family and other relevant history

11.10 Before a prospective donor provides gametes, the recruiting centre should take their medical and family histories, and details of previous donations. The centre should encourage prospective donors to provide as much other non-identifying biographical information as possible, so that it may be available to prospective recipients, parents and resulting children. If a prospective donor cannot give a full and accurate family history, the centre should record this fact and take it into account in deciding whether or not to accept their gametes or embryos for treatment.

11.11 The centre should seek the prospective donor's consent to approach their GP for further factual information if it suspects the donor might be unsuitable. The centre should always seek further information if:

(a) information provided by the patient suggests there are risk factors that may affect anyone treated using their gametes or any child born as a result
(b) the prospective donor has failed to provide any information requested
(c) the information provided by the prospective donor is inconsistent, or
(d) there is evidence of deception.

11.12 If the prospective donor refuses to give such consent, the centre should take this into consideration when deciding whether to accept that donor. Such refusal should not in itself be grounds for not accepting the donor. The centre should discuss with the prospective donor their reason for refusing.

See also

HFEA consent forms

Suitability as a donor

Interpretation of mandatory requirements 11A

A donor must not be selected because they are known to have a particular gene, chromosome or mitochondrial abnormality that, if inherited by any child born as a result of the donation, may result in that child having or developing:

(a) a serious physical or mental disability

(b) a serious illness, or

(c) any other serious medical condition.

11.13 The use of gametes from a donor known to have an abnormality as described above, should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

11.14 If a centre determines that it is appropriate to provide treatment services for a woman using a donor known to have an abnormality as described above, it should document the reason for the use of that donor.

See also

Guidance note 10 – Embryo testing and sex selection

11.15 Before accepting gametes for the treatment of others, the recruiting centre should consider the suitability of the prospective donor. In particular, the centre should consider:

(a) personal or family history of heritable disorders
(b) personal history of transmissible infection (as outlined in Department of Health guidance, there should be no specific restrictions on donations from men who have sex with men (MSM), the centre should assess the risks and benefits of accepting donations from each such individual – ie, document MSM behaviour)
(c) the level of potential fertility indicated by semen analysis (where appropriate)
(d) the implications of the donation for the prospective donor and their family, especially for any children they may have at the time of donation or in the future, and
(e) the implications for any children born as a result of the donation, in the short and long term.

11.16 Centres are not expected to match the ethnic background of the recipient to that of the donor. Where a prospective recipient is happy to accept a donor from a different ethnic background, the centre can offer treatment, subject to the normal welfare of the child assessment.

11.17 A centre should not perform treatment that involves mixing gametes (eg, through insemination, IVF or ICSI) of close relatives who are genetically related, including between:

(a) grandfather and granddaughter
(b) grandmother and grandson
(c) father and daughter
(d) mother and son
(e) brother and sister
(f) half-brother and half-sister
(g) uncle and niece
(h) aunt and nephew
(i) uncle and half-niece
(j) aunt and half-nephew

11.18 The restriction described in 11.17 does not include treatment that involves replacing the gametes of close relatives who are genetically related (eg, sister-to-sister egg donation).

See also

Guidance note 8 – Welfare of the child

Guidance note 20 – Donor assisted conception

11.19 The centre should ensure that its procedures for recruiting donors are fair and non-discriminatory.

See also

Guidance note 29 – Treating people fairly

Conditions placed on a donation

11.20 The centre should inform anyone providing gametes that they can, if they wish, specify extra conditions for storing or using their gametes (or embryos created using them).

11.21 However, some conditions imposed by donors may be incompatible with the Equality Act 2010. The Equality Act prohibits service providers (such as clinics) from discriminating by treating people less favourably because of various protected characteristics. The protected characteristics are:

(a) age
(b) disability
(c) gender reassignment
(d) marriage and civil partnership
(e) pregnancy and maternity
(f) race
(g) religion or belief
(h) sex
(i) sexual orientation.

11.22 When deciding whether or not to recruit donors who place conditions on the use of their gametes or embryos, the centre should judge whether this will result in less favourable treatment because of a protected characteristic (eg, if it will reduce the choice of donors for a particular person by virtue of a protected characteristic).

See also

Guidance note 29 – Treating people fairly

Medical and laboratory tests

11.23 In addition to meeting the requirements set out in licence conditions, donors of gametes and embryos should be screened in accordance with current professional guidance produced by the relevant professional bodies and the Advisory Committee on the Safety of Blood, Tissues, and Organs (SaBTO)

11.24 Centres should take a blood sample and screen potential donors both before accepting them as donors, and before using the donated gametes and embryos in treatment.

11.25 In addition to meeting the mandatory requirements outlined in this guidance note, the centre should quarantine donated gametes and embryos in line with guidance from the relevant professional bodies.

People considered unsuitable as donors

11.26 A prospective donor should not be accepted if the centre:

(a) concludes that a recipient or any child born as a result of treatment using the donor's gametes is likely to experience serious physical, psychological or medical harm, or
(b) cannot get enough further information to conclude there is no significant risk.

11.27 Equality legislation prohibits service providers (such as clinics) from discriminating by treating people less favourably because of various protected characteristics or statuses. The protected characteristics set out in the Equality Act 2010 are listed at paragraph 11.21. Centres that consider a person unsuitable to donate due to one or more of these protected characteristics, or the person's status, are likely to be in breach of equality legislation and exposing themselves to liability.

See also

Guidance note 8 – Welfare of the child

Guidance note 29 – Treating people fairly

Guidance note 30 – Confidentiality and privacy

11.28 When the centre decides that a prospective donor is unsuitable to donate, it should record the reasons and explain them to the prospective donor. The centre should present the reasons for the decision sensitively and answer any questions in a straightforward and comprehensive way.

11.29 The centre should offer counselling to all prospective donors who are considered unsuitable for any reason. When the centre refuses to accept a prospective gamete donor because of physical or psychological problems that require separate treatment or specialist counselling, the centre should provide reasonable assistance to the individual to obtain relevant treatment or counselling.

11.30 If information affecting the suitability of a prospective donor becomes known after the selection process, the centre should review the prospective donor's suitability and take appropriate action.

Unsuspected heritable conditions in donors

11.31 At registration, donors should indicate whether or not they wish to be notified if the centre learns (eg, through the birth of an affected child) that they have a previously unsuspected genetic disease or they are a carrier of a harmful inherited condition. They should also be asked whether or not they would like their primary care physician to be informed. Their wishes should be recorded in the donors' medical records.

11.32 If a centre learns that a donor has a previously unsuspected genetic disease or is a carrier of a harmful inherited condition, the centre should:

(a) notify the primary centre (where there is one) and the HFEA immediately (the primary centre should immediately notify other centres who have received gametes obtained from that donor)
(b) inform patients who have had a live birth as a result of treatment with gametes from that donor, and offer these patients appropriate counselling
(c) carefully consider when and how a woman who is pregnant, as a result of treatment with gametes from that donor, is given this information, and

(d) refer to the donor's medical records to establish whether, and in what way, they would like to be given the information. If the donor has indicated that they would like to be given such information, the centre should notify their primary care physician, so that the donor can be referred for the appropriate medical care and counselling. If the donor has indicated that they would not like their primary care physician to be informed, the centre should contact the donor directly.

11.33 The centre should tell gamete donors that they should inform the centre if, after the donation:

(a) they discover they are affected by an unsuspected genetic disease, or
(b) they find they are a carrier of a harmful recessively inherited condition (eg, through the birth of an affected child).

The centre should then proceed as indicated above.

See also

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Information for prospective donors

11.34 Before any consents or samples are obtained from a prospective donor, the recruiting centre should provide information about:

(a) the screening that will be done, and why it is necessary
(b) the possibility that the screening may reveal unsuspected conditions (eg, low sperm count, genetic anomalies or HIV infection) and the practical implications
(c) the scope and limitations of the genetic testing that will be done and the implications for the donor and their family
(d) the importance of informing the recruiting centre of any medical information that may come to light after donation that may have health implications for any woman who receives treatment with those gametes or for any child born as a result of such treatment
(e) the procedure used to collect gametes, including any discomfort, pain and risk to the donor (eg, from the use of superovulatory drugs)
(f) the legal parenthood of any child born as a result of their donation
(g) the restriction on using gametes and embryos from an individual donor when the number of families that have already had children as a result of treatment using such gametes or embryos has reached 10 (or any lower figure specified by the donor)
(h) what information about the donor must be collected by the centre and held on the HFEA Register
(i) the fact that the centre or the HFEA (or both) may disclose non-identifying information about the donor, for example to prospective recipients or to the parents of donor-conceived children
(j) the HFEA's obligation to disclose non-identifying information (and identifying information if donation took place after 31 March 2005), to someone who applies for such information if:

(i) the applicant is aged over 16 (to access non-identifying information) or 18 (to access identifying information), and
(ii) the applicant appears to have been conceived using the donor's gametes, or embryos created using the donor's gametes

(k) the importance of supplying up-to-date contact information so that they can be informed if and when disclosure of identifiable information will be made
(l) the importance of the information provided at 11.29 and 11.30 to people born as a result of their donation
(m) the possibility that a donor-conceived person who is disabled as a result of an inherited condition that the donor knew about, or ought reasonably to have known about, but failed to disclose, may be able to sue the donor for damages
(n) the procedure for donors to withdraw consent for the use of their gametes, or embryos created with their gametes, and
(o) the fact that if the donor is an egg donor who is not a patient, she is free to withdraw from the donation process after preparation for egg recovery has begun without incurring a financial or other penalty.

11.35 Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:

(a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
(b) referred to information on the HFEA's website on this issue, and
(c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

11.36 Centres must consider whether there may be additional information requirements for trans donors and provide relevant information tailored to their specific needs and circumstances. Where the donor is transitioning, the purpose for which they are intending to donate their gametes will determine what kind of information centres should provide and the consent requirements. For example, a trans donor who is consenting to donate their gametes for use in someone else's treatment, may require different information from a trans patient who is being screened as a donor for the use of their gametes in a surrogacy arrangement.

See also

Guidance note 4 – Information to be provided prior to consent
Guidance note 5 – Consent to treatment, storage, donation and disclosure of information
Guidance note 12 – Egg sharing arrangements
Guidance note 20 – Donor assisted conception

Giving donors information about children born as a result of their donation

Interpretation of mandatory requirements 11B

If donors of gametes and embryos ask, centres must provide the following information about any children born as a result of their donation:

(a) number
(b) sex, and
(c) year of birth.

If the centre is unable to provide this information, it should direct donors to the Authority.

11.37 The centre should inform donors and potential donors that they may ask at any time how many children have been born as a result of their donation.

11.38 The centre should inform donors seeking information about children born as a result of their donation that they may find counselling, or similar support services, helpful in considering the implications of receiving such information.

11.39 The centre should inform anonymous donors seeking information about children resulting from their donation that they have the right to re-register as identifiable, if they wish.

Informing donors about information available to donor-conceived people

11.40 The centre should inform donors that anyone born as a result of their donation will have access to the following non-identifying information provided by them, from the age of 16:

(a) physical description (height, weight, and eye, hair and skin colours)
(b) year and country of birth
(c) ethnic group
(d) whether the donor had any genetic children when they registered, and the number and sex of those children
(e) other details the donor may have chosen to supply (eg, occupation, religion, gender history and interests)
(f) the ethnic group(s) of the donor's parents
(g) whether the donor was adopted or donor conceived (if they are aware of this)
(h) marital status (at the time of donation)
(i) details of any screening tests and medical history
(j) skills
(k) reason for donating
(l) a goodwill message, and
(m) a description of themselves as a person (pen portrait).

11.41 The centre should also inform donors who register or re-register after 31 March 2005 that anyone born as a result of their donation will have access to the following identifying information, from the age of 18:

(a) full names (and any previous names)
(b) date of birth, and town or district where born, and
(c) last known postal address (or address at time of registration).

11.42 The centre should inform identifiable donors that it will make a reasonable attempt to contact and forewarn them before disclosing identifiable details to anyone born as a result of their donation. The centre should encourage donors to provide up-to-date contact details to facilitate this.

11.43 The centre should advise trans donors that information disclosed by the HFEA to anyone born as a result of their donation may reveal the donor's gender history (eg, where a trans woman

donated sperm and registered with the clinic and the HFEA in her acquired female gender. On disclosure of her identifying information, it will be apparent to the person born as a result of her donation that the she is a trans woman having donated sperm).

11.44 The centre should inform donors who are, or will be, transitioning that following their donation, they have the option to notify the clinic or HFEA that they have transitioned and may, if they wish, provide details of their acquired identity so that the HFEA Register can be updated. This will allow anyone conceived as a result of their donation at age 18 to find out about the donor's current identity.

11.45 The centre should inform donors that the HFEA is legally obliged to disclose the information set out at 11.43 and 11.44 to anyone conceived as a result of their donation.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 20 – Donor assisted conception

Guidance note 30 – Confidentiality and privacy

Provision of counselling to those considering donation

Interpretation of mandatory requirements 11C

All prospective donors must be given a suitable opportunity to receive proper counselling. Where embryos are to be donated, the recruiting centre must offer counselling to each person whose gametes were used to create the embryos.

11.46 If the possibility of donating gametes or embryos for the treatment of others, or for research or training, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.

Consent

Interpretation of mandatory requirements 11D

The law requires the centre to obtain written informed consent from a person before it uses:

(a) their gametes for the treatment of others or for non-medical fertility services, or

(b) embryos created with their gametes for the treatment of others.

Those giving consent can specify conditions for the use of their gametes and embryos.

The use of donor gametes or embryos to create more families than a donor has consented to is a breach of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

11.47 Where someone intends to donate gametes or embryos for the treatment of others, the centre should ensure it obtains written consent to do so from that person. Such consent should include the number of families that may have children using the donated gametes or embryos.

11.48 Centres should aim to make best use of donated sperm within the maximum number of families the donor has consented to (up to the 10-family limit).

11.49 If the donor has consented to using the sperm for more than one family, the recruiting centre should not allow patients to reserve more sperm than is reasonable for one family allocation.

11.50 Where the centre uses sperm from donors who have been recruited at another centre, the centre should take reasonable steps to assure itself that patients have not reserved more sperm than is reasonable for one family allocation.

11.51 The centre is not required to obtain the consent of the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Monitoring and complying with the 10-family limit

11.52 The centre should establish documented procedures to ensure that if the number of families created using gametes (or embryos created using donated gametes) from a particular donor has reached 10 (or any lower figure specified by the donor), that those gametes or embryos are not used or distributed for use in further treatment.

11.53 Before authorising a secondary centre to use gametes (or embryos created using gametes) from a particular donor, the primary centre should ensure that no more than 10 families (or any lower figure specified by the donor) at any time:

(a) have had live births as a result of treatment using that donor's gametes
(b) have embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer, or
(c) are being treated using that donor's gametes (or embryos created using gametes).

11.54 If a centre uses gametes (or embryos created using gametes) from a particular donor who was recruited by another centre, it should notify that primary centre each time a new patient has:

(a) a live birth as a result of treatment using that donor's gametes, or
(b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

Where a centre uses the sperm of a donor in pronuclear transfer and where the donor will consequently be genetically related to any child born, a) and b) must be complied with. In the case of egg donors who have donated their mitochondria only, or sperm donors who have donated for pronuclear transfer where they will not be genetically related to the child, clinics do not need to comply with the above.

11.55 The primary centre for a particular donor should notify any secondary centres having or using gametes (or embryos created using gametes) from that donor, within two working days, when it becomes aware that six families (The six-family alert applies where the donor has not specified a family limit lower than 10) have had:

(a) a live birth as a result of treatment using that donor's gametes, or
(b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

After this, gametes (or embryos created using gametes) from that donor should not be used without authorisation from the primary centre, unless they are used to treat a family who already has a child using that donor. However, if recipients have already begun or had medical, surgical or obstetric treatment (such as ovarian stimulation or egg collection) when the notification is given, this should be allowed to continue.

11.56 When using gametes (or embryos created using gametes) from a particular donor authorised in this way by a primary centre, a secondary centre should notify the primary centre each time a woman starts or ends relevant treatment.

11.57 Relevant treatment situations are where the woman has:

(a) begun, but not completed, a treatment cycle (eg, ovarian stimulation)
(b) received treatment (insemination or embryo transfer) and is awaiting confirmation of pregnancy
(c) a confirmed ongoing pregnancy
(d) embryos created that have not yet been transferred (eg, placed in storage), or
(e) received treatment but has not reported the outcome.

11.58 Primary centres should notify secondary centres, and vice versa, when embryos created using a donor's gametes are removed from storage and allowed to perish, donated to research or used for training.

See also

Guidance note 17 – Storage of gametes and embryos

Benefits in kind

11.59 Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for the treatment of others.

11.60 The centre should, as appropriate, treat gamete providers donating for benefits in kind in the same way as other potential gamete donors.

See also

Guidance note 12 – Egg sharing arrangements

Other legislation, professional guidelines and information

Legislation

General Data Protection Regulation (EU) 2016/679 (GDPR)

Equalities Act 2010

Gender Recognition Act 2004

Professional guidelines

Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society and Royal College of Obstetricians and Gynaecologists: UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008)

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (third edition, 2012)

Department of Health (Advisory Committee on the Safety of Blood, Tissues and Organs): Donor selection criteria for men who have had sex with men (2013)

Clinic Focus articles

Information on HTLV screening, issued in Clinic Focus (November 2010)

Clinic Focus article: Photographs of donors (May 2014)

Clinic Focus article: Pathology tests (July 2014)

Clinic Focus article: Zika virus (what it means for donors and fertility patients) (February 2016)

Clinic Focus article: Updated guidance on Ebola (March 2016)

12. Egg sharing arrangements

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General conditions

(1) The following shall be conditions of any licence granted under this Act—

…(e) that no money or other benefit shall be given or received in respect of any supply of gametes, embryos or human admixed embryos unless authorised by Directions…

Directions

0001 – Gamete and embryo donation

NOTE Gamete donors may receive licensed services, such as treatment, storage, or access to licensed services, in return for supplying gametes or mitochondria for donation (including mitochondrial donation). Egg or mitochondrial donors who receive a benefit should be provided with that benefit in the course of the donation cycle unless there is a medical reason why they cannot be. An egg donation cycle is defined as the period from the first consultation to the end of the donor's recuperation.

HFEA guidance

Selection of egg and sperm providers

12.1 Where relevant, the possibility of donating gametes for fertility treatment, mitochondrial donation or research should be raised before a potential donor's treatment begins. Patients should not be put under pressure or unduly influenced to donate gametes or embryos.

12.2 The centre should, as appropriate, treat gamete providers receiving benefits in kind in the same way as other potential gamete donors.

12.3 The centre should ensure that:

(a) care is taken when selecting egg and sperm providers donating for benefits in kind
(b) egg and sperm providers are fully assessed and medically suitable, and

(c) the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

See also

Guidance note 8 – Welfare of the child

Guidance note 11 – Donor recruitment, assessment and screening

Benefits

12.4 Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for fertility treatment or mitochondrial donation.

12.5 If benefits in the form of licensed services are offered to an egg provider (including a mitochondrial donor), they should be given in connection with the cycle in which eggs are supplied for a recipient's treatment unless providing treatment to the egg provider at this stage could be harmful, or there is a clinical reason(s) to defer treatment to the egg provider.

In the exceptional circumstance where deferring treatment to the egg provider is appropriate, egg or embryo freezing should be offered where possible.

12.6 In an egg sharing arrangement, centres should ensure that, where the minimum number of eggs required for the arrangement are collected, eggs are distributed equally between the egg provider and the recipient(s). Where an odd number of eggs is collected, the benefits in kind agreements should clearly set out who will receive the additional egg.

See also

Guidance note 11 – Donor recruitment, assessment and screening

Information

12.7 The centre should provide women receiving eggs or sperm with the same information as other people seeking treatment with donated gametes. Also, before treatment begins, the centre should give the gamete provider and the recipient the following written information setting out:

(a) the criteria for selecting people providing and receiving gametes in exchange for benefits in kind
(b) how the centre proposes to distribute the gametes between the provider and the recipient(s) (where relevant)
(c) the screening that the gamete provider in a benefit in kind arrangement will undergo
(d) the terms of the agreement to be made

(e) the law relating to consent, in particular the rights of a person providing gametes to vary or withdraw consent, and the implications of doing so
(f) available alternative treatment options.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 11 – Donor recruitment, assessment and screening

Consent

12.8 The person obtaining consent should ensure that the gamete provider's consent is recorded so that different conditions can be placed on:

(a) the use or storage of the gametes, and the use and storage of embryos created for the gamete provider's own treatment, and
(b) the use of eggs or sperm, and the use and storage of embryos created for the treatment of the recipient(s).

These conditions should be able to be varied independently of each other.

12.9 The person obtaining consent should tell the gamete provider and recipient(s) that the gamete provider may withdraw or vary their consent up to when the gametes or embryo(s) are:

(a) transferred to a woman
(b) used in a research project (defined as being under the control of the researchers and being cultured for use in research)
(c) used for training, or
(d) allowed to perish.

If the gamete provider is providing gametes or embryos solely for use in mitochondrial donation treatment, the donor cannot withdraw or vary their consent once the patient's nuclear DNA has been inserted into their egg or embryo.

The possible consequences of this should:

(a) be made clear to the gamete provider and the recipient(s) before the treatment begins, and
(b) be set out in the written patient information included with the benefits in kind agreement.

12.10 Centres should ensure that where a gamete provider elects not to have counselling, the implications of donation are discussed with the gamete provider. Centres should record that the implications of donation have been discussed and why the gamete provider has elected not to have counselling. The gamete provider should be given enough time to consider the implications of donating, before giving consent.

12.11 If either the gamete provider or the recipient in a benefits in kind arrangement withdraws their consent to treatment after preparation has begun, the centre should bear any financial loss it sustains as a result.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Counselling

Interpretation of mandatory requirements 12A

The centre must offer anyone intending to participate in a benefits in kind arrangement the opportunity for counselling.

12.12 The counselling of those intending to participate in a benefits in kind arrangement should accord with the guidance from the British Infertility Counselling Association.

See also

Guidance note 3 – Counselling

Confidentiality

12.13 In addition to following standard procedures for protecting patient and donor confidentiality, the centre should ensure it keeps all notes, facilities and procedures for the gamete provider separate from those for the recipient(s) (where relevant). Care should be taken to ensure that confidentiality is not compromised, for example, if the gamete provider and recipient(s) are treated at the same centre at the same time.

See also

Guidance note 30 – Confidentiality and privacy

Benefits in kind agreements

12.14 The centre should draw up separate agreements with the gamete provider and with recipient(s). These agreements should be consistent with each other. The centre should abide by the terms of benefits in kind agreements it has made.

Agreement between a licensed centre and a gamete provider

12.15 When drawing up agreements between the centre and gamete providers, centres should seek legal advice.

12.16 The agreement between the centre and the gamete provider should set out all the terms of the arrangement. It should identify clearly the gamete provider and the centre, and be signed by both parties.

12.17 The agreement should include a statement confirming:

(a) that any patient who has consented to providing eggs or sperm for the treatment of others in licensed treatment under the HFE Act 1990 (as amended) will not be the legal parent of any resulting child/(ren)
(b) what information will be available to the gamete provider about the recipient and the outcome of her treatment, for example the number and sex of any resulting children, and
(c) what information will be available to the recipient about the gamete provider and the outcome of the treatment, for example the number and sex of any resulting children.

12.18 The agreement should include a full description of what the benefits in kind are expected to involve, including:

(a) the number of treatment cycles or length of storage covered by the agreement, and
(b) the expected waiting time for treatment.

12.19 The agreement should include a statement from the egg or sperm provider confirming that they have:

(a) had an opportunity to talk with a member of staff qualified to explain the procedures involved in providing gametes as part of a benefits in kind arrangement
(b) received verbal and written information about the treatment
(c) received all the appropriate information listed in the relevant parts of this Code of Practice
(d) been offered counselling
(e) received information about the implications of the treatment and donation, and
(f) been made aware of the screening that will be done before treatment begins.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 11 – Donor recruitment, assessment and screening

12.20 The agreement should include a statement confirming:

(a) that the centre has obtained the patient's consent to the treatment
(b) that the centre has recorded appropriately the gamete provider's consent to the use of their gametes and to the creation, use and storage of embryos from the gametes
(c) that the agreement does not override the terms of paragraph 4A of Schedule 3 to the HFE Act 1990 (as amended). This states that the gamete provider may withdraw or vary their consent about any embryo created using their gametes at any time, until that embryo is:

(i) transferred to a woman
(ii) used in a research project
(iii) used in training, or
(iv) allowed to perish
(v) in the case of mitochondrial donation, up until the nuclear DNA of the patient is inserted into the donor egg or the nuclear DNA taken from the patient's embryo is inserted into the donor embryo.

(d) the consequences of any variation or withdrawal of consent, and the liability of the parties involved to pay any resulting extra charges.

12.21 The agreement should include a statement setting out:

(a) what charges (if any) the gamete provider is expected to pay to the treatment centre, and
(b) if the gamete provider's treatment or storage of their gametes is provided at a discount, the circumstances under which they would be liable for the full cost of this treatment or storage, and the amount they would have to pay.

NOTE If too few eggs are collected for use in a benefits in kind agreement, the woman should be given the option of using or storing all the eggs for her own treatment, at the agreed discount.

12.22 The agreement should include full details of the proposed arrangements for distributing the eggs or sperm between the provider and recipient(s), including:

(a) the minimum number of eggs required for a benefits in kind arrangement
(b) the number of recipients among whom the eggs or sperm will be shared (which for eggs should be no more than two, excluding the egg provider), and
(c) who will receive the additional egg where an odd number is collected.

Agreement between a licensed centre and a recipient

12.23 When drawing up agreements between the centre and recipient, centres should seek legal advice.

12.24 The agreement between the centre and the recipient should set out all the terms of the arrangement. It should identify clearly the recipient and the centre, and be signed by both parties.

12.25 The agreement should include a statement confirming:

(a) that anyone who has consented to providing eggs or sperm for the treatment of others in licensed treatment under the HFE Act 1990 (as amended) will not be the legal parent of any resulting child/(ren)
(b) the information that will be available to the egg or sperm provider about the recipient and the outcome of her treatment, for example the number and sex of any resulting children, and
(c) the information that will be available to the recipient about the egg or sperm provider and the outcome of the treatment, for example the number and sex of any resulting children, and the information that will be available to any children of the recipient about the egg or sperm provider, including:

(i) information recorded on the HFEA Register that the children are entitled to receive, and
(ii) the circumstances under which they may receive such information.

12.26 The agreement should set out what the treatment is expected to involve, including:

(a) the number of treatment cycles
(b) the expected waiting time for treatment, and
(c) that a proportion of the eggs collected from the egg provider will be used for the provider's own treatment.

12.27 The agreement should include a statement from the recipient confirming that she has:

(a) had an opportunity to discuss with an experienced member of the centre's staff the procedures involved in receiving eggs or sperm as part of a benefits in kind arrangement
(b) received verbal and written information about her treatment
(c) received all the appropriate information listed in the relevant parts of this Code of Practice (written information should be attached to the agreement)
(d) been offered counselling
(e) received information about the implications of the treatment and using donated gametes, and
(f) been informed about the screening that the egg or sperm provider has undergone and the limitations of that screening in avoiding transmissible conditions.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 20 – Donor assisted conception

12.28 The agreement should include a statement confirming that the agreement does not override the terms of paragraph 4A of Schedule 3 to the HFE Act 1990 (as amended). This states that the egg or sperm provider may withdraw or vary their consent about any embryo created using their eggs or sperm at any time until that embryo is:

(a) transferred to a woman
(b) used in a research project
(c) used in training, or
(d) allowed to perish.

In the case of mitochondrial donation, up until the nuclear DNA of the patient is inserted into the donor egg or the nuclear DNA taken from the patient's embryo is inserted into the donor embryo.

12.29 The agreement should include a statement describing:

(a) what charges the egg recipient is expected to pay to the centre, and
(b) what treatment these charges will cover.

12.30 The agreement should set out the proposed arrangements for distributing the eggs between the provider and recipient(s), including:

(a) the minimum number of eggs required for the benefits in kind arrangement
(b) the number of recipients among whom the eggs or sperm will be shared (which for eggs should be no more than two, excluding the egg provider), and
(c) who will receive the additional egg where an odd number is collected.

Benefits in kind for research

12.31 As outlined in the previous sections, the centre should draw up agreements between the centre and the gamete provider, and the centre and the recipient (in this case, the research group), including all relevant information.

12.32 If gametes are being donated to research through a benefits in kind agreement, the centre must ensure that the eggs are divided between the donor and the recipient (the research project) by someone not directly involved in the research project.

12.33 If a centre offers benefits in kind in exchange for donating gametes to fertility treatment, mitochondrial donation and to research, equal benefits in kind should be available. This ensures there is no advantage in donating to one recipient rather than the other.

See also

Guidance note 22 – Research and training

Other legislation, professional guidelines and information

Professional guidelines

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (third edition, 2012)

Clinic Focus articles

Clinic Focus article: Guidance on egg giving (March 2016)

13. Payments for donors

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General conditions

(1) The following shall be conditions of any licence granted under this Act -

…(e) that no money or other benefit shall be given or received in respect of any supply of gametes, embryos or human admixed embryos unless authorised by Directions…

41 Offences

(8) Where a person to whom a licence applies or the holder of the licence gives or receives any money or other benefit, not authorised by Directions, in respect of any supply of gametes, embryos or human admixed embryos, he is guilty of an offence.

(9) A person guilty of an offence under subsection (8) above is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.

Licence conditions

T69 No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions.

Directions

0001 – Gamete and embryo donation

HFEA guidance

Payments or other benefits for donors

Interpretation of mandatory requirements 13A

If the person responsible or the licence holder gives or receives any money or benefit for the supply of gametes, embryos or human admixed embryos that is not authorised by the applicable HFEA Directions, they have committed a criminal offence. Conviction may result in a prison term, a fine or both.

Centres must not accept an individual as a donor who is known (or is reasonably suspected) by that centre to have received or to be about to receive money or other benefits not in line with HFEA Directions.

Where the person responsible is aware that a person wishes to be treated using gametes obtained from a donor sourced by another agency or intermediary, including introductory agencies and internet websites, the person responsible:

(a) should take reasonable steps to satisfy themselves that the requirements specified in HFEA Directions have not been breached, and

(b) must keep a record of the steps taken for this purpose.

Centres may compensate sperm donors with a fixed sum of up to £35 per clinic visit.

Centres may compensate egg donors with a fixed sum of up to £750 per cycle of donation. Where a prospective egg donor does not complete the cycle, the centre may compensate the egg donor on a 'per clinic visit' basis, as specified in HFEA Directions.

Where a person has stored gametes or embryos for use in their own treatment but then consents to donate them, a centre may compensate the donor for subsequent visits on a 'per clinic visit' basis, as specified in HFEA Directions.

Centres may compensate donors with an excess amount in cases where expenses (such as for travel, accommodation or childcare) exceed the amounts specified in HFEA Directions. Centres may only provide excess expenses which:

(a) are reasonable

(b) do not include loss of earnings

(c) have been incurred by the donor in connection with the donation of gametes provided to that centre, and

(d) have been incurred by the donor solely within the United Kingdom.

Donors who are not permanent residents of the UK should be compensated in the same way as UK donors without an excess for overseas travel expenses. Centres must not directly or indirectly pay the overseas travel of a non-UK donor.

Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for the treatment of others.

13.1 Advertising or publicity aimed at recruiting gamete or embryo donors, or at encouraging donation, should not refer to the possibility of financial gain or similar advantage, although it may refer to compensation permitted under relevant HFEA Directions.

13.2 The person responsible has a duty to assure themselves that no payments or benefits (except those in line with relevant HFEA Directions) have been given or promised to the donor by another agency or intermediary, including introductory agencies.

13.3 Donors may be compensated with a fixed amount of money, as specified in HFEA Directions, which reasonably covers any financial losses incurred in connection with donating gametes provided to that centre.

13.4 If donors have incurred expenses (not including loss of earnings) that exceed the amounts specified in HFEA Directions, the centre may compensate donors with excess expenses in line with HFEA Directions.

13.5 The centre should ensure that donors understand that donating gametes and embryos is voluntary and unpaid and that they may be compensated only in line with relevant HFEA Directions.

13.6 If an egg donor becomes ill as a direct result of donating, the centre may also reimburse their reasonable expenses arising from the illness.

See also

Guidance note 12 – Egg sharing arrangements

Giving and receiving money or other benefits in respect to any import of gametes or embryos from outside the UK

Interpretation of mandatory requirements 13B

As specified in HFEA Directions, when considering whether to import gametes donated overseas, the centre should ensure the donor has not received compensation which exceeds:

(a) reasonable expenses incurred by the donor in connection with the donation of gametes provided to that centre, and

(b) loss of earnings (but not for other costs or inconveniences) incurred by the donor up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation (local currency equivalent).

When receiving donated gametes from overseas, the centre must keep a record (provided by the overseas centre) of:

(a) the actual expenses incurred by the donor

(b) the amount reimbursed to the donor, and

(c) the receipts produced by the donor, and/or the steps taken by the person responsible to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred.

Recording excess expenses for donors

Interpretation of mandatory requirements 13C

Where centres compensate donors with an excess amount, as specified in HFEA Directions, the centre must keep:

(a) a record of the actual excess expenses incurred by the donor

(b) a record of the amount reimbursed to the donor, and

(c) the receipts produced by the donor, and/or the steps taken by the person responsible to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred.

The records referred to in HFEA Directions must be made available to the centre's inspector or provided directly to the HFEA, on request.

13.7 Centres should keep a central log of all excess expenses paid to donors. This log should be made available to HFEA inspectors, and should contain the following information:

(a) date of payment
(b) amount of payment
(c) donor (name or unique identifier)
(d) reason for payment (nature of expense)
(e) total amount paid to the donor to date for the clinic visits (for sperm donation) or cycle (for egg donation),
(f) receipts that show excess expenses incurred.

14. Surrogacy

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology Act 2008

PART 2 – Parenthood in cases involving assisted reproduction

Parental orders

54 (1) On an application made by two people ("the applicants"), the court may make an order providing for a child to be treated in law as the child of the applicants if—

(a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,

(b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and

(c) the conditions in subsections (2) to (8) are satisfied.

(1A) For the purposes of this section, neither of the following is to be treated as a person whose gametes were used to create an embryo ("embryo E")—

(a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;

(b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

(3B) For the purposes of this Schedule, in a case where an egg is permitted egg by virtue of regulations under section 3ZA(5) the egg is not to be treated as the egg of the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

(2) The applicants must be—

(a) husband and wife,

(b) civil partners of each other, or

(c) two persons who are living as partners in an enduring family relationship and are not within prohibited degrees of relationship in relation to each other.

(3) Except in a case falling within subsection (11), the applicants must apply for the order during the period of 6 months beginning with the day on which the child is born.

(4) At the time of the application and the making of the order—

(a) the child's home must be with the applicants, and

(b) either or both of the applicants must be domiciled in the United Kingdom or in the

Channel Islands or the Isle of Man.

(5) At the time of the making of the order both the applicants must have attained the age of 18.

(6) The court must be satisfied that both—

(a) the woman who carried the child, and

(b) any other person who is a parent of the child but is not one of the applicants (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(7) Subsection (6) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(8) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by either of the applicants for or in consideration of—

(a) the making of the order,

(b) any agreement required by subsection (6),

(c) the handing over of the child to the applicants, or

(d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

(9) For the purposes of an application under this section—

(a) in relation to England and Wales, section 92(7) to (10) of, and Part 1 of Schedule 11 to, the Children Act 1989 (c. 41) (jurisdiction of courts) apply for the purposes of this section to determine the meaning of "the court" as they apply for the purposes of that Act and proceedings on the application are to be "family proceedings" for the purposes of that Act,

(b) in relation to Scotland, "the court" means the Court of Session or the sheriff court of the sheriffdom within which the child is, and

(c) in relation to Northern Ireland, "the court" means the High Court or any county court within whose division the child is.

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which—

(a) relates to a child born before the coming into force of this section, and

(b) is made by two persons who, throughout the period applicable under subsection (2) of section 30 of the 1990 Act, were not eligible to apply for an order under that section in relation to the child as husband and wife,

may be made within the period of six months beginning with the day on which this section comes into force.

Interpretation of Part 2

58 (1) In this Part "enactment" means an enactment contained in, or in an instrument made under—

(a) an Act of Parliament,

(b) an Act of the Scottish Parliament,

(c) a Measure or Act of the National Assembly for Wales, or

(d) Northern Ireland legislation.

(2) For the purposes of this Part, two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships—

(a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and

(b) include the relationship of a child with his adoptive, or former adoptive, parents, but do not include any other adoptive relationships.

(3) Other expressions used in this Part and in the 1990 Act have the same meaning in this Part as in that Act.

Regulations

The Parental Orders (Human Fertilisation and Embryology) Regulations 2010

The Parental Orders (Human Fertilisation and Embryology) (Scotland) Regulations 1994

Directions

0005 – Collecting and recording information for the HFEA

HFEA guidance

Assessment and screening in surrogacy arrangements

Interpretation of mandatory requirements 14A

Intended parents providing gametes in surrogacy arrangements must be screened in line with requirements for gamete donors.

14.1 The centre should assess all those involved in surrogacy arrangements before providing treatment, in line with the welfare of the child assessment process, outlined in guidance note 8.

See also

Guidance note 8 – Welfare of the child

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Additional information for those involved in surrogacy arrangements

14.2 The centre should ensure that those involved in surrogacy arrangements have received information about legal parenthood under the HFE Act 2008 and other relevant legislation. This information should cover who may be the legal parent(s) when the child is born, as outlined in guidance note 6.

14.3 The centre should ensure that those involved in surrogacy arrangements have received information about the effect of the parenthood provisions in the HFE Act 2008 and in particular the Parental Orders provisions in the Act. These state that parental rights and obligations in respect of surrogacy arrangements may be transferred from the birth parent(s) to those who commissioned the surrogacy arrangement, as long as certain conditions are met. One of the conditions that must be met is that the gametes of one or more of the intended parents must be used, so that one partner has a genetic link to the child born. In the case of mitochondria donation, the mitochondria donor is not considered to be the biological parent (ie, because their nuclear DNA is not passed on to the child). Therefore, they cannot be an applicant for a parental order on the basis of that donation.

14.4 The centre should advise patients that surrogacy arrangements are unenforceable and that they are encouraged to seek legal advice about this and any other legal aspect of surrogacy.

14.5 The centre should satisfy itself that those involved in surrogacy arrangements have received enough information and understand the legal implications of these arrangements well enough to be able to give informed consent to treatment.

14.6 The centre should advise patients intending to travel to another country for the purpose of entering into a surrogacy arrangement that they are encouraged not to do so until they have sought legal advice about:

(a) legal parenthood of the prospective child
(b) immigration status and passport arrangements
(c) the adoption or parental orders procedures for that country, and
(d) the degree to which those procedures would be recognised under the law of the part of the United Kingdom in which the patients live.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 6 – Legal parenthood

Offer of counselling to those considering surrogacy

14.7 The centre should ensure that all those involved in a surrogacy arrangement receive proper counselling about the implications of the steps they are considering. The counselling requirements are outlined in guidance note 3.

14.8 The centre should encourage those involved in a surrogacy arrangement to reflect on their decisions before it obtains their consent. The centre should provide detailed information, advice and guidance and encourage questions. The centre should be satisfied that all parties fully understand all aspects of the surrogacy arrangement and are entering into the arrangement

freely and voluntarily, before obtaining their consent. This should include testing the understanding of both the intended surrogate and intended parents and ensuring that information is provided clearly and at an appropriate level of complexity tailored to an individual's capacity to understand it.

14. 9 The centre should exercise particular caution and sensitivity when discussing and taking consents for surrogacy arrangements and be aware of the vulnerable positions of both the intended surrogate and intended parents and serious implications for all concerned of a surrogacy arrangement breaking down. The centre should be alert to any sign of coercion. The centre's role should be to protect both parties from entering into a surrogacy arrangement which it suspects may be unsuitable or unethical for any reason.

See also

Guidance note 3 – Counselling

Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information

Other legislation, professional guidelines and information

Legislation

Surrogacy Arrangements Act 1985

General information

Home Office: UK visas and immigration

15. Procuring, processing and transporting gametes and embryos

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Requirements for holding a licence for gametes and embryo preparation processes

11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with -

(a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and

(b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

Relevant provisions of the third Directive	
Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedures	Annex II, Part C
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

NOTE Directive 2006/86/EC (the third Directive) implements Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

Directions

0001 – Gamete and embryo donation

0009 – Keeping gametes and embryos in the course of carriage between premises

HFEA guidance

Documented procedures: general

Mandatory requirements

Licence conditions

T70 There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use or disposal.

T74 There must be a documented system in place for ratifying that gametes and/or embryos meet appropriate specifications of safety and quality for use and for their transportation/distribution.

15.1 The centre should, where appropriate, have documented procedures that cover:

(a) superovulation regimes
(b) egg retrieval
(c) sedation
(d) resuscitation
(e) sperm aspiration
(f) gamete and embryo transfer
(g) insemination
(h) follow-up after treatment, including management of complications and establishing if any patients have experienced OHSS, and
(i) prevention and management of ovarian hyper-stimulation syndrome including maintaining clinical relationships with local hospitals who may treat the licensed centre's patients for OHSS, and seeking to put in place agreements around related appropriate information and data sharing.

See also

Specific documented procedures are referenced in the following sections of this guidance note:

- Home procurement
- Reception at the centre
- Processing and disposal of gametes and embryos
- Packaging, distribution and recall of gametes and embryos
- Quality and safety of gametes and embryos

Guidance note 31 – Record keeping and document control

Patient selection and procurement

Mandatory requirements

Licence conditions

T49 The clinician responsible for the patient must document the justification for the use of their gametes or embryos created with their gametes in treatment, based on the patient's medical history and therapeutic indications.

Interpretation of mandatory requirements 15A

Procurement of gametes is a licensable activity which must be undertaken at licensed premises or in accordance with a third party agreement.

15.2 In addition to meeting the requirements in licence conditions, the centre should, at the time of procurement, label each package containing gametes and embryos in a way that is not susceptible to unauthorised or undetectable alteration. If the size of the packaging permits, the identity of the patient, patient's partner or donor should also be noted.

15.3 The centre should not obtain gametes for treatment from anyone under the age of 18 unless:

(a) those gametes are intended for the patient's own treatment or that of their partner
(b) the centre can satisfy itself that the patient is capable of giving effective consent to the use of the gametes for that purpose, and
(c) the patient has given effective consent to the use of their gametes for that purpose

Home insemination

Interpretation of mandatory requirements 15B

The centre may supply cryopreserved sperm only to a person covered by a licence. Sperm supplied for home insemination must therefore be thawed or thawing. The use of a dry shipper or any other container that would preserve the sperm in a frozen or preserved state when it leaves the treatment centre is prohibited.

15.4 Sperm should be supplied for insemination at home (or another unlicensed site) only in exceptional circumstances. When this occurs, the treatment centre should:

(a) record this fact and explain the relevant exceptional circumstances in the medical records, and
(b) complete the relevant DI (Donor Insemination) treatment form in the usual way, except that the date of supply or posting should be entered as the date of insemination and a note made that the sperm was supplied for home insemination.

15.5 Provided that the woman has attended the treatment centre for assessment, sperm for insemination at home (or another unlicensed site) may be either handed to her in person or sent to her by courier.

See also

HFEA Donor Insemination treatment forms

Home procurement

Mandatory requirements

Licence conditions

T68 Where the sperm is procured at home, the centre must record this in the gamete provider's records.

15.6 A centre should normally store or use only sperm that has been obtained directly from the provider, another licensed clinic or a centre with which the licensed centre has a transport arrangement, or that has been imported in line with HFEA Directions.

15.7 The centre may use sperm produced by a man at home (or another unlicensed site). The centre should follow protocols to ensure, as far as possible, that:

(a) the identity of the sperm provider is confirmed
(b) the sperm provider confirms he produced the sperm
(c) the date and time of the sperm production is confirmed (and is no more than two hours before the centre received the sperm)
(d) the sperm has not been interfered with, and
(e) the sperm receptacle is clearly labelled with the sperm provider's full name and unique identifier.

The centre's documented procedures should ensure that this information is recorded in the patient's medical records.

15.8 If embryos have been created using partner sperm produced at home (or another unlicensed site) and donation is being considered, the centre should consider the fact that the sperm was not produced at a licensed treatment centre and tell prospective recipients.

15.9 The requirements for receipt from another centre also apply to sperm procured at home or another unlicensed site (see 'Reception at the centre' below).

See also

Guidance note 16 – Imports and exports

Reception at the centre

Mandatory requirements

Licence conditions

T109 The centre must put in place, maintain and implement a procedure for the receipt of gametes and/or embryos from another centre or third party premises to ensure that:

a. the consignment of gametes and/or embryos is verified against SOPs and specifications. These must include information relating to the transport conditions, packaging, labelling, patient/donor documentation, and any other associated documentation and samples. These must also include the technical requirements and other criteria considered by the establishment to be essential for the maintenance of acceptable quality, and

b. the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant patient/donor and procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.

T110 The following data must be registered at the centre:

a. consent including the purpose(s) for which the gametes and/or embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the consented purpose

b. patient/donor identification and characteristics: age, sex and presence of risk

c. all required records relating to the procurement and the taking of the patient/donor history

d. gametes and embryos obtained and relevant characteristics

e. the results of laboratory tests and of other tests, and

f. a properly documented review of the complete patient/donor evaluation against the selection criteria by an authorised and trained person.

15.10 In addition to the requirements in licence conditions, the documented procedures against which each consignment of gametes and embryos is verified should include requirements for:

(a) patient, patient's partner and donor verification
(b) packaging and transport
(c) labelling of containers for procured gametes, and
(d) labelling of shipping containers and any associated documents.

15.11 The documented procedure for the receipt of gametes or embryos from another centre should also ensure that records are kept to demonstrate that before gametes or embryos are released, all appropriate specifications have been met.

15.12 The centre's documented procedures should ensure that the relevant legal requirements are met for registering patients, patients' partners and donors.

Processing and disposal of gametes and embryos

Mandatory requirements

Licence conditions

T72 The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.

T73 Before implementing any significant change in processing, the modified process must be validated and documented.

15.13 The centre should take account of the special status of the human embryo when the development of an embryo is to be brought to an end. Terminating the development of embryos and disposing of the remaining material should be approached with appropriate sensitivity, having regard to the interests of the gamete providers and anyone for whose treatment the embryos were being kept.

See also

Guidance note 10 – Embryo testing and sex selection

Packaging, distribution and recall of gametes and embryos

Mandatory requirements

Licence conditions

T105 All gametes and embryos must be packaged and transported in a manner that minimises the risk of contamination and preserves the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.

T106 The packaged gametes/embryos must be shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos.

T107 The transport conditions, including temperature and time limit, must be specified and the labelling of every shipping container must include as a minimum:

a. a label marked “TISSUES AND CELLS” and “HANDLE WITH CARE”

b. the identification of the establishment from which the package is being transported (address and telephone number) and a contact person in the event of problems

c. the identification of the tissue establishment of destination (address and telephone number) and the person to be contacted to take delivery of the package

d. the date and time of the start of transportation

e. the type of gametes/embryos plus their identification code

f. specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos

g. specifications concerning storage conditions such as “DO NOT FREEZE”

h. in the case of all gametes and embryos, the following indication: “DO NOT IRRADIATE”,

and

i. when a product is known to be positive for a relevant infectious disease marker, the following indication: “BIOLOGICAL HAZARD”.

If any of the information under the points above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. The sheet must be packaged with the primary container in a manner that ensures that they remain together.

T108 The container/package must be secure and ensure that the gametes or embryos are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.

Interpretation of mandatory requirements 15C

When a third party transports gametes or embryos, they must be subject to a third party agreement, and a documented agreement must be in place to ensure that the required conditions are fulfilled.

The centre originating the distribution must have a recall procedure that defines the responsibilities and actions required when a distribution is recalled. Such a recall should be investigated using the procedure for investigating adverse incidents. There must be a procedure for handling returned gametes and embryos that includes their reacceptance into the inventory, if applicable.

15.14 If a container used to ship packaged gametes or embryos has not been validated by the manufacturer or supplier for specified transport conditions, these conditions should be monitored during transport, or validated by the centre or third party responsible for transport.

15.15 The centre’s documented procedures should ensure that the following are recorded:

(a) packaging and labelling procured gametes for distribution
(b) transporting gametes and embryos
(c) labelling shipping containers, and
(d) recalling gametes and embryos.

See also

Guidance note 24 – Third party agreements

Guidance note 27 – Adverse incidents

Quality and safety of gametes and embryos

Mandatory requirements

Licence conditions

T50 Prior to the processing of patient gametes or embryos, intended for use in treatment or

storage, the centre must:

a. carry out the following biological tests to assess the risk of cross contamination:

- HIV 1 and 2: Anti-HIV – 1, 2
- Hepatitis B: HBsAg and Anti-HBc
- Hepatitis C: Anti-HCV-Ab

b. devise a system of storage which clearly separates:

- quarantined/unscreened gametes and embryos,
- gametes and embryos which have tested negative, and
- gametes and embryos which have tested positive

c. perform HTLV- 1 antibody testing for patients living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas, and

d. in certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi) Positive results will not necessarily prevent the use of the partners' gametes.

T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:

a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and

b. blood samples must be obtained within a timeframe specified by the Authority.

Interpretation of mandatory requirements 15D

The law requires centres to obtain blood samples for HIV 1 and HIV 2, hepatitis B and hepatitis C screening from patients and their partners within three months before they first provide their gametes for use in treatment. Where the same person provides gametes for further treatment of their partner, the centre must obtain new blood samples within two years of the previous sampling. Patients who have screening tests at one licensed clinic and then move to another do not have to have repeat screening tests if within these timescales. However, individual clinics must decide whether the appropriate screening has taken place in the required timeframe. These screening requirements apply to individuals who provide gametes, or embryos created with their gametes, that will be processed or stored.

Where treatment involves the use of gametes, or embryos created with gametes, from two people who are not in an intimate physical relationship:

(a) the person providing the gametes to the woman being treated must be screened according to licence condition T52 on donor screening

(b) the centre, in discussion with the patient, should consider the merit of additional donor screening in line with guidance by professional bodies.

15.16 The centre should establish and use documented procedures to ensure that:

(a) procedures involving the manipulation of gametes or embryos (for example,

sperm preparation, separation of eggs from cumulus cells, and fertilisation of eggs) are performed in a controlled environment with appropriate air quality
(b) the risk of bacterial or other contamination is minimised
(c) appropriate measures are in place for handling contaminated samples
(d) gametes or embryos are handled in a way that protects those properties that are required for their ultimate clinical use
(e) where permitted, the mixture of gametes or embryos that have been subject to different laboratory procedures before transfer (eg, IVF and ICSI) is recorded and the reasons for their mixture are clearly set out, and
(f) all blood products with which gametes or embryos may come into contact, except those of the woman receiving treatment, are pre-tested for HIV, hepatitis B and hepatitis C.

15.17 If it is impractical to carry out a procedure involving the manipulation of gametes or embryos in a Grade C environment, it should be done in an environment of at least Grade D air quality. If the environmental air quality drops below Grade D during a procedure involving the manipulation of gametes or embryos, those gametes or embryos should be used in treatment only if the centre can assure itself that this poses no extra risk to the woman to be treated or to any resulting child.

15.18 Air quality monitoring should be used as a routine measure of quality assurance (for example, through particle counts or the use of settle plates, recording any cultures observed). The process of validating air quality should include:

(a) documenting culture conditions, and
(b) mapping temperature and using control charts to predict the effects of any change in procedures.

15.19 Where possible, cryopreserved gametes should be accompanied by documents that indicate their expected post-thaw quality.

15.20 The centre should not use for treatment gametes or embryos exposed to a material risk of contamination or damage that may harm recipients or resulting children. If in any doubt about these risks, the centre should seek expert advice.

Single European Code (SEC)

15.21 The EU Commission Directive 2004/23/EC sets out standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application. It also sets out that to facilitate traceability it is necessary to establish a unique identifier applied to tissues and cells (including reproductive cells) distributed in the EU (by way of a SEC) providing information on the main characteristics and properties of those tissues and cells.

15.22 The SEC is applied to the movement of donor gametes and embryos between licensed clinics (or tissue establishments) within and outside the UK. Movement of ‘partner’ embryos and gametes are exempt from the requirements.

15.23 A further exemption relates to where gametes and embryos are imported from a tissue establishment and not distributed thereafter (that is for use in that clinic). The SEC need not be applied in such cases.

15.24 The SEC is the unique identifier for tissues and cells distributed in the EU. It is made up of the following (six) features.

Donation identification sequence			**Product identification sequence**		
ISO Country code	Tissue Establishment code	Unique Donation Number	Product code	Split number	Expiry date
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
GB	**000123** HFEA Licensed Centre number	**00000000XX456** the Clinic's donor registration 'number' and a donation event-specific identifier, which together function as a unique donation number or code	**E0000059** 1 of 5 for reproductive cells (EUTC system) -Embryos (56) -Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	**001** If sperm, for example, is distributed to more than one TE	**20181231** Date of expiry of consent, for example, 31 December 2018
SEC GB00012300000000XX456 E000005900120181231					

15.25 There are three coding platforms permitted by the EU (and HFEA) one of which must be accessed to identify a product code.

1. The EU coding platform: https://webgate.ec.europa.eu/eucoding.
2. to ICCBBA ISBT128 https://www.iccbba.org (International Council for Commonality in Blood Banking Automation).
3. Eurocode international blood labelling system (IBLS) http://www.eurocode.org/.

15.26 Each coding platform provides tools to create a SEC. The EU coding platform contains detailed information on all Tissue Establishments in Europe in the Tissue Establishment compendium. If your clinic distributes embryos or gametes to a licensed clinic or tissue establishment, or similarly receives them, then you must access the EU coding platform to access the compendium.

15.27 The HFEA has a responsibility for ensuring the details of all UK HFEA licensed clinics on the compendium are current. We will do so further to changes we make to the Register of licensed clinics as part of our usual licensing activity.

15.28 We will check compliance at inspection, by sampling donor gamete and embryo movements into and out of the clinic to ensure the SEC has been applied appropriately.

15.29 Clinics identifying an error or change in relation to its details held on the EU Tissue Establishment compendium must notify their HFEA inspector as soon as practicable.

15.30 Clinics receiving gametes or embryos from a licensed clinic or tissue establishment without a SEC must note this is a serious adverse incident, and report it to the HFEA using the current incident reporting channel.

15.31 A licensed centre must notify the HFEA when:

(a) information about the centre which is contained in the EU Tissue Establishment Compendium requires and update or correction;

(b) the EU Tissue and Cell Product Compendium requires an update; or

(c) the licensed centre identifies a situation of significant non-compliance with requirements relating to the SERC concerning embryos and gametes received from other EU tissue establishments.

Other legislation, professional guidelines and information

Legislation

Commission Directive 2006/17/EC of 8 February 2006

Professional guidelines

British Fertility Society Policy and Practice Committee: Prevention of Ovarian Hyperstimulation Syndrome (2014)

Medicines and Healthcare Products Regulatory Agency: Good manufacturing practice and good distribution practice (2014)

Clinic Focus articles

Information on HTLV screening, issued in Clinic Focus (November 2010)

16. Imports and exports

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

24 Directions as to particular matters

(3) In relation to gametes or embryos that are not intended for human application, directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of gametes or embryos in the course of their carriage to or from any premises.

(3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage -

(a) between premises to which licences relate,

(b) between such premises and relevant third party premises,

(c) between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or

(d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state, pursuant to directions given under subsection (4), in such circumstances and subject to such conditions as may be specified in directions.

(3B) Directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of human admixed embryos in the course of their carriage to or from any premises.

(4) Directions may authorise any person to whom a licence applies to receive gametes, embryos or human admixed embryos from outside the United Kingdom or to send gametes, embryos or human admixed embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.

(4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to export from the United Kingdom to a third party country, gametes or embryos intended for human application, the Authority shall -

(a) include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such exports meet standards of quality and safety equivalent to those laid down in the Act, and

(b) have regard to ensuring traceability.

(4AA) Directions must, in accordance with paragraph 1 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make qualifying imports (other than a one-off import) must comply before the Authority gives any directions under subsection (4) authorising the person to make qualifying imports.

(4AB) Directions must, in accordance with paragraph 2 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make a qualifying import which is a one-off import must comply before the Authority gives any directions under subsection (4) authorising the person to make the import.

(4AC) In giving any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, the Authority must include the directions specified in paragraph 3 of Schedule 3AA.

(4AD) Where the Authority gives any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, it must provide that person with a certificate in the form set out in Annex II to the fourth Directive.

(4AE) In subsections (4AA) and (4AB) a reference to a one-off import, in relation to gametes or embryos, is to gametes or embryos imported for the purposes of providing services to a particular person or persons on one occasion only.

(4AF) In subsections (4AA) to (4AD) and Schedule 3AA "qualifying import" means the import into the United Kingdom from a third country of gametes or embryos intended for human application.

Directions

0005 – Collecting and recording information for the HFEA

0006 – Import and export of gametes and embryos

HFEA guidance

Registering patients and donors

Interpretation of mandatory requirements 16A

Where a centre wishes to import gametes or embryos into the UK, or export them from the UK, the person responsible must ensure that:

- a donor information form is completed in respect of any donated gametes, and
- where the gametes are exported or imported for the use of a patient, that the patient is registered with the HFEA, and the relevant registration forms are completed.

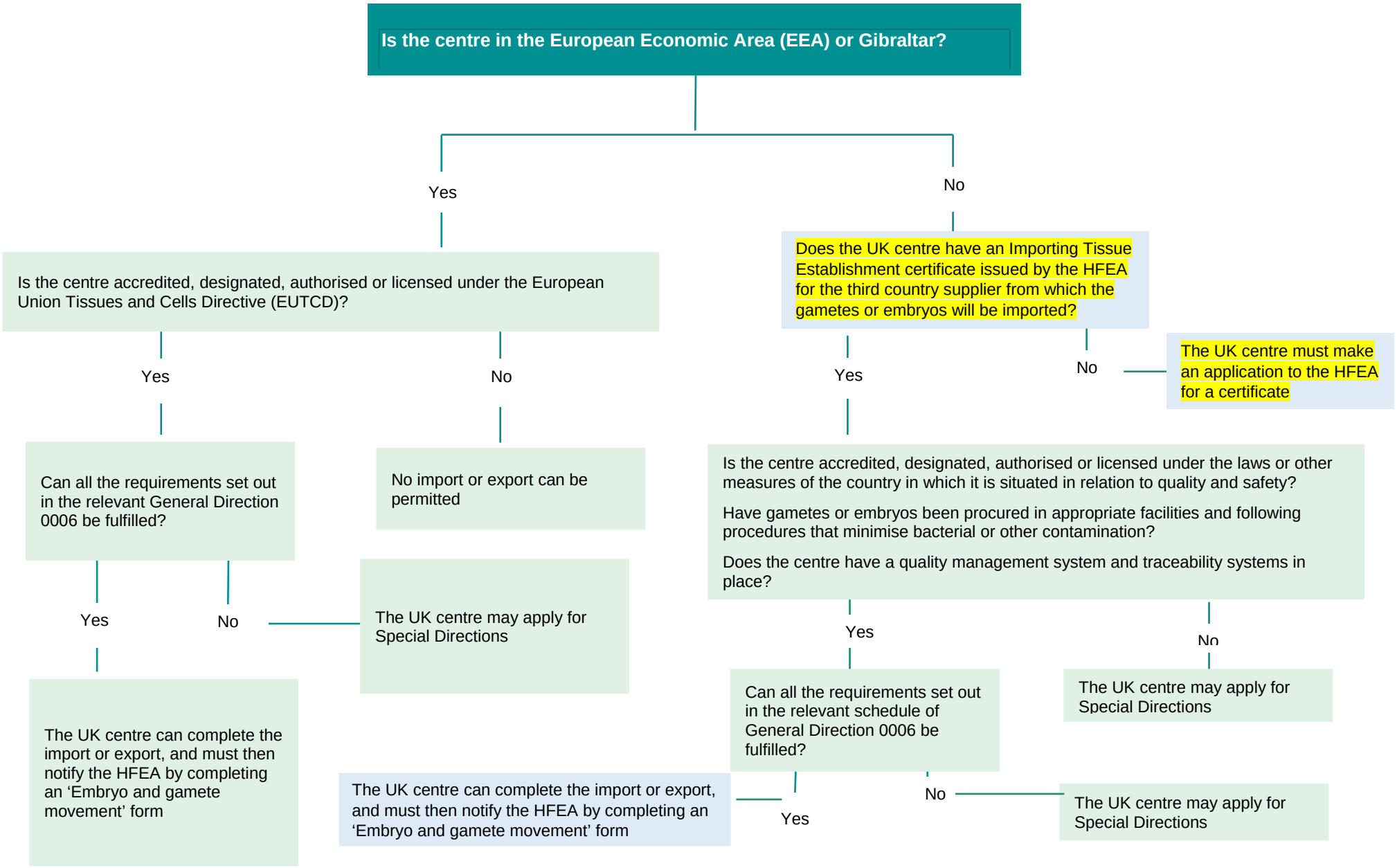
Information for patients and donors

16.1 Before a patient or donor considers obtaining gametes or embryos from outside the UK, the centre should inform them that special criteria relating to UK standards must be met.

Imports and exports decision tree

16.2 The decision tree on the following page summarises what centres must consider when transferring gametes and embryos:

(a) within the European Economic Area (EEA) and Gibraltar, or
(b) outside the EEA and Gibraltar.


Is the centre in the European Economic Area (EEA) or Gibraltar?
Yes
No
Is the centre accredited, designated, authorised or licensed under the European Union Tissues and Cells Directive (EUTCD)?
Does the UK centre have an Importing Tissue Establishment certificate issued by the HFEA for the third country supplier from which the gametes or embryos will be imported?
Yes
No
Yes
No
The UK centre must make an application to the HFEA for a certificate
Can all the requirements set out in the relevant General Direction 0006 be fulfilled?
No import or export can be permitted
Is the centre accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety?
Have gametes or embryos been procured in appropriate facilities and following procedures that minimise bacterial or other contamination?
Does the centre have a quality management system and traceability systems in place?
Yes
No
Yes
No
The UK centre may apply for Special Directions
The UK centre can complete the import or export, and must then notify the HFEA by completing an 'Embryo and gamete movement' form
Yes
No
Can all the requirements set out in the relevant schedule of General Direction 0006 be fulfilled?
The UK centre may apply for Special Directions
The UK centre can complete the import or export, and must then notify the HFEA by completing an 'Embryo and gamete movement' form
Yes
No
The UK centre may apply for Special Directions

General Directions: evidence of compliance

Interpretation of mandatory requirements 16B

(a) Within the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from another EEA state or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that the receiving or sending centre is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD).

(b) Outside the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from a country outside the EEA or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that:

(i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety

(ii) the centre has appropriate quality management and traceability systems, and

(iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination.

Where a centre wants to import from a third country supplier, the person responsible at the UK clinic must:

(i) ensure that, before undertaking any import from a third country supplier, the UK clinic has an Importing Tissue Establishment Certificate issued by the HFEA for the third country supplier it proposes to import from has a certificate

(ii) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety

(iii) provide the HFEA with the information specified in the relevant schedule to General Direction 0006 for ongoing imports

(iv) provide the HFEA with the documents specified in the relevant schedule to General Direction 0006 for one-off imports

(v) make available for inspection any documents specified in General Direction 0006

(vi) establish a written agreement with any proposed third country supplier that complies with the requirements set out in General Direction 0006.

When a certificate is issued to the Importing Tissue Establishment, the Person Responsible must:

(i) Seek written approval from the HFEA for any planned substantial changes to their import activities (i.e if it has previously only imported sperm and now wishes to import oocytes a written approval from the HFEA will be needed).

(ii) Inform the HFEA of their decision to cease their import activities in part or in full.

(iii) Inform the HFEA of any suspected or actual serious adverse events or reaction, reported to them by the third country supplier and which may influence the quality and safety of the tissues and cells they import.

(iv) Notify the HFEA of any revocation or suspension of a third country supplier's authorisation to export tissues and cells

(v) Notify the HFEA of any decision taken for reasons of non-compliance by the competent authority of the country that the third country supplier is based in where the quality and safety of imported tissues and cells are affected.

(vi) Notify the HFEA if a further import is anticipated for a couple on whose behalf a one-off import has previously been made whether by your clinic or any other clinic in the UK

In each case, a copy of the information retained must be provided to the Authority on request.

In all cases, all the remaining requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met.

No import of eggs or embryos that have undergone maternal spindle transfer (MST) or pronuclear transfer (PNT) is permitted to the UK.

16.3 The systems referred to in the interpretation box above should include the traceability of all materials and equipment that could affect the quality and safety of the gametes or embryos. For transfers to or from centres within the EEA and Gibraltar, this evidence may include documented certification from the competent authority that the centre complies with the requirements of the EUTCD, is included in a national database of registered tissue establishments, or both.

See also

Guidance note 19 – Traceability

Guidance note 31 – Record keeping and document control

Special Directions: imports or exports within the EEA and Gibraltar

16.4 An application to the HFEA for Special Directions should be made when patients wish to transfer gametes or embryos to or from an EEA centre that is accredited, designated, authorised or licensed in line with the EUTCD, but where compliance with other condition(s) in the relevant General Directions cannot be assured.

16.5 The HFEA has no power to issue Special Directions to allow imports to or exports from unaccredited tissue establishments within the EEA. Centres should tell patients that imports or exports of gametes or embryos are permitted only if the EEA centre has been accredited and licensed as complying with the requirements of the EUTCD.

Special Directions: imports or exports outside the EEA and Gibraltar

16.6 If compliance with all conditions in the relevant General Directions cannot be assured, then an application to the HFEA for Special Directions may be made

16.7 Before applying for Special Directions for the import of any gametes or embryos from a third country supplier, the UK clinic must ensure that it has an Importing Tissue Establishment Certificate issued by the HFEA for the third country supplier it proposes to import from.

See also

Special Direction – Export of Embryos form

Special Direction – Export of Gametes form

Special Direction – Import of Embryos form

Special Direction – Import of Gametes form

Notifying the HFEA about transfers

Interpretation of mandatory requirements 16C

When transferring gametes or embryos to or from the UK under General Directions, the centre must complete the relevant transfer notification form. In this form, the person responsible must declare that they are satisfied that the centre to or from which the transfer is being made meets the requirements listed in the Directions. Completed forms must be returned to the HFEA no later than 10 working days after the transfer has taken place.

When transferring gametes or embryos under Special Directions, the person responsible must notify the HFEA within two working days.

See also

Embryo and gamete movement – Out (GO) form

Embryo and gamete movement – In (GI) form

Other legislation, professional guidance and information

General information

For information on the relevant competent authorities in countries within the European Union, you may find the following links useful:

List of European Union (EU) and European Economic Area (EEA) countries

List of national competent authorities for tissues and cells within the EU and EEA

17. Storage of gametes and embryos

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

1 Meaning of "embryo", "gamete" and associated expressions

(4) In this Act (except in section 4A) -

(a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,

(b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and

(c) references to gametes are to be read accordingly.

3 Prohibitions in connection with embryos

(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except -

(a) in pursuance of a licence, or

(b) in the case of-

(i) the keeping, without storage, of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo in pursuance of a third party agreement.

in pursuance of a third party agreement.

(3) A licence cannot authorise -

…(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use

4 Prohibitions in connection with gametes

(1) No person shall -

(a) store any gametes…

except in pursuance of a licence.

(2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.

14 Conditions of storage licences

(1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos

(a) that gametes of a person shall be placed in storage only if -

(i) received from that person,

(ii) acquired in circumstances in which by virtue of paragraph 9 or 10 of Schedule 3 that person's consent to the storage is not required, or

(iii) acquired from a person to whom a licence or third party agreement applies,

(aa) that an embryo taken from a woman shall be placed in storage only if -

(i) received from that woman, or

(ii) acquired from a person to whom a licence or third party agreement applies,

(ab) that an embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence or third party agreement applies,

(ac) that a human admixed embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies,

(b) that gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies,

(ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,

(c) that no gametes, embryos or human admixed embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish, and

(d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.

(2) No information shall be removed from any records maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.

(3) The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.

(4) The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.

(4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.

(5) Regulations may provide that subsection (3), (4) or (4A) above shall have effect as if for ten years there were substituted -

(a) such shorter period, or

(b) in such circumstances as may be specified in the regulations, such longer period, as may be specified in the regulations.

14A Conditions of licences: human application

(1) This section applies to -

(a) every licence under paragraph 1 or 1A of Schedule 2,

(b) every licence under paragraph 2 of that Schedule, so far as authorising storage of gametes or embryos intended for human application, and

(c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.

(3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.

(4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.

41 Offences

(1) A person who -

(b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence, is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.

(2) A person who -

(a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,…

(b) keeps any gametes in contravention of section 4(1)(a) of this Act,…

is guilty of an offence.

Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc

Storage of gametes and embryos

8 (1) A person’s gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.

(2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

Cases where consent not required for storage

9 (1) The gametes of a person ("C") may be kept in storage without C's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -

(a) the treatment is likely to cause a significant impairment of C's fertility, and

(b) the storage of the gametes is in C's best interests.

(4) Condition C is that, at the time when the gametes are first stored, either -

(a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes -

(a) given consent under this Schedule to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications -

(a) for sub-paragraph (4), substitute -

"(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.", and

(b) in sub-paragraph (5), for "becoming competent to deal with the issue of consent to the storage of the gametes" substitute "acquiring such capacity".

10 (1) The gametes of a person ("P") may be kept in storage without P's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -

(a) the treatment is likely to cause a significant impairment of P's fertility,

(b) P lacks capacity to consent to the storage of the gametes,

(c) P is likely at some time to have that capacity, and

(d) the storage of the gametes is in P's best interests.

(4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.

(5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule -

(a) given consent to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.

(6) In relation to Scotland -

(a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,

(b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and

(c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.

11 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death

Regulations

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

Licence conditions

T50 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the centre must:

a. carry out the following biological tests to assess the risk of cross contamination:

- HIV 1 and 2: Anti-HIV – 1, 2
- Hepatitis B: HBsAg and Anti-HBc
- Hepatitis C: Anti-HCV-Ab

b. devise a system of storage which clearly separates:

- quarantined/unscreened gametes and embryos,
- gametes and embryos which have tested negative, and
- gametes and embryos which have tested positive.

c. perform HTLV- 1 antibody testing for patients living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas

d. in certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi)

Positive results will not necessarily prevent the use of the partners' gametes.

T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:

a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and

b. blood samples must be obtained within a timeframe specified by the Authority

T75 Centres must ensure that all storage processes are carried out under controlled conditions.

T76 Gametes of a person must be placed in storage only if -

a. received from that person,

b. acquired in circumstances in which by virtue of paragraph 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or

c. acquired from a person to whom a licence or third party agreement applies.

T77 Embryos taken from a woman must be placed in storage only if -

a. received from that woman, or

b. acquired from a person to whom a licence or third party agreement applies.

T78 Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.

T79 No gametes or embryos must be kept in storage for longer than the statutory storage period and, if stored at the end of the period, must be allowed to perish.

T80 The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.

T81 The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.

T82 Regulations may provide that licence conditions T80 and T81 must have effect as if for ten years there were substituted -

a. such shorter period, or

b. in such circumstances as may be specified in the relevant Regulations, such longer period, as may be specified in the relevant Regulations.

T83 Gametes or embryos which are or have been stored must not be supplied to a person otherwise than in the course of providing treatment services, unless that person is a person to whom a licence applies.

T85 A documented risk assessment must be undertaken to determine the fate of all stored gametes and embryos following the introduction of any new donor/patient selection or testing criterion or any significantly modified processing step that enhances safety or quality.

Directions

0007 – Consent

HFEA guidance

Facilities and documented procedures

17.1 The centre should establish documented procedures to ensure that all storage and handling of gametes and embryos comply with licence conditions, regulations, and relevant patient and donor consent.

17.2 The centre should ensure that the storage facilities for gametes and embryos:

(a) are dedicated for the purpose, and adequate for the volume and types of activities
(b) are designed to avoid proximity to ionising radiation (radioactive material), any known potential source of infection, or chemical or atmospheric contamination, and
(c) have a storage-location system that minimises the amount of handling required to retrieve gametes and embryos.

17.3 The centre should also have emergency procedures to deal with damage to storage vessels, failure of storage conditions or both.

17.4 The centre's documented procedures should also ensure that:

(a) gametes and embryos are stored under controlled conditions that are validated and monitored
(b) gametes and embryos are packaged for storage in a way that:

    (i) prevents any adverse effects on the material
    (ii) minimises the risk of contamination

(c) records are kept indicating every occasion when gametes and embryos are handled during storage and release, and by whom
(d) records are kept indicating that gametes and embryos meet requirements for safety and quality before release, and
(e) risk assessments (approved by the person responsible) are done to determine the fate of all stored material whenever any of the following is introduced:

    (i) a new donor selection criterion
    (ii) a new criterion for testing donors, patients' partners or patients
    (iii) a new processing step to enhance safety, quality or both
    (iv) a new procedure for appropriate disposal of gametes and embryos.

Safety of equipment used to store cryopreserved gametes and embryos

17.5 Centres should store gametes and embryos in a designated area. Access to this area should be limited to staff authorised under the terms of the centre's licence. Cryopreservation dewars should be fitted with local alarms and be linked to an auto-dial or similar facility, (eg, a link to a fire alarm board) to alert staff to non-conformities outside normal working hours.

17.6 The centre should have adequate staff and funding for an 'on-call' system for responding to alarms out of hours, and adequate spare storage capacity to enable transfer of samples if a dewar fails.

17.7 A centre storing gametes and/or embryos for patients whose future fertility may be impaired by a medical condition or procedure should divide individual patients' samples into separate storage vessels, in case of dewar failure.

See also

Guidance note 26 – Equipment and materials

Screening and storage of samples to prevent cross-contamination

Interpretation of mandatory requirements 17A

The law requires centres to obtain blood samples for HIV 1 and HIV 2, hepatitis B and hepatitis C screening from patients and their partners within three months before they first provide their gametes for use in treatment. Where the same person provides gametes for further treatment of their partner, the centre must obtain new blood samples within two years of the previous sampling. Patients who have screening tests at one licensed clinic and then move to another do not have to have repeat screening tests if within these timescales. However, individual clinics must decide whether the appropriate screening has taken place in the required timeframe. These screening requirements apply to individuals who provide gametes, or embryos created with their gametes, that will be processed or stored.

Where treatment involves the use of gametes, or embryos created with gametes, from two people who are not in an intimate physical relationship:

(a) the person providing the gametes to the woman being treated must be screened according to licence condition T52 on donor screening

(b) the centre, in discussion with the patient, should consider the merit of additional donor screening in line with guidance by professional bodies.

17.8 The centre should ensure that no gametes or embryos are placed in storage unless the people who provided the gametes have been screened in accordance with current recommended professional guidelines.

17.9 Centres should:

(a) assess the risks of cross-contamination during the quarantine period
(b) put procedures in place to minimise these risks, and
(c) document the rationale for the chosen quarantine procedures.

See also

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Guidance note 19 – Traceability

Guidance note 20 – Donor assisted conception

Storing ovarian and testicular tissue

Interpretation of mandatory requirements 17B

Ovarian and testicular tissue, as cells of the germ line, fall within the definition of gamete in the Human Fertilisation and Embryology Act 1990 (as amended) and so are subject to the same storage requirements as sperm and eggs.

HFEA-licensed clinics currently storing ovarian or testicular tissue can continue to do so without a licence from the Human Tissue Authority (HTA) until the tissue is to be used. If a patient's own tissue is to be transplanted (known as autologous transplant), it must be transferred at the time of use to an HTA-licensed facility for processing and/or distribution to the transplant facility. Details of HTA-licensed facilities are on the HTA website.

An HTA licence is not needed to store ovarian or testicular tissue intended for fertility treatment (eg, in vitro maturation of gametes). HFEA centres licensed to store gametes can store, process and use ovarian or testicular tissue to extract gametes for patients' own use in licensed fertility treatment, subject to the same conditions that apply to the use of sperm and eggs.

Storing gametes and embryos following mitochondrial donation

17.10 Only centres that are licensed to undertake mitochondrial donation can store gametes or embryos following maternal spindle transfer or pronuclear transfer.

Information for those seeking storage of gametes or embryos

17.11 If the treatment involves the creation of embryos in vitro, the centre should give people seeking treatment information about the availability of facilities for freezing embryos, and about the implications of storing and then using stored embryos.

17.12 When a centre enters into a contractual agreement with a patient regarding the practicalities of storage (eg, an agreement to pay storage fees or store whilst funding is available) the patient should be given enough information to understand the terms and conditions of the agreement and the steps the centre will take if these terms and conditions are broken. This agreement should be separate from the consent provided by the patient – see guidance note 5 – information for those seeking storage of gametes or embryos. Depending on the terms of the agreement, the centre should provide information about the circumstances in which the patient's gametes or embryos could be removed from storage before their consent expires. For example, that the centre may only continue to store the patient's gametes or embryos for the period specified in their consent if the patient, or their funding provider, continues to pay the storage fees.

17.13 If there is an intention to store gametes or embryos, or where this possibility arises during treatment, in addition to relevant information about treatment and donation, the centre should give those providing the gametes or embryos relevant information about:

(a) the possible deterioration or loss of viability of gametes or embryos as a result of storage, and the potential risk of cross-contamination between samples
(b) statutory storage periods for gametes and embryos which permit patients to store for a maximum of 10 years, and regulations for extending storage periods up to a maximum of 55 years. In the case of embryos, patients should also be given relevant information about the requirement for both gamete providers to consent to any extension of storage
(c) the likelihood of a live birth resulting from previously cryopreserved embryos or gametes, and

(d) screening tests to be done, the cost of these, the reason for them and the implications of the tests for the gamete providers.

Oncology patients and other patients requiring long-term storage should be given specific information tailored to their needs and circumstances. Where relevant, this should include information appropriate for children and young people. This information should include the options available if the patient dies and, in particular:

(i) the consequences for posthumous use in cases where they have not provided written consent to their gametes or embryos being used in the treatment of a named partner in the event of their death, and
(ii) the maximum storage period, subject to satisfying the regulations and the fact that gametes or embryos cannot be used posthumously for longer than the storage period to which the gamete provider has consented.

17.14 The centre should ensure that, before someone consents to gametes or embryos being stored, they are told:

(a) the options available if a person providing gametes or resulting embryos dies or becomes mentally incapacitated
(b) that it may be possible to register a deceased partner as the parent of a child resulting from treatment, and the conditions for doing so, and
(c) that it is unlawful to store embryos and gametes beyond the period of consent, the centre having a legal obligation to dispose of them once consent has expired.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Treatment using cryopreserved eggs or embryos

17.15 The centre should ensure that the following sets of eggs or embryos are only transferred during the same treatment cycle in exceptional circumstances, with an upper limit of 2% of all cases:

(a) fresh eggs and eggs that have been cryopreserved, or
(b) embryos that have been created using cryopreserved eggs, and embryos created using fresh eggs, or
(c) cryopreserved embryos that have been created using cryopreserved eggs and cryopreserved embryos that have been created using fresh eggs.

The circumstances justifying such a transfer should be specified in the patient's notes.

Consent to storage and cases where consent is not required for storage

Interpretation of mandatory requirements 17C

The law requires the centre to obtain written informed consent from a person before it stores their gametes or embryos created with their gametes.

The law allows gametes to be stored without consent if the conditions met in paragraph 9 or 10, and 11 of Schedule 3 of the HFE Act 1990 (as amended) are met.

Gametes stored following the application of these paragraphs may be used only if the person from whom they were collected gives written effective consent to their use (and has sufficient capacity and competence to do so).

In certain limited circumstances involving premature infertility, gametes and embryos can be stored beyond the statutory maximum storage period.

Gametes first placed in storage before 1 August 1991

Any gametes currently in storage which were originally placed into storage prior to 1 August 1991 i.e. prior to statutory regulation, can only continue to be stored if the original 10-year storage period was properly extended under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 (the 1991 Regulations) and has not expired. Any gametes in storage as at 31 July 2001 (10 years after the storage period was deemed to commence) and which were not eligible for extension of storage under the 1991 Regulations should have been allowed to perish. The Schedule to the 1991 Regulations sets out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period must be calculated from 1 August 1991.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage between 1 August 1991 and 1 October 2009

Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period ~~without the written consent of the gamete provider~~ if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied. The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period begins on the date that the gametes were stored. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

Embryos first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period but only if both people whose gametes were used to bring about the creation of the embryo confirm in writing that they have no objection to the extension (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are satisfied). The Schedule to these Regulations set out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage after 1 October 2009

Gametes or embryos first placed in storage after 1 October 2009 may continue to be stored beyond the statutory maximum storage period, to a maximum of 55 years, but only with the written consent of the gamete provider or the people whose gametes were used to bring about the creation of the embryo (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 Regulations') are satisfied). Gametes and embryos first stored

earlier than 1 October 2009 may be stored for an extended period under the 2009 Regulations but only where the gametes or embryos are either still within the statutory storage period, or are being stored subject to a lawfully extended period under the 1991 or 1996 Regulations respectively.

For guidance about steps to take when consent is not required, see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Extension of storage

Interpretation of mandatory requirements 17D

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 Regulations') allow gametes or embryos to be stored for longer than the

10-year standard storage period, up to a maximum of 55 years, provided that the conditions set out in those Regulations have been met.

There are two criteria that must be met; the first is that the relevant person(s) have provided written consent to the gametes or embryos being stored for longer than 10 years; and the second is that on any day within the relevant period a registered medical practitioner has given a written opinion that the person who provided the gametes, or in the case of embryos, one of the persons whose gametes were used to create the embryos, or the person to be treated, is prematurely infertile or likely to become prematurely infertile.

To meet the statutory requirements, the written consent to storage for a period of more than 10 years must be given before expiry of the original 10-year statutory storage period or, in the case of gametes or embryos which have already been stored pursuant to an extended period under the 2009 Regulations, before expiry of that extended period.

The written opinion on premature infertility must be provided by a medical practitioner who is registered with the General Medical Council and must be provided within 10 years from the date that the gametes or embryos were first placed in storage or, in the case of gametes or embryos which are being stored pursuant to an extended period under the 2009 Regulations, within 10 years of the date of the most recent medical opinion.

The statement from the medical practitioner must be renewed for every 10-year storage period beyond the initial statutory period.

17.16 The centre should inform patients wishing to store gametes or embryos for more than 10 years of criteria set out in the 2009 Regulations and how these must be satisfied. It is important that, in the case of patients who wish to store gametes or embryos for more than 10 years, centres take steps to satisfy the requirements of the 2009 Regulations before expiry of the patient's current storage period.

17.17 To satisfy the Regulations for extended storage periods, the centre should seek a written medical opinion to certify that one of the gamete providers, the woman who is to be treated with the gametes, or the person who the gametes or embryos have been allocated to, is prematurely

infertile or likely to become prematurely infertile. This medical opinion should be obtained before expiry of the current storage period and needs to come from a medical practitioner registered with the General Medical Council (GMC). A medical opinion from an overseas medical practitioner who is not registered with the GMC does not satisfy the requirements of the 2009 Regulations.

17.18 The centre should seek the written medical opinion on premature infertility whilst the gamete provider is alive. However, if the gamete provider (who has provided consent to extended storage) dies before a medical opinion is in place, the medical opinion may be sought after death based on evidence that the person would have satisfied the premature infertility criteria when they were alive. Although the medical opinion may be provided after the gamete provider's death, it must nevertheless be provided within the relevant period; that is within the 10-year statutory storage period, or in the case of gametes or embryos that are being stored pursuant to an extended period under the 2009 Regulations, within ten years of the most recent medical opinion.

17.19 Whether a person is or is likely to become prematurely infertile is a clinical judgment taking into account all relevant considerations and information known to the clinician at the time. A woman who has reached menopausal age will not however be considered prematurely infertile and similarly, a same-sex couple will not be considered prematurely infertile.

17.20 Provided the provisions of the 2009 Regulations have been met, the centre can store the gametes and embryos for a further 10 years from the date the criteria are met. The centre can extend the storage period by further 10-year periods (up to the maximum of 55 years) if it is shown at any time within each extended storage period that the criteria continue to be met.

Disputes involving the withdrawal of consent to storage

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc

4A (1) This paragraph applies where -

(a) a permitted embryo, the creation of which was brought about in vitro, is in storage,

(b) it was created for use in providing treatment services,

(c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation ("P") gives the person keeping the embryo notice withdrawing P's consent to the storage of the embryo, and

(d) the embryo was not to be used in providing treatment services to P alone.

(2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P's withdrawal of consent.

(3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.

(4) Storage of the embryo remains lawful until-

(a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or

(b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.

(5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.

Interpretation of mandatory requirements 17E

If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment (created from their gametes), the law requires the centre to take all reasonable steps to notify the intended recipient(s).

The law allows embryos to be stored for 12 months from the date that the centre receives written withdrawal of consent, or less if the centre receives written signed consent from all intended recipients for the embryos to be destroyed. This 12-month 'cooling off' period must not extend beyond the end of the period for which valid consent exists.

For guidance about the withdrawal of consent see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

HFEA consent forms

Storage review

17.21 The centre should establish documented procedures to ensure that:

(a) reviews of stored gametes and embryos are done at least once every two years to:

(i) reconcile the centre's records with material in storage
(ii) review the purpose and duration of storage, and
(iii) identify any action needed

(b) if the number of families created using gametes (or embryos created using donated gametes) from a particular donor has reached 10, those gametes or embryos are not used or distributed for use in further treatment.

See also

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 20 – Donor assisted conception

17.22 The centre should operate a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes or embryos in storage. The centre should ensure the bring-forward system links to clinical processes regarding extension of storage periods.

End of storage

Interpretation of mandatory requirements 17F

No centre may keep embryos or store gametes after the expiry of the statutory storage period, or after the end of any shorter period specified by the gamete provider(s). Storing embryos or gametes beyond the relevant period is a criminal offence, punishable by a prison sentence, fine or both.

17.23 The centre should make efforts to stay in contact with patients who have gametes or embryos in storage for their own treatment, and with any woman to be treated with stored gametes or embryos (where she is not a gamete provider.) The centre should also explain to gamete providers and current patients the importance of informing the centre of any change in their contact details, including that their gametes or embryos may be removed from storage if they do not keep their contact details up to date.

17.24 The centre should establish and use documented procedures to contact patients who have gametes or embryos in storage for their own treatment when the end of the permitted storage period is approaching but long enough in advance to allow the centre and patient to take any steps necessary to comply with the 2009 Regulations where extension of storage is an option for the patients. The centre should use all contact details available to them, including at least one written form of contact. Patients should be provided with information about the options available to them as the end of their permitted storage period approaches. They should be given enough notice to enable them to consider those options and to access appropriate advice. Options could include the donation of the gametes or embryos for research, training or for the treatment of others. If contact with the patient is not possible, the centre should record the steps it has taken in the patient's medical records.

Other legislation, professional guidelines and information

Professional guidelines

Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society and Royal College of Obstetricians and Gynaecologists: UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008)

Department of Health: Guidance on the microbiological safety of human organs (2011)

The Human Tissue Authority: The regulator for human tissue and organs

Clinic Focus articles

Information on HTLV screening, issued in Clinic Focus (November 2010)

18. Witnessing and assuring patient and donor identification

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Act guidance section

Licence conditions

T71 Centres must have in place robust and effective processes to ensure that no mismatches of gametes or embryos or identification errors occur. Centres must double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place. A record must be kept in each patient's/donor's medical record.

HFEA guidance

Witnessing clinical and laboratory procedures

18.1 Witnessing protocols should ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process to prevent any mismatches of gametes or embryos.

18.2 Centres are responsible for ensuring that witnessing protocols are relevant to their local systems and conditions, based on HFEA model protocols. Where appropriate, clinics may adapt HFEA model protocols to take into account their local systems.

See also

Relevant HFEA model protocols

18.3 Electronic systems such as barcoding and radio frequency identification (RFID) for assisted conception are appropriate, subject to a risk assessment as set out at 18.34–18.43.

18.4 Witnessing protocols should be followed when any of the following clinical or laboratory procedures take place:

(a) Collecting eggs

- Cross-check identifying information that the egg provider gives against patient records and laboratory data sheets, or cross-check information entered into the electronic system and the allocation of the barcode or RFID tag.
- Cross-check information marked on egg collection dishes against the patient's records. This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

(b) Collecting sperm

- Cross-check identifying information that the sperm provider gives patient against patient records, the laboratory data sheet and sperm receptacle, or cross-check information entered into the system and the allocation of the barcode or RFID tag.

(c) Preparing sperm

- Cross-check information on tubes against the patient records and information on the sperm receptacle (when the sperm sample is transferred onto a preparation column). This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

(d) Mixing sperm and eggs or injecting sperm into eggs

- Verify identifying information on the dishes and tubes and confirm that the sperm and eggs should be mixed or the sperm injected into eggs.

(e) Transferring gametes or embryos between tubes or dishes

- Cross-check information marked on dishes and tubes against the patient or donor records, and the information marked on the dishes and tubes that the gametes or embryos are being transferred from.

(f) Transferring embryos into a woman

- Cross-check identifying information that the patient provides against the patient records or the electronic system (or both) and the laboratory data sheet.
- Cross-check information marked on the embryo-transfer dish against the patient records.

(g) Inseminating a woman with sperm prepared in the laboratory

- Cross-check identifying information that the patient provides against the patient records, or cross-check information entered into the electronic system and the allocation of a barcode or RFID tag.
- Verify the sperm provider's identifying information in their records, the electronic system and on the sperm container, and confirm that this is the correct sperm provider.

(h) Placing gametes or embryos into cryopreservation

- Cross-check identifying information on the storage container against the patient or donor records and the information on the tube or dish that the gametes or embryos are being transferred from.

- Cross-check where in the dewar the gametes or embryos are placed.

(i) Removing gametes or embryos from cryopreservation

- Cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to remove.
- Cross-refer information from the storage container and the patient or donor records or their information on the electronic system against the thaw dish or tube (and, if applicable, attach a barcode or RFID tag to the thaw dish or tube).

(j) Disposing of gametes or embryos

- Cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to dispose of.

(k) Transporting gametes or embryos

- Cross-check information on the storage container against information in the patient records to check that these are the correct gametes or embryos to transport.
- Check that information on the storage container is correct.

(l) Transferring nuclear material from one egg/embryo to another, for the purposes of mitochondrial donation.

- Verify identifying information on the dishes and tubes and confirm that the nuclear material should be moved from one egg or embryo to another.

18.5 Each stage of the witnessing trail should check the patient's or donor's full name and their identifying code.

18.6 Centres performing embryo biopsy should have witnessing protocols in place to ensure that embryos and the material removed from them for analysis are labelled.

Keeping a record of witnessing

18.7 The checking of identifying samples, patients and donors, and the witnessing of these checks, should be recorded when the clinical and laboratory procedures take place. This means that embryologists performing procedures that need to be witnessed cannot work alone. In particular, when performing procedures that cannot be reversed (eg, thawing gametes or embryos, and mixing gametes), centres should ensure witnessing checks have taken place beforehand. This will ensure that the witnessing protocol has the maximum potential to identify errors in the treatment process at the time the procedures take place.

18.8 When a witnessing check takes place, a record should be made in the patient or donor notes stating:

(a) the witnessing check
(b) the date and time of the witnessing check
(c) the signature of the person doing the check, and
(d) the signature of the witness.

18.9 There should be a separate record of the name, job title and signature of everyone who carries out or witnesses laboratory and clinical procedures.

Witnessing training

18.10 Centres should have an induction programme for new staff to ensure they understand the principles of witnessing and follow the centre's protocols. Staff should receive refresher training as the centre decides is appropriate.

18.11 Staff should receive appropriate training if a new system for witnessing is introduced.

See also

Guidance note 2 – Staff

Appropriate person to witness

18.12 Centres should consider who is the most appropriate person to witness clinical and laboratory procedures. This will usually be someone who has completed the centre's training programme for new staff, and refresher training (as appropriate), to ensure they fully understand the principles of witnessing checks and follow the centre's protocols. For exceptions to this, refer to paragraphs 18.14 and 18.15.

18.13 At egg collection and embryo transfer, the appropriate person to witness is another embryologist, clinician or nurse.

18.14 At sperm collection, centres may consider the patient or donor to be the appropriate person to witness the cross-checking of their identifying information against their records, the laboratory data sheet and the sperm receptacle.

18.15 Insemination centres performing intrauterine insemination (IUI) with partner sperm may consider the patient to be the appropriate person to verify the sperm provider's details.

Interruptions and distractions in the clinic and laboratory

18.16 The centre should consider the implications of distractions in the clinic and laboratory, such as from phones and external noise, and ensure they are minimised.

18.17 When considering the protocol it uses for witnessing procedures, and the most appropriate person to witness checks, the centre may wish to take into account the implications of interruptions to the work of laboratory and clinical staff, particularly embryologists performing critical procedures. Interrupting and returning to a task is a common source of error.

Patient and donor identification

18.18 Centres should establish procedures to ensure patients, donors, and their gametes and embryos are accurately identified.

At the assessment stage, centres should use appropriate evidence to verify the identity of donors and self-referred patients seeking treatment (eg, passport or photocard driving licence).

18.19 When collecting eggs or sperm, transferring embryos and carrying out insemination, staff should ask patients and donors to give their own identifying information (full name and date of birth), rather than asking the donor or patient to confirm or reject information read out to them.

18.20 Centres should consider how patients and donors with disabilities or whose first language is not English will be asked to identify themselves. If possible, centres should provide an independent interpreter for patients and donors whose first language is not English.

18.21 Centres should ensure that each sample of gametes and embryos is uniquely identified. All samples of gametes and embryos should be labelled with at least the patient's or donor's full name and a further identifier. If, when using donor gametes, it is not possible to label the dishes or tubes with the donor name:

(a) the dishes or tubes should be labelled with the donor code to uniquely identify that donor, and
(b) the dishes or tubes should be labelled with the female patient's name and further identifier as soon as possible.

18.22 To uniquely identify each sample of gametes and embryos, centres should use the patient's or donor's full name and one or more of the following identifiers:

(a) the patient's or donor's date of birth
(b) hospital number
(c) NHS number/CHI (Community Health Index) number
(d) a donor code.

18.23 Centres should be aware that a patient's or donor's full name and one further identifier, such as date of birth, may not be uniquely identifying. If centres routinely use only these two identifiers, they should ensure they:

(a) have robust systems in place to identify when they have two patients with the same details
(b) take steps to be able to uniquely identify those samples.

Alternatively, centres may choose to use a patient's full name and two identifiers from the list in 18.22 to uniquely identify each sample.

18.24 Centres should consider the most appropriate way to label dishes or tubes when they are likely to be seen by the patient.

18.25 Centres should consider when to change the labelling from showing the donor's or male partner's identifying information to the female patient's identifying information. Centres may consider it appropriate to label all dishes and tubes with both partners' names and identifying codes throughout.

18.26 Centres should ensure that other patients' or donors' gametes or embryos are not introduced into the critical working area until the procedure is complete.

See also

Guidance note 19 – Traceability

Risk assessment

18.27 Centres should consider how this witnessing guidance applies to their local environment, and the risks involved with departing from the guidance.

18.28 Centres should conduct a formal risk assessment before introducing or changing witnessing protocols, or departing from HFEA guidance. In doing so, they may wish to consider:

(a) why they are making the change
(b) the impact of any error
(c) what barriers or safeguards are in place to avoid errors, and
(d) any risks in changing procedures, and how to reduce these.

Centres should monitor new protocols to ensure they are effective.

18.29 Centres should consider the integration of witnessing protocols into the whole laboratory and clinical process, and into risk-reduction procedures. They may wish to identify points at which mismatching of gametes and embryos is most likely to occur.

18.30 Centres should be aware of the risks associated with staff doing repetitive activities. The risk of mismatching gametes and embryos is higher when repetitive activities are taking place. Centres should bear this in mind when selecting the most appropriate person to witness procedures. Similarly, when using witnesses, centres should consider staff workload and hours, and should ensure staff take regular breaks.

18.31 Centres should have formal risk control measures to minimise the risk of writing incorrect or incomplete identifying data on patient records. There is a risk of error when copying details from sample containers and the patient records to other records. The risk is particularly high when a record sheet becomes separated from the patient records and is relied on during a witnessed step.

18.32 As part of a quality review, audits of the patient records should include checking for transcription errors (or omissions) in patient identifiers, such as the misspelling of names and the absence of unique identifiers on a record sheet, particularly in laboratory records.

18.33 Centres should check their compliance with witnessing protocols regularly, including during the audit of their quality management system.

See also

Guidance note 23 – The quality management system

Risk assessment: electronic witnessing systems

18.34 Before introducing new electronic systems or protocols for witnessing, centres should do a risk assessment covering the following:

(a) Centres should ensure that any system will not harm gametes and embryos. In establishing that this is the case, centres should consider what the supplier or manufacturer has done to satisfy itself that the system will not harm gametes and embryos (eg, commissioned independent reports or carried out irradiance readings)

(b) Centres should be aware that the reliability and safety of different electronic systems may vary
(c) Centres should evaluate the evidence that the supplier or manufacturer provides to support the safety and reliability of its system (eg, false positive and negative matches and breakdown), plus any other relevant studies.
(d) Any software should be fully tested, quality assured and risk assessed, and
(e) Centres should consider what the manufacturer has done to ensure that any labels and tags will continue to be effective when placed in long-term cryostorage.

18.35 Electronic systems rely on people entering accurate information. Centres should therefore consider how they can ensure the quality of information through system validation, staff training and audit.

18.36 Centres should be aware that although they cannot completely eliminate the potential for error in any electronic witnessing system, effective risk assessment should mitigate this.

18.37 Electronic systems record all errors that occur. The person operating the system must resolve any errors, and record an explanation or description of this before continuing with the procedure. Centres should review any mismatches that electronic systems have identified, and be able to show they have taken steps to avoid them in the future.

18.38 If centres use an electronic system (barcode or RFID) with 'forcing functions' (which prevent the user omitting key matching tasks in the process by preventing them from proceeding with subsequent task steps), then as part of their risk assessment they may wish to consider that manually witnessing transfer steps between containers is not necessary. This exemption should not apply however to mixing sperm and eggs; injecting sperm into eggs; and placing gametes or embryos into and removing them from cryopreservation.

18.39 Centres should consider any potential loopholes in the system that could allow users to circumvent key steps, thus negating safeguards against error. Centres should consider implementing a system that allocates a unique identifier to each system user.

18.40 Centres should not rely solely on electronic systems to check the identity of patients, donors and samples. Centres should follow protocols for witnessing in line with HFEA model protocols; these include several manual witnessing steps.

18.41 Centres should have procedures to ensure that all witnessing steps can still be done if the electronic system fails, and that witnessing staff maintain their manual witnessing skills for all critical steps.

18.42 In addition to using the electronic system of identification (information stored on barcodes or RFID tags), centres should continue to manually label all culture dishes, tubes and straws with the patient's full name and unique identifier. If the electronic identification fails (for example losing a barcode label or RFID tag from a sample), centres should revert to manual identification.

18.43 Centres should consider whether the barcode or RFID tags are suitable for use on storage containers (ie, are able to withstand long periods of cryopreservation).

Risk assessment: barcoding

18.44 Centres considering installing a barcode system should consider as part of their risk assessment:

(a) the type and power of light used in the barcode equipment
(b) the length of time the gametes and embryos are likely to be exposed to it, and
(c) whether exposure to this light is likely to harm the gametes and embryos.

18.45 Although there is substantial evidence about using barcodes with human tissue, as far as the HFEA is aware no independent studies have yet been done on the effect of light on human gametes and embryos. So the HFEA does not have enough evidence to consider barcoding to be risk free.

18.46 Barcoding equipment may use a range of light sources. The HFEA is aware of two types of barcoding systems marketed for use in assisted conception: those using white-light-emitting diodes and those using laser light.

18.47 Considering the evidence of damage to human cells from some powers of laser light, centres must weigh up the degree of possible risk of using laser light barcoding systems. Centres should only consider using class 1 or 2 lasers.

18.48 Barcode equipment that uses ultraviolet or infrared light should not be used. These sources of radiation are known to heat, and so potentially damage, human cells.

Risk assessment: radio frequency identification systems

18.49 Centres considering installing an RFID system should, as part of their risk assessment, consider the frequency of the radio waves used in the RFID system and whether exposure to them is likely to harm gametes and embryos. Centres should be aware that detectable changes in temperature may result in DNA damage. Centres should do this risk assessment in the context of other risk factors in the centre and the environment (eg, mobile phone signals).

18.50 Although there is evidence for the use of RFID in a medical setting, as far as the HFEA is aware no independent studies have yet been done on the effect of electromagnetic radiation on human gametes and embryos. So there is not yet a compelling evidence base to enable the HFEA to consider RFID systems to be risk free.

Establishing, maintaining and documenting the quality management system

18.51 Centres should identify and evaluate risks and the impact of work processes. Any potential failures that may affect patient safety should be taken into account. A risk should be:

(a) adequately identified
(b) assessed
(c) entered into a risk register
(d) maintained and reviewed in accordance with the level of risk identified
(e) all decisions and actions in response to a risk should be adequately documented
(f) written documentation should be available to support and oversee the process.

Other legislation, professional guidelines and information

Clinic Focus articles

Clinic Focus article: Witnessing guidance clarification (September 2013)

19. Traceability

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

2 Other terms

(1) "traceability" means the ability -

(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,

(b) identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and

(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

12 General Conditions

(3) It shall be a condition of every licence to which this subsection applies that -

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

Schedule 3A

Traceability and coding system

1 Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure -

(a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive, and

(b) in relation to the coding of information, compliance with the requirements of Article 25 (coding of information) of the first Directive and Article 10 (European coding system) of the third Directive.

2 Licence conditions imposed in accordance with paragraph 1 may specify the coding system which must be applied in relation to gametes and embryos intended for human application.

Licence conditions

T99 The centre must establish, implement and comply with documented procedures to ensure that:

a. all gametes and embryos, and

b. all relevant data relating to anything coming into contact with those gametes or embryos

are traceable from procurement of gametes to patient treatment or disposal and vice versa.

T100 The documented procedures referred to in licence condition T99 include the following information:

a. the unique and accurate identification of each patient/donor

b. the unique and accurate identification of each set of gametes and embryos

c. date of procurement

d. place of procurement

e. type of treatment

f. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and

g. description of all processing steps applied to the procurement, use and storage of gametes and embryos.

T101 The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.

T102 The centre must record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.

T103 The centre must keep data necessary to ensure traceability for a minimum of thirty years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium.

T104 Records not covered by licence condition T103 and test results that impact on the safety and quality of the embryos and gametes, must be kept so as to ensure access to the data for at least 10 years after the expiry date, clinical use or disposal.

HFEA guidance

Traceability requirements

19.1 Procedures for ensuring traceability of gametes and embryos should be documented. Centres should ensure that:

(a) they uniquely and accurately identify:

(i) the patient
(ii) the patient's partner, donor or both, as applicable
(iii) gametes and embryos, and
(iv) any containers used for the receipt and distribution of gametes and embryos.

(b) quarantined, non-quarantined and rejected material is clearly distinguishable at all processing stages.
(c) they keep records of the equipment and materials used to receive, process, store and discard gametes and embryos
(d) they keep registers of received, processed, stored, distributed and discarded gametes or embryos. Registers should enable a centre to investigate adequately if a problem is identified after the gametes have been used. Registers should also enable the centre to identify:

(i) a patient, patient's partner or donor
(ii) processing steps applied to gametes or embryos (or both) and, if applicable, third parties involved in processing
(iii) individual procurement of gametes and embryos
(iv) the institution from which gametes and embryos have come
(v) distributed gametes or embryos, and
(vi) the institutions to which gametes or embryos have been sent (whether for a patient's use or for research).

19.2 For the system of identification, centres should use an identifying code that contains at least the following information:

(a) for donors:

(i) their identity, and
(ii) the centre's identity.

(b) for gametes and embryos:

i) a unique code
ii) split number (if applicable), and
iii) end of statutory storage period.

19.3 The centre's traceability procedures should cover any materials or equipment that could affect the quality or safety of gametes and embryos, for example:

(a) culture media
(b) serial numbers or batch numbers of equipment and materials coming into contact with gametes and embryos, and
(c) records of the monitoring and maintenance of the required conditions in incubators and storage tanks.

See also

Guidance note 26 – Equipment and materials

19.4 For gametes that have been stored at the centre (eg, for oncology or pre-vasectomy patients) and then supplied to another centre (eg, to be stored or used in treatment), the centre will not be expected to hold traceability data for subsequent processes involving those gametes outside the centre. However, the storing centre's record keeping procedures should show a link to the centre to which the gametes are supplied, so that the complete process from procurement to use or disposal can be traced if needed.

Single European Code (SEC)

19.5. For details on the SEC, please see Guidance Note 15.

20. Donor assisted conception

Version1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Conditions of licences for treatment

13 (6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about -

(a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and

(b) suitable methods of informing such a child of that fact.

13 (13) The person responsible shall comply with any requirement imposed on that person by section 31ZD.

31ZA Request for information as to genetic parentage or mitochondrial donors etc.

(1) A person who has attained the age of 16 ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2) or (2A).

(2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person (“the donor”) other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that -

(a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information), or

(b) stating whether or not that information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so -

(i) the number of those other persons,

(ii) the sex of each of them, and

(iii) the year of birth of each of them.

(2A) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person is the applicant’s mitochondrial donor, and if it does show that, giving the applicant the following information contained in the register —

(a) the screening tests carried out on the mitochondrial donor and information on that

donor's personal and family medical history,

(b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and

(c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person who requests information under this section, but not giving any information which may identify the mitochondrial donor or any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor, by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.

(3) The Authority shall comply with a request under subsection (2) if--

(a) the information contained in the register shows that the applicant is a relevant individual, and

(b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(3A) The Authority must comply with a request under subsection (2A) if—

(a) the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, and

(b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

31ZB Request for information as to intended spouse etc.

(1) Subject to subsection (4), a person ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2).

(2) The applicant may request the Authority to give the applicant notice stating whether or not information contained in the register shows that, but for the relevant statutory provisions, the applicant would or might be related to a person specified in the request ("the specified person") as -

(a) a person whom the applicant proposes to marry,

(b) a person with whom the applicant proposes to enter into a civil partnership, or

(c) a person with whom the applicant is in an intimate physical relationship or with whom the applicant proposes to enter into an intimate physical relationship.

(3) Subject to subsection (5), the Authority shall comply with a request under subsection (2) if -

(a) the information contained in the register shows that the applicant is a relevant individual,

(b) the Authority receives notice in writing from the specified person consenting to the request being made and that notice has not been withdrawn, and

(c) the applicant and the specified person have each been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(4) A request may not be made under subsection (2)(c) by a person who has not attained the age of 16.

(5) Where a request is made under subsection (2)(c) and the specified person has not attained the age of 16 when the applicant gives notice to the Authority under subsection

(1), the Authority must not comply with the request.

(6A) For the purposes of this section, in a case where the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, the applicant is not a person who, but for the relevant statutory provisions, would or might be related to—

(a) the applicant's mitochondrial donor, or

(b) any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor.

31ZD Provision to donor of information about resulting children

(3) The donor may by notice request the appropriate person to give the donor notice stating -

(a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,

(ab) the number of persons in respect of whom the donor is a mitochondrial donor,

(b) the sex of each of those persons, and

(c) the year of birth of each of those persons.

(4) Subject to subsections (5) and (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.

(5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify the persons falling within paragraphs (a) to (c) of subsection (3).

31ZE Provision of information about donor-conceived genetic siblings

(1) For the purposes of this section two relevant individuals are donor-conceived genetic siblings of each other if a person ("the donor") who is not the parent of either of them would or might, but for the relevant statutory provisions, be the parent of both of them.

(1A) Subsection (1B) applies in respect of a mitochondrial donor-conceived person ("P") and P's mitochondrial donor ("D").

(1B) For the purposes of this section, D is not a person who would or might, but for the relevant statutory provisions, be the parent of P.

(2) Where -

(a) the information on the register shows that a relevant individual ("A") is the donor-conceived genetic sibling of another relevant individual ("B"),

(b) A has provided information to the Authority ("the agreed information") which consists of or includes information which enables A to be identified with the request that it should be disclosed to –

(i) any donor-conceived genetic sibling of A, or

(ii) such siblings of A of a specified description which includes B, and

(c) the conditions in subsection (3) are satisfied, then, subject to subsection (4), the Authority shall disclose the agreed information to B.

(3) The conditions referred to in subsection (2)(c) are –

(a) that each of A and B has attained the age of 18,

(b) that B had requested the disclosure to B of information about any donor-conceived genetic sibling of B, and

(c) that each of A and B has been given a suitable opportunity to receive proper counselling about the implications of disclosure under subsection (2).

(4) The Authority need not disclose any information under subsection (2) if it considers that the disclosure of information will lead to A or B identifying the donor unless -

(a) the donor has consented to the donor's identity being disclosed to A or B, or

(b) were A or B to make a request under section 31ZA(2)(a), the Authority would be required by regulations under that provision to give A or B information which would identify the donor.

Regulations

The Human Fertilisation and Embryology Authority (Disclosure of Information) Regulations 2004

Information that the Authority is required to give

2 (1) Subject to paragraph (4), the information contained in the register which the Authority is required to give an applicant by virtue of section 31(4)(a) of the Act is any information to which paragraph (2) or (3) applies.

(2) This paragraph applies to information as to -

(a) the sex, height, weight, ethnic group, eye colour, hair colour, skin colour, year of birth, country of birth and marital status of the donor;

(b) whether the donor was adopted;

(c) the ethnic group or groups of the donor's parents;

(d) the screening tests carried out on the donor and information on his personal and family medical history;

(e) where the donor has a child, the sex of that child and where the donor has children, the number of those children and the sex of each of them;

(f) the donor's religion, occupation, interests and skills and why the donor provided sperm, eggs or embryos;

(g) matters contained in any description of himself as a person which the donor has provided;

(h) any additional matter which the donor has provided with the intention that it be made available to an applicant;

but does not include information which may identify the donor by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.

(3) This paragraph applies to information from which the donor may be identified which he provides after 31st March 2005 to a person to whom a licence applies, being information as to -

(a) any matter specified in sub-paragraphs (a) to (h) of paragraph (2);

(b) the surname and each forename of the donor and, if different, the surname and each forename of the donor used for the registration of his birth;

(c) the date of birth of the donor and the town or district in which he was born;

(d) the appearance of the donor;

(e) the last known postal address of the donor.

(4) The information which the Authority is required to give to the applicant does not include any information which at the time of his request the applicant indicates that he does not wish to receive.

Licence conditions

T54 Gametes from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

a. The gametes were supplied to the centre before 1 April 2005; and

b. The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the gametes before 1 April 2006; and

c. The gametes are to be used to create a genetically related sibling for that child

Embryos from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

a. The embryos were created before 1 April 2005; and

b. The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the embryos before 1 April 2006; and

c. The embryo is to be used to create a genetically related sibling for that child

Embryos which were created before 1 April 2006, and which were created using the gametes of the woman to be treated (or the person that she is being treated with) and the gametes of a non-identifiable donor, may continue to be used in treatment (regardless of whether or not there are any existing genetically related siblings).

HFEA guidance

Information for people seeking treatment with donated gametes and embryos

20.1 The centre should give people seeking treatment with donated gametes or embryos:

(a) non-identifying information about donors whose gametes are available to them, including the goodwill message and the pen-portrait (if available),
(b) information about genetic inheritance and, in particular, the likelihood of inheriting physical characteristics from the donor, and
(c) information about the age of the donor and the associated risk of miscarriage and chromosomal abnormalities.

See also

Guidance note 4 – Information to be provided prior to consent

20.2 The centre should provide information to people seeking treatment with donated gametes or embryos about legal parenthood, and the collection and provision of information, specifically:

(a) who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation (nationals or residents of other countries, or anyone treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the UK)
(b) information that centres must collect and register with the HFEA about the donors
(c) what information may be disclosed to people born as a result of donation and in what circumstances, and
(d) a donor-conceived person's right to access:

(i) anonymous information about the donor and any donor-conceived genetic siblings, from the age of 16
(ii) identifying information about the donor (where applicable), from the age of 18
(iii) identifying information about donor-conceived genetic siblings, with mutual consent, from the age of 18
(iv) information about the possibility of being related to the person they intend to marry or enter into a civil partnership with, at any age, and
(v) information about the possibility of being related to the person they intend to enter into an intimate physical relationship with, from the age of 16.

20.3 The centre should give people seeking treatment with donated gametes or embryos information about genetic and other screening of people providing gametes. This information should include details about:

(a) the sensitivity and suitability of the tests, and
(b) the possibility that a screened provider of gametes may be a carrier of a genetic disease or infection.
(c) in the case of fresh egg donation, the screening requirement of the donor and the risk of infection for the recipient

20.4 The centre should provide information that explains the limitations of testing procedures and the risks of treatment to anyone seeking treatment with donated gametes or embryos. The centre should make available appropriate counselling.

See also

Guidance note 3 – Counselling

20.5 If a woman is to receive donor insemination treatment, then, before treatment commences, the centre should discuss with her the number of treatment cycles to be attempted if she does not conceive initially. The centre and the woman should together review this situation regularly.

20.6 Women should not be treated with gametes, or with embryos derived from gametes, of more than one man or more than one woman during any treatment cycle (except for in treatment involving mitochondrial donation where embryos are created using gametes of two women and one man).

The importance of informing children of their donor origins

Interpretation of mandatory requirements 20A

The centre must give patients seeking treatment with donor gametes and embryos information about the importance of telling any resultant children, at an early age, of their donor-conceived origins. The centre must also give patients information on suitable methods of informing children of their donor-conceived origins.

20.7 The centre should tell people who seek treatment with donated gametes or embryos that it is best for any resulting child to be told about their origin early in childhood. There is evidence that finding out suddenly, later in life, about donor origins can be emotionally damaging to children and to family relations.

20.8 The centre should encourage and prepare patients to be open with their children from an early age about how they were conceived. The centre should give patients information about how counselling may allow them to explore the implications of treatment, in particular how information may be shared with any resultant children.

Implications of donor conception and the provision of counselling

20.9 If it is possible that the question of treatment with donated gametes or embryos may arise, the centre should raise this with the person or couple seeking treatment before their treatment starts. The centre should allow people enough time to consider the implications of using donated gametes or embryos, and to receive counselling before giving consent.

See also

Guidance note 3 – Counselling

Access to information for donors, donor-conceived people and parents

Interpretation of mandatory requirements 20B

A donor may request information from a centre as to the number, sex, and birth year of any children born by means of their gametes or embryos (including mitochondrial donation). If the centre holds that information, it must provide it, unless the person responsible considers that special circumstances increase the likelihood of the donor being able to identify any of those children.

20.10 The centre should inform people seeking treatment with donated gametes or embryos (including mitochondrial donation) that the donor will be able to request the following information about any children born as a result of their donated gametes or embryos:

(a) the number of children born
(b) their sex, and
(c) their year of birth.

20.11 The centre should inform people seeking treatment with donated gametes or embryos that any resulting children will have access to the following non-identifying information about the donor (if the donor has provided it) from the age of 16:

(a) physical description (height, weight, and eye, hair and skin colours)
(b) year and country of birth
(c) ethnic group
(d) whether the donor had any genetic children when they registered, and the number and sex of those children
(e) other details the donor may have chosen to supply (eg, occupation, religion and interests)
(f) the ethnic group(s) of the donor's parents
(g) whether the donor was adopted or donor conceived (if they are aware of this)
(h) marital status (at the time of donation)
(i) details of any screening tests and medical history
(j) skills
(k) reason for donating
(l) a goodwill message, and
(m) a description of themselves as a person (pen portrait)

20.12 The centre should inform people seeking treatment with gametes or embryos donated after 31 March 2005, or with those donated before this date by a donor who subsequently re-registered as identifiable, that any children born as a result of the donation will have access to the following identifying information about the donor, from the age of 18:

(a) full names (and any previous names)
(b) date of birth, and town or district where born, and
(c) last known postal address (or address at time of registration).

20.13 The centre should inform people seeking treatment with donated gametes or embryos that, once they give birth to a child as a result of that donation, they will be entitled to access:

(a) all non-identifying information about the donor.
(b) information about the number, sex and year of birth of their children's genetically related donor-conceived siblings.

It is recommended that this information is shared with the child born as a result of donation. If the centre is unable to provide this information, it should direct parents to the HFEA.

20.14 Centres should inform parents seeking information about their child's donor or genetically related donor-conceived siblings that they may find counselling, or similar support services, on the implications of receiving such information helpful.

Other legislation, professional guidelines and information

Professional guidelines

British Infertility Counselling Association: Guidelines for good practice in infertility counselling (third edition, 2012)

Royal College of Obstetricians and Gynaecologists: Reproductive ageing (Scientific Impact Paper No. 24) (2011)

Other information

Donor Conception Network: provides information to parents on how to tell children of their donor-conceived origins

21. Intra-cytoplasmic sperm injection (ICSI)

Version 1.0

HFEA guidance

Information for people seeking treatment with ICSI

21.1 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, specific information about the risks of ICSI which might lead to:

(a) a reduced number of eggs being available for treatment (compared to IVF), due to eggs being immature or damaged by the process of ICSI
(b) children conceived having inherited genetic, epigenetic or chromosomal abnormalities (including cystic fibrosis gene mutations, imprinting disorders, sex chromosome defects and heritable sub-fertility).

21.2 Where appropriate, centres should also provide patients with information about the possibility of genetic testing of the male partner.

See also

Guidance note 4 – Information to be provided prior to consent

The use of ICSI

21.3 The centre's clinical protocols should set out when ICSI can be used. The reasons for using ICSI in any particular case should be explained in the patient's medical records.

21.4 With respect to any ICSI programme, the centre should ensure that:

(a) ICSI and other embryos are transferred during the same treatment cycle only in exceptional circumstances, with an upper limit of 2% of all ICSI embryo transfers,
(b) the circumstances justifying such a transfer are specified in the patient's notes, and
(c) eggs that have failed to fertilise by normal IVF or ICSI are not re-inseminated by any means.

Other legislation, professional guidelines and information

Professional guidelines

Association of Clinical Embryologists: Guidelines on good practice in clinical embryology laboratories (2012)

22. Research and training

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

3 Prohibitions in connection with embryos

(2) No person shall place in a woman -

(a) an embryo other than a permitted embryo (as defined by section 3ZA), or

(b) any gametes other than permitted eggs or permitted sperm (as so defined).

(3) A licence cannot authorise -

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal, or

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use.

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day on which the process of creating the embryo began, not counting any time during which the embryo is stored.

4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman -

(a) a human admixed embryo,

(b) any other embryo that is not a human embryo, or

(c) any gametes other than human gametes.

14 Conditions of licences for treatment

(12) No embryo appropriated for the purpose mentioned in paragraph 1(1)ca of Schedule 2 (training in embryological techniques) shall be kept or used for the provision of treatment services.

15 Conditions of research licences

(1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.

(2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.

(3) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.

(4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

12 General conditions

(1) The following shall be conditions of every licence granted under this Act -

(a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,

41 Offences

(1) A person who -

(a) contravenes section 3(2), 3A or 4A(1) of this Act, or

(b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,

is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.

(2) A person who -

(a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something, which by virtue of section 3(3) of this Act, cannot be authorised by a licence

…

is guilty of an offence.

Schedule 2

Licences for treatment

1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –

(ca) using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques,

Licences for research

3 (1) A licence under this paragraph may authorise any of the following -

(a) bringing about the creation of embryos in vitro, and

(b) keeping or using embryos,

for the purposes of a project of research specified in the licence.

(2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in Directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.

(3) A licence under this paragraph may authorise any of the following -

(a) bringing about the creation of human admixed embryos in vitro, and

(b) keeping or using human admixed embryos,

for the purposes of a project of research specified in the licence.

(4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).

(5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

(6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.

(7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.

(8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.

(9) This paragraph has effect subject to paragraph 3A.

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority -

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are -

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos.

General

4 (1) A licence under this Schedule can only authorise activities to be carried on -

(a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises, and

(b) under the supervision of an individual designated in the licence.

(1A) A licence which authorises activities falling within paragraph 1 or 1A above may not also authorise activities falling within paragraph 3 above.

(2) A licence cannot -

(a) authorise activities falling within both paragraph 1 [Licenses for treatment] and paragraph 3 above,

(b) apply to more than one project of research,

(c) authorise activities to be carried on under the supervision of more than one individual, or

(d) apply to premises of the person who holds the licence in different places.

Schedule 3

Consent

2 (1) A consent to the use of any embryo must specify one or more of the following purposes -

…

(ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or

(c) use for the purposes of any project of research,

and may specify conditions subject to which the embryo may be so used.

Variation and withdrawal of consent

4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

(1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “egg A” and “egg B” have the same meanings in this paragraph as in that regulation).

(1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

(2) Subject to sub-paragraphs (3) to (3B), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used -

(aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or

(b) for the purposes of any project of research.

(3) Where the terms of any consent to the use of an embryo (“embryo A”) include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

(3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “embryo A” and “embryo B” have the same meanings in sub-paragraph (3B) as in that regulation).

(3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A…

In vitro fertilisation and subsequent use of embryos

6 (1) A person's gametes or human cells must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for one or more of the purposes mentioned in paragraph 2(1) … (c) above.

(2) An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) … (ba) and (c) above of the embryo.

(3) An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each relevant person in relation to the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

Embryos obtained by lavage etc.

7 (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.

(2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.

(4) An embryo taken from a woman must not be used to bring about the creation of any embryo in vitro or any human admixed embryo in vitro.

Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 2009

Licence conditions

R18 The provisions of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) must be complied with (relating to consent to the use of embryos and human admixed embryos and for the storage of gametes, embryos and human admixed embryos for use in research).

R19 Prior to giving consent, persons providing gametes or human cells must be provided with the necessary information including:

a. the nature of the research project

b. that the decision whether to donate will not affect their treatment in any way

c. that they can vary or withdraw the terms of their consent until the point the embryos or human admixed embryos are used in the project of research

d. whether the embryos or human admixed embryos will be reversibly or irreversibly anonymised, and the implications of this

e. whether any information will be fed back to the them, and

f. how the research is funded, including any benefit which will accrue to the researchers and/or their departments.

R20 Prior to giving consent persons providing gametes or human cells for use in research that involves the derivation of embryonic stem cells/lines, must be provided with the following additional information:

a. that once an embryo or human admixed embryo has been used in the project of research they will have no control over any future use of the embryonic cells or any stem cells derived

b. that any stem cells/lines created may continue indefinitely and be used in many different research projects and/or clinical therapy

c. that stem cells derived in this research project will be deposited in the UK Stem Cell Bank and the implications of this including that they may be available to other research groups nationally or internationally

d. that the stem cells/lines may be used for commercial purposes, but that they will not benefit financially from this, and

e. that any stem cells/lines derived or discoveries made using them, could be patented, but that they will not benefit financially from this.

R21 The information referred to in licence conditions R19 and R20 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes or human cells.

R22 The centre must ensure that a designated individual, who is not directly involved in the patient's treatment is available to discuss with the patient the project of research and the possibility of donating material to the project.

R23 No embryo/human admixed embryo obtained for the purposes of any research project may be kept or used for any purpose other than the purposes of that research project.

R24 No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions.

R26 Each embryo or human admixed embryo must be uniquely labelled in accordance with any directions and/or guidance issued by the Authority.

R27 The centre must establish, implement and comply with documented procedures to ensure that clinical and research roles are separated.

R28 The centre must establish, implement and comply with documented procedures to ensure that embryos or human admixed embryos do not develop after 14 days or the primitive streak has appeared (if earlier).

R29 If embryos or human admixed embryos have been created using human cells that have been stored before 1 October 2009 then the centre must take steps to ensure that the embryos or human admixed embryos cannot subsequently be attributed to the person whose cells were so used.

R31 Gametes of a person must only be placed in storage (for use in licensed research) only if

a. received from that person

b. acquired in circumstances in which by virtue of paragraphs 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or

c. acquired from a person to whom a licence or third party agreement applies.

R32 Embryos taken from a woman must be placed in storage only if –

a. received from that woman, or

b. acquired from a person to whom a licence or third party agreement applies.

R33 Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.

R34 Human admixed embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 to the Human Fertilisation and Embryology Act 1990 (as amended) applies.

R35 The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.

R36 The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.

R37 The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.

R38 Regulations may provide that licence conditions R35, R36 and R37 must have effect as if for ten years there were substituted -

a. such shorter period, or

b. in such circumstances as may be specified in the relevant Regulations, such longer period, as may be specified in the relevant Regulations.

R39 No gametes, embryos or human admixed embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, must be allowed to perish.

T92 No embryo appropriated for the purpose of training staff in embryological techniques must be kept or used for the provision of treatment services.

T93 Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques and in those activities that are expressly authorised by the Authority.

T94 Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, where both gamete providers have consented to the use of embryos, created using their gametes, for the purpose of training.

T95 The centre must have procedures in place to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services.

This would normally consist of:

a. having a designated individual, who is not directly involved in the patient's treatment, to discuss with the patient the training activity and the possibility of donating material for it; and

b. making sure that the person obtaining consent for the use of the embryos in training is not involved in the training project.

Where limited staffing makes this difficult to achieve, the centre must develop its own robust procedures for ensuring that the conflict of interest requirement is met.

T97 Prior to giving consent, each gamete provider must be provided with the necessary information including:

a. the nature of the training for which embryos will be used

b. that the decision whether to donate will not affect their treatment in any way

c. that they can vary or withdraw the terms of their consent until the point the embryos are used in training, and

d. whether any information will be fed back to them.

T98 The information referred to in licence condition T97 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes.

Directions

0002 – Recording and providing information to the HFEA under a research licence

0008 – Information to be submitted to the HFEA as part of the licensing process

HFEA guidance

General

Interpretation of mandatory requirements 22A

The law prohibits:

(a) embryos being placed in any animal

(b) embryos that are not human being placed in a woman

(c) gametes that are not human being placed in a woman

(d) mixing human gametes with animal gametes, except for when carrying out the ‘hamster test’ in line with a licence

(e) embryos being kept or used after 14 days from when the process of creating the embryo began, or after the primitive streak has appeared (if earlier than 14 days)

(f) embryos intended for a research project being used for any purposes other than those of that research project

(g) an embryo created or obtained for research being placed in a woman

(h) keeping the results of the ‘hamster test’ after any research is complete or, in any event, after the two cell stage

(i) a research licence being used for any project other than the one specified in that licence

(j) research activities being carried out on premises other than those specified in the licence

(k) research activities being carried out under the supervision of anyone other than the specific person designated in the licence

(l) a treatment licence authorising the activities of a research project, and

(m) a research licence applying to more than one research project.

The HFE (Special Exemptions) Regulations 2009 allow gametes to be stored without a licence for research on gametes, for developing pharmaceutical or contraceptive products, or for teaching, provided that the gametes are not used for treatment purposes or for other prohibited purposes set out in the Regulations.

22.1 The person named as the person responsible on a research licence should not also be named as the person responsible on a treatment licence.

22.2 The centre should have documented procedures for:

(a) obtaining embryos to be used for research or training purposes, and
(b) obtaining written informed consent from donors for research and training purposes, and ensuring that embryos are used only in line with this consent.

22.3 If embryos or human admixed embryos will be used for research or training purposes, the research centre should record, before the project starts:

(a) the proposed duration of the culture period
(b) the procedure that will be used to ensure that embryos do not develop after 14 days or the primitive streak has appeared (if earlier), and
(c) the method that will be used to terminate development.

22.4 The centre should have documented procedures for ensuring that embryos and human admixed embryos are used within the maximum period of storage permitted by law or within any period of storage specified in the donor's consent (if shorter).

See also

Guidance note 17 – Storage of gametes and embryos

Disclosure of interests

22.5 Staff involved in research should follow relevant guidelines produced by the respective professional bodies (eg, the General Medical Council, or the Nursing and Midwifery Council). The centre should ensure that:

(a) all financial interests and sums of money known or estimated to be paid for the research are disclosed to a research ethics committee, and
(b) all members of the research team, including nurses and non-medical staff, are informed about how the research is being financed and managed.

Information provided to donors

Interpretation of mandatory requirements 22B

The law requires that before a person consents to donating embryos, or gametes or cells to be used to create embryos, for research or training, they should be given:

(a) enough information to understand the nature, purpose and implications of their donation, and

(b) information about the procedure for varying or withdrawing any consent given, including the fact that they can do this only until the embryos are used in the research project.

An embryo is regarded as being used in research when any of the methods, techniques or processes associated with the particular licensed research project are applied to it. An embryo is regarded as being used in training when it is under the control of the trainers/trainees or is being cultured for use in training.

Specific additional information must be given to individuals before they consent to any donation of their embryos to research projects involving, or intending to involve, human embryonic stem cell lines.

22.6 The centre should ensure that donors are given information about how the research is funded, including any direct payments or benefits that researchers, their departments or both would receive, and any financial interests the centre has in the research project or in its sponsoring organisations.

22.7 For any research project, the centre should ensure that before donors give their consent to their gametes or embryos, or cells used to create embryos, being used in research, they are given oral information (supported by relevant written material) that confirms:

(a) the specific research project and its aims
(b) details of the research project, including likely outcomes and how any individual donation will impact on the overall project
(c) whether the embryos will be reversibly or irreversibly anonymised, and the implications of this
(d) whether donors will be given any information that is obtained during the research and is relevant to their health and welfare
(e) that donors are expected to have an opportunity to ask questions and discuss the research project
(f) that donating gametes or embryos to research in the course of treatment services will not affect the patient's treatment in any way
(g) that patients are under no obligation to donate gametes and embryos for research and that their decision whether to do so will have no repercussions for any treatment they may receive
(h) that only fresh or frozen gametes and embryos not required for treatment can be used for research
(i) that research is experimental, and so any gametes and embryos used and created for any research project must not be used in treatment
(j) that donors may specify conditions for the use of the gametes or embryos
(k) that after the research has been completed, all donated gametes and embryos will be allowed to perish, and
(l) that, for any individual who donates cells for creating embryos for research, consent to use these cells includes consent to do so after the individual's death, unless stated otherwise.

22.8 If donated gametes or embryos could be used in secondary research, the centre should inform those considering donation of this possibility and explain that:

(a) secondary research could include the fixing of gametes, embryos or embryo cell samples for future studies
(b) secondary research could also include genetic research (the implications of which the centre should describe)

(c) to protect confidentiality, gametes and embryos for secondary research may be anonymised but this may be reversible
(d) if gametes and embryos will be reversibly anonymised and genetic research proposed, those considering donation will be offered counselling about the implications and given the opportunity to reconsider the terms of their consent
(e) if gametes and embryos will be irreversibly anonymised, those considering donation will be fully informed of the implications, ie, that no information or results from the research, including clinically relevant information, could be fed back to them, and
(f) if embryos will be used for stem cell research, those considering donation will be given thorough and appropriate information about the nature of this kind of research and its implications, including that any stem cell lines created may continue indefinitely and be used in different research projects.

22.9 If genetic research will be done on identifiable samples, the centre should:

(a) first inform the donor about the project and what, if any, information may be fed back to them, and
(b) then obtain the explicit consent of those considering donation.

22.10 The centre should ensure that before donors consent to their gametes or embryos being used for training purposes, they are given oral information (supported by relevant written material) that confirms:

(a) the specific training
(b) details of the training, including likely outcomes and how any individual donation will impact on the overall training
(c) whether the gametes or embryos will be reversibly or irreversibly anonymised, and the implications of this
(d) whether any information, obtained during the training, that is relevant to the donor's health and welfare will be fed back to the donor
(e) that donors are expected to have an opportunity to ask questions and discuss the training
(f) that donating gametes or embryos to training in the course of treatment services will not affect the patient's treatment in any way
(g) that patients are under no obligation to donate gametes or embryos for training and that their decision whether to do so will have no repercussions for any treatment they may receive
(h) that only fresh or frozen gametes or embryos not required for treatment can be used for training
(i) that any embryos used in training must not be used in treatment
(j) that donors may specify conditions for the use of the embryos, and
(k) that after the training has been completed, all donated embryos will be allowed to perish.

22.11 If genetic research will be done on identifiable samples, the centre should:

(a) first inform the donor about the training and what, if any, information may be fed back to them, and
(b) then obtain the explicit consent of those considering donation.

Consent

Interpretation of mandatory requirements 22C

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate embryos, or gametes or human cells used to create embryos in vitro, for the use in any research project. This consent can be varied or withdrawn at any time until the resulting embryo has been used for the purposes of the research project.

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate embryos for training. This consent can be varied or withdrawn at any time until the embryo has been used for training people in embryo biopsy, embryo storage or other embryo techniques.

The HFE (Special Exemptions) Regulations 2009 allow gametes to be stored without a licence for research on gametes, for developing pharmaceutical or contraceptive products, or for teaching, provided that the gametes are not used for treatment purposes.

The law also requires the centre to obtain written informed consent from a person before procuring their gametes.

22.12 The centre should obtain written informed consent from a person before using their gametes for research or training.

22.13 If donated material is used for research or training, the centre should ensure that clinical and research roles are separated. Individuals involved in advising patients when making clinical decisions about their licensed treatment should not be involved in research or training that patients are considering donating to.

22.14 If embryos or gametes, or cells used to create embryos, are used for licensed research, the centre should ensure that:

(a) a designated individual who is not directly involved in the donor's treatment (but could be part of the clinical team) is available to discuss with the donor the research project and the possibility of donating material
(b) the individual obtaining consent is suitably trained and qualified, has sufficient knowledge of the proposed research, understands the risks involved, complies with professional guidelines, and is not directly involved with the research, and
(c) the donor is given sufficient time to consider the implications of their donation before the donated material is used in any research project.

22.15 Consent should not be obtained under duress, especially if the donor is in a dependent relationship with someone involved in the research project.

22.16 The centre should not take gametes or cells from people under the age of 18 for research unless it can satisfy itself that the donor is capable of giving and actually gives effective consent to such research. The exception is in cases where cells may be taken from a person under the age of 18 for research if certain parental consent conditions have been met (as outlined below).

22.17 The centre should ensure that all the appropriate consents from all the gamete or embryo donors are in place before embryos are transferred between centres.

See also

Guidance note 3 – Counselling

Guidance note 5 – Consent to treatment, storage, donation, and disclosure of information

Guidance note 12 – Egg sharing arrangements

HFEA consent forms

Additional requirements for stem cell research

Mandatory requirements

Human Fertilisation and Embryology Act 1990 (as amended)

Licence conditions

12 General conditions

(2) Subsection (3) applies to-

… (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(3) It shall be a condition of every licence to which this subsection applies that –

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos,

Shall be recorded and provided to the Authority upon request.

14A Conditions of licences: human application

(1) This section applies to -

(c) every licence under paragraph 3 of that Schedule [Schedule 2], so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.

(3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.

(4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.

Licence conditions

R20 Prior to giving consent persons providing gametes or human cells for use in research that involves the derivation of embryonic stem cells/lines, must be provided with the following additional information:

a. that once an embryo or human admixed embryo has been used in the project of research they will have no control over any future use of the embryonic cells or any stem cells derived

b. that any stem cells/lines created may continue indefinitely and be used in many different research projects and/or clinical therapy

c. that stem cells derived in this research project will be deposited in the UK Stem Cell Bank and the implications of this including that they may be available to other research groups nationally or internationally

d. that the stem cells/lines may be used for commercial purposes, but that they will not benefit financially from this, and

e. that any stem cells/lines derived or discoveries made using them, could be patented, but that they will not benefit financially from this.

R30 Where this licence authorises the derivation of human embryonic stem cell lines:

a. a sample of all stem cell lines derived must be deposited in the UK Stem Cell Bank in accordance with any relevant Bank guidelines, and

b. the remainder of all stem cell lines (in so far as not used or destroyed as part of or in the course of the research project) must be deposited in the UK Stem Cell Bank or distributed in accordance with any relevant guidelines issued by the UK Stem Cell Bank.

R41 Centres deriving stem cells for intended human application must comply with the additional conditions set out in Annex A to the Research Licence.

R68 The centre must record such information as is necessary to facilitate the traceability of stem cells derived from embryos that are intended for human application and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.

Centres deriving stem cells for human application should adhere to the mandatory requirements and guidance, outlined in other guidance notes, regarding:

Traceability and coding system (guidance note 19 – Traceability)

Serious adverse events and serious adverse reactions (guidance note 27 – Adverse incidents)

Third party agreements and termination of licensed activities (guidance note 24 – Third party agreements)

Procurement of gametes and embryos (guidance note 15 – Procuring, processing and transporting gametes and embryos)

Selection criteria and laboratory tests required for donors of reproductive cells (guidance note 11 – Donor recruitment, assessment and screening)

Donation and procurement procedures and reception at the tissue establishment (guidance note 15 – Procuring, processing and transporting gametes and embryos)

22.18 The centre should have documented procedures for depositing samples of all embryonic stem cell lines developed or used in a research project in a stem cell bank.

22.19 Donors must give specific consent to their gametes, or embryos created with their gametes, being used in stem cell research.

See also

Guidance note 19 – Traceability

Use of human cells

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

15 Conditions of research licences

(5) If by virtue of paragraph 15F of Schedule 3 (existing cell lines) qualifying cells, as defined by paragraph 15F(2) of that Schedule, of a person ("P") are used to bring about the creation in vitro of an embryo or human admixed embryo without P's consent, steps shall be taken to ensure that the embryo or human admixed embryo cannot subsequently be attributed to P.

Schedule 3

In vitro fertilisation and subsequent use of embryos

6 (3A) If the Authority is satisfied that the parental consent conditions in paragraph 15A are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (3B) in relation to C.

(3B) Where the licence authorises the application of this sub-paragraph, the effective consent of a person having parental responsibility for C -

(a) to the use of C's human cells to bring about the creation of an embryo in vitro for use for the purposes of a project of research, or

(b) to the use for those purposes of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells,

is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.

(3C) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (3B) ceases to apply in relation to C.

(3ZD) Sub-paragraphs (1) to (3) have effect subject to paragraphs 15B and 15F.

Storage of gametes and embryos

8 (2A) Where a licence authorises the application of paragraph 6(3B) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (2) as the effective consent of C.

(2B) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraph (2) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2A) ceases to apply in relation to C.

(2C) For the purposes of sub-paragraphs (2) and (2A), each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A") -

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.

Parental consent conditions

15 (1) In relation to a person who has not attained the age of 18 years ("C"), the parental consent conditions referred to in paragraphs 6(3A) and 12(4) are as follows.

(2) Condition A is that C suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

(3) Condition B is that either -

(a) C is not competent to deal with the issue of consent to the use of C's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, or

(b) C has attained the age of 16 years but lacks capacity to consent to such use of C's human cells.

(4) Condition C is that any embryo or human admixed embryo to be created in vitro is to be used for the purposes of a project of research which is intended to increase knowledge about -

(a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or

(b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.

(5) Condition D is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who -

(a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, or

(b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications -

(a) for sub-paragraph (3) substitute -

"(3) Condition B is that C does not have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the use of C's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research.",

(b) in sub-paragraph (5)(a), for "have capacity to consent" substitute "are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent", and

(c) in sub-paragraph (5)(b), for "are competent to deal with the issue of" substitute "have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to".

Adults lacking capacity: exemption relating to use of human cells etc.

16 (1) If, in relation to the proposed use under a licence of the human cells of a person who has attained the age of 18 years ("P"), the Authority is satisfied -

(a) that the conditions in paragraph 17 are met,

(b) that paragraphs (1) to (4) of paragraph 18 have been complied with, and

(c) that the condition in paragraph 18(5) is met,

the Authority may in the licence authorise the application of this paragraph in relation to P.

(2) Where a licence authorises the application of this paragraph, this Schedule does not require the consent of P -

(a) to the use (whether during P's life or after P's death) of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research,

(b) to the storage or the use for those purposes (whether during P's life or after P's death) of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of P's human cells.

(3) This paragraph has effect subject to paragraph 19.

Consent to use of human cells etc. not required: adult lacking capacity

17 (1) The conditions referred to in paragraph 16(1)(a) are as follows.

(2) Condition A is that P suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

(3) Condition B is that P lacks capacity to consent to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research.

(4) Condition C is that the person responsible under the licence has no reason to believe that P had refused such consent at a time when P had that capacity.

(5) Condition D is that it appears unlikely that P will at some time have that capacity.

(6) Condition E is that any embryo or human admixed embryo to be created in vitro is to be used for the purposes of a project of research which is intended to increase knowledge about -

(a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or

(b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.

(7) Condition F is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who -

(a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, or

(b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(8) In this paragraph and paragraph 18 references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.

(9) In relation to Scotland -

(a) references in sub-paragraphs (3) to (5) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent, and

(b) sub-paragraph (7) is to be read with the following modifications -

(i) in paragraph (a), for “have capacity to consent” substitute “are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent”, and

(ii) in paragraph (b), for “are competent to deal with the issue of” substitute “have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to”.

Consulting carers etc. in case of adult lacking capacity

18 (1) This paragraph applies in relation to a person who has attained the age of 18 years (“P”) where the person responsible under the licence (“R”) wishes to use P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, in a case where P lacks capacity to consent to their use.

(2) R must take reasonable steps to identify a person who -

(a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P’s welfare, and

(b) is prepared to be consulted by R under this paragraph of this Schedule.

(3) If R is unable to identify such a person R must nominate a person who -

(a) is prepared to be consulted by R under this paragraph of this Schedule, but

(b) has no connection with the project.

(4) R must provide the person identified under sub-paragraph (2) or nominated under sub-paragraph (3) (“F”) with information about the proposed use of human cells to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project and ask F what, in F’s opinion, P’s wishes and feelings about the use of P’s human cells for that purpose would be likely to be if P had capacity in relation to the matter.

(5) The condition referred to in paragraph 16(1)(c) is that, on being consulted, F has not advised R that in F's opinion P's wishes and feelings would be likely to lead P to decline to consent to the use of P's human cells for that purpose.

(6) In relation to Scotland, the references in sub-paragraphs (1) and (4) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Effect of acquiring capacity

19 (1) Paragraph 16 does not apply to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo if, at a time before the human cells are used for that purpose, P-

(a) has capacity to consent to their use, and

(b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.

(2) Paragraph 16 does not apply to the storage or use of an embryo or human admixed embryo whose creation in vitro was brought about with the use of P's human cells if, at a time before the embryo or human admixed embryo is used for the purposes of the project of research, P -

(a) has capacity to consent to the storage or use, and

(b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.

(3) In relation to Scotland, the references in sub-paragraphs (1)(a) and (2)(a) to P having capacity to consent are to be read as references to P not being incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Use of cells or cell lines

20 (1) Where a licence authorises the application of this paragraph in relation to qualifying cells, this Schedule does not require the consent of a person ("P") -

(a) to the use of qualifying cells of P to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, or

(b) to the storage or the use for those purposes of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of qualifying cells of P.

(2) "Qualifying cells" are human cells which -

(a) were lawfully stored for research purposes immediately before the commencement date, or

(b) are derived from human cells which were lawfully stored for those purposes at that time.

(3) The "commencement date" is the date on which paragraph 9(2)(a) of Schedule 3 to the Human Fertilisation and Embryology Act 2008 (requirement for consent to use of human cells to create an embryo) comes into force.

Conditions for grant of exemption in paragraph 20

21 (1) A licence may not authorise the application of paragraph 20 unless the Authority is satisfied -

(a) that there are reasonable grounds for believing that scientific research will be adversely affected to a significant extent if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project of research are -

(i) human cells in respect of which there is an effective consent to their use to bring about the creation in vitro of embryos or human admixed embryos for use for those purposes, or

(ii) human cells which by virtue of paragraph 16 can be used without such consent, and

(b) that any of the following conditions is met in relation to each of the persons whose human cells are qualifying cells which are to be used for the purposes of the project of research.

(2) Condition A is that -

(a) it is not reasonably possible for the person responsible under the licence ("R") to identify the person falling within sub-paragraph (1)(b) ("P"), and

(b) where any information that relates to P (without identifying P or enabling P to be identified) is available to R, that information does not suggest that P would have objected to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.

(3) Condition B is that -

(a) the person responsible under the licence ("R") has taken all reasonable steps to contact the person falling within subparagraph (1)(b) ("P") but has been unable to do so,

(b) R does not have any reason to believe P to have died, and

(c) the information relating to P that is available to R does not suggest that P would have objected to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.

(4) Condition C is that -

(a) the person falling within sub-paragraph (1)(b) ("P") has died since P's human cells were first stored,

(b) the information relating to P that is available to the person responsible under the licence ("R") does not suggest that P would have objected to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, and

(c) a person who stood in a qualifying relationship to P immediately before P died has given consent in writing to the use of P's human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.

(5) The HTA consent provisions apply in relation to consent for the purposes of sub-paragraph (4)(c) as they apply in relation to consent for the purposes of section 3(6)(c) of the Human Tissue Act 2004; and for the purposes of this sub-paragraph the HTA consent provisions are to be treated as if they extended to Scotland.

(6) In sub-paragraph (5) "the HTA consent provisions" means subsections (4), (5), (6), (7) and (8)(a) and (b) of section 27 of the Human Tissue Act 2004.

(7) In this paragraph references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.

(8) Paragraphs 1 to 4 of this Schedule do not apply in relation to a consent given for the purposes of sub-paragraph (4)(c).

Interpretation

22 (1) In this Schedule references to human cells are to human cells which are not -

(a) cells of the female or male germ line, or

(b) cells of an embryo.

(4) Reference in this Schedule (however expressed) to the use of human cells to bring about the creation of an embryo or a human admixed embryo include the use of human cells to alter the embryo or, as the case may be, the human admixed embryo.

(5) References in this Schedule to parental responsibility are -

(a) in relation to England and Wales, to be read in accordance with the Children Act 1989,

(b) in relation to Northern Ireland, to be read in accordance with the Children (Northern Ireland) Order 1995, and

(c) in relation to Scotland, to be read as references to parental responsibilities and parental rights within the meaning of the Children (Scotland) Act 1995.

(6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

(7) References in this Schedule to the age of 18 years are, in relation to Scotland, to be read as references to the age of 16 years.

Interpretation of mandatory requirements 22D

Human cells may be used to create embryos or human admixed embryos in vitro for use in research, or embryos may be used in research, without the consent of the person providing the cells in the following circumstances:

(a) If the person is under the age of 18

(i) The Authority must be satisfied that specified parental consent conditions have been met.

(ii) A parent of the person must have given effective consent on their behalf.

(iii) The parental conditions must remain satisfied.

(iv) The child must not have reached the age of 18, and must not have withdrawn or varied the consent, before the embryo is used for the research project.

(b) If the person is an adult

(i) The Authority must be satisfied that specified conditions relating to adults and consent have been met.

(ii) An appropriate person must have been consulted by the person responsible, and given suitable information and an opportunity to state what the adult's wishes and feelings would have been about the proposed use of their cells for that purpose.

(iii) The person consulted must not have stated that the adult would have been likely to refuse to consent.

(iv) Consent must not have been validly withdrawn by the person providing the cells before the use of the cells or any resulting embryo or human admixed embryo.

For both (a) and (b), the cells or embryos (or cells derived from these) must have been lawfully stored for research purposes before 1 October 2009, and certain conditions must have been met.

Human admixed embryos: general requirements

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman -

(a) a human admixed embryo,

(b) any other embryo that is not a human embryo, or

(c) any gametes other than human gametes.

(2) No person shall -

(a) mix human gametes with animal gametes,

(b) bring about the creation of a human admixed embryo, or

(c) keep or use a human admixed embryo,

except in pursuance of a licence.

(3) A licence cannot authorise the keeping or using of a human admixed embryo after the earliest of the following -

(a) the appearance of the primitive streak, or

(b) the end of the period of 14 days beginning with the day on which the process of creating the human admixed embryo began, but not counting any time during which the human admixed embryo is stored.

(4) A licence cannot authorise placing a human admixed embryo in an animal.

(5) A licence cannot authorise keeping or using a human admixed embryo in any circumstances in which regulations prohibit its keeping or use.

(6) For the purposes of this Act a human admixed embryo is -

(a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with -

(i) two human pronuclei,

(ii) one nucleus of a human gamete or of any other human cell, or

(iii) one human gamete or other human cell,

(b) any other embryo created by using -

(i) human gametes and animal gametes, or

(ii) one human pronucleus and one animal pronucleus,

(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of the embryo,

(d) a human embryo that has been altered by the introduction of one or more animal cells, or

(e) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal ("animal DNA") but in which the animal DNA is not predominant.

(7) In subsection (6) -

(a) references to animal cells are to cells of an animal or of an animal embryo, and

(b) references to human cells are to cells of a human or of a human embryo.

(8) For the purposes of this section an "animal" is an animal other than man.

(9) In this section "embryo" means a live embryo, including an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

11 Licences for treatment, storage and research

(1) The Authority may grant the following and no other licences -

(b) licences under that Schedule authorising the storage of gametes, embryos or human admixed embryos

14 Conditions of storage licences

(1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos -

(ac) that a human admixed embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies…

(ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,

(c) that no gametes, embryos or human admixed embryo shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish,

(4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.

Schedule 2

Licences for storage

2 (1A) A licence under this paragraph or paragraph 3 may authorise the storage of human admixed embryos (whether or not the licence also authorises the storage of gametes or embryos or both).

Licences for research

3 (3) A licence under this paragraph may authorise any of the following -

(a) bringing about the creation in vitro of things that are human admixed embryos by virtue of paragraph (a), (b), (c) or (d) of section 4A(5), and

(b) keeping or using things that are human admixed embryos by virtue of any of those paragraphs, for the purposes of a project of research specified in the licence.

(4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).

(5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority -

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are -

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos.

Schedule 3

Terms of consent

2 (1A) A consent to the use of any human admixed embryo must specify use for the purposes of a project of research and may specify conditions subject to which the human admixed embryo may be so used.

(2) A consent to the storage of any gametes, any embryo or any human admixed embryo must -

(a) specify the maximum period of storage (if less than the statutory storage period),

(b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and

(c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,
and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.

(2A) A consent to the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.

(4) A consent under this Schedule may apply -

(a) to the use or storage of a particular embryo or human admixed embryo, or

(b) in the case of a person providing gametes or human cells, to the use or storage of -

(i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and

(ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.

(5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to -

(a) a particular embryo or particular embryos, or

(b) a particular human admixed embryo or particular human admixed embryos.

Variation and withdrawal of consent

4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

(4) Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.

(5) Where the terms of any consent to the use of a human admixed embryo ("human admixed embryo A") include consent to the use of a human admixed embryo or embryo whose creation may be brought about in vitro using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research.

Creation, use and storage of human admixed embryos

12 (1) A person's gametes or human cells must not be used to bring about the creation of any human admixed embryo in vitro unless there is an effective consent by that person to any human admixed embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for the purposes of any project of research.

(2) A human admixed embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for the purposes of any project of research.

(3) A human admixed embryo the creation of which was brought about in vitro must not be used for the purposes of a project of research unless -

(a) there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for that purpose, and

(b) the human admixed embryo is used in accordance with those consents.

(4) If the Authority is satisfied that the parental consent conditions in paragraph 15 are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (5) in relation to C.

(5) Where the licence authorises the application of this subparagraph, the effective consent of a person having parental responsibility for C -

(a) to the use of C's human cells to bring about the creation of a human admixed embryo in vitro for use for the purposes of a project of research, or

(b) to the use for those purposes of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells,

is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.

(6) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under subparagraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (5) ceases to apply in relation to C.

13 (1) A human admixed embryo the creation of which was brought about in vitro must not be kept in storage unless -

(a) there is an effective consent by each relevant person in relation to the human admixed embryo to the storage of the human admixed embryo, and

(b) the human admixed embryo is stored in accordance with those consents.

(2) Where a licence authorises the application of paragraph 12(5) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (1) as the effective consent of C.

(3) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under subparagraph (1) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2) ceases to apply in relation to C.

14 For the purposes of paragraphs 12 and 13, each of the following is a relevant person in relation to a human admixed embryo the creation of which was brought about in vitro ("human admixed embryo A") -

(a) each person whose gametes or human cells were used to bring about the creation of human admixed embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any embryo, the creation of which was brought about in vitro, which was used to bring about the creation of human admixed embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any other human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of human admixed embryo A.

Interpretation of mandatory requirements 22E

The law prohibits:

(a) human admixed embryos being placed in a woman, or

(b) human admixed embryos being kept or used after 14 days from when the process of creating the embryo began or after the primitive streak has appeared (if earlier than 14 days).

Human admixed embryos: information provided to donors

Interpretation of mandatory requirements 22F

The law requires that before a person consents to donating embryos, gametes or cells to create human admixed embryos for research purposes, they should be given:

(a) enough information to understand the nature, purpose and implications of their donation

(b) information about the procedure for varying or withdrawing any consent given, including the fact that they can do this only until the human admixed embryos are used in the research project.

NOTE Human admixed embryos will be regarded as having been used for research as soon as they are under the control of the researchers and are being cultured for use in research.

22.20 The centre should inform any individual who donates cells for creating human admixed embryos for research that, unless they state otherwise, consent to use these cells includes consent to do so after the individual's death.

Human admixed embryos: consent and storage

Interpretation of mandatory requirements 22G

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate gametes or human cells used to create human admixed embryos in vitro for use in any research project.

The consent must specify the maximum storage period (which must be less than the 10-year statutory storage period for human admixed embryos).

This consent can be varied or withdrawn at any time until the embryo has been used for the purposes of the research project.

In certain situations, the law permits human cells to be used to create human admixed embryos without the consent of the person providing them.

See also

Guidance note 5 – Consent to treatment, storage, donation, and disclosure of information

Guidance note 17 – Storage of gametes and embryos

Other legislation, professional guidelines and information

Professional guidelines

Department of Health (Advisory Committee on the Safety of Blood, Tissues and Organs): Donation of starting material for cell-based advanced therapies (2014)

The Health Research Authority: Protects and promotes the interests of patients and the public in health and social care research

Medical Research Council (UK Stem Cell Bank steering committee)

UK Stem Cell Bank

UK Stem Cell Bank: Code of Practice – use of human stem cell lines (2010)

23. The quality management system

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3A – Supplementary licence conditions: human application

Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2

10 Licence conditions shall require compliance with the requirements laid down in the provisions of the third Directive…

Relevant provisions of the third Directive

Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

Licence conditions

T32 The centre must put in place a quality management system and implement this system to continually improve the quality and effectiveness of the service provided in accordance with the conditions of this licence and the guidance on good practice as set out in the HFEA's Code of Practice.

T33 The following documentation must form part of the quality management system:

a. a quality manual

b. standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence

c. guidelines

d. training and reference manuals, and

e. reporting forms.

T35 Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.

T36 Centres must audit the activities and processes authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the regulatory requirements and their own approved protocols and quality indicators. These audits must be performed at least every two years, by trained and

competent staff and in an independent way. Findings and corrective actions must be documented and implemented.

HFEA guidance

Definition of the quality management system

23.1 The quality management system is defined as:

'the organisational structure, defined responsibilities, procedures, processes and resources for implementing quality management (ie, the co-ordinated activities to direct and control an organisation with regard to quality), including all activities which contribute to quality, directly or indirectly'. (International Organization for Standardization)

NOTE This definition indicates that every process and activity taking place in the centre is a part of the quality management system.

23.2 The centre should:

(a) identify the processes needed for quality management, for providing and managing resources and for assisted conception procedures, and
(b) ensure these processes, including the interaction between them, are effective and continually improved.

Establishing, maintaining and documenting the quality management system

23.3 Centre management should ensure the quality management system is established and maintained by:

(a) appointing a quality manager
(b) establishing a quality policy
(c) establishing quality objectives and plans
(d) ensuring resources are available to implement and maintain the system
(e) making centre staff aware of the importance of the system and the need to keep to its requirements
(f) defining responsibilities, authorities and reporting relationships in the centre
(g) conducting management reviews of the system, and
(h) establishing and reviewing contracts with third parties.

See also

Guidance note 24 – Third party agreements

23.4 Centre management should appoint a quality manager who, regardless of their other responsibilities, must be responsible for:

(a) ensuring that the quality management system is implemented and maintained
(b) reporting to centre management on how the quality management system works and how effective it is, and
(c) co-ordinating awareness of centre users' needs and requirements.

23.5 The centre's documents to support its quality management system should include:

(a) the quality policy, with quality objectives and plans
(b) a quality manual
(c) documents needed to ensure the centre's processes are planned and operate effectively, and
(d) records and procedures required by this Code of Practice.

The centre should ensure that all documents are available for inspection by the HFEA.

Quality policy and quality objectives

23.6 The quality policy is defined as:

'the overall intentions and direction of an organisation related to quality as formally expressed by centre management. A quality policy statement defines or describes an organisation's intentions and commitment to quality and provides a framework for setting quality objectives and planning.' (International Organization for Standardization)

23.7 Centre management should ensure the quality policy includes a commitment to:

(a) providing a service that meets its users' needs and requirements. This should include ensuring that all staff who come into contact with patients, donors and their partners (where applicable) provide the good quality supportive care before, during and after treatment, as outlined in the centre's patient support policy
(b) meeting the provisions of this Code of Practice and statutory provisions and standard licence conditions
(c) continually improving the effectiveness of the quality management system
(d) upholding good professional practice, and
(e) ensuring the health, safety and welfare of all staff and visitors to the centre.

23.8 The quality policy should be:

(a) signed and issued by the person responsible
(b) communicated, understood and available throughout the centre, and
(c) reviewed for continuing suitability.

23.9 Centre management should establish documented quality objectives. These should:

(a) include objectives needed to meet users' needs and requirements, including their need for supportive care and treatment, from clinic staff, before, during and after treatment or donation (see GN 3 paragraph 3.14)
(b) be measurable and consistent with the quality policy, and
(c) be reviewed regularly.

23.10 Centre management should establish a plan to achieve and maintain the quality objectives. The plans should be reviewed regularly.

Quality manual

23.11 The centre should establish and maintain a quality manual. The quality manual should include:

(a) a brief description of the centre, including its legal identity, and the scope of its services
(b) the quality policy, or reference to it
(c) an organisation chart defining accountability and reporting relationships in the centre
(d) text to accompany the organisational chart and a definition of the centre's place in any parent organisation, and
(e) an outline of the processes and documentation established for the quality management system.

See also

Guidance note 31 – Record keeping and document control

The quality management review

Interpretation of mandatory requirements 23A

The centre management must regularly review the centre's quality management system and all its services, identifying the need for changes and opportunities for improvement.

23.12 The review of the quality management system should include consideration of changes in:

(a) the volume and scope of work
(b) staff
(c) premises
(d) the performance of third parties that could affect the quality management system or the centre's services, and
(e) the results of the following activities:

(i) quality indicators for monitoring the centre's performance in the provision of emotional support and patient care generally,
(ii) assessment of user satisfaction, and the monitoring and resolution of complaints
(iii) staff suggestions
(iv) an internal audit of all elements of the quality management system, including assisted conception processes
(v) participation in external reviews, and inter-centre and inter-laboratory comparisons
(vi) identification, investigation, control, recording and notification of serious

adverse events and reactions, and
(vii) continual improvement, including the status of corrective and preventive actions.

23.13 The centre should normally review its quality management system at least every 12 months but more often when a quality management system is being established.

23.14 The management review should include the results of monitoring, evaluation and improvement activities.

23.15 The results of the review of the quality management system should be recorded and should include the decisions and actions for improving the quality management system. Centre staff should be informed of the results of the quality management review.

See also

Guidance note 27 – Adverse incidents

Guidance note 28 – Complaints

Quality indicators

23.16 The centre should establish quality indicators for systematically monitoring and evaluating the centre's provision of emotional support and patient care generally.

Assessing user satisfaction

23.17 The centre should assess whether or not the service has met users' needs and requirements, including the extent to which they felt supported before, during and after their treatment or donation. It should keep records of the information it collects and the actions it takes. Methods should include user surveys for all aspects of the service.

Staff suggestions

23.18 Centre management should encourage staff to make suggestions for improving any aspect of the centre's service. Suggestions should be evaluated, implemented as appropriate, and feedback provided to the staff. Records of suggestions and management action should be maintained.

Internal audit

23.19 The centre should establish an internal audit process to determine whether the quality management system:

(a) conforms to the planned arrangements for assisted conception processes
(b) conforms to the requirements of this Code of Practice and to the standards established by the centre, and
(c) is effectively implemented and maintained.

23.20 The centre should establish a documented procedure to:

(a) define the responsibilities for planning and conducting audits
(b) define the audit criteria, scope, frequency and methods
(c) ensure audits are carried out by trained staff
(d) ensure action is taken promptly to start corrective action
(e) check the effectiveness of the action taken, in a subsequent audit, and
(f) keep records of audits, to include:

(i) the processes, areas or items audited
(ii) any areas that do not comply with the quality management system
(iii) recommendations and timescales for action, and
(iv) action taken and its effectiveness.

23.21 The quality manager should plan the audit programme. It must take into account the importance of the processes and areas to be audited, and the results of previous audits. Auditors should not audit their own areas of responsibility. The Quality Manager should ensure that second party audits are carried out wherever necessary on procured suppliers taking evidence obtained from Third Party Agreements.

23.22 The audit should focus in particular on quality indicators established for systematically monitoring and evaluating the centre's assisted conception processes.

Participating in external reviews, and inter-centre and inter-laboratory comparisons

23.23 The centre should, where possible, participate in inter-centre comparisons and inter-laboratory comparisons. The centre should evaluate the results of these comparisons and use relevant findings to improve its service.

23.24 For inter-laboratory comparisons, the laboratory should establish documented procedures to define the responsibilities and requirements for participation to ensure that:

(a) a record of participation is maintained, to include reasons for failure to participate
(b) supervisory staff and staff doing the examinations evaluate the returned results against agreed performance criteria, and, when nonconformities are identified, participate in implementing and recording corrective action, and
(c) the effectiveness of the corrective action is verified. When a formal inter-laboratory comparison programme is not available, the laboratory should develop a way of determining the acceptability of procedures not otherwise evaluated. Whenever possible, this should use external materials, such as exchange of samples with other laboratories.

23.25 The centre should assess any external reviews indicating nonconformities or potential nonconformities and take appropriate corrective or preventive action to

ensure it continues to comply with the requirements and expectations of this Code of Practice. The centre must keep a record of corrective and preventive action it takes.

Monitoring, evaluation and improvement

Interpretation of mandatory requirements 23B

The centre must plan and implement processes for monitoring, evaluation and improvement.

23.26 The centre's processes for monitoring, evaluation and improvement should:

(a) show that procedures and outcomes are satisfactory when judged against relevant professional standards
(b) show that the assisted conception processes are followed in a way that meets users' needs and requirements
(c) ensure conformity of the quality management system, and
(d) continually improve the effectiveness of the quality management system.

23.27 The centre should establish a documented procedure to identify and manage nonconformities and incident findings. These findings should be appropriately investigated and documented to include the following actions taken:

(a) remedial or immediate actions
(b) root cause analysis to determine the causes of nonconformities
(c) evaluating the need for action to ensure nonconformities do not recur
(d) promptly determining and implementing action needed
(e) recording the results of corrective action taken
(f) reviewing the corrective action taken and its effectiveness, and
(g) risk based thinking (preventive actions).

NOTE Action taken at the time of the nonconformity to mitigate its immediate effects is considered remedial or immediate action. Only action taken to remove the root cause of the nonconformities is considered corrective action. This is a reactive process.

23.28 The centre should establish a documented procedure to take risk based thinking (preventive action) to eliminate the causes of potential nonconformities and so prevent them happening. It should include:

(a) determining potential nonconformities and their causes
(b) evaluating the need for action to prevent nonconformities happening
(c) promptly determining and implementing action needed
(d) recording the results of preventive action taken, and
(e) reviewing any risk based thinking (preventive action) taken.

NOTE Risk based thinking (preventive action) is a way of actively identifying opportunities for improvement rather than reacting to problems or complaints when they happen. This is a proactive process as opposed to reactive.

Other legislation, professional guidelines and information

General information

International Organisation for Standardization

24. Third party agreements

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

2A Third party agreements

(1) For the purposes of this Act, a "third party agreement" is an agreement in writing between a person who holds a licence and another person which is made in accordance with any licence conditions imposed by the Authority for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties) and under which the other person -

(a) procures, tests or processes gametes or embryos (or both), on behalf of the holder of the licence, or

(b) supplies to the holder of the licence any goods or services (including distribution services) which may affect the quality or safety of gametes or embryos.

(2) In this Act -

"relevant third party premises", in relation to a licence, means any premises (other than premises to which the licence relates) -

(a) on which a third party procures, tests, processes or distributes gametes or embryos on behalf of any person in connection with activities carried out by that person under a licence, or

(b) from which a third party provides any goods or services which may affect the quality and safety of gametes or embryos to any person in connection with activities carried out by that person under a licence; "third party" means a person with whom a person who holds a licence has a third party agreement.

(3) References in this Act to the persons to whom a third party agreement applies are to -

(a) the third party,

(b) any person designated in the third party agreement as a person to whom the agreement applies, and

(c) any person acting under the direction of a third party or of any person so designated.

16 Grant of licence

(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.

(2) The requirements mentioned in subsection (1) above are -

(d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities…

Licence conditions

T111 The centre must establish a written agreement with those third parties who provide goods or services that influence the quality and safety of gametes and embryos, and in particular where:

a. the centre entrusts one of the stages of gamete or embryo processing to a third party

b. a third party provides goods or services that affect gamete or embryo quality and safety assurance, including the process of distribution, and

c. the centre distributes gametes or embryos processed by third parties.

T112 The centre must evaluate and select third parties on the basis of their ability to meet the requirements of these licence conditions and the guidance set out in the HFEA Code of Practice.

T113 Agreements with third parties must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.

T114 The centre must ensure that the following core requirements are included in any third party agreement, namely:

a. full address and contact details of the third party, and nature of the service to be provided

b. identification of person(s) responsible for managing arrangement between the centre and the third party

c. provision setting out how often the agreement will be reviewed and by whom

d. summary of the responsibilities of the third party and agreed procedures with regard to each party's respective responsibilities,

e. any specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety, and

f. description of how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.

T115 The centre must keep a complete list of agreements referred to in licence condition T111 that they have established with third parties. Copies of these agreements must be made available to the Authority upon request.

T116 The centre must ensure that it is made a condition of any agreement with a third party, a satellite or a transport centre that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice.

T117 Where the third party procures gametes and/or embryos on behalf of a licensed centre, the third party agreement must require the procuring establishment to produce a report to the licensed centre which must include, but not be limited to, a record of the following:

a. where the procurement took place

b. patient/donor identification data including how and by whom identified

c. description and identification of the procured gametes/embryos including samples for testing

d. identification of the person responsible for the procurement process

e. date, time and location of procurement and SOP used

f. details of any incidents, including any serious adverse events and/or reactions, that

occurred during the procurement process

g. where appropriate, the environmental conditions at the procurement facility, and

h. where appropriate, the identification/batch numbers for any reagents and transport media used.

T124 a. No clinic may carry out either the process of pronuclear transfer* (PNT) or maternal spindle transfer* (MST) or part of either process, unless express provision has been made on the clinic's licence permitting it to undertake either or both processes.

b. Neither PNT nor MST may be carried out under third party, satellite or transport agreements.

c. No clinic may provide treatment using gametes or embryos which have been created using PNT or MST unless express provision has been made on the clinic's licence permitting the clinic to undertake either or both processes.

*Wherever reference is made in this licence to PNT or MST, or to the process of PNT or MST, it is to be treated as a reference to the process described in Regulation 4 or Regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

T125 PNT and MST must only be carried out on premises of clinics licensed to undertake mitochondrial donation ('MD'). These processes must not be carried out on the premises of a clinic that is operating under a third party, satellite or transport agreement with a clinic that holds a licence to undertake MD.

Directions

0010 – Satellite and transport IVF

HFEA guidance

Scope

Interpretation of mandatory requirements 24A

The law requires licensed centres to establish written agreements with third parties every time an external activity will be carried out that influences the quality and safety of gametes procured, tested or processed.

24.1 A licensed centre should establish a third party agreement where a third party is carrying out the following two categories of activity:

(a) procuring, testing or processing gametes and embryos, or both, for example:

(i) laboratories preparing sperm
(ii) centres where patients are assessed, given fertility-stimulating drugs and monitored, and eggs are retrieved (transport centres)
(iii) centres where sperm is procured

Neither pronuclear transfer (PNT) nor maternal spindle transfer (MST) can be carried out under a third party agreement. Only the centre licensed to carry out mitochondrial donation can carry out these activities and they must be done on their premises.

(b) supplying goods or services (including distribution services) that may affect the quality and safety of gametes and embryos, for example:

(i) companies supplying equipment and materials, eg, suppliers of culture media
(ii) companies monitoring air quality in laboratories
(iii) clinical or laboratory premises leased from a hospital or other institution, eg, using theatres for collecting eggs under general anaesthetic
(iv) courier companies.

24.2 Third party premises may be inspected as part of the licensing process and when investigating adverse incidents. If third party premises are unsuitable, the licence holder's licence may be varied or revoked.

24.3 If facilities or services that a third party provides are used in a treatment process, the person responsible for that process should be satisfied that the provider's procedures can be integrated with the centre's quality system. In particular, the third party's procedures should:

(a) allow the entire service to be audited, and samples to be fully traced
(b) minimise cross-contamination (where relevant)
(c) follow relevant professional guidelines, and
(d) ensure that adverse incidents are reported and that any affected gametes and embryos can be effectively recalled.

See also

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Guidance note 23 – The quality management system

Guidance note 27 – Adverse incidents

Transport centres

Interpretation of mandatory requirements 24B

If any part of treatment takes place in a transport centre, the person responsible for providing the licensable treatment must ensure that the treatment complies with the relevant legal requirements.

24.4 Transport centres should give attention to requirements covering information, counselling, the welfare of the child and confidentiality. The person responsible should put in place effective procedures to ensure such centres are given relevant information about these requirements and any changes to them, in a clear and timely way. These requirements should form part of a third party agreement.

Third party procurement of gametes and embryos

24.5 If a centre has a third party agreement with another centre for procuring gametes and embryos, that centre should keep extra third party procurement documents that should include, but not be limited to:

(a) identification, name and address of the centre to receive the gametes

(b) patient, patient's partner or donor identification
(c) identification of the procured gametes and embryos
(d) identification of the staff member responsible for the procurement session
(e) date and time of procurement
(f) a record of any procedures performed on the gametes
(g) a record of any adverse incidents, and
(h) where appropriate, identification or batch numbers (or both) of any reagents and transport media used.

Agreements between licensed centres

24.6 Where a licensed centre arranges for any part of treatment to take place at another licensed centre, the person responsible at the original centre retains overall responsibility for that treatment. The person responsible at the original centre should therefore satisfy themselves that treatment arranged at other licensed centres complies with all relevant legal requirements, quality and safety considerations, and Code of Practice guidance. This will include giving attention to requirements covering information, counselling, the welfare of the child and confidentiality.

The person responsible at the original centre should check HFEA inspection reports about the second centre, and establish regular written confirmation from the second centre. Where the original centre sends a large volume of treatment to a particular centre, checks should be carried out regularly, and no less than annually.

25. Premises, practices and facilities

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General conditions

(1) The following shall be conditions of every licence granted under this Act –

(a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried out on only on the premises to which the licence relates and under the supervision of the person responsible, (aa) that any activities to which section 3(1A)(b) or (1B) or 4(1A) applies shall be carried on only on the premises to which the licence relates or on relevant third party premises,…

16 Grant of licence

(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.

(2) The requirements mentioned in subsection (1) above are—

…

(d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities…

(2) The Authority may revoke a licence otherwise than on application under subsection (1) if—

…

(d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,

(e) it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence…

Schedule 2 – Activities for which licences may be granted

4 (1) a licence under this Schedule can only authorise activities to be carried out on –

(a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or

4 (1A) applies, on relevant third party premises…

(2) A licence cannot –

…

(d) apply to premises of the person who holds the licence in different places.

Licence conditions

T1 The activities authorised by the licence must be carried out only on the premises specified in this licence and under the supervision of the person responsible (PR). However, where authorised by a licence, procurement, testing, processing or distribution of gametes or embryos intended for human application can also be carried out on relevant third party premises, provided that such premises, and the activities undertaken there, are covered by the terms of a written third party agreement.

T2 Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.

T17 A centre must have suitable facilities to carry out licensed activities, or other activities carried out for the purposes of providing treatment services that do not require a licence.

T20 In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP_ Annex 1 and Directive 2003/94/EC). It must be demonstrated and documented that the chosen environment achieves the quality and safety required.

NOTE Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.

T21 If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics, (cytogenetics and molecular genetics) haematology, bacteriology, virology and clinical biochemistry.

T124
a. No clinic may carry out either the process of pronuclear transfer* (PNT) or maternal spindle transfer* (MST) or part of either process, unless express provision has been made on the clinic's licence permitting it to undertake either or both processes.

b. Neither PNT nor MST may be carried out under third party, satellite or transport agreements.

c. No clinic may provide treatment using gametes or embryos which have been created using PNT or MST unless express provision has been made on the clinic's licence permitting the clinic to undertake either or both processes.

*Wherever reference is made in this licence to PNT or MST, or to the process of PNT or MST, it is to be treated as a reference to the process described in Regulation 4 or Regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

T125 PNT and MST must only be carried out on premises of clinics licensed to undertake mitochondrial donation ('MD'). These processes must not be carried out on the premises of a clinic that is operating under a third party, satellite or transport agreement with a clinic that holds a licence to undertake MD.

HFEA guidance

Definition of premises

Interpretation of mandatory requirements 25A

A licence can apply only to one premises; if a centre wishes to conduct licensed activities in a building different from the licensed premises, and not subject to a third party agreement, a separate licence will be required.

The HFEA must approve all new premises or changes to existing premises before use.

25.1 The HFEA defines premises as the specific area where a centre conducts its business, as identified on a floor plan submitted by the centre to the HFEA.

25.2 The centre should provide the HFEA with a floor plan that defines the premises to be licensed, including the purpose of each room.

25.3 When setting up or altering premises, the centre should review Health Technical Memoranda and Health Building Notes (published by the Department of Health) in considering the location and the services to be provided. In particular, the centre should consider Health Building Notes on day surgery and outpatient departments.

25.4 The centre should ensure it can provide ongoing assurance that its premises are fit for purpose, and evidence of:

(a) maintenance of lifts
(b) fire safety
(c) maintenance of ventilation and heating systems
(d) electrical safety
(e) medical gas safety.

Detailed guidance on these can be found in the relevant Health Technical Memoranda.

Moving to new premises

25.5 Before moving to new premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of the intended move by submitting an application to vary the licence with information about the new premises. The HFEA will consider the application and information, and may need to inspect the premises.

Changing existing premises

25.6 Before planning any changes to the existing premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of any planned changes to the premises by submitting, in advance, an application for a variation of the licence with information on the planned changes.

25.7 The HFEA will consider the application and information, and may need to inspect the premises.

Acquiring additional premises

25.8 If a centre wishes to conduct licensed activities not subject to a third party agreement in premises other than those specified on the current licence (eg, in a different building), it should contact its inspector for advice and notify the HFEA in writing. The centre should also submit an application for a new licence with information about the additional premises.

Centre facilities

25.9 The centre should provide for the privacy, dignity and respect of all prospective and current patients and donors, as well as providing a safe working environment for all staff. Consultation and the exchange of personal information should be carried out in private (ie, cannot be overlooked or overheard by others).

25.10 The centre should have facilities for reception, clinical and counselling activity, laboratory work, storage of confidential records, storing gametes and embryos, and staff.

25.11 The centre should display a copy of its Certificate of Licence where it can easily be read by current and potential patients and donors.

25.12 The centre should have appropriate procedures to ensure premises comply with relevant requirements for safety and air quality, and these procedures should be validated.

25.13 The person responsible should assess how many treatment cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skill mix of staff members. Activity should be adjusted according to the findings of the assessment.

Clinical facilities

25.14 The centre should ensure that its clinical facilities:

(a) provide privacy and comfort for those:

(i) considering donation and seeking treatment
(ii) undergoing examination and treatment, and
(iii) producing semen specimens.

(b) are equipped with backup and emergency clinical facilities that:

(i) are equivalent to those provided as standard practice in other medical facilities
(ii) are appropriate to the degree of risk involved in any planned procedure, and
(iii) can cope with emergencies known to occur in this clinical field.

Counselling facilities

25.15 The centre should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions.

See also

Guidance note 3 – Counselling

Laboratory facilities

25.16 The centre's laboratories should comply with current professional guidelines, legislation and regulations.

25.17 Procedures must be evaluated for hazards to laboratory staff, and precautions put in place to minimise potential hazards.

See also

Guidance note 15 – Procuring, processing and transporting gametes and embryos

Guidance note 24 – Third party agreements

Staff facilities

25.18 The centre should have staff amenities that are easily accessible and include:

(a) toilet facilities
(b) a rest area with basic catering facilities and a supply of drinking water
(c) a changing area and secure storage for personal belongings, and
(d) storage for protective clothing.

Infection control

25.19 When developing infection control policies and procedures, centres should consider the Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance.

25.20 Infection control policies should ensure that staff and patients are protected from acquiring infections in the course of providing treatment. In particular, these policies should ensure that:

(a) there are effective procedures in place for preventing and controlling infections, such as hand decontamination, policies on wearing sterile gloves, dress code, and the safe use and disposal of sharps
(b) staff are aware of their role in these procedures
(c) a person is identified as the infection control lead for the centre
(d) management systems are in place to ensure infection control issues are dealt with.

Management of medicines

25.21 Where controlled drugs are used, centres should be aware of the legal requirements, and have a controlled drugs accountable officer registered with the Care Quality Commission.

25.22 Centres should have policies and procedures in place for:

(a) storing, disposing of, and managing the wastage of medicines, ensuring medicines can be accurately identified, are within date, and are kept safely (to prevent unauthorised access)
(b) managing medicine stock, ensuring staff can identify and respond when new stock is needed
(c) prescribing and dispensing medicines, ensuring only suitably qualified staff prescribe medicines, patients are given information on the risks and side effects, and patients receive appropriate medicines (taking into account factors such as medical history and allergies)
(d) administering medicines, ensuring only suitably qualified staff do so, and patients who self-administer receive clear written and spoken instructions
(e) dealing effectively with any emergencies following the administration of medicines by developing appropriate contingency plans.

25.23 Centres should ensure they keep accurate records that clearly set out the medication a patient is receiving.

The surgical pathway

25.24 Before doing an operation, centres should assess the suitability of a patient to have this, including a review of their medical history, allergies and known reactions to medicines.

25.25 The consultant anaesthetist or person administering the sedative should review the patient's notes before an operation. This review should take into account that patients having operations, under either general anaesthetic or sedation, are at risk of compromise to airway, breathing and circulation. There should be an anaesthetic chart in the patient's notes, containing information such as:

(a) known drug allergies
(b) previous problems with anaesthetics or sedatives
(c) airway assessment
(d) whether the patient is taking any regular medication
(e) any post-operative instructions (eg, whether the patient will need antibiotics).

25.26 When doing a surgical procedure, centres should ensure that they:

(a) use a theatre check list
(b) monitor the patient before inducing the anaesthetic or sedative, and throughout the procedure
(c) have contingency plans in case problems arise during an operation, such as a severe allergic reaction or major bleeding
(d) have a discharge policy, ensuring that patients are discharged appropriately and by suitably trained staff.

25.27 Centres should keep accurate documentation about the operation undertaken, including the anaesthetic or sedative given, and details of patient monitoring.

25.28 Centres should ensure patients receive safe and appropriate post-operative care in line with professional guidelines. Where a general anaesthetic or sedative is used, centres should have a fully equipped recovery area, staffed by recovery staff trained to professional standards. Second recovery areas should provide close and continued supervision of all patients, who should be visible to the nursing staff.

25.29 Where recovery areas are not available or not required, centres should consider how they can be sure that the relevant staff and equipment are in place for safe post-operative care.

25.30 Centres should ensure that their procedures are suitable for the type of anaesthetic or sedative provided.

25.31 Centres should ensure that only an appropriately qualified person provides an anaesthetic.

25.32 If an anaesthetic is used at remote sites, centres should have a resuscitation team led by an Advanced Life Support provider. Where this is not the case, the anaesthetists should provide competency-based evidence of their ability to provide both advanced life support and the safe transport of a patient requiring multi-system support.

Safeguarding

25.33 Centres are expected to have a policy and procedures for safeguarding those who use their services. These should set out what staff should do if they suspect that a person has been abused, neglected or harmed in any way. The policy and procedure should include:

(a) a statement of roles and responsibilities, authority and accountability that is specific enough to ensure all staff understand their roles and limitations
(b) how to deal with allegations of abuse, including procedures for providing immediate protection in emergency situations, assessing abuse and deciding when intervention is appropriate, and reporting suspicions to the police when necessary
(c) what to do if necessary action is not taken
(d) a comprehensive list of points of referral, explaining how to access support, advice and protection at all times (including outside normal working hours), with contact addresses and telephone numbers
(e) how to record allegations of abuse, any investigations and subsequent action
(f) a list of sources of expert advice
(g) a full description of channels of inter-agency communication, for example with local authorities, and procedures for decision making
(h) a list of all services that might offer victims access to support or redress.

25.34 Centres should review procedures annually, or more often to incorporate any lessons learned or changes to legislation.

25.35 Centres should provide training for staff on the safeguarding policy and their responsibilities, including:

(a) awareness that abuse can happen, and the duty to report this
(b) recognition of abuse, and responsibilities for reporting this.

25.36 If abuse, neglect or harm is suspected, it may be in the best interests of the individual to disclose confidential patient information. The safeguarding policy should set out the principles governing the sharing of information. These principles can be summarised as follows:

(a) Information should be shared only on a ‘need to know’ basis, when it is in the best interests of the patient or donor.
(b) Confidentiality and secrecy are two different things.
(c) The individual should give informed consent to disclosure, but if this is not possible, it may be necessary to disclose personal or sensitive personal

information, despite a duty of confidentiality or legislation that would ordinarily prohibit disclosure.

(d) It is inappropriate to give assurances of absolute confidentiality in cases where there are concerns about abuse.

(e) Exchange or disclosure of personal information should be in line with the General Data Protection Regulation (EU) 2016/679 (GDPR)where this applies.

Other legislation, professional guidelines and information

Legislation

The Human Medicines Regulations 2012

The Misuse of Drugs Regulations 2001

Professional guidelines

Academy of Medical Royal Colleges: Safe sedation practice for healthcare procedures – standards and guidance (2013)

Association of Anaesthetists of Great Britain and Ireland: Checking anaesthetic equipment (2012)

Association of Anaesthetists of Great Britain and Ireland: Controlled drugs in perioperative care (2006)

Association of Anaesthetists of Great Britain and Ireland: Immediate post-anaesthesia recovery (2013)

Association of Anaesthetists of Great Britain and Ireland: Infection control in anaesthesia (2008)

Association of Anaesthetists of Great Britain and Ireland: Pre-operative assessment and patient preparation – the role of the anaesthetist (2010)

Care Quality Commission: Controlled drugs

Department for Health: Health Building Notes (2013)

Department for Health: Health Technical Memoranda (2013)

Department of Health: No Secrets – guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse (2000)

General Medical Council: Good practice in prescribing and managing medicines and devices (2013)

General Data Protection Regulation (EU) 2016/679 (GDPR)

Nursing and Midwifery Council: Standards for medicine management (2007)

Royal College of Anaesthetists: Guidelines for the provision of anaesthetic services (2015)

Royal College of Radiologists: Standards for the reporting and interpretation of imaging investigations

United Kingdom Accreditation Service: Clinical pathology accreditation

World Health Organisation: Surgical safety checklist and implementation manual (2008)

Clinic Focus articles

Clinic Focus article: Surgical procedures: an evaluation (April 2014)

Other information

Human Fertilisation and Embryology Authority: Medicines management – supplying and dispensing medicines for self-administration (2017)

26. Equipment and materials

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 Person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure—

…

(b) that proper equipment is used,

…

Licence conditions

T22 For every critical activity, identifying information about all of the materials and equipment must be documented.

T23 Activities must be carried out using equipment and materials designated for the purpose and maintained to suit their intended purpose and must minumise any hazard to patients and/or staff.

T24 All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.

T25 New, repaired and recommissioned equipment must be tested and validated before use. Test results must be documented.

T26 Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises must be performed regularly and recorded accordingly.

T27 Procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure.

T28 Sterile instruments and devices must be used for the procurement of gametes and embryos. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.

T29 When reusable instruments are used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.

T30 Wherever possible only CE marked medical devices must be used.

T31 The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament under the Council of 27 October 1998 on In vitro Diagnostic Medical Devices.

HFEA guidance

Scope

26.1 For the purpose of this Code of Practice, 'equipment and materials' includes all equipment, disposables, reagents, and calibrations and control materials used in the conduct of assisted conception process.

Protection and hygiene

26.2 The centre should provide proper clothing and equipment for the personal protection and hygiene of staff carrying out licensed activities, together with written instructions for their use.

Managing equipment and material

26.3 The centre should establish documented procedures for managing equipment and materials, including:

(a) selecting and procuring equipment and materials
(b) ensuring the traceability of any products or materials that come into contact with gametes or embryos and that affect their quality and safety, and
(c) maintaining inventory information and records for stock control.
(d) ensuring software-driven equipment is effectively validated, and revalidated after any software update.

CE marking

26.4 The centre should use only media and consumables that have been CE-marked at a classification suitable for their intended purpose. Modifying existing devices (for example, adding calcium ionophore to culture medium) or using them ‘off label’ for purposes not intended by the manufacturer (for example, using a medium for a different purpose from that specified) has safety implications. It may also count as manufacture of a new device under the Medical Devices Regulations.

26.5 If the centre does choose to modify an existing product or use a product ‘off label’, it should (as the ‘manufacturer’) complete a risk analysis and validation to ensure the product or process is safe.

See also

Guidance note 19 – Traceability

Guidance note 27 – Adverse incidents

Guidance note 31 – Record keeping and document control

Safety of equipment used to store cryopreserved gametes and embryos

26.6 All centres storing gametes and embryos should have effective alarms and monitoring systems to ensure the safety of cryopreserved gametes and embryos. These systems should have:

(a) local alarms (ie, on individual dewars for either temperature or liquid nitrogen level)
(b) an auto-dial facility or similar (eg, link to fire-alarm board) to contact staff outside normal working hours
(c) adequate staffing and funding to implement formal emergency procedures, including having on-call arrangements, and
(d) adequate spare storage space or vessels to enable transfer of samples if a vessel fails.

See also

Guidance note 17 – Storage of gametes and embryos

Other legislation, professional guidelines and information

General information

Medicines and Healthcare products Regulatory Agency: Alerts and recalls for drugs and medical devices

Clinic Focus articles

Clinic Focus article: Notice to centres use of calcium ionophore (March 2012)

Clinic Focus article: CE marking and ART

Clinic Focus article: Incidents case study - a cautionary tale on the use of benchtop incubators (January 2015)

Clinic Focus article: For action - off-label use of intralipid infusions (July 2015)

Clinic Focus article: Learning from the inspection of medicines management (July 2015)

Clinic Focus article: FAQs on the use of CE marked products (January 2016)

27. Adverse incidents

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure -

(g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

24 Directions as to particular matters

(13) The Authority may give directions as to the information to be provided to it and any measures to be taken by the person responsible in the event of -

(a) any occurrence which may adversely influence the quality or safety of gametes or embryos intended for human application

(b) any adverse incident which may be linked to the quality or safety of gametes or embryos intended for human application, or

(c) any misidentification or mix-up of gametes or embryos intended for human application.

Schedule 3A – Supplementary licence conditions: human application

Serious adverse events and serious adverse reactions

3 Licence conditions shall require such -

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction, to be in place as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.

Licence conditions

T118 The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a licence relates and any relevant third party premises.

T119 The documented procedures referred to in licence condition T118 must enable the centre to communicate to the Authority, without delay:

a. all relevant available information about suspected serious adverse events and reactions, and

b. the conclusion of the investigation to analyse the cause and ensuing outcome in relation to serious adverse events and reactions.

T120 The PR must notify the Authority of any suspected serious adverse events and serious adverse reactions by providing the information set out below and such other information as the Authority may specify in Directions:

a. identification of the centre

b. identification of the premises concerned

c. report identification

d. date of notification, and

e. date of serious adverse event/serious adverse reaction

In relation to serious adverse events the following information is also required:

f. an evaluation of the event by activity, (procurement, testing, transport, processing, storage, distribution or other) and specification of the source of error, (defect in gametes or embryos, equipment or material failure or defect), human error or other (to identify preventable causes), to be followed by a conclusion report including items (a) to (e) above.

In relation to serious adverse reaction(s) the following additional information is also required:

g. date and place of procurement of gametes or application of gametes or embryos

h. unique donation identification number

i. date of suspected serious adverse reaction

j. details of gametes or embryos involved in the suspected serious adverse reaction, and

k. type of suspected serious adverse reaction(s).

T121 The centre must thereafter notify the Authority of the conclusion of the investigation into the serious adverse event/serious adverse reaction by providing at least the information set out below and any such other information as the Authority may specify in Directions:

a. identification of the centre

b. identification of the premises concerned

c. report identification

d. date when the serious adverse event/serious adverse reaction was confirmed

e. date of the serious adverse event/serious adverse reaction, and

f. corrective measures taken.

In relation to serious adverse reaction(s) the following additional information is also required:

g. date when the serious adverse reaction was confirmed

h. unique donation identification number

i. confirmation of the type of reaction(s) or a change in the type of reaction(s),

j. clinical outcome, if known:

i. complete recovery

ii. minor sequelae

iii. serious sequelae, or

iv. death

k. root cause analysis

l. outcome of investigation and final conclusions, and

m. recommendations for preventive and corrective actions.

T122 The centre must ensure that an accurate, rapid and verifiable procedure is in place, which will enable it to recall from distribution any product that may be related to a serious adverse event or reaction.

Directions

0011 – Reporting adverse incidents and near misses

HFEA guidance

Definitions

27.1 An 'adverse incident' is any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre. This includes serious adverse events, serious adverse reactions, breaches of confidentiality, anomalies or deficiencies in the obtaining or recording of consent, and ovarian hyperstimulation syndrome (OHSS) which ~~requires a hospital admission and~~ has a severity grading of severe or critical.

27.2 A serious adverse event is defined in the HFE Act 1990 (as amended) as:

(a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services—

(i) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or
(ii) might result in, or prolong, hospitalisation or illness, or

(b) any type of gametes or embryo misidentification or mix-up'.

27.3 A serious adverse reaction is defined in the HFE Act 1990 (as amended) as:

'an unintended response, including a communicable disease, in a donor of gametes intended for human application or a person who receives treatment services or non-

medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness'.

27.4 A 'near miss' is an occurrence that, but for luck, skill or judgment, would in all probability have become an adverse incident.

Reporting and timescales

Interpretation of mandatory requirements 27A

HFEA Directions require centres to report all adverse incidents and near misses to the HFEA. This includes adverse incidents occurring at third party premises, where there is a third party agreement in force between the centre and that third party.

Centres must report all adverse incidents to the HFEA by telephone within 12 working hours of their identification. This verbal notification must include the:

(a) centre's name

(b) HFEA centre identification number

(c) contact details of the person responsible

(d) date of the initial notification or report

(e) name of any individual affected

(f) date and time of the serious adverse event or reaction

(g) details of gametes or embryos involved in the incident, and

(h) type of incident, including any transmission of infectious agents.

In addition, the centre must inform the HFEA in writing of all adverse incidents and near misses occurring at that centre (or, if the event relates to treatment that involves a third party, at a centre with which it has a third party agreement) by completing an adverse incident form. A 'near miss' is an occurrence that, but for luck, skill or judgment, would probably have become an adverse incident.

The centre must email the completed form to incident.reporting@hfea.gov.uk within 24 working hours of discovering the incident.

27.5 The centre's documented procedures should ensure that any adverse incident or near miss that may result in harm to the patient, patient's partner or donor is recorded and reviewed.

27.6 If an adverse incident or near miss occurs, centres are expected to:

(a) review relevant procedures to minimise the risk of the incident happening again, and
(b) inform the HFEA of the revised procedures.

27.7 When investigating serious adverse events and reactions, the centre should evaluate all assisted- conception processes directly related to the adverse event or reaction, and all relevant processes involving the:

(a) management of resources

(b) training and competence of staff
(c) equipment
(d) materials
(e) information systems, and
(f) control of environment.

A copy of the investigation report should be submitted to the HFEA.

27.8 When reporting cases of OHSS with a severity grading of severe or critical the centre must complete the OHSS form within 25 working days.

27.9 The HFEA also expects centres to report adverse incidents that arise from the use of equipment and materials. Reports of this nature should be sent to the Medicines and Healthcare products Regulatory Agency (MHRA), as the relevant 'competent authority'. An 'adverse incident' in this context is an incident that produces, or has the potential to produce, unwanted effects involving the safety of patients, users and others. This reporting is distinct from, but complementary to, that required by the HFEA.

27.10 If a centre becomes aware that a child born following mitochondrial donation has been born with a mitochondrial disease, birth defect, or genetic abnormality, or if there has been some other adverse outcome (including but not limited to failed or no embryo development, miscarriage or premature birth) following treatment involving mitochondrial donation, the centre must regard this as an adverse incident and report this to the HFEA in line with the requirements on adverse incidents. This is to capture information about any abnormalities that may occur as a result of carrying out the maternal spindle transfer (MST) or pronuclear transfer (PNT) treatment, to inform any regulatory or licensing action that the HFEA may wish to take and to inform the scientific sector.

27.11 The centre should, in line with professional body guidance, inform patients/donors of any adverse incidents that may have resulted in harm to them, their gametes or their embryos.

See also

Guidance note 26 – Equipment and materials

Guidance note 32 – Obligations and reporting requirements of centres

Guidance note 33 – Mitochondrial donation

Other legislation, professional guidelines and information

Professional guidelines

Care Quality Commission: guidance for NHS providers on Duty of Candour

General Medical Council: Good medical practice (2013)

National Patient Safety Agency: Being open – communicating patient safety incidents with patients, their families and carers (2009)

National Health Service Litigation Authority: Apologies and explanations (2009)

National Health Service Litigation Authority: Guidance on ‘saying sorry’

Nursing and Midwifery Council: The code – professional standards of practice and behaviour for nurses and midwives

Royal College of Obstetricians & Gynaecologists: Ovarian Hyperstimulation Syndrome, Management (Green-top Guideline No. 5) (2016)

28. Complaints

Version 1.0

HFEA guidance

Relevant legislation

Interpretation of mandatory requirements 28A

The law requires NHS and private centres to have, and adhere to, a complaints procedure. References to the relevant legislation can be found in the 'Other legislation, professional guidelines and information' box at the end of this guidance note.

Complaints procedure

28.1 The centre should ensure that staff understand the complaints procedure and the right of people to complain.

28.2 It may be appropriate to deal with a complaint as soon as it arises, without using a formal complaints procedure. In such cases, staff should deal promptly and thoroughly with issues as they are raised. Staff should treat all complaints seriously and show the complainant due respect, however minor the complaint may appear. Staff should not deter people from making formal complaints if they wish to do so.

28.3 The centre should ensure that staff are given appropriate training in complaints handling and that there are written procedures for:

(a) acknowledging and investigating complaints, and
(b) collecting suggestions and compliments.

The complaints officer and complaints register

28.4 The centre should nominate a member of staff to act as complaints officer. The complaints officer should be:

(a) the first point of contact when a person makes a formal complaint, and
(b) responsible for investigating complaints and ensuring the complaints procedure operates effectively.

28.5 The centre should display notices prominently to explain the complaints procedure and give the complaints officer's name and contact details. This information should also be given to patients and donors.

28.6 The centre should ensure there is someone else of at least equivalent seniority available to deal with complaints in case a person feels unable to complain to the complaints officer.

28.7 The centre's complaints officer should keep an accurate complaints register. For each complaint, the following should be recorded in the register:

(a) what has been done to resolve the complaint
(b) all communication with the complainant (including verbal), and
(c) the outcome, and any action taken as a result.

28.8 The centre's complaints register should be made available to HFEA inspectors during inspections.

Investigating complaints

28.9 Complaints should be investigated by staff who were not involved in the circumstances that gave rise to the complaint.

28.10 If a complainant is unhappy with the outcome of the investigation of their complaint, they should be informed of further action they could take (eg, going to the Health Commissioner in the NHS, the HFEA, or the Ombudsman).

28.11 In NHS centres, the complaints procedure should comply with standards required of NHS services. In private centres, the procedures should comply with this Code of Practice and with the standards required by:

(a) the Care Quality Commission (England)
(b) the Care Commission (Scotland)
(c) the Care and Social Services Standards Inspectorate Wales (Wales)
(d) the Regulation and Quality Improvement Authority (Northern Ireland), or
(e) relevant successor bodies.

Other legislation, professional guidelines and information

Legislation

The National Health Service (Complaints) Regulations 2004

The Private and Voluntary Health Care (England) Regulations 2001

General information

Care Quality Commission (England)

Healthcare Improvement Scotland (Scotland)

Healthcare Inspectorate Wales (Wales)

The Regulation and Quality Improvement Authority (Northern Ireland)

29. Treating people fairly

Version 1.0

HFEA guidance

Treating people fairly

Interpretation of mandatory requirements 29A

The law, mainly the Equality Act 2010, protects people who have a 'protected characteristic' (including centre staff, current and prospective patients, and donors) from less favourable treatment than others who do not have that characteristic. There are nine protected characteristics:

(a) age

(b) disability

(c) gender reassignment

(d) marriage and civil partnership

(e) pregnancy and maternity

(f) race

(g) religion or belief

(h) sex

(i) sexual orientation.

Equality law applies to both NHS and private centres, as employers and providers to the public of goods, facilities or services (paid for or free of charge).

The law protects people by prohibiting the following:

(a) Direct discrimination: where, because of a protected characteristic, a person with that characteristic is treated less favourably than others who do not share that characteristic.

(b) Discrimination by perception: where a person who is thought to have a protected characteristic is treated less favourably than others, even though they do not, in fact, have that characteristic.

(c) Discrimination by association: where a person is treated less favourably than others because of their association with someone who has a protected characteristic.

(d) Discrimination arising from disability: where a person with a disability is treated less favourably than others because of something that is a result of their disability.

(e) Combined discrimination: where a person who has two protected characteristics is treated less favourably than others who have neither of those characteristics.

(f) Harassment: where a person experiences unwanted conduct related to a protected characteristic (other than characteristics (d) and (e)) that violates their dignity or creates an intimidating, hostile, degrading or offensive environment for them, or is intended to do so.

(g) Victimisation: where a person is treated badly because they have made or supported a complaint or grievance under the Equality Act.

(h) Indirect discrimination: where a rule, policy or practice applies to everyone but disadvantages people who have a protected characteristic.

For some protected characteristics and in some contexts, unequal treatment may be justified if it is a proportionate way of achieving a legitimate aim.

The law requires reasonable adjustments to be made for people with a disability, including finding a way around arrangements that disadvantage them, helping them overcome disadvantage caused by physical features of the premises, and providing auxiliary aids (for example, extra equipment).

The law also requires those carrying out a public function to consider the need to eliminate prohibited conduct, promote equal opportunities, and encourage good relations between people with protected characteristics and those without.

The Human Rights Act 1998, which gives effect to the rights guaranteed in the European Convention for the Protection of Human Rights and Fundamental Freedoms, is also relevant to broader issues of equality, discrimination and human rights.

29.1 The person responsible should ensure that the centre's systems, policies and procedures comply with current equality legislation and guidance. A list of relevant legislation is included in the 'Other legislation, professional guidelines and information' section at the end of this guidance note.

29.2 Centres should ensure that staff, donors, patients and other visitors to the centre are treated fairly and with respect for their dignity and human rights. Centre staff should have received up-to-date training and be able to show they are competent in their obligations under equality law.

29.3 Attitudes towards assisted conception, gamete donation, embryo testing, mitochondrial donation and the use of gametes and embryos may vary significantly between individuals, cultures and religions. All healthcare professionals should be sensitive to this; the person responsible should ensure employees have access to training and support to help them identify and meet the widest possible range of patients' and donors' needs and preferences.

29.4 Equality legislation prohibits service providers (such as clinics) from discriminating against service users (patients and donors) by treating them less favourably because of a protected characteristic or particular status. Centres that consider a person unsuitable for treatment, donation or storage or stop providing services, provide services on less favourable terms than they do for other service users who do not share that protected characteristic or status, or subject the service-user to any other detriment due to one or more of these protected characteristics or statuses, may be in breach of, for example, the Equality Act and therefore likely to be at risk of regulatory sanction or other legal liability.

29.5 Gender reassignment is a protected characteristic under the Equality Act 2010. A person has the protected characteristic of gender reassignment if they are proposing to undergo, are undergoing or have undergone a process (or part of the process) of gender reassignment, by changing their physical or physiological attributes. The protected characteristic also includes an intention to transition or state of mind; the person need not have taken any steps toward gender reassignment to be protected.

29.6 Centres should be aware that for some patients, gender identity and anatomical sex may be distinct and different. Centres treating trans patients or donors with gender dysphoria or gender

identity disorder should ensure that they take account of the particular needs of these patients and make appropriate changes to relevant processes and practices to accommodate their needs.

29.7 Centres should ensure that all business and clinical structures and functions show respect for equality and diversity. Centres should review policies and procedures regularly to ensure they reflect equality and diversity adequately. Centres should also consider having equality policies.

29.8 Centres should put in place suitable procedures for monitoring and auditing the number and quality of services they provide for people with protected characteristics.

29.9 Centres should provide or arrange investigations and treatments based on professional assessment and clinical judgment. They should take into account the needs and preferences of prospective or current patients, donors and others visiting the centre, including any reasonable adjustments, aids or help they may need.

29.10 Centres must decide fairly whether to offer or refuse treatment. Staff at a centre should not refuse or delay treatment because they believe that what a patient has done or not done has contributed to their condition. The reasons for any refusal, delay or interruption of treatment should be fully documented.

29.11 As outlined in Department of Health guidance, there should be no specific restrictions on donations from men who have sex with men (MSM). The centre should assess the risks and benefits of accepting donations from each such individual – ie, document MSM behaviour.

29.12 The person responsible for an NHS centre should consider relevant policies of their primary care trust or NHS board before refusing treatment.

29.13 Staff at the centre must not harass or victimise patients or donors by allowing their own personal views or judgments (For instance, their views about a patient's age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation) to adversely affect their professional relationship with the patients or donors, or the treatment they provide or arrange. Staff should challenge colleagues if they believe that their behaviour does not comply with this guidance, or with the relevant legislative requirements. (This guidance is based on a paragraph taken from Good Medical Practice. (GMC, 2006))

29.14 Centres carrying out a public function should consider taking positive action to help people overcome disadvantage or to meet their needs, where this is consistent with centres' duties towards others.

Conscientious objection

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

38 Conscientious objection

(1) No person who has a conscientious objection to participating in any activity governed by this Act shall be under any duty, however arising, to do so.

(2) In any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming to rely on it.

(3) In any proceedings before a court in Scotland, a statement on oath by any person to the effect that he has a conscientious objection to participating in a particular activity governed by this Act shall be sufficient evidence of that fact for the purpose of discharging the burden of proof imposed by subsection (2) above.

29.15 The centre should give prospective employees a full description of the centre's activities, and at the interview draw their attention to the provision that anyone who has a conscientious objection to participating in a particular activity done in the centre must not be obliged to do so.

29.16 If a staff member has a conscientious objection to providing a particular licensed activity governed by the Act, they should inform the person responsible. The person responsible should ensure that the patient, patient's partner or donor is given information on or referred to alternative sources of the treatment.

29.17 The person responsible should satisfy themselves that the staff member has a conscientious objection to providing a particular licensed activity, and is not unlawfully discriminating against a patient on the basis of a protected characteristic.

29.18 If all staff at the centre conscientiously object to providing a particular licensed activity, the person responsible should:

(a) try to refer the person to another centre for treatment, and
(b) provide the patient with a written explanation of why the centre cannot treat them.

29.19 The person responsible should record:

(a) the reason(s) for the conscientious objection of any member of staff
(b) their efforts to provide the particular activity at the centre, and
(c) if that activity cannot be provided at the centre, efforts they have made to ensure the patient receives treatment elsewhere.

Addressing communication barriers

29.20 The centre should consider the needs of people whose first language is not English and those who face other communication barriers. Where consent is obtained, the centre should record any difficulties in communicating the implications of giving consent and in providing other information to the person (eg, language barriers or hearing impairment) and an explanation of how these difficulties were overcome (eg, the use of an independent interpreter). (This guidance is based on a paragraph taken from the Human Tissue Authority's Code of Practice on Consent (2008)).

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 23 – The quality management system

29.21 The centre should ensure it establishes and accommodates the preferred means of communication of any patient or donor with a disability. If appropriate, it should consider providing information in a variety of formats such as large print, 'easy read' or Braille.

Other legislation, professional guidelines and information

Legislation

Equality Act 2010

Gender Recognition Act 2004

Human Rights Act 1998

General guidelines

The Equality and Human Rights Commission was established under the Equality Act 2006 to champion equality and human rights for all, and to work to eliminate discrimination. Among other things, its website, provides practical information for businesses to help them meet their obligations, including a summary of relevant law. Case studies illustrate the various forms of discrimination. The Commission produces guidance and Codes of Practice for employment, service provision and other matters in relation to the Equality Act 2010.

To illustrate discrimination on the grounds of sexual orientation, the Equality and Human Rights Commission uses the example of a couple who are refused fertility treatment because they are lesbians.

The General Medical Council's 'Good medical practice' (2013) links to a range of other diversity and equality websites can be found on the site.

The HFEA Diversity Strategy outlines the way we intend to promote diversity and a set of action plans in relation to race, disability, gender, sexual orientation, religion or belief, and age. Centres may wish to refer to this when producing or revising their own diversity strategy.

30. Confidentiality and privacy

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

31 Register information

(1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which -

(a) immediately before the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008, was contained in the register kept under this section by the Authority, or

(b) is obtained by the Authority.

(2) Subject to subsection (3), information falls within this subsection if it relates to -

(a) the provision for any identifiable individual of treatment services other than basic partner treatment services,

(b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual,

(c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,

(d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or

(e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a relevant individual.

(3) Information does not fall within subsection (2) if it is provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZF(1).

(4) In this section “relevant individual” means an individual who was or may have been born in consequence of -

(a) treatment services, other than basic partner treatment services, or

(b) the procurement or distribution of any sperm (other than partner donated sperm which has not been stored) in the course of providing non-medical fertility services.

33A Disclosure of information

(1) No person shall disclose any information falling within section 31(2) which the person obtained (whether before or after the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008) in the person's capacity as -

(a) a member or employee of the Authority,

(b) any person exercising functions of the Authority by virtue of section 8B or 8C of this Act (including a person exercising such functions by virtue of either of those sections as a member of staff or as an employee),

(c) any person engaged by the Authority to provide services to the Authority,

(d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c),

(e) a person to whom a licence applies,

(f) a person to whom a third party agreement applies, or

(g) a person to whom Directions have been given.

(2) Subsection (1) does not apply where -

(a) the disclosure is made to a person as a member or employee of the Authority or as a person exercising functions of the Authority as mentioned in subsection (1)(b),

(b) the disclosure is made to or by a person falling within subsection (1)(c) for the purpose of the provision of services which that person is engaged to provide to the Authority,

(c) the disclosure is made by a person mentioned in subsection (1)(d) for the purpose of enabling a person falling within subsection (1)(c) to provide services which that person is engaged to provide to the Authority,

(d) the disclosure is made to a person to whom a licence applies for the purpose of that person's functions as such,

(e) the disclosure is made to a person to whom a third party agreement applies for the purpose of that person's functions under that agreement,

(f) the disclosure is made in pursuance of Directions given by virtue of section 24,

(g) the disclosure is made so that no individual can be identified from the information,

(h) the disclosure is of information other than identifying donor information and is made with the consent required by section 33B,

(i) the disclosure -

(i) is made by a person who is satisfied that it is necessary to make the disclosure to avert an imminent danger to the health of an individual (''P''),

(ii) is of information falling within section 31(2)(a) which could be disclosed by virtue of paragraph (h) with P's consent or could be disclosed to P by virtue of subsection (5), and

(iii) is made in circumstances where it is not reasonably practicable to obtain P's consent.

(j) the disclosure is of information which has been lawfully made available to the public before the disclosure is made,

(k) the disclosure is made in accordance with sections 31ZA to 31ZE,

(l) the disclosure is required or authorised to be made -

(i) under regulations made under section 33D, or

(ii) in relation to any time before the coming into force of the first regulations under that section, under regulations made under section 251 of the National Health Service Act 2006,

(m) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) for the purpose of carrying out the Authority's duties under section 8A,

(n) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) in pursuance of an order of a court under section 34 or 35,

(o) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to the Registrar General in pursuance of a request under section 32,

(p) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to any body or person discharging a regulatory function for the purpose of assisting that body or person to carry out that function,

(q) the disclosure is made for the purpose of establishing in any proceedings relating to an application for an order under subsection (1) of section 54 of the Human Fertilisation and Embryology Act 2008 whether the condition specified in paragraph (a) or (b) of that subsection is met,

(r) the disclosure is made under section 3 of the Access to Health Records Act 1990,

(s) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or

(t) the disclosure is made necessarily for -

(i) the purpose of the investigation of any offence (or suspected offence), or

(ii) any purpose preliminary to proceedings, or for the purposes of, or in connection with, any proceedings.

(3) Subsection (1) does not apply to the disclosure of information in so far as -

(a) the information identifies a person who, but for sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, and

(b) the disclosure is made for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent.

(4) Paragraph (t) of subsection (2), so far as relating to disclosure for the purpose of the investigation of an offence or suspected offence, or for any purpose preliminary to, or in connection with proceedings, does not apply -

(a) to disclosure of identifying donor information, or

(b) to disclosure, in circumstances in which subsection (1) of section 34 of this Act applies, of information relevant to the determination of the question mentioned in that subsection, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1).

(5) Subsection (1) does not apply to the disclosure to any individual of information which -

(a) falls within subsection (2) of section 31 of this Act by virtue of any of paragraphs (a) to (e) of that subsection, and

(b) relates only to that individual or, in the case of an individual who is treated together with, or gives a notice under section 37 or 44 of the Human Fertilisation and Embryology Act 2008 in respect of, another, only to that individual and that other.

(6) In subsection (2) -

(i) in paragraph (p) "regulatory function" has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006, and

(ii) in paragraph (t) references to "proceedings" include any formal procedure for dealing with a complaint.

(7) In this section ''identifying donor information'' means information enabling a person to be identified as a person whose gametes were used in accordance with consent given under paragraph 5 of Schedule 3 for the purposes of treatment services or non-medical fertility services in consequence of which an identifiable individual was, or may have been, born.

33C Power to provide for additional exceptions from section 33A(1)

(1) Power to provide for additional exceptions from section 33A(1)

(2) No exception may be made under this section for -

(a) disclosure of a kind mentioned in paragraph (a) or (b) of subsection (4) of section 33A, or

(b) disclosure in circumstances in which section 32 of this Act applies of information having the tendency mentioned in subsection (2) of that section, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1) of section 33A.

34 Disclosure in interests of justice

(1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008 falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Authority -

(a) to disclose whether or not any information relevant to that question is contained in the register kept in pursuance of section 31 of this Act, and

(b) if it is, to disclose so much of it as is specified in the order, but such an order may not require the Authority to disclose any information falling within section 31(2) (c) to (e) of this Act.

(2) The court must not make an order under subsection (1) above unless it is satisfied that the interests of justice require it to do so, taking into account -

(a) any representations made by any individual who may be affected by the disclosure, and

(b) the welfare of the child, if under 18 years old, and of any other person under that age who may be affected by the disclosure.

(3) If the proceedings before the court are civil proceedings, it -

(a) may direct that the whole or any part of the proceedings on the application for an order under subsection (2) above shall be heard in camera, and

(b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.

(4) An application for a direction under subsection (3) above shall be heard in camera unless the court otherwise directs.

35 Disclosure in interests of justice: congenital disabilities, etc

(1) Where for the purpose of instituting proceedings under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of the child, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.

(2) Where, for the purposes of any action for damages in Scotland (including any such action which is likely to be brought) in which the damages claimed consist of or include damages or solatium in respect of personal injury (including any disease and any impairment of physical or mental condition), it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of any party to the action or, if the proceedings have not been commenced, the prospective pursuer, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.

(2A) In subsections (1) and (2) “the relevant statutory provisions” means -

(a) sections 27 to 29 of this Act, and

(b) sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.

(3) Subsections (2) to (4) of section 34 of this Act apply for the purposes of this section as they apply for the purposes of that.

(4) After section 4(4) of the Congenital Disabilities (Civil Liability) Act 1976 there is inserted -

"(4A) In any case where a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, any reference in section 1 of this Act to a parent includes a reference to a person who would be a parent but for sections 27 to 29 of the Human Fertilisation and Embryology Act 1990."

41 Offences

(5) A person who discloses any information in contravention of section 33A of this Act is guilty of an offence and liable -

(a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and

(b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Licence conditions

T43 The centre must ensure that all information is kept confidential and only disclosed in circumstances permitted by law.

T44 The centre must have processes in place to ensure that access to a centre’s health data and records is secure at all times; conforms with legislative requirements; and is only available to

persons named on a centre's licence or authorised by the Person Responsible. Such processes shall include:

a. establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records, and the transfer of information

b. establishing and maintaining procedures to resolve all data discrepancies

c. preventing unauthorised disclosure of information whilst guaranteeing the traceability of gamete, embryo or tissue (cell) donations

d. considering and responding to applications for access to confidential records and correctly identifying applicants, and

e. receiving, checking and arranging authorised access to confidential data and records.

T45 Access to registers and data must be restricted to persons authorised by the PR and to the Authority for the purpose of inspection and control measures.

HFEA guidance

Confidentiality

30.1 Centres must treat all patients with dignity and respect and must take appropriate measures to maintain their confidentiality.

30.2 The centre should ensure that information provided in confidence, including all information relating to donors, patients and children born as a result of treatment, is kept confidential and disclosed only in the circumstances permitted by law. The centre should ensure that patients, their partners, and donors do not have access to any other person's records without first getting that person's consent.

30.3 If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

30.4 In relation to the treatment of trans patients and donors, there are additional points on confidentiality that must be taken into consideration. The centre should be aware that under the General Data Protection Regulation (EU) 2016/679 (GDPR), information about a person's gender reassignment or any other information relating to a person's gender history will be classed as 'special category data' and should ensure that appropriate safeguards are in place for the processing of this data. This includes, among other things, the information not being shared or disclosed unless the relevant requirements of the GDPR have been met.

The centre should take appropriate measures to ensure that they comply with strict prohibitions set out under the Gender Recognition Act 2004 on the disclosure of information concerning a patient or a donor who has applied for a gender recognition certificate (GRC), or about the gender history of a person who has a GRC.

Centres may wish to seek legal advice if they are uncertain about the lawful use, sharing or disclosure of the sensitive personal data of transgender patients.

30.5 In relation to the treatment of patients and donors entering into surrogacy arrangements, centres

must ensure that appropriate arrangements are in place to maintain confidentiality. The centre must keep separate up-to-date records for the surrogate and the intended parents. The centre should provide separate implications counselling sessions for the surrogate and the intended parents, on different dates. Throughout treatment the clinic should allow opportunity for separate consultations with the surrogate and with the intended parents. During any appointment or occasion where both the surrogate and intended parent(s) are present, the centre should ensure that consideration is given to their confidentiality and ensure that parties are offered an opportunity to speak to members of staff in private should they wish to.

See also

Guidance note 29 – Treating people fairly

Guidance note 30 – Confidentiality and privacy

Breach of confidentiality

30.6 If confidentiality is breached (including disclosure of information in breach of either the HFE Act 1990, the General Data Protection Regulation (EU) 2016/679 (GDPR)or the Gender Recognition Act 2004), the centre should consider it an adverse incident and therefore investigate the cause(s) of the breach, take appropriate remedial action, and notify and submit a full explanation to the HFEA that includes what mitigating actions have been put in place to prevent a similar breach taking place. Consideration should also be given, depending on the level of risk to the data subject, to whether the breach should be reported to the Information Commissioner, and whether any patients affected by the breach should be informed, particularly if their sensitive personal data (including 'special category data') has been disclosed or if there is a risk of detriment to the patient.

30.7 The centre should be aware that certain breaches of confidentiality pertaining to a person's gender reassignment or gender history may amount to a criminal offence. For example, the disclosure of certain information in breach of the provisions of section 33A of the HFE Act 1990 and section 22 of the Gender Recognition Act 2004. The centre should consider circumstances where they may need to disclose a person's gender reassignment or gender history (eg, to those within the centre who need to know of a trans patient's previous identity to deliver safe and appropriate care), to determine whether it needs to obtain the person's consent to disclose this information.

See also

Guidance note 27 – Adverse incidents

Access to medical records

30.8 For the purposes of this Code of Practice, a record is defined as information created, received and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium provided they are readily accessible, legible and indelible.

30.9 The centre must establish a documented procedure for controlling access to medical records.

This should ensure that arrangements are in place for:

(a) properly identifying applicants
(b) promptly considering and responding to applications for access to confidential records
(c) a designated individual in the centre being responsible for receiving, checking and arranging authorised access to confidential records
(d) notifying the Information Commissioner in line with the General Data Protection Regulation (GDPR)
(e) giving all individual donors and recipients who provide information about themselves access to their own records and an opportunity to correct any information that is incorrect
(f) ensuring proper procedures are in place to maintain confidentiality when records are stored off site, and
(g) ensuring that individuals are aware of their rights under the General Data Protection Regulation (GDPR) to access their own medical records.

NOTE When the centre is part of a larger organisation, the appropriate department of the parent organisation may do some of these procedures, where relevant.

30.10 The centre should have clear security procedures to prevent unauthorised access to records, and take particular care if records are kept outside the licensed premises (eg, when counselling takes place outside the centre). The security procedures should be appropriate to the record keeping system, whether paper-based, electronic or in any other format. Extra scrutiny is recommended if the centre has laboratory equipment that stores patient-identifying information electronically.

30.11 To mitigate the risks of unauthorised people inadvertently gaining access to patient-identifying information through electronic records, the centre should:

(a) ensure that such information cannot be transferred to portable media-storage devices
(b) ensure that when hardware is removed from the premises, identifying information has been removed
(c) consider making it a policy that no data is stored on any third-party device unless there is a process for anonymising or deleting the data
(d) record and audit potential access to identifying information
(e) have systems in place to reduce the risks of malicious access to data; these systems should include anti-virus software, firewalls, and network segmentation (including user-/network-level usernames and passwords)
(f) know what software is installed on centre systems and what it allows
(g) ensure agreements/contracts with the relevant providers set out expectations.

30.12 If the centre's service providers require access to identifying information to do their job, then the centre must take steps to ensure that any person accessing data is suitable.

30.13 A person whose medical records are held by the centre is normally entitled to receive a copy of their own medical records, so long as they ask in writing (including by electronic means) ~~and pay any fee required~~. The source of the information and an explanation of any unusual or technical terms should be given.

See also

Guidance note 4 – Information to be provided prior to consent

Guidance note 31 – Record keeping and document control

The General Data Protection Regulation (EU) 2016/679 (GDPR)

30.14 The General Data Protection Regulation will be implemented in the UK on 25 May 2018. On that date a new Data Protection Act also entered into force, repealing and replacing the existing Data Protection Act 1998. Many of the requirements of the GDPR are similar to those in the Data Protection Act 1998 (DPA 1998) therefore, if centres are compliant with the DPA 1998, they are likely to be compliant with the GDPR. However, GDPR does introduce some new requirements and significant enhancements to existing requirements. GDPR introduces much more severe financial penalties for organisations that get it wrong. Each centre is responsible for ensuring that it complies with the new legislation.

30.15 GDPR introduces some new rights for individuals and enhances other rights, but in general an individual's rights under GDPR are not absolute and will only apply in certain circumstances. For example, although GDPR introduces a right for individuals to have personal data erased, that right does not apply if the processing of the individual's personal data is necessary to comply with a legal obligation. In other words, centres will not need to comply with a patient's request for erasure of their IVF treatment records given that it is a legal requirement, by virtue of General Direction 0012, that the centre retains those records for at least 30 years. Matters which raise questions about the application of GDPR and the HFE Act 1990 should be considered on a case by case basis and centres should consult the Information Commissioner's website for guidance and take their own legal advice where necessary.

30.16 GDPR applies to both NHS and private centres and all centres are expected to do an audit of their current Data Protection arrangements as against the new requirements of the GDPR to determine whether they are fully compliant, and where indicated, make the necessary changes to bring practices and procedures in line with the new requirements of the GDPR.

The audit should assess amongst other things, what and when personal data is collected, the legal basis for the processing of personal data (for example to fulfil legal obligations to report certain personal data, including data about treatment, to the HFEA or for employment purposes), where data is stored and what measures are in place to protect it, whether it is shared with third parties and why it is shared.

30.17 Centres should also review practices to ensure that all individuals (this includes patients and their partners, donors and members of staff) are provided with sufficient information about what the centre does with their personal data. Where indicated by the audit, centres should revise processes and procedures to ensure that they are fully compliant with all the individual rights set out in GDPR.

30.18 GDPR introduces a duty to report certain types of personal data breaches to the Information Commissioner. Centres must report notifiable breaches to the ICO within 72 hours of becoming aware of the breach, where feasible.

If the breach is likely to result in a high risk of adversely affecting individuals' rights and freedoms, centres must also inform the affected individuals without undue delay.

30.19 Centres should ensure that they have robust procedures for detecting and investigating any data breaches. This should include a clear procedure for staff to alert the PR of any personal data breaches and a procedure for notifying the ICO of reportable breaches. A record should be kept of any personal data breaches regardless of whether the centre is required to report the breach.

30.20 The centre should comply promptly with 'subject access requests' made under the General Data Protection Regulation (GDPR). Usually, such requests will be for copies of medical records. The centre must check the identity of the person making the request and may also request written consent to disclosure and proof of identity from the partners of applicants if the medical record contains information relating to them. ~~The centre may also levy a fee of between £10 and £50 for copying medical records.~~

30.21 When proof of identity ~~and payment~~ has been received, the centre has one month to respond to the request. The centre should be aware that some requests for information may fall under different information access regimes; they must ensure that they comply within the appropriate timeframes (eg, 20 working days under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004).

30.22 The centre should take into account any other exceptions and modifications to the General Data Protection Regulation (GDPR) before giving access.

Disclosing non-identifying information: general

30.23 The centre may disclose information that does not identify or could not reasonably be expected to lead to the identification of a person owed a duty of confidentiality. If the centre is unsure whether information it proposes to disclose could identify the person, it should seek independent legal advice.

Disclosure authorised by statute

Interpretation of mandatory requirements 30A

A centre may hold information that could lead to the identification of:

(a) an individual donor or recipient of gametes or embryos (including mitochondrial donation)

(b) an individual or couple seeking or receiving treatment services (other than basic partner services), or

(c) an individual who may have been born as a result of such services or as a result of donated sperm.

The centre may disclose this information only in the specific circumstances set out in the HFE Act 1990 (as amended). The information may, for example, be disclosed:

(a) to anyone, provided that it is disclosed in such a way that no individual can be identified from it

(b) to the Authority

(c) to another licensed centre to enable that centre to carry out its functions under its licence

(d) to the person to whom the information relates, and to their partner (if they are being treated together, or their partner has served notice of consent to be treated as the legal parent of any resulting child)

(e) with the consent of each person who could be identified from the information (although disclosure in this case is limited to information other than that from which a donor of gametes could be identified)

(f) in connection with specific proceedings, including, for example, in relation to the formal complaints procedure, or

(g) in an emergency, if disclosure is necessary to avert imminent danger to the health of the person to whom the information relates, and it is not reasonably practicable to obtain their consent to disclosure.

If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

30.24 If the centre refers a person seeking treatment to another licensed centre, it should provide relevant information in line with good clinical practice. The centre must always supply information relevant to the welfare of the child.

See also

Guidance note 8 – Welfare of the child

Disclosing information to gamete and embryo donors

Interpretation of mandatory requirements 30B

A donor may request information from a centre about the number, sex and birth year of any children born using their gametes or embryos (including mitochondrial donation). If the centre holds that information, it must provide it unless the person responsible considers that special circumstances exist that increase the likelihood of the donor being able to identify any of those children.

Once a person conceived using donor gametes reaches the age of 16, they may ask the Authority to give them certain non-identifying information about the donor and the number, sex and year of birth of any donor-conceived siblings.

Once a person conceived using donor gametes reaches the age of 18, they may also ask the Authority for certain identifying information about the donor, where that information was provided to the centre after the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 came into force.

30.25 The HFEA will seek to inform donors of gametes and embryos that it has received an application by a donor-conceived person for identifying information about them. The HFEA will 5not give the donor any information about the person making the application.

Disclosing information to recipients of donated gametes and embryos

30.26 The centre may give non-identifying information about the donor to those who receive donor-assisted conception treatment or treatment involving mitochondrial donation and those who have received such treatment in the past.

30.27 The HFEA may also disclose the information that centres may disclose in these circumstances, if that information is contained on its Register.

30.28 The centre should:

(a) reassure donors and potential donors that they may ask at any time how many children have resulted from their donation

(b) reassure identifiable donors that attempts will be made to contact them before their identity is disclosed to a donor-conceived person
(c) encourage identifiable donors to provide up-to-date contact details to help this, and
(d) respond as fully as possible to patients' requests for non-identifying information about the donor(s) used in their treatment.

Consent to disclose identifying information

Interpretation of mandatory requirements 30C

Patients have the right to decide what identifying information should be disclosed and to whom. Centres should obtain a patient's written consent before disclosing information relating to their treatment (or providing gametes for a partner's treatment), or storage of their gametes or embryos.

In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or storage. For example, if a patient's partner could be incidentally identified through disclosure of information about a patient's treatment.

If a child born as a result of treatment could be identified, consent must be obtained from the parent(s), unless identification is necessarily incidental to the disclosure of information about the patient's treatment. Once a child born as a result of treatment is considered competent to consent, then their consent (if given) will override the consent of the parent(s).

30.29 Before obtaining consent to disclose information, the centre should give the person enough information for them to make a properly informed decision, including:

(a) precisely what information is to be disclosed
(b) the terms on which it is disclosed
(c) the reasons for disclosure (eg, to keep the person's GP informed about the fertility treatment)
(d) the implications of disclosure, in particular the fact that, once it is disclosed, the information will be subject no longer to the special provisions of the HFE Act 1990 (as amended) but only to the general law of confidentiality, and
(e) the categories of people to whom the information is to be disclosed.

30.30 The centre should seek consent to disclosure to the following categories of people:

(a) the patient's GP or the patient's partner's GP
(b) other healthcare professionals outside the centre (to enable them to provide the patient or the patient's partner with the best possible medical care)
(c) auditors or administrative staff outside of the centre (to enable them to perform functions designated to them in connection with the centre's licensable activities), and
(d) medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).

30.31 The centre should renew consent to disclosure if the nature of the treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used instead of the patient's own, or if the patient moves from unlicensed to licensed fertility treatment).

30.32 The centre should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:

(a) the precise terms upon which it was disclosed and for which consent has been given, and
(b) that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 31 – Record keeping and document control

HFEA consent forms

Other legislation, professional guidelines and information

Legislation

Access to Health Records Act 1990

The Access to Health Records (Northern Ireland) Order 1993

General Data Protection Regulation (GDPR)

The Data Protection (Subject Access Modification) (Health) Order 2000

European Convention for the Protection of Human Rights and Fundamental Freedoms

Equalities Act 2010

Gender Recognition Act 2004

Human Rights Act 1998

Professional guidelines

Care Quality Commission: Code of Practice – confidential personal information (2016)

National Health Service: Code of Practice – confidentiality (2003)

General Medical Council: Confidentiality guidance – protecting information (2009)

Information Commissioner's Office: upholds information rights in the public interest

National Health Service Digital: Code of Practice for health and social care – records management (2016)

31. Record keeping and document control

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

12 General conditions

(1) The following shall be conditions of every licence granted under this Act -

…

(b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity),…

…

(d) that proper records shall be maintained in such form as the Authority may specify in Directions,…

…

(g) that the Authority shall be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

(2) Subsection (3) applies to -

(a) every licence under paragraph 1 or 1A of Schedule 2,

(b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application, and

(c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(3) Subsection (3) applies to -

(a) every licence under paragraph 1 or 1A of Schedule 2,

(b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application, and

(c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

13 Conditions of licences for treatment

(2) Such information shall be recorded as the Authority may specify in Directions about the following -

(a) the persons for whom services are provided in pursuance of the licence,

(b) the services provided for them,

(c) the persons whose gametes are kept or used for the purposes of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used,

(d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence,

(e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and

(f) such other matters as the Authority may specify in Directions.

(3) The records maintained in pursuance of the licence shall include any information recorded in pursuance of subsection (2) above and any consent of a person whose consent is required under Schedule 3 to this Act.

(4) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.

Schedule 3B – Inspection, entry, search and seizure – Inspection of statutory records

(1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.

(2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection -

(a) in a visible and legible form, or

(b) in a form from which they can be readily produced in a visible and legible form.

3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

Licence conditions

T34 A document control procedure must be established that records the history of document reviews and ensures that only current versions of documents are in use.

T37 Proper records must be maintained in such form as the Authority may specify in Directions.

T38 Records must be legible and indelible and may be hand written or transferred to another validated system, such as a computer or microfilm.

T39 Such information must be recorded as the Authority may specify in Directions about the following:

a. the persons for whom services are provided in pursuance of the licence,

b. the services provided for them

c. the persons whose gametes are kept or used for the purpose of services provided in pursuance of the licence or whose gametes have been used in bringing about the

creation of embryos so kept or used

d. any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence

e. any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo

f. such information as the Authority may specify in directions as to the persons whose consent is required under schedule to the Human Fertilisation and Embryology Act 1990 (as amended), the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions must be included in the records maintained in pursuance of the licence, and

g. such other matters as the Authority may specify in Directions.

T40 Information must not be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.

T42 Where gametes or embryos are supplied to a person to whom another licence applies, that person must be provided with such information as the Authority may specify in Directions.

T46 For each patient/donor the centre must maintain a record containing:

a. patient/donor identification: first name, surname, date of birth, age and sex

b. how, and by whom, the patient/donor has been reliably identified

c. the services provided to them

d. medical history

e. welfare of the child assessment

f. consent, including the purpose or purposes for which their gametes or embryos created using their gametes may be used, and any specific instructions for use and/or disposal, and

g. clinical and laboratory data and the results of any test carried out.

T47 All records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

T48 Patient/donor records required for full traceability must be kept for a minimum of 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority.

Directions

0001 – Gametes and embryos

0003 – Multiple births

0005 – Collecting and recording information for the HFEA

0007 – Consent

0012 – Retention of records

Records to keep

31.1 This guidance note does not summarise all the record keeping requirements of a licensed centre. The person responsible should familiarise themselves with these, which are discussed in the following guidance notes:

2 – Staff
3 – Counselling
4 – Information to be provided prior to consent
5 – Consent to treatment, storage, donation, and disclosure of information
6 – Legal parenthood
7 – Multiple births
8 – Welfare of the child
9 – Preimplantation genetic screening (PGS)
11 – Donor recruitment, assessment and screening
12 – Egg sharing arrangements
15 – Procuring, processing and transporting gametes and embryos
16 – Imports and exports
17 – Storage of gametes and embryos
18 – Witnessing and assuring patient and donor identification
19 – Traceability
21 – Intra-cytoplasmic sperm injection (ICSI)
22 – Research and training
23 – The quality management system
24 – Third party agreements
26 – Equipment and materials
27 – Adverse incidents
28 – Complaints
29 – Treating people fairly
30 – Confidentiality and privacy
32 – Obligations and reporting requirements of centres
33 – Mitochondrial donation

Definitions

31.2 A record is defined as ‘information created or received, and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium providing they are readily accessible, legible and indelible.’

31.3 A documented procedure is defined as ‘a set of written instructions describing the steps in a specific process, including the materials and methods to be used, and the expected end product. This term has the same meaning as standard operating procedures.’

Document control

31.4 The centre should have document control procedures in place to:

(a) ensure that all documents include:

(i) a unique identifier (for instance, the edition, or current revision date or revision number)
(ii) page numbers and total number of pages (for example ‘page 3 of 10’)

(iii) authority for their issue, and
(iv) author identification

(b) control all records required to:

(i) provide evidence of conforming to legal requirements
(ii) operate the quality management system effectively, and
(iii) conduct assisted conception processes.

The procedures must cover the identification, collection, indexing, access, storage, maintenance, confidentiality and safe disposal of records.

See also

Guidance note 23 – The quality management system

31.5 A centre that treats trans patients should be aware that other than in a limited number of circumstances, it is unlawful to disclose information about a trans patient's gender reassignment, gender history or application for a Gender Recognition Certificate (GRC). Centres treating trans patients should give consideration to the need or justification for collecting this information, and should have appropriate processes in place to secure that it is only disclosed to those members of the clinical team who need to know how to deliver safe and appropriate care or for other lawful reasons, and that appropriate consent is obtained where necessary. When considering disclosure of information pertaining to trans patients, centres may wish to seek advice from appropriately experienced information law specialists.

31.6 Where a trans person, who has previously been a patient, has since taken on a new identity or has obtained a GRC, centres should accurately update medical records to reflect the patient's newly acquired identity once they have been informed. This does not necessarily mean erasing records containing the patient's previous identity, but ensuring appropriate measures are put in place to ensure all records pertaining to future treatment reflect the patient's acquired identity. Necessary safeguards to protect personal data should be in place.

31.7 When a centre registers a donor with the HFEA, they are required to indicate the donor's gender which must correlate with the gametes being donated (eg, if the donor is donating sperm they must be recorded as a male). However, clinics may add a comment when submitting this information to the HFEA to indicate a trans person's preferred gender, where the donor has consented to disclosure of this information to the HFEA.

31.8 When a centre's document control system allows documents to be amended by hand pending their re-issue, the procedures and authority for such amendments should be defined; amendments should be clearly marked, initialled and dated; and a revised document should be re-issued as soon as practicable.

31.9 Documents should be reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months.

31.10 Access to registers and data must be restricted to people authorised by the person responsible and the HFEA for inspection purposes.

See also

Guidance note 30 – Confidentiality and privacy

Managing information

31.11 The centre should establish documented procedures for managing data and information. These should include:

(a) accurate recording of information
(b) security of data and safeguards against unauthorised modification, addition, deletion, disclosure or transfer of information
(c) resolution of data discrepancies
(d) maintenance and disaster recovery
(e) storage, archiving and retrieval, and
(f) secure disposal.

31.12 If using off-site storage facilities for archived records, the centre should establish procedures to ensure patient confidentiality is maintained. These should include:

(a) removal of all patient identifying information that might be visible to staff outside the licensed centre, and
(b) ensuring files are properly sealed when they are being transported between the centre and storage facility.

Other legislation, professional guidelines and information

Legislation

Equality Act 2010

Gender Recognition Act 2004

32. Obligations and reporting requirements of centres

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

31 Register information

(1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which—

(a) immediately before the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008, was contained in the register kept under this section by the Authority, or

(b) is obtained by the Authority.

(2) Subject to subsection (3), information falls within this subsection if it relates to—

(a) the provision for any identifiable individual of treatment services other than basic partner treatment services,

(b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual,

(c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,

(d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or

(e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a relevant individual.

(3) Information does not fall within subsection (2) if it is provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZF(1).

(4) In this section “relevant individual” means an individual who was or may have been born in consequence of—

(a) treatment services, other than basic partner treatment services, or

(b) the procurement or distribution of any sperm (other than partner donated sperm which has not been stored) in the course of providing non-medical fertility services.

12 General conditions

(1) The following shall be conditions of every licence granted under this Act—

…

(b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity)

…

(g) that the Authority shall be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

(3) It shall be a condition of every licence to which this subsection applies that—

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

17 Persons Responsible

It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure—

…

(g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

Schedule 3B Inspection, Entry, Search and Seizure

Inspection of statutory records

1 (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.

(2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—

(a) in a visible and legible form, or

(b) in a form from which they can be readily produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

Arranging inspections

2 (1) Where a person—

(a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or

(b) has made a relevant application to the Authority which the Authority has not yet considered,

the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3).

(2) For the purposes of sub-paragraph (1) a "relevant application" means—

(a) an application for authorisation for a person to carry on an activity governed by this Act which the person is not then authorised to carry on, or

(b) an application for authorisation for a person to carry on any such activity on premises where the person is not then authorised to carry it on.

(3) The premises referred to in sub-paragraph (1) are—

(a) the premises where any activity referred to in sub-paragraph (2) is to be carried on;

(b) any premises that will be relevant third party premises for the purposes of any application.

(4) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences and third party agreements.

Entry and inspection of premises

3 (1) A duly authorised person may at any reasonable time enter and inspect any premises to which a licence relates or relevant third party premises.

(2) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences and third party agreements.

4 (1) Subject to sub-paragraph (2), the Authority shall arrange for any premises to which a licence relates to be inspected under paragraph 3 by a duly authorised person at intervals not exceeding two years.

(2) The Authority need not comply with sub-paragraph (1) where the premises in question have been inspected in pursuance of paragraph 2 or 3 at any point within the previous two years.

Entry and search in connection with suspected offence

5 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—

(a) that an offence under this Act is being, or has been committed on any premises, and

(b) that any of the conditions in sub-paragraph (2) is met in relation to the premises, the justice of the peace may by signed warrant authorise a duly authorised person, together with any constables, to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

(a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent;

(d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) In relation to Scotland—

(a) any reference in sub-paragraph (1) to a justice of the peace includes any reference to a sheriff, and

(b) the reference in that sub-paragraph to “on sworn information” is to be read as a reference to “by evidence on oath”.

Execution of warrants

6 (1) Entry and search under a warrant under paragraph 5 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

(a) produce the warrant to the occupier, and

(b) give the occupier—

(i) a copy of the warrant, and

(ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

(a) produce the warrant to that other person,

(b) give that other person—

(i) a copy of the warrant, and

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(7) Where the premises in relation to which a warrant under paragraph 5 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall when leaving the premises, leave them as effectively secured as the person found them.

Seizure in the course of inspection or search

7 (1) A duly authorised person entering and inspecting premises under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for -

(a) the purposes of the Authority’s functions relating to the grant, revocation, variation or suspension of licences, or

(b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.

(2) A duly authorised person entering or searching premises under a warrant under paragraph 5 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.

(3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.

(4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of sub-paragraph (1) or (2) a person ("P") seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

Supplementary provision

8 (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Power under this Schedule to inspect or search any premises includes, in particular—

(a) power to inspect any equipment found on the premises,

(b) power to inspect and take copies of any records found on the premises, and

(c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on of the licensed activity on the premises.

(3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

9 (1) A person's right to exercise a power under this Schedule is subject to production of evidence of the person's entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having inspected premises in pursuance of arrangements made under paragraph 2 or after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—

(a) prepare a written report of the inspection, or as the case may be, the inspection and search, and

(b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.

(3) In sub-paragraph (2), the "appropriate person" means—

(a) in relation to premises to which a licence relates, the person responsible, or

(b) in relation to any other premises, the occupier.

Enforcement

10A person who—

(a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 8(3), or

(b) intentionally obstructs the exercise of any right under this Schedule,

is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Interpretation

11 In this Schedule—

(a) "duly authorised person", in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision, and

(b) "licensed activity", in relation to a licence, means the activity which the licence authorises to be carried on.

35B Fees

The Authority may charge a fee in respect of any of the following—

(a) an application for a licence,

(b) the grant or renewal of a licence,

(c) an application for the revocation or variation of a licence, …

Licence conditions

T2 Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.

T3 Any member or employee of the Authority, on production of a document identifying the person as such, if so required, must at all reasonable times be permitted to enter those premises and inspect them (including inspecting any equipment or records and observing any activity).

T4 In support of an inspection, the Authority must be provided, within 28 days of a request in writing being made, with such information as specified in the written requests or in Directions.

T6 When carrying out licensable activities, the centre shall only use those processes which have been expressly authorised by the Authority and published on the HFEA website (as amended from time to time).

T41 The Authority must be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

Directions

0005 – Collecting and recording information for the HFEA

0008 – Information to be submitted to the HFEA as part of the licensing process

0011 – Reporting adverse incidents and near misses

HFEA guidance

Legal obligations toward the HFEA

Interpretation of mandatory requirements 32A

Centres have various legal obligations toward the HFEA. The person responsible should familiarise themselves with these, which include:

(a) allowing HFEA inspectors to enter centre premises or relevant third party premises at reasonable hours

(b) allowing HFEA inspectors to inspect centre or relevant third party premises, including inspecting equipment and records, taking away copies of records and other required items, and observing any activity, and

(c) notifying the HFEA of any new activities or treatment services, before those services or activities are carried out.

The law also requires centres to provide certain information to the HFEA, either on request or at intervals or by deadlines specified in Directions. This includes information relating to:

(a) the quality or safety of gametes and embryos

(b) the traceability of gametes and embryos

(c) adverse incidents and near misses, and

(d) register information, including:

  (i) registration information for donors, patients and patients' partners

  (ii) information on the intention to treat

  (iii) IVF treatment and embryo creation information

  (iv) donor insemination information

  (v) treatment outcome information.

Directions also outline how and when information should be submitted. For example, licensed centres must report using the Electronic Data Interchange (EDI) system unless they are given prior written authority to use a different method.

Collecting and recording information for the HFEA

32.1 The person responsible should ensure that:

(a) data is submitted in line with Directions, using HFEA guidance on the completion of forms
(b) data is submitted within the timeframe required by Directions
(c) the data submitted is of good quality, and any errors and omissions are identified and corrected within the timeframe specified by Directions
(d) suitable processes support verification and sign-off of the centre's data in line with Directions and 'HFEA Policy on Collection, Confirmation and Publication of Register Data'
(e) staff who submit data to the HFEA are adequately trained, and supported with standard operating procedures, and
(f) data collection, recording and submission processes are monitored and audited, and information from these is used to trigger any corrective action needed.

32.2 The person responsible should ensure that mechanisms used to monitor data collection, recording and submission are regularly reviewed to ensure that requirements are met.

32.3 The person responsible should ensure that checks on the quality of data submitted to the HFEA include reconciliation of Register data to source documentation (ie, patient and donor records) held by the centre. Some system and process errors may be identified only in this way.

32.4 The person responsible should tell the HFEA as early as possible if they plan to move to a different IT system for submitting Register data. Such a move may mean staff no longer have access to previous data, or cannot correct records on the old IT system (ie, patient and donor registration, and linked gamete source/treatments and pregnancy outcomes).

32.5 The person responsible should tell the HFEA as early as possible if they expect to close the centre, and should make adequate arrangements for:

(a) accessing and storing patient and donor records in the future
(b) submitting outstanding information to the Authority, and
(c) providing outcome data that will be pending when the centre closes.

Requests under the Freedom of Information Act 2000

32.6 The Freedom of Information Act 2000 (FOIA) gives the public the right to access information held by central government, local government and other public organisations. The FOIA is intended to improve openness and accountability to the public. Therefore, any recorded information (eg, on paper, computer file, email, disk, tape or microfiche) submitted to the HFEA may be disclosed under the FOIA. This excludes information covered by the confidentiality provisions of the HFE Act 1990 (as amended). The HFEA will consider arguments from information providers for non-disclosure, but may decide that the information must be disclosed.

Other legislation, professional guidelines and information

Legislation

Freedom of Information Act 2000

The Environmental Information Regulations 2004

Professional guidelines

National Health Service Digital: Code of Practice for health and social care – records management (2016)

33. Mitochondrial donation

Version 1.0

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

In cases where an egg or embryo has been created following mitochondrial donation, the following provisions of the HFE Act 1990 should be read so that they are modified as set out below:

3 Prohibitions in connection with embryos

(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except -

(a) in pursuance of a licence, or

(b) in the case of -

(i) the keeping, without storage, of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo,

in pursuance of a third party agreement.

(1B) No person shall procure or distribute an embryo intended for human application except in pursuance of a licence or a third party agreement.

(2) No person shall place in a woman -

(a) an embryo other than a permitted embryo (as defined by section 3ZA), or

(b) any gametes other than permitted eggs or permitted sperm (as so defined).

(3) A licence cannot authorise -

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal, or

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, ...

(d) ....

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with [the day on which the process of creating the embryo began], not counting any time during which the embryo is stored.

3ZA Permitted eggs, permitted sperm and permitted embryos

(1) This section has effect for the interpretation of section 3(2).

(2) A permitted egg is one -

(a) which has been produced by or extracted from the ovaries of a woman, and

(b) whose nuclear or mitochondrial DNA has not been altered.

(3) Permitted sperm are sperm -

(a) which have been produced by or extracted from the testes of a man, and

(b) whose nuclear or mitochondrial DNA has not been altered.

(4) An embryo is a permitted embryo if -

(a) it has been created by the fertilisation of a permitted egg by permitted sperm,

(b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and

(c) no cell has been added to it other than by division of the embryo's own cells.

(5) Regulations may provide that -

(a) an egg can be a permitted egg, or

(b) an embryo can be a permitted embryo,

even though the egg or embryo has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.

(6) In this section -

(a) "woman" and "man" include respectively a girl and a boy (from birth), and

(b) "prescribed" means prescribed by regulations.]

Modification of section 31ZA: Request for information as to genetic parentage or mitochondrial donors etc,

(1) A person who has attained the age of 16 ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2) or (2A).

(2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person (“the donor”) other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that -

(a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information), or

(b) stating whether or not that information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so -

(i) the number of those other persons,

(ii) the sex of each of them, and

(iii) the year of birth of each of them.

(2A) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person is the applicant’s mitochondrial donor, and if it does show that, giving the applicant the following information contained in the register -

(a) the screening tests carried out on the mitochondrial donor and information on that donor’s personal and family medical history,

(b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and

(c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person who requests information under this section, but not giving any information which may identify the mitochondrial donor or any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor, by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.

(3) The Authority shall comply with a request under subsection (2) if -

(a) the information contained in the register shows that the applicant is a relevant individual, and

(b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(3A) The Authority must comply with a request under subsection (2A) if -

(a) the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, and

(b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(4) Where a request is made under subsection (2)(a) and the applicant has not attained the age of 18 when the applicant gives notice to the Authority under subsection (1), regulations cannot require the Authority to give the applicant any information which identifies the donor.

(5) Regulations under subsection (2)(a) cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority could not have been required to give information of the kind in question.

(6) The Authority need not comply with a request made under subsection (2)(b) by any applicant if it considers that special circumstances exist which increase the likelihood that compliance with the request would enable the applicant -

(a) to identify the donor, in a case where the Authority is not required by regulations under subsection (2)(a) to give the applicant information which identifies the donor, or

(b) to identify any person about whom information is given under subsection (2)(b).

(7) In this section -

"relevant individual" has the same meaning as in section 31;

"the relevant statutory provisions" means sections 27 to 29 of this Act and sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.

(8) In this section and sections 31ZB to 31ZE -

"mitochondrial donor-conceived person" means a person who was or may have been born in consequence of treatment services using -

(a) an egg which is a permitted egg for the purposes of section 3(2) by virtue of regulations under section 3ZA(5), or

(b) an embryo which is a permitted embryo for those purposes by virtue of such regulations;

the "mitochondrial donor" in respect of a person who was or may have been born in consequence of treatment services using such a permitted egg or such a permitted embryo is the person whose mitochondrial DNA (but not nuclear DNA) was used to create that egg or embryo.

Modification of section 31ZD: Provision to donor of information about resulting children

(1) This section applies where a person ("the donor") has consented under Schedule 3 (whether before or after the coming into force of this section) to -

(a) the use of the donor's gametes, or an embryo the creation of which was brought about using the donor's gametes, for the purposes of treatment services provided under a licence, or

(b) the use of the donor's gametes for the purposes of non-medical fertility services provided under a licence.

(2) In subsection (1) -

(a) "treatment services" do not include treatment services provided to the donor, or to the donor and another person together, and

(b) "non-medical fertility services" do not include any services involving partner-donated sperm.

(3) The donor may by notice request the appropriate person to give the donor notice stating -

(a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,

(ab) the number of persons in respect of whom the donor is a mitochondrial donor,

(b) the sex of each of those persons, and

(c) the year of birth of each of those persons.

(4) Subject to subsections (5) to (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.

(5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify the persons falling within paragraphs (a) to (c) of subsection (3).

(6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible -

(a) has notified the donor that the information concerned is not held, or

(b) has failed to comply with the request within a reasonable period.

(7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of

Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible -

(a) has notified the donor that the information concerned is not held, or

(b) has failed to comply with the request within a reasonable period.

(8) In this section "the appropriate person" means -

(a) in the case of a donor who consented as described in paragraph (a) of subsection (1) -

(i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or

(ii) the Authority, and

(b) in the case of a donor who consented as described in paragraph (b) of subsection (1) -

(i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or

(ii) the Authority.

(9) In this section "the relevant statutory provisions" has the same meaning as in section 31ZA.

Modification of paragraph 4 of Schedule 3

Variation and withdrawal of consent

(1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

(1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and "egg A" and "egg B" have the same meanings in this paragraph as in that regulation).

(1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

(2) Subject to sub-paragraphs (3) to (3B), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used -

(a) in providing treatment services,

(aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or

(b) for the purposes of any project of research.

(3) Where the terms of any consent to the use of an embryo ("embryo A") include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

(3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and "embryo A" and "embryo B" have the same meanings in sub-paragraph (3B) as in that regulation).

(3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.

(4) Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.

(5) Where the terms of any consent to the use of a human admixed embryo ("human admixed embryo A") include consent to the use of a human admixed embryo or embryo whose creation may be brought about in vitro using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research.

Modification of paragraph 22 of Schedule 3 (paragraphs which apply to mitochondrial donation)

Consent for use of eggs or embryos created following mitochondrial donation

(A1) For the purposes of this Schedule, neither of the following is to be treated as a person whose gametes were used to create an embryo ("embryo E") -

(a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5), the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;

(b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5), the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

(3B) For the purposes of this Schedule, in a case where an egg is a permitted egg by virtue of regulations under section 3ZA(5) the egg is not to be treated as the egg of the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

Regulations

Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015

Interpretation

2.- (1) In these Regulations "the Act" means the Human Fertilisation and Embryology Act 1990.

(2) In these Regulations "polar body nuclear DNA" means any nuclear DNA located in a polar body.

(3) In these Regulations a reference to the removal of any nuclear DNA (including polar body nuclear DNA) includes a reference to the removal of any material which is necessarily removed along with that DNA, and such material may include any associated organelles.

(4) For the purposes of these Regulations, the following are to be treated as removed from an egg -

(a) any polar body nuclear DNA which is destroyed while still located in the egg; and

(b) any material which is necessarily destroyed along with that DNA, and such material may include any associated organelles.

(5) In these Regulations a reference to the insertion of nuclear DNA includes a reference to the insertion of any material which is necessarily inserted along with that DNA, and such material may include any associated organelles.

Permitted eggs and permitted embryos

Permitted egg

3. An egg ("egg P") is a permitted egg for the purposes of section 3(2)(b) of the Act if -

(a) egg P results from the application of the process specified in regulation 4 to two eggs, each of which -

(i) is a permitted egg as defined in section 3ZA(2) of the Act (not an egg which is a permitted egg by virtue of these regulations), and

(ii) was extracted from the ovaries of a different woman;

(b) that process has been applied to those eggs in the circumstances specified in regulation 5; and

(c) there have been no alterations in the nuclear or mitochondrial DNA of egg P since egg P was created by means of the application of that process.

Permitted egg: process

4.- (1) The process referred to in regulation 3(a) consists of the following two steps.

(2) In step 1 -

(a) either -

(i) all the nuclear DNA of an egg ("egg A") is removed, or

(ii) all the nuclear DNA of egg A other than polar body nuclear DNA is removed; and

(b) either -

(i) all the nuclear DNA of another egg ("egg B") is removed, or

(ii) all the nuclear DNA of egg B other than polar body nuclear DNA is removed.

(3) In step 2 all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

Permitted egg: circumstances

5. The circumstances referred to in regulation 3(b) are that -

(a) the Authority has issued a determination that -

(i) there is a particular risk that any egg extracted from the ovaries of a woman named in the determination may have mitochondrial abnormalities caused by mitochondrial DNA; and

(ii) there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease; and

(b) egg B was extracted from the ovaries of the woman so named.

Permitted embryo

6. An embryo ("embryo P") is a permitted embryo for the purposes of section 3(2)(a) of the Act if -

(a) embryo P results from the application of the process specified in regulation 7 to two embryos, each of which -

(i) is a permitted embryo as defined in section 3ZA(4) of the Act (not an embryo which is a permitted embryo by virtue of these regulations), and

(ii) was created by the fertilisation of a permitted egg as defined in section 3ZA(2) of the Act (not an egg which was a permitted egg by virtue of these regulations) extracted from the ovaries of a different woman;

(b) that process has been applied to those embryos in the circumstances specified in regulation 8; and

(c) since embryo P was created by means of the application of that process -

(i) there have been no alterations in the nuclear or mitochondrial DNA of any cell of embryo P, and

(ii) no cell has been added to embryo P other than by the division of embryo P's own cells.

Permitted embryo: process

7.- (1) The process referred to in regulation 6(a) consists of the following two steps.

(2) In step 1 -

(a) either -

(i) all the nuclear DNA of an embryo ("embryo A") is removed, or

(ii) all the nuclear DNA of embryo A other than polar body nuclear DNA is removed; and

(b) either -

(i) all the nuclear DNA of another embryo ("embryo B") is removed, or

(ii) all the nuclear DNA of embryo B other than polar body nuclear DNA is removed.

(3) In step 2 all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.

Permitted embryo: circumstances

8. The circumstances referred to in regulation 6(b) are that -

(a) the Authority has issued a determination that -

(i) there is a particular risk that any embryo which is created by the fertilisation of an egg extracted from the ovaries of a woman named in the determination may have mitochondrial abnormalities caused by mitochondrial DNA; and

(ii) there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease; and

(b) embryo B was created by the fertilisation of an egg extracted from the ovaries of the woman so named.

Supplemental provision – licences

9. (1) Any reference to a permitted egg in a licence whenever issued does not include an egg which is a permitted egg for the purposes of section 3(2) of the Act by virtue of regulation 3 unless express provision is made in the licence to that effect.

(2) Any reference to a permitted embryo in a licence whenever issued does not include an embryo which is a permitted embryo for the purposes of section 3(2) of the Act by virtue of regulation 6 unless express provision is made in the licence to that effect.

Licence conditions

T124 a. No clinic may carry out either the process of pronuclear transfer* (PNT) or maternal spindle transfer* (MST) or part of either process, unless express provision has been made on the clinic's licence permitting it to undertake either or both processes.

b. Neither PNT nor MST may be carried out under third party, satellite or transport agreements.

c. No clinic may provide treatment using gametes or embryos which have been created using PNT or MST unless express provision has been made on the clinic's licence permitting the clinic to undertake either or both processes.

*Wherever reference is made in this licence to PNT or MST, or to the process of PNT or MST, it is to be treated as a reference to the process described in Regulation 4 or Regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

T125 PNT and MST must only be carried out on premises of clinics that are licensed to undertake mitochondrial donation ('MD'). These processes must not be carried out on the premises of a clinic that is operating under a third party, satellite or transport agreement with a clinic that holds a licence to undertake MD.

T127 a. No alterations may be made to the nuclear or mitochondrial DNA of an egg created by means of the application of MST.

b. No alterations may be made to the nuclear or mitochondrial DNA of an embryo created by means of the application of PNT, and no cell may be added to an embryo created by means of the application of PNT other than by the division of the embryo's own cells.

T128 In the case of treatment involving mitochondrial donation, the clinic must ensure that it only carries out the process of PNT or MST for a particular, named patient once the Authority has issued a determination that:

- there is a particular risk that any egg extracted from the ovaries of the named woman, or any embryo created by the fertilisation of an egg extracted from the ovaries of the named woman, may have mitochondrial abnormalities cause by mitochondrial DNA, and
- there is a significant risk that a person with those abnormalities will have or develop a serious mitochondrial disease.

T129 Only those embryologists assessed as competent by the Authority to undertake PNT, MST or both, and named on the front of this licence, are permitted to undertake those processes or any part thereof.

Directions

0001 – Gametes and embryo donation

0005 – Collecting and recording information for the HFEA

0006 – Import and export of gametes and embryos

0007 – Consent

0008 – Information to be submitted to the HFEA as part of the licensing process

HFEA guidance

Staff to be involved in mitochondrial donation

33.1 A senior clinical geneticist/mitochondrial disease specialist should be involved in deciding whether a particular patient should receive mitochondrial donation treatment.

33.2 The centre should ensure that a multidisciplinary team is involved in providing the treatment. The team should include mitochondrial disease specialists, reproductive specialists, embryologists, clinical geneticists, genetic counsellors and molecular geneticists. It should maintain close contact with the primary care physician, the referring clinician, or the mitochondrial disease centre.

33.3 Only embryologists who have been assessed as competent by the HFEA and named on the clinic's licence can perform maternal spindle transfer (MST) or pronuclear transfer (PNT) techniques as defined in Regulation 4 and 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015. An application for an assessment of the competence of an embryologist must be submitted to the HFEA and will be considered by a Licence Committee. When submitting an application to the HFEA for a competency assessment, the person responsible (PR) and the relevant embryologist should provide:

(a) evidence of the embryologist's experience of carrying out MST or PNT in treatment, training or research on human eggs or embryos (eg, embryo survival rates, blastocyst development, and rate of carryover of mitochondria, in line with key performance indicators (KPIs) determined by the HFEA)
(b) references to support the embryologist's experience and knowledge, and
(c) any other information that may demonstrate competence (such as the embryologist's experience of performing micro-manipulation on human or animal (eg, mice) eggs or embryos).

33.4 The PR should submit an application to the HFEA for an assessment of the competence of each embryologist who intends to perform MST or PNT or any part thereof. A PR wishing to make any changes to the authorised embryologists must submit an application to the HFEA for a variation of the clinic's licence, accompanied by the relevant evidence of competency for each proposed embryologist.

Mitochondrial donation for the avoidance of serious mitochondrial disease

Interpretation of mandatory requirements 33A

Maternal spindle transfer (MST) can only be carried out where the Authority has issued a determination that —

- there is a particular risk that any eggs collected from the patient named in the application form may have mitochondrial abnormalities caused by mitochondrial DNA; and

- there is a significant risk that a person with those abnormalities will have, or develop, serious mitochondrial disease.

Pronuclear transfer (PNT) can only be carried out where the Authority has issued a determination that—

- there is a particular risk that any embryos created with eggs collected from the patient named in the application form may have mitochondrial abnormalities caused by mitochondrial DNA; and
- there is a significant risk that a person with those abnormalities will have, or develop, serious mitochondrial disease.

Treatment involving mitochondrial donation can only be carried out by a clinic that is licensed to do so, as evidenced by express provision on the clinic's licence permitting it to undertake either MST, PNT or both.

The process of MST or PNT (as defined in Regulation 4 and 7 of the Human Fertilisation and Embryology Authority (Mitochondrial Donation) Regulations 2015) may only be carried out by embryologists who have been assessed by the HFEA as competent to undertake these processes and who are named on the clinic's licence.

MST or PNT may only be carried out on the premises of a clinic licensed to undertake mitochondrial donation and may not be done on third party premises or the premises of any satellite centre.

Clinics that are not licensed to undertake MST or PNT for treatment purposes may not use eggs or embryos created using these techniques in treatment services.

33.5 The centre should discuss with the patient the likely outcomes of the proposed treatment, the nature and potential risks of the treatment, and any other treatment options that may be suitable, such as preimplantation genetic diagnosis (PGD) or egg donation.

33.6 When deciding if it is appropriate to offer MST or PNT in particular cases, the seriousness of the disease in that case should be discussed between the patient seeking treatment and the clinical team. The level of risk for those seeking treatment and any child that may be born will also be an important factor for the centre to consider, and should be discussed with the patient. The centre should only offer MST or PNT to patients for whom PGD is inappropriate or likely to be unsuccessful and who exhibit (or are predicted to exhibit) high levels of germ line heteroplasmy or homoplasmy. In making this assessment, the centre should take into account:

- the particular mutation involved,
- the inheritance pattern in the family, and
- the likely clinical manifestations of disease and the efficacy of any previous treatments such as PGD.

For an overview of how the Statutory Approvals Committee will assess a case by case application, download 'Mitochondrial donation: explanatory note for Statutory Approvals Committee'.

33.7 The centre should consider the following factors before deciding whether it is appropriate to offer MST or PNT in particular cases. Having considered these factors, if a decision is taken to offer MST or PNT, the clinic would need to submit an application for authorisation to the HFEA.

The Authority's assessment of the seriousness of a mitochondrial disease will be made, where possible, based on the most severe symptoms that could be expected for a particular patient's

case. When submitting an application to the HFEA, the PR must, wherever possible, provide supporting evidence detailing:

(a) the patient's medical history
(b) the patient's family medical history of mitochondrial disease (to include previous cases of PGD treatment or details of affected family members)
(c) the patient's mutant mitochondrial DNA (mtDNA) load and threshold associated with symptoms of disease (to include details about the level of heteroplasmy or whether the patient is homoplasmic for a mitochondrial mutation)
(d) scientific literature relevant to the mtDNA mutation or disease, and
(e) any additional information which the clinician may consider is relevant to the application, such as a statement from a genetic counsellor.

Embryo transfer using embryos following mitochondrial donation

33.8 Embryos that have undergone either MST or PNT (or any other technique) should not be transferred with any other embryos that have not undergone the same technique in the same treatment cycle.

33.9 A centre should not perform embryo biopsy (such as for the purpose of PGD or preimplantation genetic screening (PGS)) on embryos that have undergone MST or PNT.

33.10 A centre should use the same sperm provider for both steps of PNT unless there is a good reason for not doing so (ie, if the mitochondria donor is a close genetic relative of the intended father).

Genetic consultation and counselling

33.11 The centre should ensure that people seeking treatment have access to mitochondrial specialists, clinical geneticists, genetic counsellors and, where appropriate, infertility counsellors. Patients who have been referred by one clinic to another for the purposes of mitochondrial donation must be offered specific counselling about mitochondrial donation by the clinic licensed to do mitochondrial donation, regardless of whether the patient has previously been offered counselling by the referring centre.

33.12 The centre should work closely with the local genetics/mitochondrial disease centre of those seeking treatment.

Information for those seeking mitochondrial donation

33.13 The centre should ensure that people seeking MST or PNT are given appropriate information about the treatment. Where a patient has been referred by one clinic to another for the purposes of mitochondrial donation, the clinic licensed to provide mitochondrial donation must ensure that it provides the patient with appropriate information including:

(a) information about the process, procedures and possible risks involved in mitochondrial donation, including the risks for any child that may be born following the mitochondrial donation, and the risks of IVF treatment
(b) information about prenatal testing following treatment (in these circumstances, the patient should be counselled about the specific additional risks associated with prenatal testing), and

(c) information about the experience of the centre and embryologist(s) carrying out the techniques.

33.14 The centre should also provide information to those seeking treatment to help them make decisions about their treatment, including:

(a) genetic and clinical information about the mitochondrial disease
(b) the possible impact (if known) of the mitochondrial disease on those affected and their families
(c) the importance of telling any resulting children of the mitochondrial donation treatment
(d) information about treatment and social support available, and
(e) information from a relevant patient support group or the testimony of people living with the condition, if those seeking treatment have no direct experience of it themselves.

33.15 If the person seeking treatment has already been given information about the particular mitochondrial disease, for example from a regional mitochondrial disease centre with appropriate expertise, the centre does not need to provide this information again. However, the centre should ensure that the information which has been provided is accurate, sufficiently detailed and that the patient fully understands the information.

33.16 Before providing mitochondrial donation treatment, the centre should ensure that those seeking treatment have had sufficient opportunity to fully consider the possible outcomes and risks of these techniques and their implications.

33.17 The centre should provide information to people seeking mitochondrial donation treatment about the collection and provision of information, specifically:

(a) information that centres must collect and register with the HFEA about the donors
(b) what information may be disclosed to people born as a result of the mitochondrial donation and in what circumstances, and
(c) that person's right to access anonymous information about the mitochondrial donor from the age of 16.

33.18 The centre should give people seeking mitochondrial donation treatment information about the screening of people providing mitochondria. This information should include details about:

(a) the sensitivity and suitability of the tests, and
(b) the possibility that a screened provider of mitochondria may be a carrier of a mitochondrial disease or infection.

33.19 The centre should provide information that explains the limitations of procedures and the risks of treatment to anyone seeking mitochondrial donation treatment. The centre should make available appropriate counselling.

See also

Guidance note 3 – Counselling

Guidance note 20 – Donor assisted conception

NOTE Guidance note 20 applies to mitochondrial donation except sections 20.1, 20.2 (d)ii)-v) and 20.12.

Importance of informing children of their origins

33.20 The centre should tell people who seek mitochondrial donation treatment that it is best for any resulting child to be told about their origin early in childhood. Centres should refer to guidance set out in guidance note 20 on the importance of informing children of their donor origins.

33.21 Centres should inform patients of the potential risk of mitochondrial disease in future generations and the potential ways to avoid this (eg, that any female born following MST or PNT, should she wish to have children of her own, could have her eggs or early embryos analysed by PGD in order to select for embryos free of abnormal mitochondria).

See also

Guidance note 20 – Donor assisted conception

Eligibility requirements for mitochondrial donors

Mandatory requirements

Licence conditions

T52 Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely:

a. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg, superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)

b. the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:

- HIV 1 and 2: Anti-HIV – 1, 2
- Hepatitis B: HBsAg and Anti-HBc
- Hepatitis C: Anti-HCV-Ab
- Syphilis: see (d) below

c. the centre must devise a system of storage which clearly separates:

- quarantined/unscreened gametes and embryos
- gametes and embryos which have tested negative, and
- gametes and embryos which have tested positive

d. a validated testing algorithm must be applied to exclude the presence of active infection with Treponema pallidum. The non-reactive test, specific or non-specific, can allow

gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific Treponema confirmatory test is non-reactive. The donor whose specimen test reacted on a Treponema-specific test will require a thorough risk assessment to determine eligibility for clinical use

e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)

f. This requirement has been removed.

g. HTLV-1 antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas

h. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi), and

i. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

T126 Donors of gametes for use in MST and or PNT must be screened for pathogenic mitochondrial DNA mutations, and an assessment of the risk of transmission of any mitochondrial disease in the donor's family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be clearly communicated and explained to the recipient.

Interpretation of mandatory requirements 33B

Sections (a) to (h) of Licence condition T52 on medical and laboratory tests should apply to mitochondrial donors and to men providing sperm used to fertilise eggs of the mitochondrial donor in the process of PNT.

33.22 As well as taking their medical history (in line with T52 and T126), the recruiting centre should take details of previous donations. If a prospective donor cannot give a full and accurate maternal family history, the centre should record this fact and take it into account in deciding whether or not to accept their eggs for treatment.

33.23 Centres should ensure that they keep up to date with relevant literature and professional guidance, such as on refinements to the techniques, to improve their efficacy in treatment. Centres should also keep up to date with emerging research relevant to mitochondria haplotype matching and consider matching the haplotypes of donors with recipients where possible.

33.24 Before accepting a mitochondrial donor, centres should follow the same requirements and guidance as set out in guidance note 11, except guidance 11.2, 11.3, 11.32 g) and j), 11.32 i)-l), 11.36, 11.37, 11.38, 11.39, 11.42, 11.46-11.52.

33.25 Guidance on the upper age limits for egg and embryo donors does not apply for mitochondrial donors. There is some evidence to suggest that mitochondria in a woman's eggs accumulate damage over time meaning the eggs of older donors may have reduced mitochondrial function.

Age should therefore be taken into consideration when determining the suitability of a woman donating her eggs, in conjunction with an assessment of her reproductive health, such as an assessment of ovarian reserve.

33.26 The ten family limit guidance for those providing donor gametes (or embryos created using donated gametes) outlined at 11.46, does not apply to:

(a) egg donors who have donated their mitochondria only, or
(b) sperm donors who have donated for pronuclear transfer where they will not be genetically related to the child.

See also

Guidance note 11 – Donor recruitment, assessment and screening

Information for prospective mitochondrial donors

33.27 Before any consents or samples are obtained from a prospective mitochondrial donor, the recruiting centre should provide information about:

(a) the screening that will be done and why it is necessary
(b) the possibility that the screening may reveal unsuspected conditions (eg, mitochondrial related anomalies or HIV infection) and the practical implications of this
(c) the scope and limitations of the genetic testing that will be done and the implications for the mitochondria donor and their family
(d) the importance of informing the recruiting centre of any medical information that may come to light after donation and that may have health implications for any woman who received treatment with their mitochondria, or for any child born as a result of such treatment
(e) the procedure used to collect gametes, including any discomfort, pain and risk to the mitochondria donor (eg, from the use of superovulatory drugs)
(f) the legal parenthood of any child born as a result of their mitochondrial donation
(g) what information about the mitochondrial donor must be collected by the centre and held on the HFEA Register
(h) that only non-identifying information will be disclosed when the applicant is aged over 16. No identifying information about the donor will be disclosed
(i) the possibility that a child born as a result of their mitochondrial donation who is disabled as a result of an inherited condition that the donor knew about, or ought reasonably to have known about, but failed to disclose, may be able to sue the donor for damages, and
(j) the ability of the mitochondrial donor to withdraw consent, the procedure for withdrawal of consent for the use of their mitochondria, and the point up until which the donor can withdraw consent.

Informing mitochondrial donors about information available to children born from the treatment

33.28 The centre should inform mitochondrial donors that anyone born as a result of their mitochondrial donation will have access to the following non-identifying information provided by them, from the age of 16:

(a) the screening tests carried out on the mitochondrial donor and information on that donor's personal and family medical history
(b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and
(c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person born from their donation.

Consent

33.29 The centre should obtain written informed consent from patients and their spouse or partner (if relevant), for mitochondrial donation treatment. Where a patient and their partner have been referred by one centre to another for the purposes of mitochondrial donation, the clinic that will be undertaking the mitochondrial donation must obtain consent specific to the treatment involving mitochondrial donation, regardless of what consent the patient and their partner may have provided to the referring centre. This is because the centre doing the mitochondrial treatment will have the necessary experience and expertise in mitochondrial donation and is best placed to provide the relevant information and obtain fully informed consent.

33.30 For mitochondrial donors, the centre should obtain the donor's written informed consent to the donation of her eggs or embryos for MST or PNT.

33.31 Any prospective women donating their eggs for mitochondrial donation, or men donating sperm for PNT where they will not be genetically related to the child, should be aware that they cannot withdraw or vary their consent once the donated egg or embryo has undergone the process of MST or PNT (ie, all the nuclear material has been moved from one egg or embryo to another).

33.32 Centres should follow all other requirements and guidance on consent as outlined in guidance note 11 on donor recruitment, assessment and screening and in guidance note 5 on consent to treatment, storage, donation and disclosure of information.

Import of eggs or embryos which have undergone mitochondrial donation

Interpretation of mandatory requirements 33C

It is not lawful in the UK to provide treatment using gametes or embryos created abroad following the use of pronuclear transfer or maternal spindle transfer. Schedule 1(f) and 3 (i) of General Direction 0006 provides that the purpose of importing gametes or embryos must be to provide treatment services. However, as treatment using gametes or embryos created abroad following the use of pronuclear transfer or maternal spindle transfer is not lawful, it follows that the import of such gametes or embryos should not take place.

See also

Guidance note 5 – Consent to treatment, storage, donation and disclosure of information

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 16 – Imports and exports

Follow-up arrangements

33.33 Centres offering mitochondrial donation should have a documented process setting out how children born from mitochondrial donation will be followed up, where patients have consented to follow-up. These should include long-term medical follow-up of children born as a result. Centres should establish links with mitochondrial disease centres to facilitate follow-up. If the patient is not a UK resident but nevertheless wishes to participate in follow-up, the centre and patient should discuss whether the patient wishes to be followed up at a mitochondrial disease centre based in the UK or a relevant centre overseas, in a location more convenient for the patient.

33.34 Centres should explain to patients the benefits of participating in follow-up, both immediate follow-up and long term follow-up.

33.35 If a centre becomes aware that a child born following mitochondrial donation has been born with a mitochondrial disease, birth defect, or genetic abnormality, or if there has been some other adverse outcome (including but not limited to failed or no embryo development, miscarriage or premature birth) following treatment involving mitochondrial donation, the centre must regard this as an adverse incident and report this to the HFEA in line with the requirements on adverse incidents set out in guidance note 27. This is to capture information about any abnormalities that may occur as a result of carrying out the MST or PNT treatment, to inform any regulatory or licensing action that the HFEA may wish to take and to inform the scientific sector.

See also

Guidance note 27 – Adverse incidents

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