

Authority meeting - agenda

18 January 2017

Venue: Church House, 27 Great Smith Street, London SW1P 3NZ

Agenda item	Time
1. Welcome, apologies and declaration of interests	12:45pm
2. Minutes of 15 December 2016 HFEA (18/01/17) 819 For decision	12:50pm
3. Chair's report (verbal)	12:55pm
4. Chief Executive's report (verbal)	1:05pm
5. Committee chairs' updates (verbal)	1:20pm
6. Strategic performance report HFEA (18/01/17) 820 For information	1:30pm
7. Information for Quality programme: update HFEA (18/01/17) 821 For information	1:45pm
8. Strategy 2017 - 20 HFEA (18/01/17) 822 For decision	2:05pm
9. Treatment add ons HFEA (18/01/17) 823 For decision	2.35pm
Break	3:15pm
10. Code of Practice HFEA (18/01/17) 824 For decision	3.25pm
11. Any other business	4:00pm

Minutes of the Authority meeting on 15 December 2016 held at ETC Venues, Victoria, 1 Drummond Gate, London SW1V 2QW

Members present	Sally Cheshire (Chair) Rebekah Dundas Dr Andy Greenfield Yacoub Khalaf Margaret Gilmore	Ruth Wilde Dr Anne Lampe Anthony Rutherford Kate Brian Bobbie Farsides
Apologies	Bishop Lee Rayfield Anita Bharucha	
Observers/Presenters	(Department of Health)	
Staff in attendance	Peter Thompson Juliet Tizzard Catherine Drennan Anna Rajakumar	Erin Barton

Members

There were 10 members at the meeting, 6 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. As with previous meetings, it was being audio recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations.
- 1.2. Apologies were received from Bishop Lee Rayfield and Anita Bharucha.
- 1.3. The Chair welcomed Bobbie Farsides, Professor of Clinical and Biomedical Ethics at the Brighton and Sussex Medical School, who had just been appointed to the Board. The Chair also said farewell to Rebekah Dundas who had been a member of the Authority for a decade, as this was her last meeting.
- 1.4. Declarations of interest were made by:
 - Ruth Wilde (Senior Fertility Counsellor at a licensed centre).
 - Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
 - Yacoub Khalaf (Person Responsible at a licensed centre)
 - Anthony Rutherford (Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 16 November 2016

- 2.1. Members agreed the minutes of the meeting held on 16 November, for signature by the Chair.

3. Mitochondrial donation

- 3.1.** The Chair introduced the main topic of the meeting; to decide whether to approve the use of mitochondrial donation techniques in clinical practice in the UK. Members were reminded of the long history behind the decision including the establishment of an independent expert panel of scientists and clinicians in 2011 to consider the safety and efficacy of mitochondrial donation techniques, in particular pronuclear transfer (PNT) and maternal spindle transfer (MST).
- 3.2.** Regulations were debated and passed by Parliament in February 2015 and a regulatory framework was put in place for when the regulations came into force in October that year. It was widely understood during the Parliamentary debates that the HFEA would need to take a decision, based on research evidence, as to when it would be ethical to move from research to clinical treatment. Early in 2016 key pieces of research had been published which led the HFEA to reconvene the expert panel for a fourth time. Their report, which was published on 30 November 2016, suggested that research had progressed to the point where we should consider offering it in clinical treatment.

Safety and efficacy

- 3.3.** Authority member and Chair of the expert panel, Dr Andy Greenfield, introduced the report and presented an overview of the most recent research using MST and/or PNT. The expert panel reviewed this research extensively and formed a considered judgement that the blastocysts produced using these techniques were of sufficient quality to be considered for use in clinical practice. The panel concluded that it was now appropriate to offer mitochondrial donation techniques as a clinical risk reduction treatment for carefully selected patients.
- 3.4.** The panel's main concern was a phenomenon referred to as 'reversion' observed in research on embryonic stems (ES) cell lines derived from embryos generated using these techniques. In a minority of cases, mtDNA carried over with the maternal spindle or parental pronuclei could come to predominate after extended periods of culture in vitro. The Chair of the expert panel explained the difficulties in interpreting the significance of this data. ES cells were not an exact model for post-implantation development in vivo. If reversion did occur in vivo, there was the possibility that a child might be born with a mitochondrial disease following MST or PNT.

Patient selection criteria

- 3.5.** Currently, many families with such inherited diseases had no effective treatment options for avoiding transmission of mitochondrial diseases to offspring. The Chair of the expert panel explained that the use of pre-implantation genetic diagnosis (PGD) to detect mtDNA mutations was difficult and variably successful, especially in those patients in whose germ line there were likely to be high levels of heteroplasmy or homoplasmy for the abnormal mtDNA (this meant they had either a high proportion of abnormal mtDNA or all abnormal mtDNA).
- 3.6.** In light of recent research and the potential risk of reversion, the panel believed that it would currently be inappropriate to offer MST or PNT to patients who were likely to have an unaffected child using PGD. However, the expert panel recommended that MST and PNT should be offered as a risk reduction strategy to selected patients for whom PGD would be inappropriate.
- 3.7.** The Chair of the expert panel provided clarification on the following points:

- Recent research did not indicate any significant difference between the two techniques, MST and PNT, with regard to safety, efficacy or the risk of reversion.
- Identification of patients suitable for MST or PNT on a case-by-case basis would be a matter of clinical judgement.
- PGD should not be necessary following MST or PNT on the basis that the embryologists performing these techniques would be highly skilled and performing a biopsy may cause further damage to the embryo. Prenatal testing was a more effective form of follow-up because reversion occurred post-implantation.
- The expert panel did not prescribe any definitive response to adverse incidents following either technique and the Authority would exercise their best judgment based on the circumstances. Members should be reassured that the embryologists permitted to use these techniques would have demonstrated that they could meet very high standards.
- The recommendation to offer treatment to a narrower cohort of patients initially was an ethical decision and was not based on any scientific evidence that it was easier to demonstrate efficacy or safety in these patients.
- It was unclear whether ES cells in culture would behave in the same way as a developing embryo. Therefore, the panel believed that further research using ES cells may not provide greater understanding of reversion. Gaining further knowledge of possible reversion in human embryos would require further research using clinical data.
- The panel recommended consideration of haplogroup matching because risks associated with a mito-nuclear mismatch were currently theoretical. They recommended that if these techniques were to be used in clinical practice, the latest evidence regarding how mitochondrial DNA haplotypes affected mito-nuclear interactions should be considered in order to inform the donor selection process.

- 3.8.** Members stressed the importance of monitoring clinical outcomes and ensuring that a robust system was in place to collect this data. All data collected on clinical outcomes should be reviewed. Some members felt that it would also be useful to review current guidance on PGD for mitochondrial disorders, as well as the process for collecting clinical outcomes for PGD.
- 3.9.** Given the novelty of these techniques, members felt that the provision of expert information and counselling were of paramount importance in managing patients' expectations, both during and after treatment. Members also felt that it was important to regularly review patient information and guidance for clinic staff when data on clinical outcomes became available.
- 3.10.** Members considered that, with a small number of potential patients and donors currently waiting for this treatment, any patients who chose to identify themselves in the media would be at risk of the donor identifying any resulting children. Members acknowledged that, whilst it was not possible to prevent patients from making these decisions, the implications of such a decision should be discussed during counselling.
- 3.11.** Members were asked to consider the safety and efficacy of the techniques and decide whether research on MST and/or PNT had now progressed to such a point where it would be appropriate to allow either technique in clinical practice.

Further to this, if the Authority agreed the above, they were asked to consider whether these techniques should initially be offered only to a narrower cohort of patients, who met specific criteria identified in the expert panel's report.

Decision: All members agreed with the panel's recommendation to approve the use of mitochondrial donation techniques in clinical practice in the UK as a risk reduction strategy for selected patients for whom preimplantation genetic diagnosis (PGD) would be inappropriate. The Chair confirmed that both Bishop Lee Rayfield and Anita Bharucha had previously communicated their agreement with the panel's recommendation.

- 3.12.** The Chair assured members that all of their concerns would be taken into consideration and that members should continue to work with the Executive to implement any necessary changes.

Licensing framework

- 3.13.** The Scientific Policy Manager reminded members of the previously agreed regulatory framework and explained that the decision to offer the treatment to the narrower cohort of patients would require some changes to the guidance and process for approving applications.
- 3.14.** The Scientific Policy Manager informed members that in order to implement the expert panel's recommendation, an additional requirement would need to be introduced into the Code of Practice guidance, that mitochondrial donation could only be offered to patients for whom PGD was not appropriate. Further to this, an additional requirement was proposed in General Direction 0008 and the Code of Practice Guidance which would be reflected in the Guidance Note for use by the Statutory Approvals Committee. These additions would support the explicit narrowing of the scope to those for whom PGD was not clinically prescribed or recommended. The additional wording would provide guidance around the threshold for such patients.

Implementing the patient selection criteria

Members were asked to:

- agree the proposed approach for considering patient selection
 - agree changes to the Code of Practice Guidance Note 33 on mitochondrial donation and referenced explanatory note designed to aid the Statutory Approvals Committee
 - agree changes to paragraph 7 of General Direction 0008
 - agree that the amendments of any relevant decision trees and patient application forms should be delegated to the appropriate Committees.
- 3.15.** Members raised concerns about the availability of clinical geneticists with the relevant expertise in mitochondrial disease to support both the Licence Committee and the Statutory Approvals Committee at the different stages of approval. Members were reassured that a number of appropriately qualified experts had already been identified as potential peer reviewers and specialist advisors, and that committees could call upon international expertise to avoid any potential conflict of interest in such a narrow field.

Decision: All members agreed with the proposed updates subject to minor amendments to the wording, and on the basis that all of their concerns would be addressed in the relevant documentation.

Prenatal testing

- 3.16.** The Scientific Policy Manager explained that due to the known risk of reversion, the panel had suggested that prenatal testing should be offered to all women undergoing treatment, but

recognised that it was unlikely that all women would accept this offer and that they would be under no obligation to do so. The panel also felt it was important to counsel patients on the risk of miscarriage associated with these techniques.

- 3.17.** Members were asked to agree changes to the Code of Practice Guidance Note 33 on mitochondrial donation recommending prenatal testing to all those who underwent mitochondrial donation.

Decision: All members agreed with the proposed updates.

Assessing embryologists' competency

- 3.18.** The Authority had previously agreed that in order for a clinic to vary their licence to include mitochondrial donation techniques, the PR must demonstrate that the embryologists who would be performing these techniques were able to meet a predetermined set of performance indicators.

- 3.19.** In light of recent research, the panel recommended the following thresholds be applied:

- **Embryo survival rates** - must exceed 70%
- **Blastocyst development rates** - must be no less than 50% of that observed in the control embryos at day 5. Where possible, controls should be age-matched to the karyoplast donor
- **Rates of carryover of mtDNA** - should not on average exceed 2% and be no greater than 10% per embryo. (Hyslop et al - After optimisation, mtDNA carryover was reduced to <2% in the majority (79%) of PNT blastocysts so this would be achievable)

The panel noted that these parameters would need to be reviewed, as the techniques developed over time.

- 3.20.** Some members were concerned that the wording used may prohibit a more flexible application of the thresholds where this might be appropriate.

Decision: Members agreed with the panel's recommended performance indicators, subject to further consideration of the wording.

4. Chair's signature

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

Signature

Chair

Date

Strategic performance report

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting	Authority
Agenda item	6
Paper number	HFEA (18/01/17) 820
Meeting date	18 January 2017
Author	Paula Robinson, Head of Business Planning

Output:

For information or decision?	For information
Recommendation	The Authority is asked to note and comment on the latest strategic performance report.
Resource implications	In budget
Implementation date	Ongoing – strategic period 2014-2017
Communication(s)	<p>CMG reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper.</p> <p>The Department of Health reviews our performance at each DH Update meeting (based on the CMG paper).</p> <p>The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are fed back to the subsequent CMG performance meeting.</p>
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex 1: Strategic performance report

1. Introduction

- 1.1.** The attached paper summarises the main performance indicators, following discussion by the Corporate Management Group (CMG) at its December performance meeting.
- 1.2.** Most data relates to the position at the end of October 2016.
- 1.3.** Overall performance is good, and we are making good progress towards our strategic aims.

2. Recommendation

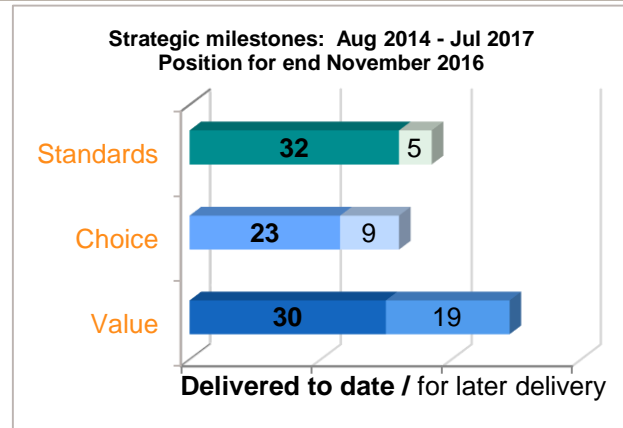
- 2.1.** The Authority is asked to note the latest strategic performance report.

1. Summary section

Dashboard – October data

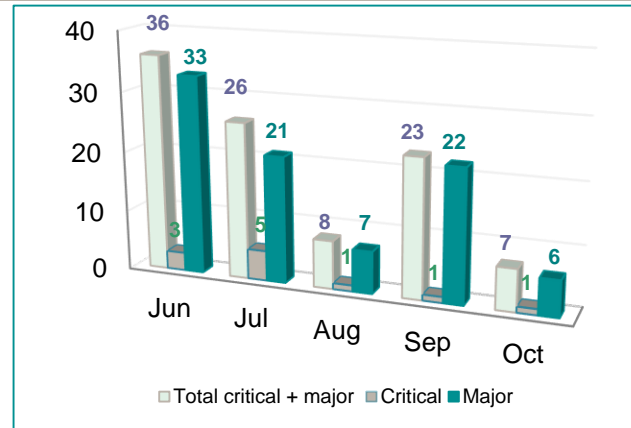
Strategic delivery totaliser

(see overleaf for more detail)



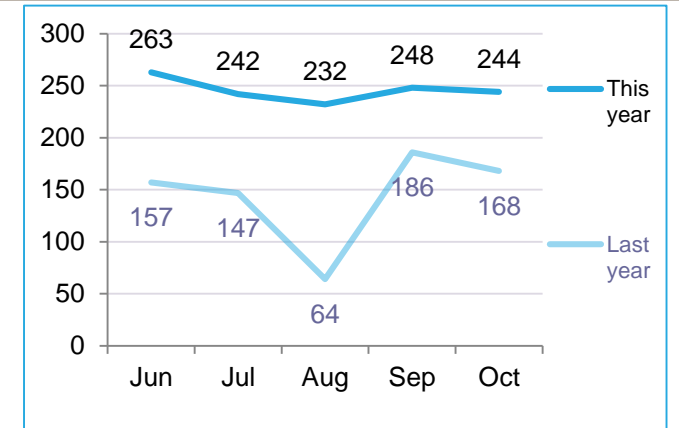
Setting standards:

critical and major recommendations on inspection

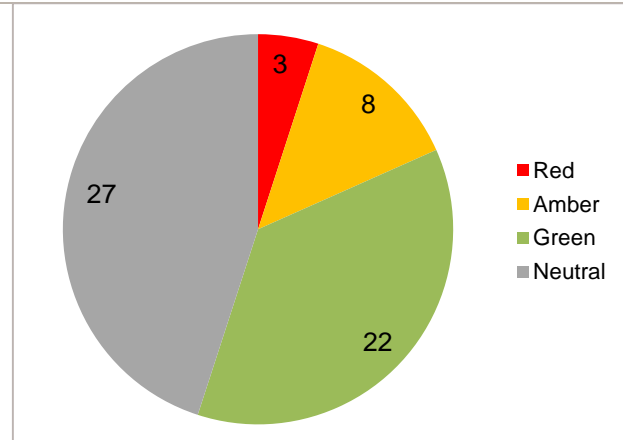


Increasing and informing choice:

public enquiries received (email)



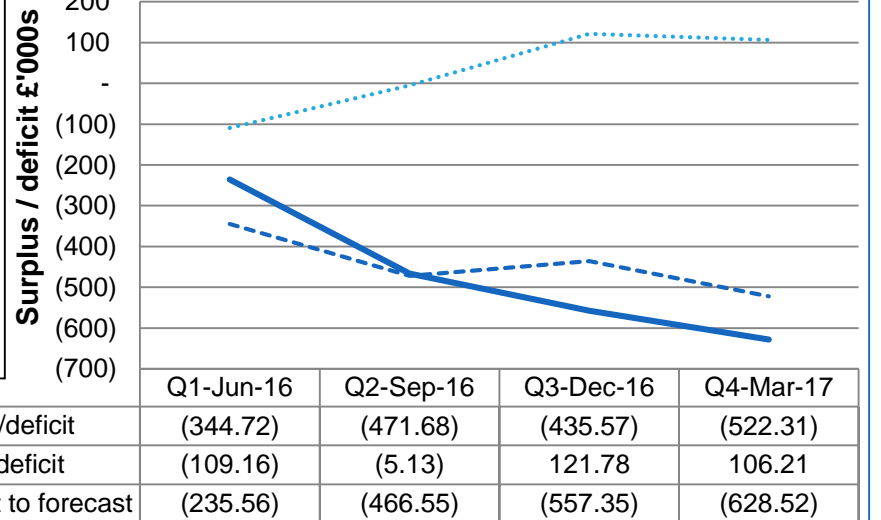
Overall performance - all indicators:



(See RAG status section for detail.)

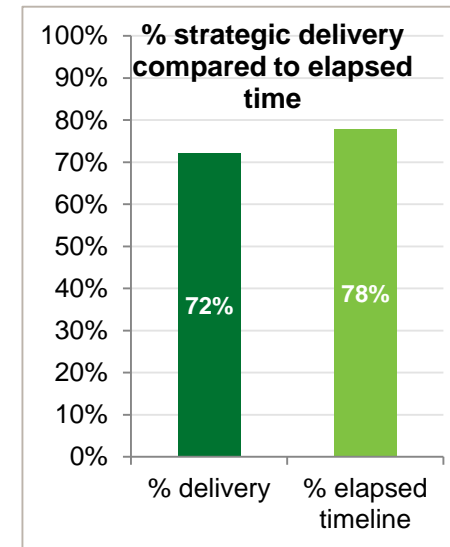
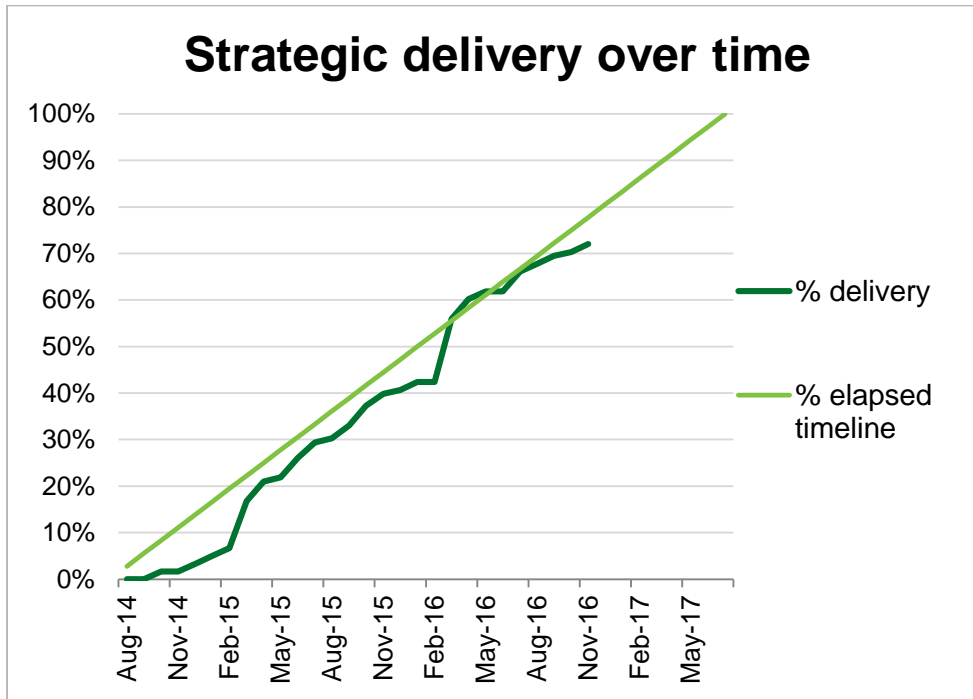
Efficiency, economy and value: Budget status: cumulative surplus/(deficit)

Net position over the year - how we perform against budget. In the seven months ending 31 October, we are under-spending or in surplus by £54k compared to the budget which shows a deficit of £498k. This is mainly due to the increase in our treatment fee income (shown graphically in the next section). For the full year we are forecasting a surplus of £106k which is net of IfQ. With capitalisation of IfQ our surplus is likely to be in the region of £600k. The continuing upward trend in our income will also impact this potential surplus.



Dashboard – Commentary

Strategic delivery (to end of November) – summary:



Progress on the Information for Quality Programme, IfQ, has been impeded for several months by a number of issues, including legal challenge, supplier resource restrictions and development complexities during the beta phase of work. This means that a number of the due milestones were necessarily deferred to later dates. However, now that we have successfully prepared for, and passed, the clinic portal live gateway, the picture has improved markedly and a number of previously overdue milestones have been completed. An annual review of the milestones that make up the 'totaliser' has also been completed, particularly those relating to IfQ. When these were last reviewed in late 2015, it seemed likely that there would be more GDS gateways involved (including some light touch gateways at certain points), and it has since been established that this is not the case. Compared to this time last year, we are now a lot clearer about our gateways and the steps involved. Therefore, some superfluous GDS-related milestones have been removed.

We are still working hard to ensure that the beta phase of IfQ can be completed as soon as possible for both products, freeing us up to focus fully on release two. The portal (release one) will go live in January.

Strategic delivery in October and November:

Setting standards

We hosted stakeholder engagement meetings with the Professional Stakeholders Group, the Association of Fertility Patient Organisations and the Licensed Centres Panel, engaging with patient and donor organisations to inform our future work, particularly in the context of our new strategy.

Project work on the new EU requirements relating to the import and coding of donor eggs and sperm is on hold pending Department of Health advice in the wake of the Brexit vote, but related work on special directions for import and export is going ahead.

Increasing and informing choice

In our original IfQ timeline, the website and choose a fertility clinic would have gone live this month. In the event that has not been possible, but a new delivery plan is in place. The live gateway assessment for the website will be booked shortly.

Our annual report on clinical incidents and alerts was published on time in November.

Efficiency, economy and value

There were three IfQ-dependent milestones originally due in this area for October, all of which were delayed. These are:

- Six monthly data publication through choose a fertility clinic (on hold pending a fresh data verification round, which will now take place early next year)
- Release two of the clinic portal (rescheduled pending release one go live)
- New electronic data interchange (EDI) system in pace (rescheduled owing to release one beta phase over-runs).

However, in November we successfully passed our GDS 'go live' assessment for release one of the clinic portal. This is an important step forward for the team. Reaching this point also means that a number of previously overdue milestones relating to portal release one development and preparing for the gateway assessment can now all be marked as completed.

Red/amber/green status of performance indicators – October 2016

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

Average number of working days from day of inspection to the day the draft report is sent to the PR

- Three reports were due to be sent to the PR in October, and our target is for 90% of these to be sent to clinics within 20 working days. One report was sent at 21 working days and another at 25 working days. The third report was sent at 32 working days, due to multiple management reviews and actions required by the PR so that the report could be completed.

Average number of working days taken for the whole process, from the day of inspection to the decision being communicated to the centre (including only items starting with an inspection)

- This KPI was affected by the above delays in completing reports, and it also took longer than usual to get these reports to a licensing committee. Performance for the month was at 79 working days, above our target of 70.

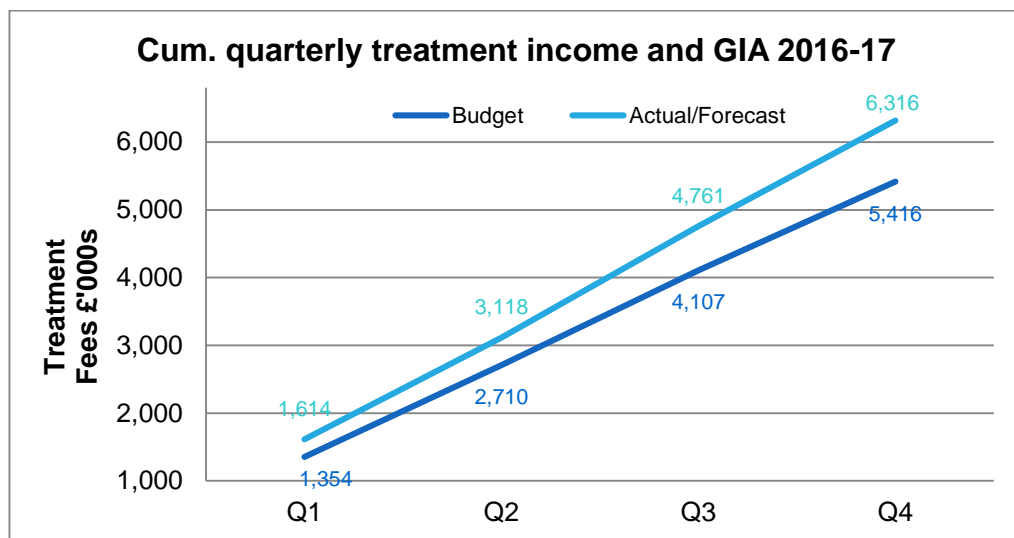
Staff sickness absence rate (%) per month.

- Our target is no more than 2.5% staff sickness absence rate in the month. The sick rate for October was comparatively high, at 3.5% (the public sector average), owing to one extended sickness period, and the normal seasonal range of cold/flu viruses.

No projects were on a red risk rating in October.

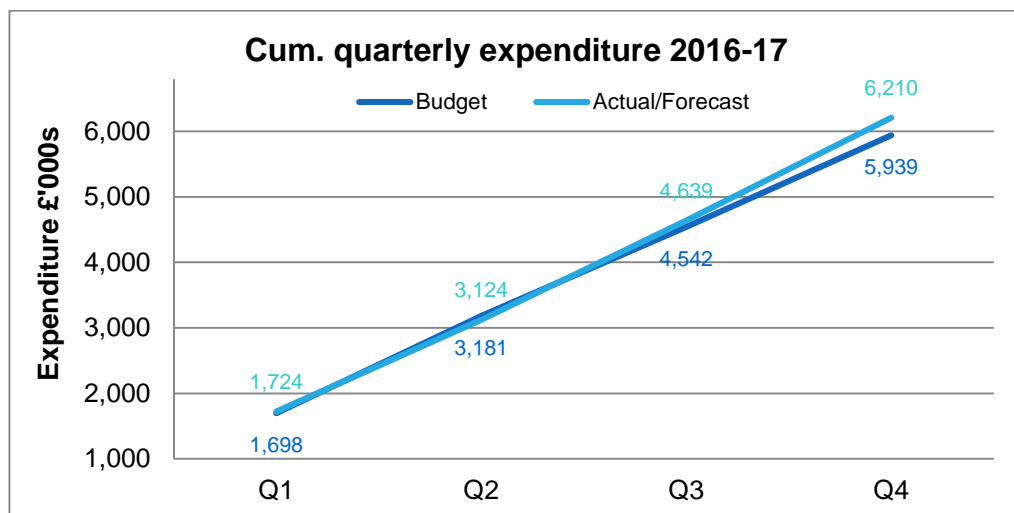
Budget status – October data

The dashboard shows the overall surplus/deficit position. The graphs below show how the surplus or deficit has arisen. These figures are updated quarterly, approximately one month after the end of each quarter.



This graph shows our budgeted (planned) income including grant-in-aid (GIA) compared to actuals and our best forecast for the remaining 5 months (2 quarters).

As of month 7 (October 2016) we have exceeded our budgeted income by £488k. Our Treatment fee income is £487k more than budget. We continue to monitor this and review our treatment fees to ensure there are no surprises in store.



This graph is the second component that makes up our surplus/(deficit). This includes costs relating to IfQ, although they are being funded from reserves and will be transferred to the balance sheet at year end. We include them currently for completeness and proper accounting practice.

As at 31 October, we are under-spending against budget by £64k which is demonstrated by the closeness of the two lines just after the Q2 period on this graph.

We are forecasting a spend of £6.2m versus £5.8m budget which is a variance of £0.4m. If all of IfQ is capitalised (removed from the revenue accounts), the variance between actual and budget would move from a negative £0.4m to £0.3m. We also hope that the provisions for legal spend either remain unchanged or are reduced by year end.

Quality and safety of care

As agreed previously, the following items are most meaningful when reported on an annual basis and will continue to be presented to the Authority each year in October:

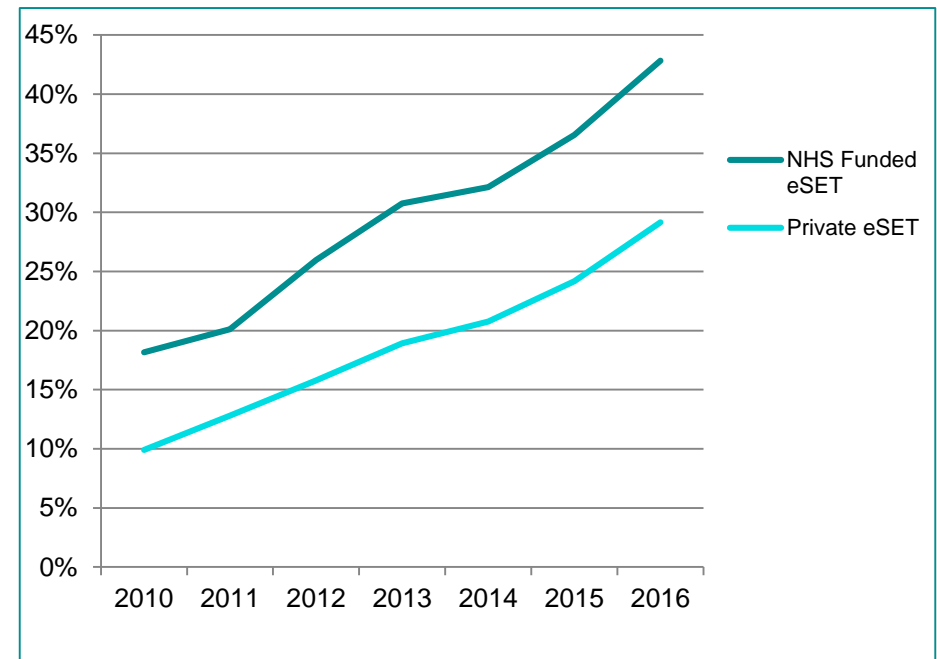
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

The following figures and graphs were run on 6 December 2016.

ESET split by private/NHS:

Funding	Year						
	2010	2011	2012	2013	2014	2015	2016
NHS Funded:							
Recorded as eSET	4285	4903	6264	7870	8444	9748	10960
	7%	8%	10%	13%	13%	15%	18%
Not recorded as eSET	19291	19490	17870	17719	17824	16929	14632
	33%	32%	30%	29%	28%	26%	23%
Relative eSET %	18%	20%	26%	31%	32%	37%	43%
Private:							
Recorded as eSET	3415	4627	5699	6857	7737	9346	10766
	6%	8%	9%	11%	12%	14%	17%
Not recorded as eSET	31031	31549	30398	29393	29515	29330	26158
	53%	52%	50%	48%	46%	45%	42%
Relative eSET %	10%	13%	16%	19%	21%	24%	29%

Graph: eSet % trends NHS/private:



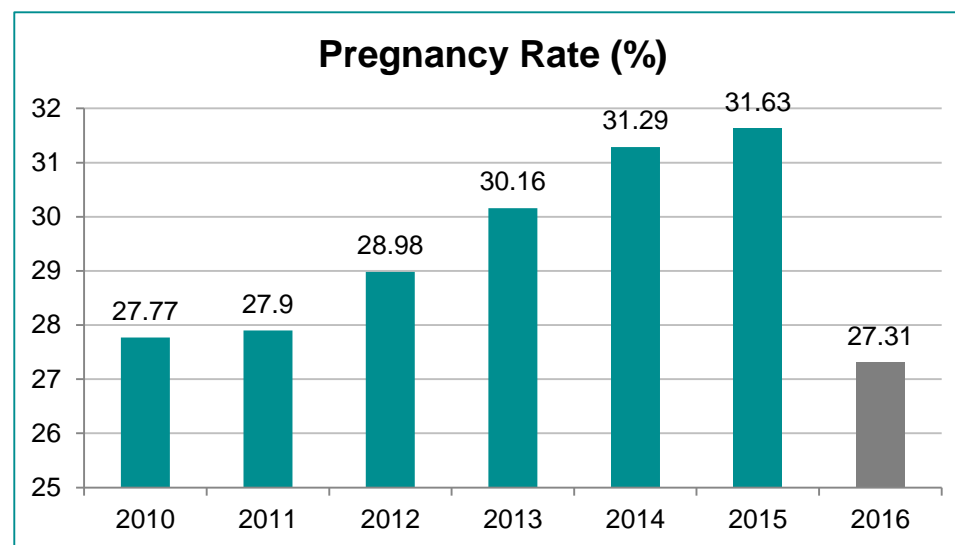
Explanatory text: Showing the total of all reported IVF treatment forms and counting those that the clinics recorded as eSET

From February 2016 data onwards, we updated this graph to display the relative percentages of eSET for NHS and privately funded cycles, rather than the percentage of all treatments as was previously shown. This relative approach gives a clearer picture, given that the number of overall cycles completed in the private sector is significantly higher than the number of NHS cycles. We have retained the raw figures in the table, so that the 'all treatment' numbers can still be seen as well.

Unfiltered success rates as % - pregnancies (rather than outcomes, since this provides a better real-time picture):

Years	All cycles	Pregnancies	Pregnancy rate %
2010	58022	16112	27.77
2011	60570	16897	27.9
2012	60231	17455	28.98
2013	61839	18652	30.16
2014	63520	19877	31.29
2015	65353	20669	31.63
2016	62517	17076	27.31

Graph showing the pregnancy rate over recent years:



Explanatory text: Looking at all IVF treatment forms, and providing a count of pregnancies - as recorded on the early outcome form.

2016 figures are in grey since there is always a lag in reporting pregnancies, which means that the figure will not be fully representative until some way into 2017.

2. Indicator section

Key performance and volume indicators – October data:

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
Setting standards: improving the quality and safety of care through our regulatory activities.					
Licensing decisions made: <ul style="list-style-type: none"> - By ELP - By Licence Committee 	7 0	↓		No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target).
Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.					
Percentage of Opening the Register requests responded to within 20 working days	100% (21)	★		Maintain at 100%	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)

¹ Blue dashed line in graphs = KPI target level. This line may be invisible when performance and target are identical (eg, 100%).

² Direction in which we are trying to drive performance. (Are we aiming to exceed, equal, or stay beneath this particular KPI target?)

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
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Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.

See graphs focused on quality of treatment outcomes – after dashboard page.

Increasing and informing choice: ensuring that patients have access to high quality meaningful information.

Number of visits to the HFEA website (compared with previous year)
(trend arrow indicates movement since previous month)

107,709
(125,613)



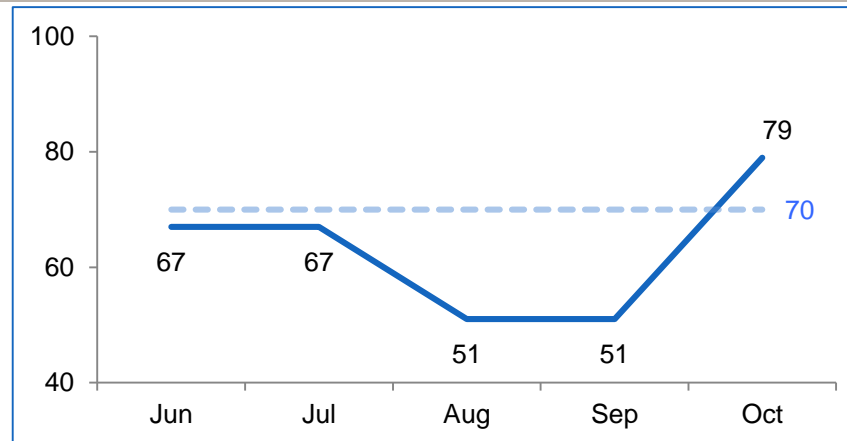
No KPI – tracked for general monitoring purposes.

Volume indicator showing general website traffic compared to the same period in previous year. Measured on the basis of 'unique visitors'.

Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.

Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.

79 working days


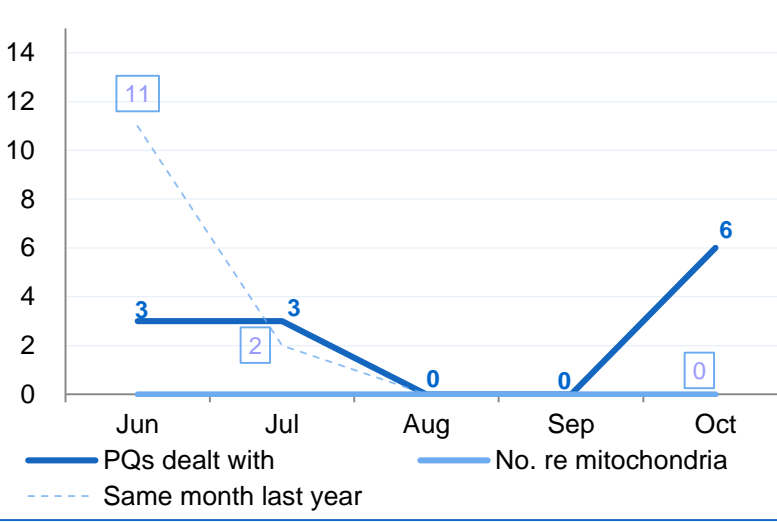

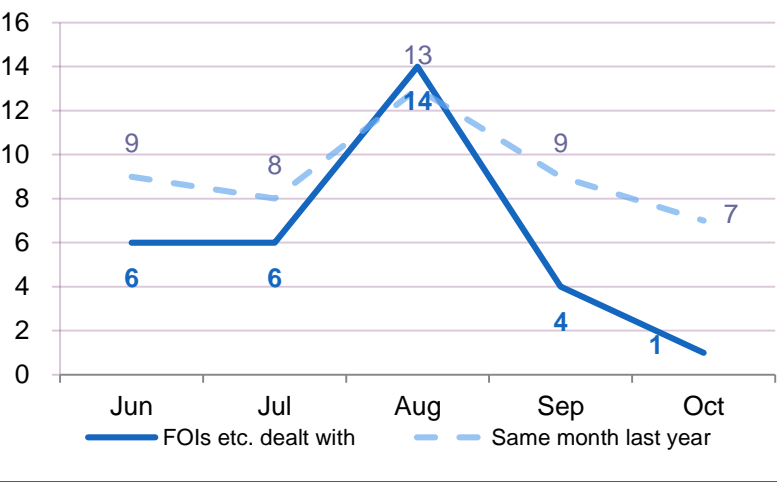


KPI: Less than or equal to 70 working days.

Return to 70wd or less

Commentary: One report was sent at 21wd and another at 25wd. One report was sent at 32wd due to multiple management reviews and actions required by the PR before the report could be completed.

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes												
Monthly percentage of PGD applications processed within three months (66 working days).	100%	★	<table border="1"> <caption>Monthly percentage of PGD applications processed within three months</caption> <thead> <tr> <th>Month</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Jun</td> <td>80%</td> </tr> <tr> <td>Jul</td> <td>100%</td> </tr> <tr> <td>Aug</td> <td>67%</td> </tr> <tr> <td>Sep</td> <td>100%</td> </tr> <tr> <td>Oct</td> <td>100%</td> </tr> </tbody> </table>	Month	Percentage	Jun	80%	Jul	100%	Aug	67%	Sep	100%	Oct	100%	Maintain 100%	KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.
Month	Percentage																
Jun	80%																
Jul	100%																
Aug	67%																
Sep	100%																
Oct	100%																
Average number of working days taken.	56	★	<table border="1"> <caption>Average number of working days taken</caption> <thead> <tr> <th>Month</th> <th>Days</th> </tr> </thead> <tbody> <tr> <td>Jun</td> <td>54</td> </tr> <tr> <td>Jul</td> <td>54</td> </tr> <tr> <td>Aug</td> <td>58</td> </tr> <tr> <td>Sep</td> <td>59</td> </tr> <tr> <td>Oct</td> <td>56</td> </tr> </tbody> </table>	Month	Days	Jun	54	Jul	54	Aug	58	Sep	59	Oct	56		
Month	Days																
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Sep	59																
Oct	56																
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	94%	↔	<table border="1"> <caption>Annualised (rolling year) percentage of PGD applications processed within three months</caption> <thead> <tr> <th>Month</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Jun</td> <td>96%</td> </tr> <tr> <td>Jul</td> <td>96%</td> </tr> <tr> <td>Aug</td> <td>94%</td> </tr> <tr> <td>Sep</td> <td>94%</td> </tr> <tr> <td>Oct</td> <td>94%</td> </tr> </tbody> </table>	Month	Percentage	Jun	96%	Jul	96%	Aug	94%	Sep	94%	Oct	94%	Maintain 100%	KPI: As above. (Annualised score). Per the above measure, performance has dropped below the target due to two complex applications falling outside the KPI in May and June 2016. The annualised figure will now be impacted until 2017.
Month	Percentage																
Jun	96%																
Jul	96%																
Aug	94%																
Sep	94%																
Oct	94%																
Average number of working days taken.	54	★	<table border="1"> <caption>Average number of working days taken</caption> <thead> <tr> <th>Month</th> <th>Days</th> </tr> </thead> <tbody> <tr> <td>Jun</td> <td>53</td> </tr> <tr> <td>Jul</td> <td>53</td> </tr> <tr> <td>Aug</td> <td>54</td> </tr> <tr> <td>Sep</td> <td>54</td> </tr> <tr> <td>Oct</td> <td>54</td> </tr> </tbody> </table>	Month	Days	Jun	53	Jul	53	Aug	54	Sep	54	Oct	54		
Month	Days																
Jun	53																
Jul	53																
Aug	54																
Sep	54																
Oct	54																

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes																								
Number of requests for contributions to Parliamentary questions	Total = 6		 <table border="1" data-bbox="801 132 1576 655"> <caption>Line Chart Data: PQs dealt with and No. re mitochondria</caption> <thead> <tr> <th>Month</th> <th>PQs dealt with</th> <th>No. re mitochondria</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>Jun</td> <td>3</td> <td>0</td> <td>11</td> </tr> <tr> <td>Jul</td> <td>3</td> <td>0</td> <td>2</td> </tr> <tr> <td>Aug</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>Sep</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>Oct</td> <td>6</td> <td>0</td> <td>0</td> </tr> </tbody> </table>	Month	PQs dealt with	No. re mitochondria	Same month last year	Jun	3	0	11	Jul	3	0	2	Aug	0	0	0	Sep	0	0	0	Oct	6	0	0	No KPI – tracked for general monitoring purposes.	Volume indicator. Last year's numbers were notably high, for a period. Many of those PQs related to the work we were then doing on mitochondria scientific review.
Month	PQs dealt with	No. re mitochondria	Same month last year																										
Jun	3	0	11																										
Jul	3	0	2																										
Aug	0	0	0																										
Sep	0	0	0																										
Oct	6	0	0																										
Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests	1		 <table border="1" data-bbox="801 675 1576 1158"> <caption>Line Chart Data: FOIs etc. dealt with and Same month last year</caption> <thead> <tr> <th>Month</th> <th>FOIs etc. dealt with</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>Jun</td> <td>6</td> <td>9</td> </tr> <tr> <td>Jul</td> <td>6</td> <td>8</td> </tr> <tr> <td>Aug</td> <td>13</td> <td>14</td> </tr> <tr> <td>Sep</td> <td>4</td> <td>9</td> </tr> <tr> <td>Oct</td> <td>1</td> <td>7</td> </tr> </tbody> </table>	Month	FOIs etc. dealt with	Same month last year	Jun	6	9	Jul	6	8	Aug	13	14	Sep	4	9	Oct	1	7	No KPI – tracked for general monitoring purposes.	Volume indicator. There does not appear to be any trend or predictability in the volume or focus of our FOI (and other) requests.						
Month	FOIs etc. dealt with	Same month last year																											
Jun	6	9																											
Jul	6	8																											
Aug	13	14																											
Sep	4	9																											
Oct	1	7																											

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes												
Staff sickness absence rate (%) per month.	3.5%	↑	<table border="1"> <caption>Staff Sickness Absence Rate (%)</caption> <thead> <tr> <th>Month</th> <th>Rate (%)</th> </tr> </thead> <tbody> <tr> <td>Jun</td> <td>2.1%</td> </tr> <tr> <td>Jul</td> <td>1.9%</td> </tr> <tr> <td>Aug</td> <td>1.1%</td> </tr> <tr> <td>Sep</td> <td>0.3%</td> </tr> <tr> <td>Oct</td> <td>3.5%</td> </tr> </tbody> </table>	Month	Rate (%)	Jun	2.1%	Jul	1.9%	Aug	1.1%	Sep	0.3%	Oct	3.5%	 Maintain 2.5% or less	KPI: Absence rate of ≤ 2.5%. Public sector sickness absence rate average is eight days lost per person per year (3.0%).
Month	Rate (%)																
Jun	2.1%																
Jul	1.9%																
Aug	1.1%																
Sep	0.3%																
Oct	3.5%																

Commentary: The sick rate is comparatively high for this month, owing to one extended period of sick leave, and the normal seasonal range of cold/flu viruses.

Cash and bank balance	£2,243k	↓	<table border="1"> <caption>Cash and Bank Balance (£k)</caption> <thead> <tr> <th>Month</th> <th>Balance (£k)</th> </tr> </thead> <tbody> <tr> <td>Jun</td> <td>£2,235</td> </tr> <tr> <td>Jul</td> <td>£1,999</td> </tr> <tr> <td>Aug</td> <td>£2,141</td> </tr> <tr> <td>Sep</td> <td>£2,363</td> </tr> <tr> <td>Oct</td> <td>£2,243</td> </tr> </tbody> </table>	Month	Balance (£k)	Jun	£2,235	Jul	£1,999	Aug	£2,141	Sep	£2,363	Oct	£2,243	 Reduce	KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH).
Month	Balance (£k)																
Jun	£2,235																
Jul	£1,999																
Aug	£2,141																
Sep	£2,363																
Oct	£2,243																

Commentary: In July, increased suppliers' activities contributed to an 11% reduction in the bank balance. However August saw an increase, owing mainly to successful chasing of debts over 60 days. The increase in September resulted again from debt chasing, and also from moneys received from grant in aid. Increased supplier activities in October contributed to a 5% reduction in the bank balance.

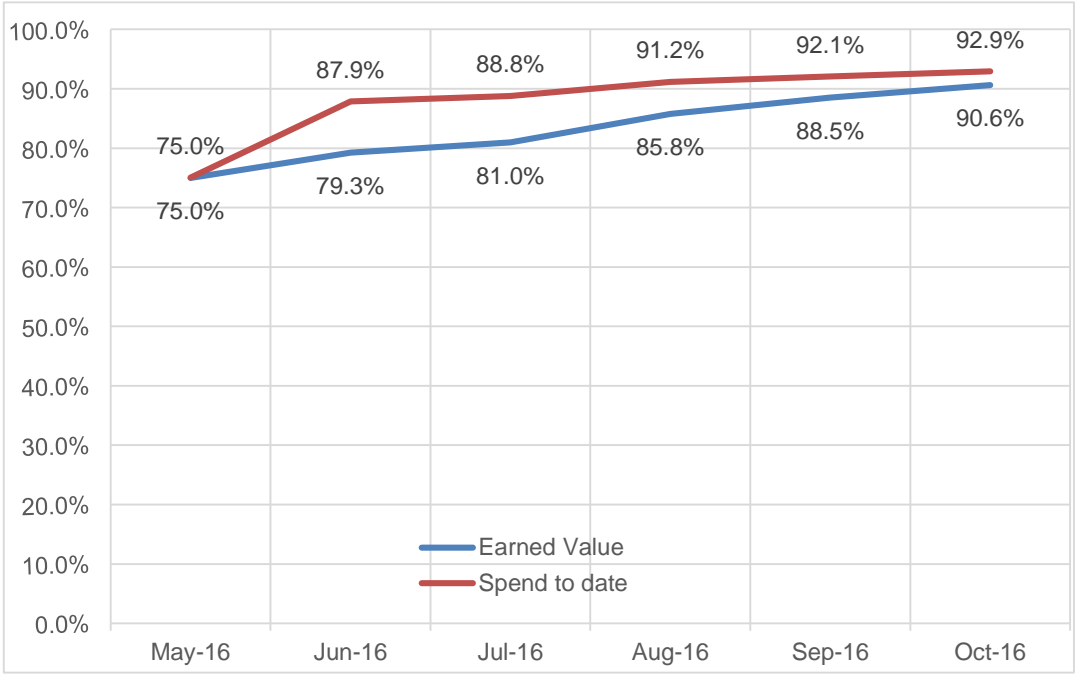
Indicator	Performance	RAG	Recent trend ¹		Aim ²	Notes	
Management accounts	October 2016:						
	Income & Expenditure Account		Oct-2016				
Accounting Period			Period 7.16-17				
Cost Centre Name			All Cost Centres				
Department Name			All Departments				
			Year to Date		Full Year		
	Actual YTD	Budget YTD	Variance YTD	% Variance YTD	Forecast	Budget	Variance
	£	£	£	%	£	£	£
Grant-in-aid	469	469	-	-	933	938	(5)
Licence Fees	3,127	2,639	488	19	5,377	4,472	905
Other Income	3	4	(1)	(28)	6	6	-
Total Income	3,599	3,111	487	16	6,316	5,416	900
Revenue Costs - Charged to Expenditure							
Salaries (excluding Authority)	1,547	1,569	22	(1)	2,653	2,679	(26)
Shared Services	41	50	9	(18)	60	81	(21)
Employer's NI Contributions	153	145	(8)	6	272	247	24
Employer's Pension Contribution	327	335	8	(2)	572	573	(1)
Authority salaries inc. NI Contributions	85	85	(1)	1	147	146	1
Temporary Staff costs	71	-	(71)		93	-	93
Other Staff Costs	135	144	14	(9)	249	265	(16)
Other Authority/Committee costs	64	91	26	(29)	148	156	(8)
Other Compliance Costs	7	17	10	(59)	20	28	(7)
Other Strategy Costs	27	66	40	(60)	133	142	(9)
Facilities Costs incl non-cash	275	303	28	(9)	483	488	(4)
IT costs Costs	66	54	(12)	23	89	93	(4)
Legal Costs	332	238	(93)	39	656	400	256
Professional Fees	41	39	(2)	4	68	67	-
Total Revenue Costs	3,171	3,137	(30)	1	5,642	5,361	280
<i>Total Surplus/(Deficit) before Capital & Project costs</i>	<i>428</i>	<i>(25)</i>	<i>518</i>	<i>2,035</i>	<i>674</i>	<i>55</i>	<i>620</i>
IFQ & Other Project Costs - Reserves funded	374	472	98	(21)	567	477	90
Other Capital Costs	10	50	40	(80)	100	100	-
TOTAL NET ACTIVITY	44	(548)	379		6	(522)	530

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
Commentary:	Summarised management accounts – commentary October 2016				
	Income				
	<p>For the seven months ended 31 October, we have exceeded our budgeted treatment fee income by £488k (18.5%) up by 0.5% on what was reported at the end of Q2 (September). This affects our forecast outturn for the year which we are currently reporting to be £5.4m which is a slight decrease from the £5.5m reported at the end of September. It is difficult to say if this will tail off or drop suddenly. Constant monitoring and re-forecasting will be carried out till the end of Q3.</p>				
	Expenditure				
	Reporting by exception:				
	<p>Staff costs year-to-date are above budget by £41k due to agency staff costs incurred to back-fill key staff working on the IfQ Programme. We are forecasting a year end variance of £71k above budget. Other areas of over spend against budget are:</p>				
	<p>IT costs year-to-date which are £12k above budget compared to £11k reported in Q2. Legal costs year-to-date continue to exceed budget by £93k against £125k reported in Q2 also. The position being reported at year end is an over spend by £256k. This is due to inclusion of accruals for at least one case that comes to fruition in December 2016.</p>				
	IfQ and other project costs				
	<p>Year-to-date IfQ is showing an underspend against budget by 21% (£98k) and forecast to overspend by 19% (£90k) at year-end which takes into account extra budget agreed by SMT. Regular meetings with the PMO to discuss the budget are taking place to ensure both finance and PMO are in agreement of what costs are outstanding.</p>				

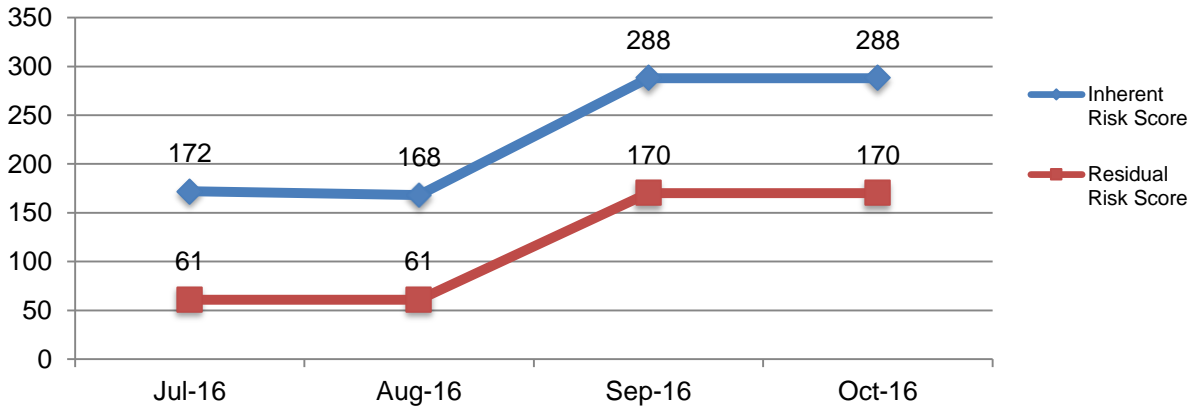
IfQ indicators: October update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:																				
At programme set-up / major reorganisation / new tranche	MSP health check overall score achieved / maximum score as a %	Is the programme set up to deliver?	<p>October update:</p> <p>The MSP health check was completed previously with the final report circulated to the IfQ programme board. The IS team has been able to evidence that enough assurance is in place for data migration and the new EDI. The assurance on data migration is set to start in January and the report will be presented to IfQ PB and CMG.</p>																				
Monthly	Timescales: we changed the burndown chart showing remaining estimate of work to a chart showing percentage of works complete.	Is there scope creep/over-run?	<p>October update:</p> <p>The Clinic portal has now passed the GDS assesment and has been allowed to progress to live. The portal team will be focusing on getting the necessary work completed in order to go live early January including addressing remaining GDS recommendations. The website work has been delayed, partially due to the focus on getting the portal ready for the GDS assessment. We are now gathering all the remaining work for the website to be scheduled with RR, although changes may materialise following the outcome of the JR in December.</p> <div style="display: flex; justify-content: space-around;"> <div data-bbox="846 790 1415 1356"> <table border="1"> <caption>Percent Complete - Clinic Portal R1 to November 2016</caption> <thead> <tr> <th>Sprint</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Total Beta Sprint 17</td> <td>92%</td> </tr> <tr> <td>Total Beta Sprint 19</td> <td>92.5%</td> </tr> <tr> <td>Total Beta Sprint 21</td> <td>93%</td> </tr> <tr> <td>Total Beta Sprint 23</td> <td>94%</td> </tr> </tbody> </table> </div> <div data-bbox="1422 790 1960 1356"> <table border="1"> <caption>Percent Complete - Website R1 to November 2016</caption> <thead> <tr> <th>Sprint</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Total Beta Sprint 17</td> <td>60%</td> </tr> <tr> <td>Total Beta Sprint 19</td> <td>70%</td> </tr> <tr> <td>Total Beta Sprint 21</td> <td>80%</td> </tr> <tr> <td>Total Beta Sprint 23</td> <td>80%</td> </tr> </tbody> </table> </div> </div>	Sprint	Percent Complete	Total Beta Sprint 17	92%	Total Beta Sprint 19	92.5%	Total Beta Sprint 21	93%	Total Beta Sprint 23	94%	Sprint	Percent Complete	Total Beta Sprint 17	60%	Total Beta Sprint 19	70%	Total Beta Sprint 21	80%	Total Beta Sprint 23	80%
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IfQ indicators: October update for beta project phase

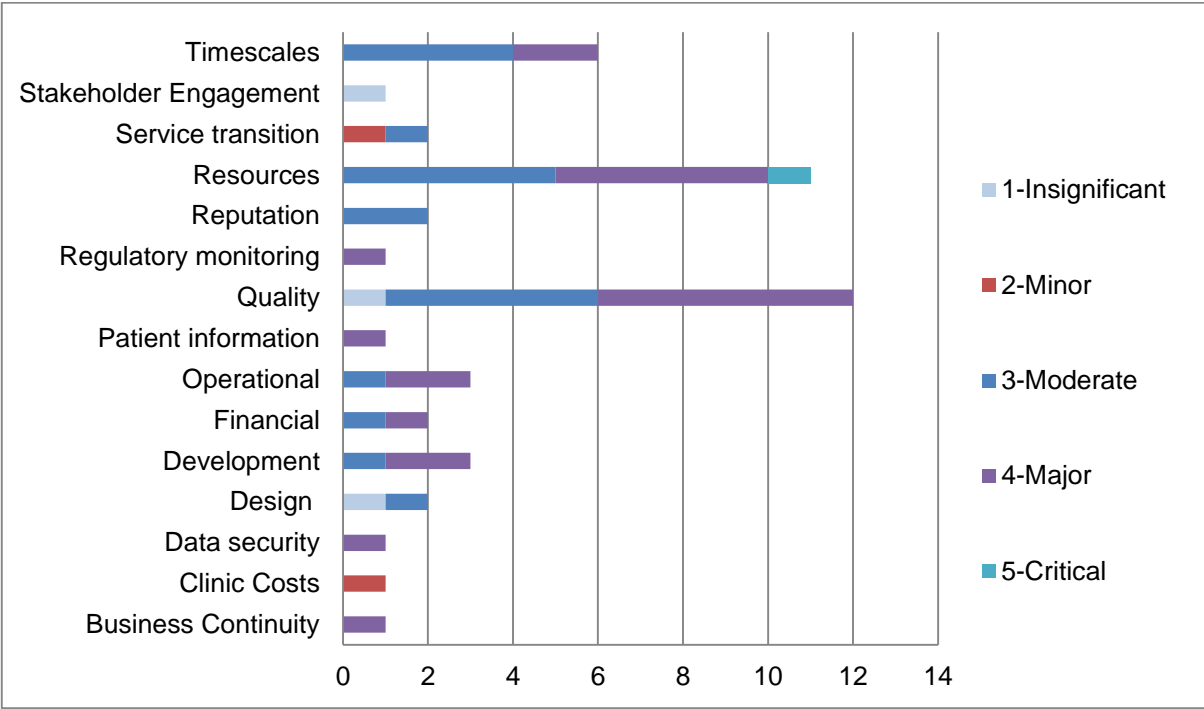
Frequency / trigger point	Metric	Purpose	Latest status:																					
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	<p>There are four things we can attribute value to: websites and CaFC; Clinic Portal; the Register and internal systems; defined dataset, discovery, stakeholder engagement etc. 25% of the value of the 1.8M programme cost at completion has been attributed to each project.</p> <p>October update: The spend to date has risen slightly compared to last month and is now again joining the earned value. As we reach the end of beta (and thus most of the expenditure on the Reading Room contract) and complete the live phase we expect the earned value to reach its peak reflecting the beta work being finished. It may make sense to discontinue this metric at that point, since most release two costs are internal staff salaries.</p>  <table border="1"> <caption>Line Chart Data: Earned Value vs Spend to date</caption> <thead> <tr> <th>Month</th> <th>Earned Value (%)</th> <th>Spend to date (%)</th> </tr> </thead> <tbody> <tr> <td>May-16</td> <td>75.0%</td> <td>75.0%</td> </tr> <tr> <td>Jun-16</td> <td>79.3%</td> <td>87.9%</td> </tr> <tr> <td>Jul-16</td> <td>81.0%</td> <td>88.8%</td> </tr> <tr> <td>Aug-16</td> <td>85.8%</td> <td>91.2%</td> </tr> <tr> <td>Sep-16</td> <td>88.5%</td> <td>92.1%</td> </tr> <tr> <td>Oct-16</td> <td>90.6%</td> <td>92.9%</td> </tr> </tbody> </table>	Month	Earned Value (%)	Spend to date (%)	May-16	75.0%	75.0%	Jun-16	79.3%	87.9%	Jul-16	81.0%	88.8%	Aug-16	85.8%	91.2%	Sep-16	88.5%	92.1%	Oct-16	90.6%	92.9%
Month	Earned Value (%)	Spend to date (%)																						
May-16	75.0%	75.0%																						
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Sep-16	88.5%	92.1%																						
Oct-16	90.6%	92.9%																						

IfQ indicators: October update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:															
Monthly	Stakeholder engagement: combined stakeholder engagement score (internal plus external stakeholder events or communications)	Are we keeping stakeholders with us? Is it getting better or worse?	<p>October update:</p> <p>In October we sent out an edition of Clinic Focus specifically around IfQ. This included information about the new clinic portal and data verification. We held two show and tell sessions for staff in October. We continued to use social media to encourage feedback for the beta website.</p> <p>Engagement score =4</p>															
Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	<p>October update:</p> <p>The line graph below represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks on hand each month.</p> <p>The overall risk score for the IfQ Programme increased significantly following a risk review meeting held in early Oct. The mitigations or acceptance of the risks have been processed although we need to make sure all risks are once more reviewed and monitored in the upcoming months.</p> <p>The major risks are associated with resources, timescales, regulatory monitoring, quality, financial, development, patient information, data security and business continuity.</p>  <table border="1"> <caption>Risk Score Data</caption> <thead> <tr> <th>Month</th> <th>Inherent Risk Score</th> <th>Residual Risk Score</th> </tr> </thead> <tbody> <tr> <td>Jul-16</td> <td>172</td> <td>61</td> </tr> <tr> <td>Aug-16</td> <td>168</td> <td>61</td> </tr> <tr> <td>Sep-16</td> <td>288</td> <td>170</td> </tr> <tr> <td>Oct-16</td> <td>288</td> <td>170</td> </tr> </tbody> </table>	Month	Inherent Risk Score	Residual Risk Score	Jul-16	172	61	Aug-16	168	61	Sep-16	288	170	Oct-16	288	170
Month	Inherent Risk Score	Residual Risk Score																
Jul-16	172	61																
Aug-16	168	61																
Sep-16	288	170																
Oct-16	288	170																

IfQ indicators: October update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
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Quarterly	Benefits: value (£) of tangible benefits planned to be delivered by the programme	Is the value of the benefits increasing or decreasing – could trigger a review of the business case?	<p>October to November update:</p> <p>The realisation of benefits should be reviewed based on the business case. No issues have been raised regarding benefits realisation to date, and we expect the business case to be delivered.</p>
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Information for Quality programme: update

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting Authority

Agenda item 7

Paper number HFEA (18/01/2017) 821

Meeting date 18 January 2017

Author Nick Jones, Director of Compliance and Information

Output:

For information or decision? For information

Recommendation The Authority is asked to:

- Note the extension of £90,000 to the Programme budget
- Note progress since the last Authority meeting, noting the launch of the Clinic Portal, and plans as regards the HFEA website;
- Note delays to Release 2 – the new data submission system
- Comment on the draft Information Policy
- Note programme expenditure

Resource implications Additional resource requirements have now been identified, above those already budgeted

Implementation date During 2016–17 business year

Communication(s) Regular, range of mechanisms

Organisational risk Low Medium High

Annexes: None

1. Background

- 1.1.** The Information for Quality (IfQ) programme encompasses:
- The redesign of our website and Choose a Fertility Clinic (CaFC) function
 - The redesign of the 'Clinic Portal' (used for interacting with clinics) and combining it with data submission functionality (Release 2) that is currently provided in our separate system (used by clinics to submit treatment data to us)
 - A revised dataset and data dictionary which will be submitted for approval by the Standardisation Committee for Care Information (SCCI)
 - A revised Register of treatments, which will include the migration of historical data contained within the existing Register
 - The redesign of our main internal systems that comprise the Authority's Register and supporting IT processes.
- 1.2.** Given the importance of IfQ to our strategy, we update the Authority on progress at each meeting and seek approval for direction and actions.
- 1.3.** This paper updates Members on:
- Concluding the Programme
 - Work in progress: website and Release 2 – data submission development
 - Information Policy – background
 - Programme budget

2. The IfQ Programme

- 2.1.** As indicated in the November 2016 meeting of the Authority the IfQ Programme is scheduled to conclude in March this year. This paper brings members up to date with progress and sets out the path to conclusion. The Audit and Governance Committee discussed some aspects, in particular the potential for applying additional funds to the Programme, at its meeting in December 2016.
- 2.2.** The Programme is progressing according to 'agile' principles required by the Government Digital Service (GDS). This week saw the launch of the live version of the HFEA Clinic Portal.
- 2.3.** Our attention is now focussed on completing the work necessary to move the HFEA website from Beta to live and producing a Beta version of the treatment submission system (Clinic Portal R2) – see below.
- 2.4.** The opportunities for learning throughout the programme period has been plentiful. In particular, whilst we have managed to balance the work on the three products through the Programme, it is clear that the 'final push' to live is all-encompassing, and requires the focus of the whole team to ensure their various competencies are utilised at the right time. This has necessarily limited the progress made elsewhere. Further, it is apparent that an element of programme

fatigue has become apparent. As such from around mid-December 2016 we have taken the opportunity to regroup – focused towards the Clinic Portal and exploring how we can support colleagues to maintain pace during what has now become an extended period.

- 2.5.** As such, an additional sum, around £90,000, (from HFEA reserves) is necessary to accelerate the final phase – principally to fund the cost of developers under contract to the HFEA directly. Permission to spend is required and is discussed further, at section 4, below.

3. Work in progress

- 3.1.** The period since the last meeting of the Authority has been principally focused towards the Clinic Portal launch. The existing version was decommissioned just before Christmas so that the team could focus on moving the new Portal to a 'live' environment.
- 3.2. Website and choose a fertility clinic:**
- 3.3.** The judicial review was heard on 19 and 20 December 2016, with an additional half day on 10 January 2017. The judgment is expected by the end of January 2017. At this stage we simply do not know whether this will have an impact on plans to launch the website.
- 3.4.** The website team is currently working on a closure plan to complete the necessary work ahead of the GDS/DH live assessment (whilst, currently scheduled for the 24 Jan 2017 we may push this back a few weeks). A plan is in place to decommission the current website and launch the new live HFEA website to the public.
- 3.5.** In the meantime, further content has been commissioned, including an animation aiming to facilitate the understanding of information for patients in respect of choose a fertility clinic.
- 3.6. Release 2 – data submission development**
- 3.7.** This is where the bulk of the work that remains to be completed is situated. Limited progress has been made since the last meeting due to the priority placed on completing the Clinic Portal and website. That said, and as reported at previous meetings, substantial foundational work has been completed.
- 3.8.** The data dictionary – the basis of all the information we need to collect and the definition of each field is complete. The Standardisation Committee for Care Information (part of NHS Digital) accreditation process for the 'UK ART dataset' has our submissions with the final stage of the accreditation postponed to match our revised timeline.

Data 'cleansing'

- 3.9.** Over the last 12 months, the Register has been subject to a thorough overhaul, and cleansing exercise. As the data are moved from the current Register structure or database to a new more efficient database, to allow for much greater ease of interrogation and less manual intervention, it is vital that critical fields are reviewed for error, absence or duplication and resolved – as far as possible.
- 3.10.** The data cleansing process is nearing completion; the remaining errors are being dealt with directly with clinics, and an internal process to address any unresolved errors has been put in place by the team.

Register data migration

- 3.11.** Having trailed the vital work in preparing for data migration over several months, we are now reaching some critical milestones. Migration takes place in stages – as each 'test' migration (or trial load, through five stages usually) reports on anomalies, which are fixed in advance of progression to the next test. Data Migration Trial Load 1 has completed and reports generated with action now being taken to resolve issues. In practice, this first trial load is the most resource intensive, and crucial.
- 3.12.** Members will recall that a data migration strategy was commissioned (from Avoca) in 2015 to support the data migration team and to provide a technical and assurance framework directing its work, recognising the inherent risks involved.
- 3.13.** We have now commissioned a further, third party expert in large scale data migration exercises, Northdoor plc. In essence, Northdoor will conduct a two-phase audit on the Register Data Migration process, assuring the Senior Responsible Owner, Senior Management Team and the Authority that our approach to data migration conforms with our own strategy and that all steps have been taken to ensure the integrity of the data being migrated.
- 3.14.** At this point it is worth emphasising that risks of 'losing the Register' as a consequence of migration are not increased during the migration exercise, due to the standard security and back-up arrangements in place. The focus here is ensuring the integrity of the data in the light of Register structure changes – such that the data are matched appropriately from 'old to new.' That said, the audit will address wider information risks.
- 3.15.** The on-site audits to be undertaken by Northdoor are scheduled for 11/12 January 2017, with a further audit taking place on 23 March 2017 – with the latter principally focused to assess the HFEA's readiness to progress to the final, Trial Load – 5.

Treatment data submission system

- 3.16.** We have utilised user-experience experts from our external supplier, Reading Room to work on the 'screens' for the EDI replacement and are currently consulting users on their preferences for screen mock-ups.
- 3.17.** Approximately half of treatment clinics submit treatment information via third-party patient record suppliers. In such cases clinic users' experiences are mediated by a third party. It is therefore important that we set out our expectations to these suppliers very clearly. We have engaged very positively with suppliers since last year and have set up a collaboration site to support them evolve their systems so that data submission to the new register structure can take place. The collaboration site includes an open forum where suppliers can ask questions and where the IT team can post answers that all suppliers can see.
- 3.18.** We have also set-up development environments for each supplier so that they are able to test their ability to send and receive data and details of our security expectations.
- 3.19.** We now need to exploit the feedback on the user interface and connect that front-end to the new Register structure.

4. Resourcing the Programme

- 4.1.** As indicated above, we have focused the Programme's efforts over the last few months' towards finalising product areas. This has not resulted in a lessening of effort or slowing of pace, rather a concentration of effort.
- 4.2.** Nonetheless, as a consequence of this focus and the sheer ambition of the Programme it is now clear that completing the treatment data submission system product for a 31 March 2017 launch is not achievable.
- 4.3.** There are considerable merits in allocating additional resources to support the team where more generically available skills can be bought in for a limited amount of time and ensure that pace is maintained and that we better manage the workloads of staff. It is clear (as it has always been) that the expertise of certain key individuals simply cannot be stretched too thinly. Even with additional resource the anticipated launch date is now expected to be towards the end of Q1 – late Spring 2017.
- 4.4.** We are seeking a modest extension to the budget of c£90,000 to support an extension of back-filling arrangements for key members of the HFEA team, and developer resource to complete the 'user interface' experienced by clinic users.
- 4.5.** As this additional £90k would take us above the spending limits we agree annually with the Department of Health we have sought their approval for this spend to be incurred in the 2016/17 financial year. Although we still await a formal response our initial conversations have been positive and we expect approval in due course.

5. Information Policy

- 5.1.** Given the substantial investment by the HFEA in developing a new information architecture, we must now take the opportunity to set out more clearly our information expectations of clinics and ourselves.
- 5.2.** Our Information for Quality programme is clearly located in the digital age, and there is a clear drive for providers to work digitally. In the NHS, as well as a commitment for it to be paperless, there is now an expectation that all trusts are digitised by 2023, with powers given to the Care Quality Commission to act as an additional incentive. The goal of digitisation of the NHS is to promote healthcare's triple aim: better health, better healthcare, and lower cost.
- 5.3.** Our policy intentions are not simply about submitting treatment data but more than that. Our emerging Strategy is positioned towards exploiting the investment we have made in the various components of IfQ. There is much potential from the better use of information to drive better performance and we have a unique role in the 'centre' to receive it, store it, analyse it, and enable others to analyse it and catalyse change. Similarly, it enables our inspectors to have conversations about variance and outliers, and trends relating to incidents and non-compliant areas and so on. And we also have a role in disseminating the information in the form of reports, discussion papers and through choose a fertility clinic.
- 5.4.** The importance of clinics' efforts in caring for the information they hold and submitting this on time and of high quality is self-evident. Without it we cannot do these things and they cannot run high quality services either. We have spent some time revising our systems and the register to be more efficient and we will now be putting much more emphasis on creating the right climate to work with clinics to improve performance.
- 5.5.** We have developed a system for clinics that is intuitive, sympathetic to clinics' processes, that saves them time. We now need to develop a policy for incentivising clinics to improve and maintain their performance; without good quality information 'in' we cannot realise our strategic objectives. The policy and full suite of supporting Directions will be presented to the March 2017 meeting of the Authority.

6. Programme budget

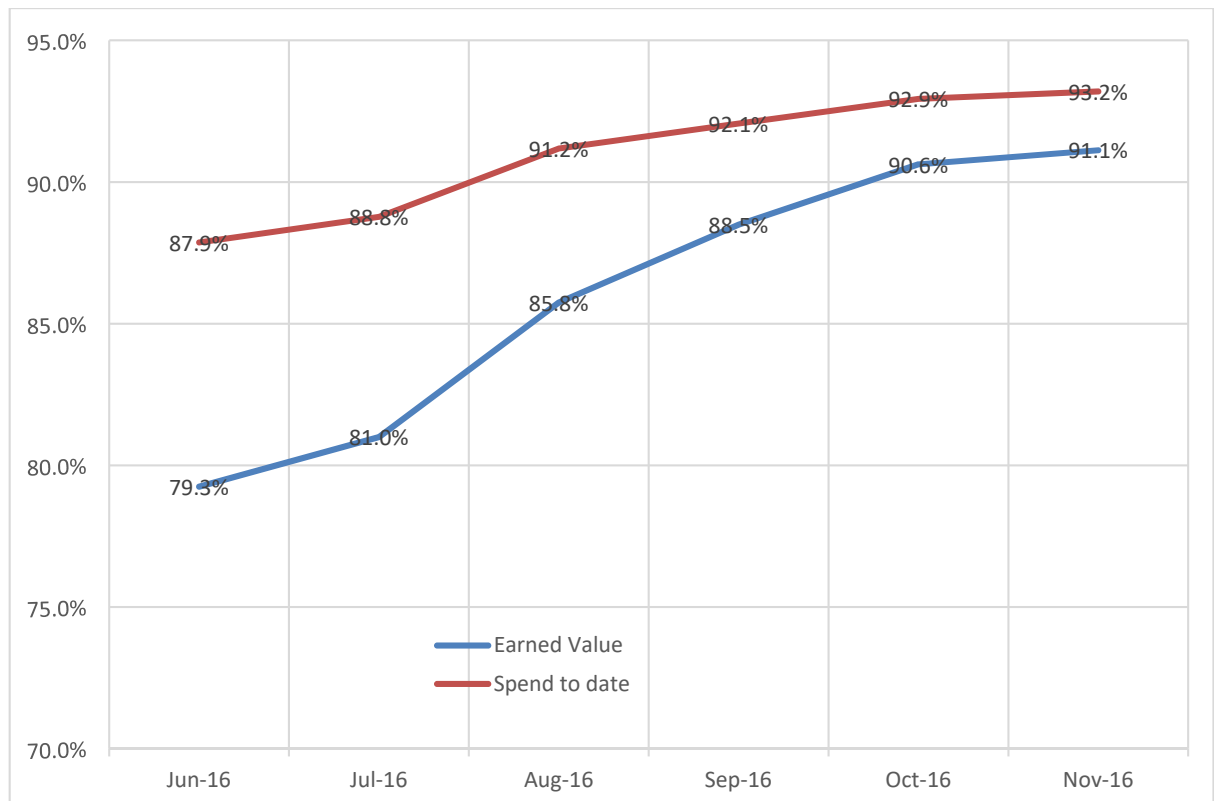
- 6.1.** As reported previously, a revised IfQ programme plan was finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by Authority. We now expect the Programme will exceed this figure at 31 March 2017 due to the proposed £90,000 injection of funding in to the Programme.
- 6.2.** This month variance is due to the delayed invoices and cost attached with user testing for both portal and website.

6.3. The current budget position for 2016/17 is as follows:

Total IfQ budget May 2016	Budget this F/Y (16/17)	Planned spend (Nov 16)	Actual to date (Nov 16)	Monthly Variance
1,134,000	£619,025	£1,168,123	£1,183,340	£15,217

6.4. The earned value and spend to date have progressed slightly, this is reflecting the minimal RR resources allocated and shared between both website and Clinic Portal. Although at this stage we are now looking at spending the remaining budget as forecasted on CLAS/Pen testing, Data migration audit and R2.

Period	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16
Earned Value	79%	81%	91.2%	92.1%	90.6%	91.1%
Spend to date	87.9%	88.8%	85.8%	88.5%	92.9%	93.1%



7. Recommendation

7.1. The Authority is asked to note:

- Note the extension of £90,000 to the Programme budget, subject to Department of Health approval;
- Progress since the last Authority meeting, noting the launch of the Clinic Portal, and plans as regards the HFEA website;
- The delays to Release 2 – the new data submission system;
- Note steps in relation to the proposed Information Policy
- Programme expenditure

Strategy 2017-2020

Strategic delivery:

Setting standards

Increasing and
informing choice

Demonstrating efficiency
economy and value

Details:

Meeting	Authority
Agenda item	8
Paper number	HFEA (18/01/17) 822
Meeting date	18 January 2017
Author	Paula Robinson, Head of Business Planning

Output:

For information or decision?	For decision
Recommendation	The Authority is asked to approve the draft strategy for publication.
Resource implications	In budget.
Implementation date	Throughout 2017/18-2019/20 business years.
Communication(s)	Launch at HFEA annual conference; publication on HFEA website.
Organisational risk	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex A: Strategy 2017-2020

1. Summary

- 1.1. Improved quality lies at the heart of the strategy, and we believe this will come from safe, effective, evidence-based care, high quality science and research, treatment information that is well explained, consistency in care and outcomes, excellent support during and after treatment, and making full use of the recent improvements to our information and our engagement channels.
- 1.2. The Authority has redefined its quality model to reflect the needs of patients, donors and donor-conceived people throughout, and after, their treatment journey. Our strategic objectives have been written with the aim of meeting these needs.
- 1.3. Throughout, we will retain the same strong vision, of high quality care for everyone affected by assisted reproduction.

2. Development of the strategy

- 2.1. The Authority developed its strategy through a series of workshops over the past year, and has publicly discussed several agenda items about the strategy.
- 2.2. We are grateful for a range of useful input, during the drafting phase, by stakeholders including the Professional Stakeholders Group, the Licensed Centres Panel, the Association of Fertility Patient Organisations, and some patients who kindly participated in a survey. A summary of the responses is included below.
- 2.3. We are now confident in our strategic direction, and ready to agree the final document so that we can launch this at our annual conference, and subsequently publish it on our website.
- 2.4. The executive's corporate management group (CMG) has also considered the implementation of the strategy across the next three business plans. Teams are now in the process of discussing delivery for the coming business year and beyond, so as to ensure that the strategy is delivered as planned. This work will enable us to build on the successes of the last three years, in particular the culmination of the Information for Quality programme work to create a new clinic portal and website, a restructured Register of treatments and outcomes, and a new data submission system.

3. Stakeholder feedback

- 3.1. All of our stakeholder feedback has been supportive. We took an earlier draft of the strategy to our three main stakeholder groups – the Professional Stakeholders Group, the Association of Fertility Patient Organisations and the Licensed Centres Panel. We also sent a short survey to 30 patients who had recently volunteered to participate, 28 of whom responded.

- 3.2.** In summary, there has been no disagreement with our vision or our objectives. Most comments were about how we might tackle particular aspects of the strategy, or editorial suggestions, or insights into the current status of issues.

Professional Stakeholder Group (PSG)

- 3.3.** The discussion at PSG focused mainly on:

- Success rates – agreement that there could be scope to improve outcomes.
- Support – agreement that we should clarify what ‘good support’ means; and an observation that this should include donation-related support such as donor traceability.
- Access to donation – questioned our focus being on sperm donation rather than egg donation (but noted that the reason for this is that we believe there is more scope for us to have a positive impact on sperm donation).
- Various useful editorial points were also made, which have been picked up in the attached final draft.

Association of Fertility Patient Organisations (AFPO)

- 3.4.** The main discussion points at AFPO were:

- Wrap-around support – recent survey information was cited, in which less than half of respondents said they were offered counselling. Provision was described as erratic and variable, often with poor timescales, and counselling availability prior to surgery was said to be ‘limited’.
- The importance of support for patients at the very earliest stage of the journey, before they have reached a fertility clinic or started treatment, was particularly emphasised. This is the stage at which we want to provide good information and sign-posting, and ensure people can and do find this information at the right time.

Licensed Centres Panel (LCP)

- 3.5.** The main discussion points at LCP were:

- Consistency and quality – acknowledgement that some clinics had repeat non-compliances, avoidable incidents and the like. The consistency and quality point applies to us, too, when inspecting.
- NHS resources – we were asked to be sensitive to NHS staffing and resource restrictions when asking for improvements or setting expectations.
- Incidents and alerts – suggested more frequent trend analysis of incidents, and that the new clinic portal could be very useful as a channel for this.
- Donation – the panel liked the way donation was incorporated throughout the strategy rather than presented as a separate issue. Strong support for giving people more advice about overseas treatment and increasing the availability of donor sperm.

- Data submission and intelligence – strong support, but with a reminder that any technical problems with data submission can take time to resolve and may require our assistance in some instances.

Patient survey

3.6. We asked patients to let us know their highest priorities and to tell us what improvements they would like to see in these areas.

3.7. The highest three priorities among the 28 respondents were:

- Improvements in success rates
- Getting access to treatment and donation
- Receiving good support.

3.8. There were some themes in the suggested improvements comments, for example:

- The largest number of comments on any one issue were about success rates, including the statistics we publish, including suggestions that a breakdown of success rates by diagnosis could be useful
- Waiting times were mentioned several times, in the context of both treatment and access to donation
- The cost of treatment was the lowest overall priority, but comments about treatment cost were made under a range of other headings (access to NHS cycles, support, add-ons)
- The phrase ‘postcode lottery’ appeared several times, in the context of geographical access and funding
- In relation to support, a number of the comments were about issues affecting donor-conceived people, such as contactability of donors and siblings, linkage with overseas donors, encouraging open/known donation, and consistency in the provision of non-identifying information
- There is a clear appetite for better information for the lay reader about science, research, and different treatments, including clarity about add-ons and their effectiveness.

3.9. All of the feedback on the strategy supports our vision and our plans for the next three years, and some of the comments will be useful when planning our detailed approach to different elements of the strategy.

4. Next steps

4.1. The strategy, once approved by the Authority, will next have its design finalised, ready for publication on our website in April, with a launch prior to that at the annual conference in March.

4.2. Alongside the development of our new organisational structure, we will be preparing a people strategy to ensure we have the skills and capacity in place to deliver all our strategic aims for the next three years.

-
- 4.3.** A communications strategy is also being prepared, with a view to promoting and influencing particular issues, namely:
- evidence based treatment (the right treatment at the right time for the right patient, at the right cost)
 - giving research a helping hand (helping to develop new treatments and improve existing ones)
 - one at a time (treatment focused on the best outcome – the birth of a healthy singleton baby)
 - excellent support (a great experience of treatment, with good support throughout).

5. Recommendation

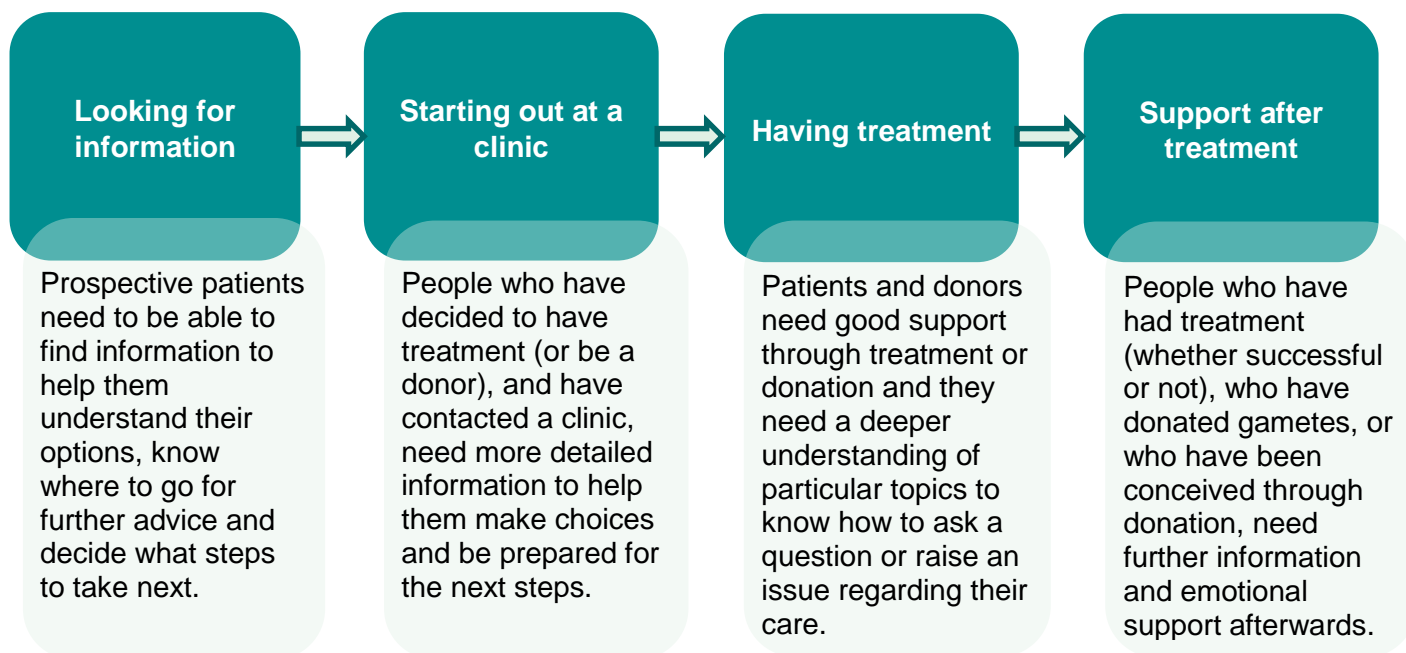
- 5.1.** The Authority is asked to approve the HFEA's new strategy for 2017-2020.

Our strategy 2017-2020

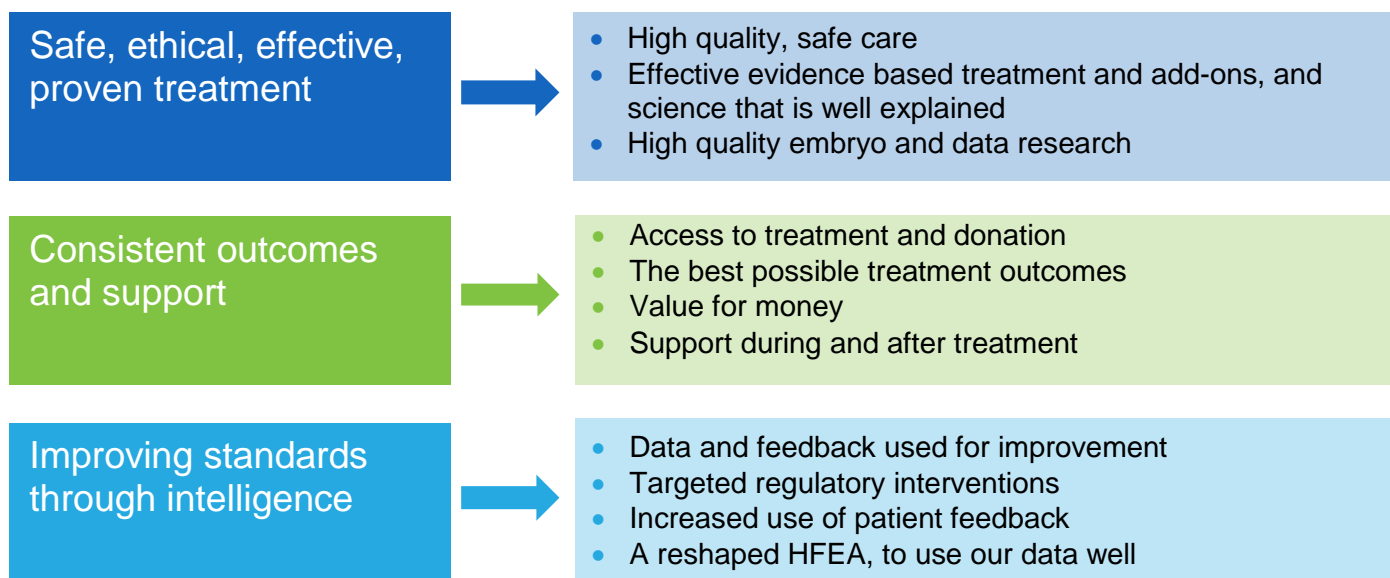
Our vision is high quality care for everyone affected by fertility treatment

Patients, donors and donor-conceived people are at the heart of our strategy, and our work. We want them all to receive high quality care and support, at every stage in their journey through fertility services.

What do people need?



To meet these needs, we will focus our efforts on the following areas:



How we will achieve our vision

Our strategic objectives describe how we will work towards our vision, focusing on people's needs throughout their fertility journey.

Safe, ethical, effective, proven treatment

Objective 1:

Ensure that consistent high quality, safe, treatment is provided by all clinics

Aim: patients know all clinics provide a high quality, consistent, safe service.

Standards	We want:	We will:
	<ul style="list-style-type: none">patients to know clinics are safefewer non-compliances and incidents in clinics, maintained over time.	<ul style="list-style-type: none">define 'good performance'help clinics to be more compliantencourage clinics to show greater consistency over timeincentivise effective, safe, ethical services.

Objective 2:

Publish clear information for patients about the efficacy and safety of treatments and treatment add-ons, while supporting innovation

Aim: increase patients' insight into science and evidence-base of treatments, including add-ons.

Evidence	We want:	We will:
	<ul style="list-style-type: none">people to turn first to us for clear, unbiased and authoritative informationpatients to know whether there is evidence of efficacy and safety for a treatment or add-onpatients to be able to make informed choices about the most effective treatment for them.	<ul style="list-style-type: none">publish information about new developmentsrefine our published datasay which add-ons are proven, effective and saferespond to science stories and correct misperceptions.

Objective 3:

Support and promote high quality embryo and data research

Aim: improve the quality of research and the rate and accuracy of patient consents.

Research	We want:	We will:
	<ul style="list-style-type: none">patients to understand the benefits of research for future patientsconsents to be recorded and reported accurately by clinicspatients to easily be able to donate embryos for research and research centres to have access to donated embryosmore patients to take part in research.	<ul style="list-style-type: none">incentivise high quality research (embryo research and data research)promote and explain research projects and their outcomesencourage more patients to participate in data research and donate embryosfocus on consent reporting accuracy in clinics.

Consistent outcomes and support for patients and donors

Objective 4:

Use our data to improve access to donation and treatment

Aim: provide advice about access to treatment and improve access to donated gametes.

Access

We want:

- people understand the process and feel prepared for donation and treatment
- people can readily find information on our website to inform their next steps
- increase in UK-based sperm donation.

We will:

- explain how to access services in UK rather than abroad
- work with others to improve donor sperm availability
- encourage better donation support, including for those considering using unlicensed services.

Objective 5:

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

Aim: increase birth rates, while avoiding adverse outcomes.

Outcomes

We want:

- the chances of a live birth to be maximised
- patients to understand the risks of multiple births
- a shared understanding of success rates
- evidenced success factors.

We will:

- involve our stakeholders
- define 'success rates'
- establish success factors
- analyse outcome data
- identify improvements
- publish information.

Aim: patients and NHS commissioners receive good value fertility services.

Value

We want:

- patients to pay what they expect to pay
- patients to question costs more often
- less variation in the price of treatment
- the NHS to pay a fair price for fertility services.

We will:

- ask patients whether they paid what they expected to
- share benchmark data with commissioners.

Aim: improve the emotional experience of care by clinics, during and after treatment or donation.

Support

We want:

- people to have a positive experience of care and aftercare
- patients (and others) to know they can expect support from the clinic beyond treatment.

We will:

- define 'good support'
- seek feedback on the quality of support
- focus on support at inspections
- make excellent support a core message.



Improving standards through intelligence

Objective 6:

Use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce

Aim: use our data and intelligence to drive quality improvements for patients.

Data

We want:

- our role and intentions to be clear
- donors, parents and donor-conceived people to understand how their information is stored and how they can access it
- patients to have confidence in their clinic as a life-long information guardian
- better outcomes from NHS treatment.

We will:

- publish an information strategy for how we will analyse, publish and use our data
- ensure we have the analytical capability and capacity to extract more value from the data we hold
- use our data to radically improve the information we publish
- use our data to improve the quality of NHS commissioning decisions.

Aim: targeted and responsive regulatory interventions in the interests of quality and consistency.

Regulation

We want:

- the ability to make earlier and more responsive regulatory interventions
- regulatory performance to be more consistent across the inspection cycle.

We will:

- apply the intelligence available to us to improve the quality and consistency of regulatory performance
- enable clinics to have access to a wider range of feedback about their own performance.

Aim: gain insight into patient experience in clinics and promote good practice based on feedback.

Feedback

We want:

- patients and donors to feel listened to
- the quality of services and support to improve as a result of patient feedback.

We will:

- collect high quality patient feedback
- analyse and use this intelligence in our activities
- share the feedback with professional stakeholders
- use patient feedback to focus inspections.

Aim: work more smartly with our resources, and capitalise on recent systems improvements.

Efficiency

We want:

- to make best use of our new website and Register
- to ensure we have the right capabilities and capacity are in place
- stakeholders to see the HFEA as a good value regulator.

We will:

- re-shape our organisation so that the capabilities and capacity we need are in place
- continue to be a good value regulator for all of our stakeholders.

Fertility treatment 'add ons'

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting Authority

Agenda item 9

Paper number HFEA (18/01/2017) 823

Meeting date 18 January 2017

Author Juliet Tizzard, Director of Strategy and Corporate Affairs

Output:

For information or decision? For decision

Recommendation

- Members are asked to discuss the questions in section 3.7 and consider the proposed next steps.

Resource implications Minimal expenditure in information phase, beyond IfQ costs

Implementation date Different phases listed in section 4

Communication(s) Milestones at section 4. Separate communications plan to be developed.

Organisational risk Low Medium High

Annexes Annex A: Add ons, their efficacy and their cost
Annex B: Code of Practice guidance for clinics on patient information

1. Background

- 1.1. As the specialist regulator of fertility treatment, we want patients to have access to high quality care – and that means high quality information and preparation for treatment, as much as it means the treatment itself. This ambition is central both to our 2014-17 strategy and to our strategy for 2017-2020, endorsed at today's Authority meeting.
- 1.2. Patient demand for good information has never been higher, a demand we are meeting through our new website, due to launch in the spring. Patients have expressed a particular desire for information about adjuncts to their fertility treatment, known as 'add ons'. Whilst being open to new treatments, patients have reported feeling confused and overwhelmed by information about add ons; whether they are safe and effective and, therefore, worth paying the additional amount that clinics often charge for them.
- 1.3. Many clinics in the UK offer add ons and their use seems to be on the rise. Innovation can of course be a force for good, yet many clinicians and scientists working in or around the field question the evidence for the safety and efficacy of many add ons, arguing that, for most add ons, there is no evidence that they increase the chance of a pregnancy or birth and, for some, there is a concern about the possible side-effects.
- 1.4. We have had concerns about the apparent proliferation of fertility treatment add ons for some time. Prompted by concerns and questions raised by patients and with advice from our Scientific and Clinical Advances Advisory Committee (SCAAC), we have produced clear, honest information for patients about add ons; how safe they are, whether they work to increase pregnancy and birth rates, and how much they are likely to cost.
- 1.5. In this paper, we set out what add ons are, what work we have done and are planning in this area, and what steps we might take next to encourage a more responsible attitude towards innovation in the sector and improve the situation for people having fertility treatment.

2. What do we know?

- 2.1. Fertility treatment add ons are additional therapies and techniques which are claimed to increase the chance of pregnancy and birth from IVF or other fertility treatments. Some add ons have been offered for some years while others are more recent developments.

2.2. There is some debate about what should be regarded as an add on¹. However, SCAAC has identified nine add ons as a first batch that patients most need information about (see annex A for an explanation of each one). They fall into four broad categories:

- Surgical procedures:
 - endometrial scratching
- Drug therapies:
 - reproductive immunology treatment (steroids, intravenous immunoglobulin, TNF-a blocking agents and intralipid infusions)
- Embryological techniques:
 - egg activation with calcium ionophore
 - intrauterine culture
 - embryo glue
 - elective freeze-all
 - assisted hatching
 - preimplantation genetic screening
- Laboratory equipment:
 - time-lapse imaging

2.3. Our own review of clinic websites carried out in August 2016² found that:

- 70% of all licensed clinics offer at least one add on
- patients are more likely to be offered an add on at a London clinic than elsewhere in the UK
- some clinics offer add ons free of charge, but most are offered at additional cost
- prices for the same add ons vary enormously from one clinic to the next
- there is also variation in the information offered to patients about add ons, with some clinics being less open than others about the lack of evidence of effectiveness. This is something that was backed up by a recent study in the BMJ.

2.4. SCAAC has reviewed the scientific literature on these add ons and discussed patient information for the new website at its February and June 2016 meetings. The committee has developed a traffic light rating to show clearly how strong the evidence of efficacy is and this rating is being independently

¹ A recent paper in the BMJ looked at claims on clinics' websites regarding 41 fertility interventions in addition to IVF and ICSI. There has been some debate about whether these interventions are all add ons, given they include established procedures such as sperm freezing and frozen embryo transfer

² We searched the websites of the 125 centres which were licensed at that time for 10 treatment add ons (this included DNA fragmentation, which is not one of the nine add ons about which we will have information on the first iteration of the new HFEA website). Of those, 87 clinics offered at least one of the 10 add ons.

validated at the moment. Only one add on currently has a green rating (ie, that there is good evidence of that it improves success rates).

- 2.5.** We have lots of feedback from patients about treatment add ons over the past few years, some in the context of our strategy and some around information for the new website. Our most recent survey of patients, regarding priorities for the 2017-2020 strategy, elicited the following comments from current or former patients about why they thought clarity about the evidence for (or against) the effectiveness of different treatments and treatment add ons was important:

'Clarity about different add on treatments. At the clinic I've had treatment at, even the staff have vastly differing opinions about what I should and shouldn't bother having done which is frustrating.'

'More information about add ons and the science behind them.'

'I would like to see add ons and their effectiveness clearly explained.'

'Openness and honesty about effectiveness of add-ons.'

- 2.6.** A recent episode of the BBC's Panorama programme covered the issue of treatment add ons, focussing on reproductive immunology, PGS and time-lapse imaging. The programme has variously been described as an unfair depiction of IVF in the UK and as a missed opportunity, in that it failed to give a true picture of the extent of the use of add ons in the sector. Whatever one's view, it certainly raised the issue with a wide, public audience.

- 2.7.** In summary, these reviews and patient feedback suggest the following:

- Add ons are offered in many clinics, often at additional cost
- Many add ons do not have a strong evidence base to show their effectiveness
- Many clinics are not making it clear to patients that the evidence of effectiveness is weak – some are even offered as standard treatments
- Patients are confused about the merits of different add ons and are not sure who to trust for information

3. How should we respond to this issue?

- 3.1.** Patients want accurate, update-to-date information about treatment add ons. They also want to be given safe and effective treatments at a reasonable price. They are open to new treatments and to trying out untested ones, but want to understand their limitations. A worrying development is that they seem to be losing faith in the sector, feeling that they are sometimes being ripped off.

- 3.2.** As noted above, we will be publishing information about nine add ons on our new website, available in spring 2017, and working with stakeholders to publicise it. But it is also worth thinking about:

- the information that clinics themselves publish and give to patients verbally

- how the add ons are offered to patients and charged for.

Information published by clinics

3.3. We publish guidance in the Code of Practice around information to be given to patients before they consent to treatment:

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

(e) the likely outcomes of the proposed treatment (data provided should include the centre's most recent live birth rate and clinical pregnancy rate per treatment cycle, verified by the HFEA, and the national live birth rate and clinical pregnancy rate per treatment cycle)

(f) the nature and potential risks of the treatment, including the risk of children conceived having developmental and birth defects

(g) the possible side effects and risks to the woman being treated and any resulting child, including ovarian hyperstimulation syndrome (OHSS).

3.4. We also expect clinics to give each patient a costed, personalised treatment plan. Finally, we give guidance about the responsible use of websites. See annex B for full guidance in these areas.

3.5. The information guidance is focussed primarily on licensed fertility treatments, rather than add ons, and the websites guidance is aimed more at how birth statistics are presented. So, it may be worth reviewing our information requirements of clinics, to make sure that they are relevant to treatment add ons. As part of that work, we could look at best practice in publishing information about untested treatments, including advice from the Advertising Standards Authority.

How services are offered to patients

3.6. Ensuring that patients have access to good information about add ons – both from us and from clinics - will be an important step in addressing the inadequacies in the way in which many of them are offered. It will make patients feel more confident about discussing add ons with their clinic and more discerning about whether to opt for them. However, information alone may not be enough in itself to effect more radical change. A more complex question is what we might do as the regulator to improve the way that add ons are offered to patients in the clinic. And how might we approach add ons over which we have limited regulatory powers, such as surgical and drug therapies?

3.7. Some questions that arise:

- **Are there any add ons that clinics should not be offering at all, either because they are unsafe or demonstrably ineffective?**
- **If an add on is new, how should they be introduced into clinical practice: should we expect to see laboratory research and/or a clinical trial first?**

- **Where there is limited evidence of effectiveness, should clinics charge extra for add ons or provide it free of charge?**

- 3.8.** These are not questions necessarily to be answered today. Rather, they are suggested as discussion points for the Authority and, perhaps, the basis of a discussion with professionals and patients about what constitutes responsible use of add ons in the clinic. One strand of work might be to develop a consensus about responsible innovation in fertility treatment that we could agree with stakeholders and encourage clinics to sign up to. Our success with changing professional and patient attitudes towards single embryo transfer suggests that we could make some mileage through this style of collaborative working, coupled with an effective public education campaign.
- 3.9.** As we have found with the One at a Time campaign, such cultural change can be a very powerful tool for bring about the improvement we want to see. Such an approach may not bring all clinics on board, but it will increasingly isolate those who do not embrace the campaign's messages. We could, whilst we are testing the effectiveness of the campaign approach, explore the extent of our regulatory powers, particularly around laboratory equipment standards, clinical trials and advertising claims.

4. Summary and next steps

- 4.1.** Treatment add ons is not a straight forward issue. We do not want to create a situation in which innovation in fertility treatment is stifled. There may well be a place for treatment add ons in the clinic. However, we want patients to have access to good quality, reasonably-priced treatments which maximise their chance of a pregnancy and birth. There is an important role for us to play in achieving that goal.
- 4.2.** Besides offering good information and advice to patients - and encouraging clinics to do the same – we may also have a role to play in increasing the amount of research taking place around different add ons. This might be through analysis of our data or perhaps through encouraging clinics to carry out studies and publish their findings – all carried out through collaboration with scientific and clinical professional bodies, patient organisations and perhaps scientific publications.
- 4.3.** During 2017-18, we might want to:
- Launch the new patient information, backed up by an awareness campaign
 - Continue to monitor the scientific literature and listen to patient feedback
 - Work with professional societies, patient groups and interested clinics to develop a consensus around what responsible innovation looks like, potentially kicked off with a workshop at the annual conference in March
 - Extend the public awareness campaign to promote responsible innovation, encouraging clinics to sign up to the consensus statement and to offer add ons in that way

- Explore how we could encourage and perhaps facilitate research which adds to the evidence base for each treatment add on (and future ones).

4.4. Beyond 2017/18, we might want to:

- Monitor the impact of this effort, explore other regulatory levers and consider introducing further requirements if progress is slow.

4.5. Members are asked to discuss the questions in section 3.7 above and consider the proposed next steps.

Annex A: Add ons, their efficacy and their cost

Category	Add on	Description	Average price
Surgical procedures	Endometrial scratching	<p>Carried out before IVF, endometrial scratching is intended to correct problems with the womb lining. The lining of the womb is 'scratched' using a small sterile plastic tube.</p> <p>The theory is that this procedure triggers the body to repair the site of the scratch, releasing chemicals and hormones that make the womb lining more receptive to an embryo implanting.</p> <p>Early results suggest that endometrial scratching could increase pregnancy rates, although stronger evidence is needed to prove this.</p>	£210
Drug therapies	Reproductive immunology	<p>Reproductive immunology is a field of study that looks at how a woman's immune system reacts when she becomes pregnant.</p> <p>Some scientists believe that in some cases of miscarriage or infertility, the mother's immune system may fail to accept the embryo, in the same way that the body rejects transplanted cells or organs.</p> <p>Drugs regimes include steroids, intravenous immunoglobulin, TNF-α blocking agents and intralipid infusions.</p> <p>Not only does reproductive immunology treatments not improve pregnancy rates, there are risks attached to all these treatments, some of which are very serious.</p>	£671
Embryological techniques	Egg activation with calcium ionophore	<p>When a sperm meets an egg, it triggers a process called 'egg activation' which starts off the process of embryo development, while at the same time allowing only one sperm to fertilise the egg. If the egg doesn't activate, then it won't develop.</p> <p>Egg activation may be stimulated by chemicals called calcium ionophores. These chemicals can be added to the embryo in the lab.</p> <p>In theory, egg activation using calcium ionophores could cause embryos to have abnormal numbers of chromosomes, which would cause the pregnancy to miscarry. As yet there's not enough evidence to decide whether these risks are a serious concern.</p> <p>Given the possible risks, clinics offering this treatment are expected to do so only in selected patients who have had failed fertilisation and to justify their reasons for doing so.</p>	Unknown

	Intrauterine culture	<p>During a conventional IVF cycle, eggs are fertilised and allowed to develop in a special culture fluid inside an incubator. Intrauterine culture differs in that it allows the early stages of embryo development to take place within the patient's womb. The eggs are fertilised and placed in an intrauterine culture device, which is inserted into the woman's womb.</p> <p>The device stays in place for several hours during the initial stages of embryo development. When the device is removed, the embryos are put in an incubator until they are ready to be transferred back to the womb or frozen for use in future treatment.</p> <p>There's currently not enough evidence to show that intrauterine culture improves birth rates and is safe.</p>	Included in cost of IVF cycle – under clinical trial
	Embryo glue	<p>Embryo glue contains a natural substance called hyaluronan, which may improve the chance of the embryo implanting in the womb. It is added to the solution in the dish in which the embryos are kept before being transferred to the woman.</p> <p>Embryo glue has been shown to increase pregnancy and births rates by 10%.</p>	£171
	Elective freeze-all	<p>Elective freeze all cycles involve creating embryos using IVF and then freezing all of them so no embryos are transferred in the 'fresh' cycle. The embryos are thawed a few months later and transferred to the woman's womb as part of a frozen embryo transfer (FET) cycle.</p> <p>There is some evidence that the body's hormonal response to fertility drugs can affect the lining of the womb, which makes it more difficult for the embryos to implant. Freezing the embryos means they can be transferred back into the woman when the womb lining is well developed.</p> <p>It's also thought by having all their embryos frozen, women are at lower risk of suffering from ovarian hyperstimulation syndrome (OHSS), an overreaction to fertility drugs. This is because OHSS is more common and more severe when it occurs during a pregnancy. There is a clinical trial underway to determine whether it is safer and more effective.</p>	Included in cost of IVF cycle – under clinical trial
	Assisted hatching	<p>The egg and early embryo are surrounded by a thick layer of special proteins called the zona pellucida. Before an embryo can implant in the womb it has to break out or 'hatch' from its zona pellucida.</p> <p>Some people think that assisted hatching - using acid, lasers or other tools to thin or make a hole in the zona pellucida - helps the embryo to hatch.</p> <p>The NICE Fertility guideline says that assisted hatching has not been shown to improve pregnancy rates.</p>	£369

	PGS	<p>PGS involves checking embryos for abnormalities in the number of chromosomes. Embryologists remove a cell, or if at a later stage, several cells, from the embryo, which is then tested for any chromosomal abnormalities.</p> <p>There is no evidence to show that this type of PGS is beneficial for women over 37, couples who had had several miscarriages or failed IVF cycles, people with a family history of chromosome problems, and men whose sperm may carry abnormal chromosomes.</p> <p>Three small studies have now shown that PGS carried out at a later stage, the blastocyst embryo on day 5 or 6, might improve success rates in younger patients who are typically under 37 with no history of miscarriage or failed IVF cycles. However, more evidence is needed to confirm these findings.</p>	£2620
Laboratory equipment	Time lapse imaging	<p>Time-lapse imaging allows the embryologist to take thousands of images of the embryos as they grow without disturbing them. Not only does this mean the embryos do not have to be removed from the incubator, it also allows the embryologist to get a continuous view of each embryo as it develops, rather than just viewing them once a day.</p> <p>The embryologist can then choose a specific embryo for implantation based on criteria such as rate of development and the number and appearance of cells. Indeed, being undisturbed while they grow may improve the quality of the embryos.</p> <p>There have been various studies to try and see if time-lapse imaging can improve birth rates. Initial research has shown some promise, but it's still very early days.</p>	£672

Annex B: Code of Practice guidance for clinics on patient information

Information for those seeking treatment

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

- (d) fertility treatments available
- (e) the likely outcomes of the proposed treatment (data provided should include the centre's most recent live birth rate and clinical pregnancy rate per treatment cycle, verified by the HFEA, and the national live birth rate and clinical pregnancy rate per treatment cycle)
- (f) the nature and potential risks of the treatment, including the risk of children conceived having developmental and birth defects
- (g) the possible side effects and risks to the woman being treated and any resulting child, including ovarian hyperstimulation syndrome (OHSS)

...

Information about the cost of treatment

4.3 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.

...

Responsible use of the centre's website

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) The website should provide the live birth rate per treatment cycle, and not highlight a high success rate that 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 website 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.
- g) The website 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 success rates: <http://www.hfea.gov.uk/fertility-clinics-success-rates.html>
- h) If the website 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.

Amendments to the Code of Practice (April 2017 update)

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting	Authority
Agenda item	10
Paper number	HFEA (18/01/2017) 824
Meeting date	18 January 2017
Author	Anjeli Kara, Regulatory Policy Manager

Output:

For information or decision?	For decision
Recommendation	Agree to the proposed amendments to the Code of Practice. These changes will be introduced in April 2017.
Resource implications	Within budget
Implementation date	April 2017
Communication(s)	Code of Practice update, Chair's Letter and Clinic Focus article
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex A: Legal parenthood (page 13) Annex B: Egg sharing arrangements (page 89) Annex C: Cases where consent to storage is not required (page 97) Annex D: Storage periods for eggs, sperm and embryos (page 119) Annex E: Corrections and minor clarifications to guidance (page 152)

1. Overview

- 1.1.** The Human Fertilisation and Embryology Act 1990 (as amended) (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 way we help licensed clinics to comply with the Act is by publishing a Code of Practice. This enables us to meet our statutory duty under the Act, to maintain a document that provides guidance on licensed activities and to those professionals that perform them. Guidance within the Code of Practice also serves as a useful reference for patients, donors, donor-conceived people and researchers.
- 1.2.** We periodically update the Code of Practice guidance and other regulatory tools (such as General Directions) to reflect technological and clinical advances in the sector, and provide clarification – typically in April and October. By reviewing the Code of Practice, we aim to ensure that it:
- a) reflects our current interpretation of the law and regulatory practice
 - b) is fit for purpose, and
 - c) makes our regulatory requirements clear, while minimising regulatory burden where possible.
- 1.3.** This update to the Code of Practice seeks to clarify guidance on various areas following feedback we have received from both the sector (on a day-to-day operational basis), as well as in-house from inspectors (eg, when analysing trends in sector non-compliances). The following areas are to be amended in April 2017:
- Mitochondrial donation
 - Legal parenthood
 - Egg sharing arrangements
 - Cases where consent to storage is not required
 - Storage periods for eggs, sperm and embryos
 - Care for transgender patients
 - Legislation, professional guidelines and information, and
 - Other minor amendments and corrections.
- 1.4.** The justification for making amendments to the Code of Practice, General Directions, and consent forms in this update are set out below. We ask that the Authority considers and agrees to all amendments to guidance so that that they may be incorporated into the Code of Practice on 3 April 2017. Where amendments involve consent forms and the 'Guide to consent', we ask the Authority to note the changes, for information.

2. Mitochondrial donation

2.1. In December 2016, the Authority took the decision to approve the use of mitochondrial donation in clinical practice in certain, specific, cases. At this meeting, it was emphasised that it must be made clear to patients that mitochondrial donation is a risk reduction strategy, and cannot guarantee a child born will not be affected by mitochondrial disease. It also noted that if patients were to identify themselves in the media, that they run the risk of being identifiable to the donor due to the small number of patients waiting for treatment. As a result, it was recommended that the implications of a patient identifying themselves should be discussed during counselling. These issues are addressed in guidance note 33 (Mitochondrial donation).

2.2. Amendments to General Directions 0008 (Information to be submitted to the HFEA as part of the licensing process) were also proposed in December 2016, which included a reference of the key performance indicators (KPI) relating to mitochondrial donation. It was highlighted that the following KPI relating to blastocyst development rates should be rephrased:

- Blastocyst development rates – which must be no less than 50% of that observed in the control embryos at day 5. Where possible, controls should be age-matched to the karyoplast donor.

We have discussed this issue offline with expert Authority members, and it has been agreed that the definition should remain the same as the KPI does not require the blastocyst development rate itself to be over 50%. This means that an embryologist will not be non-compliant if the blastocyst development rate is affected by external factors such as maternal age or egg quality.

2.3. The agreed amendments to guidance note 33 (Mitochondrial donation) and General Directions 0008 (Information to be submitted to the HFEA as part of the licensing process) can be found in the [paper](#) put before the Authority in December 2016.

Recommendation

2.4. There are no recommendations for these amendments to the Code of Practice as they have previously been agreed by the Authority in December 2016.

3. Legal parenthood

3.1. In recent years there have been a series of anomalies in the recording of consent to legal parenthood. This has led to a number of recommendations from the High Court to ensure consent is accurately recorded, as well as queries from the sector. The following amendments to the Code of Practice clarify guidance on these areas.

Informing patients of anomalies in consent to legal parenthood

- 3.2.** In the event that an anomaly in consent to legal parenthood is discovered, it was recommended by the High Court that the treating clinic should immediately inform the patient, and the person who was treated with the patient, in writing of the nature of the anomaly. The patient and person who they were receiving treatment with, should subsequently be invited to a meeting to discuss the issues arising.
- 3.3.** In response, we have considered whether guidance on this area should be strengthened and as a result propose amending guidance notes 5 (Consent to treatment, storage, donation, training and disclosure of information), 6 (Legal parenthood) and 27 (Adverse incidents) to require that:
- a documented assurance process is in place to ensure that the appropriate consent forms have been completed, and that the completed forms contain the correct information prior to treatment (guidance note 5: paragraph 5.3),
 - should the centre discover any error(s) in the consent provided by a patient or their partner – particularly in relation to legal parenthood – the centre should (guidance note 5: paragraph 5.4, 5.5; guidance note 6: paragraph 6.7; guidance note 27: paragraph 27.1):
 - take all reasonable steps to notify the affected patient at the earliest opportunity
 - assess the error and its potential impact, and consider what remedial actions should be taken
 - report the error(s) to the Executive as an adverse incident
 - seek independent legal advice, and
 - take all reasonable steps to support any affected patients (and their partner(s), if relevant) and offer independent legal assistance, where necessary.
- 3.4.** It is important to note that clinics who identify anomalies in consent which has led to harm – or has the potential to cause harm – to patients, should already report this as an adverse incident as it falls under the current definition of an ‘adverse incident’ in the Code of Practice. However, we propose revising guidance to make this clear and to formalise the process (guidance note 5: paragraph 5.4).

Recommendation

- 3.5.** Draft guidance that details the above can be found at Annex A to this paper. The Authority is asked to agree to the proposed changes.

Marital status

- 3.6.** A further recommendation from the High Court is that there should be a written record of whether a marriage or civil partnership exists between persons being treated at a clinic, and another question as to whether the patient or partner being treated with her is either married to or in a civil partnership with another person. Failure to do so may affect who may be legally recognised as the legal parent of any child born following treatment.

- 3.7.** In response to the recommendation, we suggest updating guidance note 6 (Legal Parenthood) to require clinics to record whether a patient and their partner are married or in a civil partnership with one another (or indeed with someone else).
- 3.8.** We have also made the following clarifications on the matter of marital status to guidance notes 5 (Consent to treatment, storage, donation, training and disclosure of information) and 6 (Legal parenthood):
- Clinics should re-verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment (guidance note 5: paragraph 5.13; guidance note 6: paragraph 6.3),
 - Clinics should take reasonable steps to find out whether the patient's partner still consents to their treatment if the partner of a patient who is having treatment has not visited the clinic throughout treatment, or does not return with the patient for subsequent treatment (guidance note 5: paragraph 5.14; guidance note 6: paragraph 6.11), and
 - If a woman who is married or in a civil partnership wishes to be treated with a new partner (with her new partner's sperm, donor sperm, or a donor embryo) and for her new partner to be registered as the legal parent of any child born from this treatment, then evidence to show that her ex-partner does not consent to the treatment must be obtained (guidance note 6: paragraph 6.10, 6B).

Recommendation

- 3.9.** Draft guidance that details the above further can be found at Annex A to this paper. The Authority is asked to agree to the proposed changes.

Posthumous birth registration

- 3.10.** We are aware that if an embryo, created using donor sperm, is transferred to a woman while her partner is alive then both the woman and partner will be the legal parent of any child born if they are married or in a civil partnership. However, this would not be the case in the unfortunate event that the partner dies before the embryo transfer took place.
- 3.11.** Currently, we do not provide a form that allows the partner of a woman undergoing treatment with donor sperm to consent to being posthumously registered as the legal parent of any child born in this scenario. Instead, we suggest that partners of women undergoing treatment using donor sperm complete the question relating to posthumous birth registration on the legal parenthood form. While this records the necessary consent, we have heard from the sector and our inspectors that patients often find completing this form confusing. This is because not all questions on the legal parenthood form are relevant in this instance, and asking partners to complete one question in a form is inconsistent with the approach taken on other consent forms (ie, where patients and partners must complete all questions).
- 3.12.** To help address this issue, we discussed the options with our stakeholder groups. It was agreed that a new posthumous birth registration ('PBR') form

should be created to capture the consent to posthumous birth registration in this scenario, and we subsequently sought feedback on the draft form from a patient and the Chair of the Senior Infertility Nurses Group. The PBR form sets out the legalities around this scenario and makes the reason for completing the form clear – ie, that it should be completed by the partner of a woman receiving treatment using donor sperm if they want to be registered as the legal parent of any child born from embryos that have been created before, but transferred after, the event of their death.

- 3.13.** To reflect the introduction of this new form General Directions 0007 (Consent) has also been amended.

Recommendation

- 3.14.** A draft copy of General Directions 0007 that includes the new PBR form can be found at [Annex A](#) to this paper. The Authority is asked to agree to the proposed changes.
- 3.15.** A draft version of the PBR form can be found at [Annex A](#) to this paper. The Authority is asked to note the changes involved, for information.

Other changes involving legal parenthood

- 3.16.** In addition to consent forms, we also provide a ‘Guide to consent’ to clinics to ensure forms are used appropriately and clinics understand their legal obligation to accurately record informed consent. The ‘Guide to consent’ (and its accompanying ‘How to use consent forms’ document) will also be updated on 1 April 2017 to clarify:
- what we mean by consent to legal parenthood and why it is important
 - instances where patients should be asked to complete new consent forms if they undergo on a new treatment cycle
 - examples of legal parenthood anomalies, and
 - how clinics can avoid problems with consent to legal parenthood.

Recommendation

- 3.17.** The Authority is asked to note changes to its ‘Guide to consent’ and ‘How to use consent forms’ document at Annex A, for information.

4. Egg sharing arrangements

- 4.1.** Egg sharing is currently permitted in UK clinics, while egg giving is prohibited. Essentially, this means that eggs collected in a cycle must be shared between the egg provider and recipient(s) unless there is a clinical and/or medical reason against doing so. This is to capture instances where an egg provider is, for example, at risk of ovarian hyper stimulation syndrome (OHSS) or has another medical emergency that would mean a fresh embryo transfer could not take place.

- 4.2.** Our stakeholders have raised concerns that the requirement to have a ‘clinical’ and/or ‘medical’ justification for egg sharing has been interpreted to include cycles where too few eggs are collected for sharing. In this scenario, some clinics are giving all eggs collected in a cycle to the recipient(s), while the egg provider is encouraged to undergo an additional egg collection at a reduced treatment fee – essentially, the benefit of egg sharing is deferred to a later cycle. This is concerning as the egg provider is exposed to an increased – albeit small – risk of undergoing an additional cycle, where there may not be a clinical or medical justification for doing so.
- 4.3.** We met with the Licensed Centres Panel to discuss how the policy is currently being interpreted. It was voiced that clarification is necessary, and that advances in freeze-all cycles – in the long term – may benefit those cycles where too few eggs are collected.
- 4.4.** As a result, we recommend strengthening the guidance we provide on egg sharing by stating that it is only possible to defer the benefits of egg sharing in exceptional circumstances, where there would otherwise be a risk of harm to the egg provider. To capture this point, the term ‘clinical’ will be replaced with ‘harm’ in guidance note 12 (Egg sharing arrangements), and the term ‘medical’ will remain (guidance note 12, paragraph 12.5).

Recommendation

- 4.5.** Draft guidance that details the above can be found at [Annex B](#) to this paper. The Authority is asked to agree to the proposed changes.

5. Cases where consent to storage is not required

- 5.1.** In October 2016, members of the Professional Organisations Stakeholder Group highlighted that requirements for storing eggs and embryos for persons aged under 18 years should be clarified – particularly around consent and the circumstances for which storage without consent is permitted.
- 5.2.** Through discussions with stakeholders we noted that a standalone consent form to record consent for under 18 years was not necessary; however, guidance on this area should be clarified as follows (guidance note 5: paragraph 5.34-5.37, 5G):
- when a person under 18 years is deemed to have capacity to consent to the storage of their eggs or sperm (ie, in cases where they will be undergoing medical treatment that is likely to damage their fertility), and
 - where consent is not required for storage (for both persons under and above 18 years), and what conditions need to be met in order for this to be lawful.
- 5.3.** In addition to amending guidance note 5 (Consent to treatment, storage, donation, training and disclosure of information) to reflect the changes mentioned above, we also suggest removing references to the outdated Human

Fertilisation and Embryology (Special Exemptions) Regulations 1991 (guidance note 5: paragraph 5.11, 5B).

Recommendations

- 5.4.** Draft guidance that details the above further can be found at [Annex C](#) to this paper. The Authority is asked to agree to the proposed changes.

6. Changes to storage periods for eggs, sperm and embryos

- 6.1.** In June 2016, we sent clinics an alert announcing changes to the interpretation of the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 and the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996, following a legal challenge of the original interpretations.
- 6.2.** The changes mean that in the following circumstances sperm, eggs or embryos subjected to extended storage periods may be stored for periods longer than those calculated under the current interpretations of the 1991 and 1996 Regulations:
- Sperm in storage now that was first placed in storage before 1 August 1991 and which has been kept lawfully for an extended period beyond the 10-year maximum storage period, and
 - Sperm, eggs or embryos that were first placed in storage between 1 August 1991 and 1 October 2009 and which are being kept lawfully for an extended period up to the provider's 55th birthday, or in the case of embryos, up to the 55th birthday of the woman being treated.

These changes do not affect sperm, eggs or embryos stored after 1 October 2009 or, if stored earlier than this, where the gamete provider subsequently provided a new consent under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009.

- 6.3.** The proposed amendments to the Code of Practice take these new interpretations into account, and have resulted in changes to guidance notes 5 (Consent to treatment, storage, donation, training and disclosure of information) at section 5D, and 17 (Storage of gametes and embryos) at section 17C.
- 6.4.** It should be noted that clinics were alerted to this change in June 2016, and were asked to take relevant actions as a result of this new interpretation, where necessary. These actions are also being followed-up on inspection.

Recommendation

- 6.5.** Draft guidance that details the above further can be found at [Annex D](#) to this paper. The Authority is asked to agree to the proposed changes.

7. High quality care for transgender patients

- 7.1.** Over the past year the Executive have received a number of enquiries from fertility clinics and the public about caring for transgender patients. These enquiries have mostly been concerned with fertility options, consent forms, identification documents, birth registration and legal parenthood. We have also had sight of a [House of Commons Women and Equalities Committee report](#) which highlighted significant concerns about health professional's lack of awareness and consideration in treating transgender patients and the need for government bodies to aim to improve the lives of transgender people.
- 7.2.** The Code of Practice does make reference to gender reassignment and other protected characteristics under references to the Equality Act (2010) in guidance notes 11 (Donor recruitment, assessment and screening) and 29 (Treating people fairly). We also remind clinics of their obligation not to discriminate under equalities legislation. However, we do not have patient information, Code of Practice guidance or specific forms relating to transgender patients, and recognise that these are necessary.
- 7.3.** To address this area, the Executive have set up a small internal working group to look at the guidance and information we provide to clinics and patients, respectively. This working group has engaged with members of the transgender community, transgender clinics and fertility clinics with experience of treating transgender patients, to gain insight into the area and further explore the issues entailed.
- 7.4.** Taking on board the experiences of patients, professionals and those who work with transgender people or are transgender, we have identified a number of ways we can address the issues faced by clinics when treating transgender patients and our lack of patient information. These are as follows:
- To provide a separate suite of transgender consent forms that remove references to males and females (ie, are gender neutral) on 1 April 2017
 - To publish patient information on the new HFEA website on 1 April 2017, and
 - To provide Code of Practice guidance to clinics on 1 October 2017 (Note: the Executive is currently seeking legal advice on a number of issues in order to draft guidance).

Introducing a new suite of gender neutral consent forms

- 7.5.** Through discussions with clinics that treat transgender patients, the working group has heard that transgender patients often find it difficult to complete the Authority's consent forms due to the male and female references within them. For example, a man who is transitioning to become a woman may wish to store sperm to preserve their fertility prior to transition. The man may already identify as a woman, but would need to complete a form that requires him to record that he is a man, or use a form that references that it should be completed by a man. We currently include male and female references in consent forms so that

it is clear to the majority of patients and their partners who needs to complete the relevant forms.

- 7.6.** Taking this into consideration, most stakeholders agreed that it is more important to record effective consent, and therefore the best approach is to record an individual as an egg or sperm provider on a consent form, rather than whether consent was provided by a person who identifies as male or female.
- 7.7.** Stakeholders argued strongly for a separate suite of gender neutral forms to be used by clinics when treating transgender patients. Creating a separate suite of forms without male and female references will not affect the validity of consent, but will help better meet the needs to the transgender community.

Recommendations

- 7.8.** The Authority is asked to:
- note the creation of a separate suite of gender neutral forms and patient information for transgender patients for 1 April 2017, and
 - agree to the development of guidance on this area for 1 October 2017 (Note: guidance will be brought to the Authority in Summer 2017, for inclusion in the October 2017 update to the Code of Practice).
- 7.9.** The Executive would also welcome a volunteer from the Authority to work on developing guidance and patient information on areas, including:
- Transgender conception and legal parenthood
 - Treatment options
 - Disclosure of information to donor-conceived children, and
 - Record keeping and identity checks.

8. Legislation, professional guidelines and information

- 8.1.** Links to relevant external legislation and professional guidelines will be referenced in the following guidance notes as useful additional information:
- Guidance note 27 (Adverse incidents): CQC guidance for NHS providers on Duty of Candour; National Health Service Litigation Authority guidance on “saying sorry”.
 - Guidance note 28 (Complaints): Hospitals and clinics must establish and follow a complaints procedure – The Health and Social Care (Community Health and Standards) Act (2003).
 - Guidance note 29 (Treating people fairly): CQC guidance for NHS providers on Duty of Candour.

Recommendation

- 8.2.** The Authority is asked to agree to the addition of the abovementioned links.

9. Corrections and minor clarifications to guidance

9.1. Corrections and minor clarifications to the following guidance notes are to be made as follows:

Minor clarifications

- Guidance note 27 (Adverse incidents): 'Interpretation of mandatory requirements 27A' will see 'Centres must report all adverse incidents to the HFEA by telephone...' become 'Centres must report all serious adverse incidents to the HFEA by telephone...'

Corrections

- Guidance note 16 (Imports and exports); General Directions 0006 (Import and export of gametes and embryos): 'Interpretation of mandatory requirements 16C' in guidance note 16 and Schedules 1-4 in General Directions 0006 will see references to submitting data to the HFEA within 'five working days', corrected to state 'ten working days'. This is to reflect previous changes to General Directions 0005 (Collecting and recording information for the HFEA).
- Guidance note 30 (Confidentiality and privacy): 'Interpretation of mandatory requirements 30B' will see 'identifying information' corrected to become 'non-identifying information'.

Recommendation

9.2. The Authority is asked to agree to the minor clarifications and corrections set out at [Annex E](#) to this paper.

10. Minor clarifications to consent forms

10.1. A small number of minor updates have been made to consent forms to take on board suggestions from stakeholders that make the forms easier to complete:

- Male and female treatment (MT and WT) forms: On occasion patients were providing consent to storage twice, as the section ran over two pages. Additional wording has been added to highlight that consent to storage should only be recorded once on the form.
- Consent to donating embryos (ED) and disclosing identifying information (CD) forms: Currently, patients are required to sign and date twice on one page. This has been amended to ensure a patient only needs to sign once.
- The 'Guide to consent' and 'How to use consent forms' document have been updated with the following clarifications:
 - to make it clear when an egg donor must complete the 'Women's consent to the use and storage of eggs or embryos for surrogacy' (WSG) form, and

- a new scenario has been added to illustrate which forms must be completed when eggs come from an egg donor in a surrogacy agreement.

Recommendation

- 10.2.** The Authority is asked to note the minor clarifications and corrections to consent forms, for information.

11. Recommendations and next steps

- 11.1.** The Authority is asked to consider and agree to the recommendations made throughout the paper. Where amendments involve consent forms and the 'Guide to consent', the Authority is asked to note the changes, for information.
- 11.2.** Depending on the approach taken, the Executive will work with clinics and Authority members to make suggested changes, where necessary. All changes will be incorporated in the April 2017 update to the Code of Practice.

Annex A – Amendments to the Code of Practice relating to legal parenthood

NOTE: Changes related to legal parenthood are highlighted in red; deletions are highlighted in yellow.

Enclosed within Annex A

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

Guidance note 6: Legal parenthood

Guidance note 27: Adverse incidents

General Directions 0007: Consent

Consent to posthumous birth registration (PBR) form

Consent to legal parenthood (PP) form

'Guide to consent' document (**NOTE:** only amended sections of the 'Guide to consent' are included)

'How to use consent forms' document

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

Version 9.0

On this page

[Mandatory requirements](#)

[Extracts from the HFE Act](#)

[Extracts from licence conditions](#)

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[Consent to use and storage of gametes and embryos](#)

[Procedure for obtaining consent](#)

[Recording consent and related information](#)

[Additional consent requirements for storing gametes and embryos](#)

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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(2ZA) 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.

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.

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 (3ZB) 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.

Interpretation

- 16
- (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.

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

Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes)

Regulations 2009

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 without written, effective consent from the gamete provider. There are, however, limited circumstances in which it may be possible to store a person's gametes without consent, provided that certain legal requirements are met. These are set out in paragraphs 9 and 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) (see 5G). These exemptions do not include where a person has died (including cases of brain stem death) without providing effective consent to the storage and use of their gametes, or where the gamete provider lacks capacity to give consent and is not expected to gain or regain it. The provisions of the Human Tissue Act 2004, which allow next of kin to give consent to procure, store or use other body tissues of the deceased, do not apply to gametes.

Anyone who procures, stores or uses gametes without valid and effective consent from the gamete provider may be committing an 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 informed 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 or mitochondria 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 UK centre must be satisfied that the requirements set out in General Directions 0006 are met. These include obtaining the consent of the gamete provider(s) to their export 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 person responsible for the UK centre must be satisfied that the requirements set out in General Directions 0006 are met. These include the requirement that the provider has given written consent to the transfer of the gametes or embryos to the UK, and has not withdrawn that consent.

If the provisions of General Directions 0006 cannot be met, the UK centre may need to consider applying for a special direction to permit import or export.

Further requirements and the exemptions regarding obtaining consent to the use of gametes, cells and embryos for research (including for the creation of admixed embryos), and the exemptions, are outlined in guidance note 22 – Research and training.

Requirements regarding consent to parenthood are outlined in guidance note 6 – Legal parenthood, and General Directions 0006.

- 5.1** The centre should obtain written informed 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 the appropriate consent forms have been completed and that the completed forms contain the correct information, prior to treatment.**
- 5.4** **If, following treatment, the centre discovers errors in the consent provided by a patient or their partner, particularly in relation to legal parenthood, 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.**
- 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 15 – Procuring, processing and transporting gametes and embryos

Guidance Note 6 – Legal Parenthood

Chief Executive's letter CE(12)02 – Extension of storage of gametes and embryos where one of the gamete providers is deceased

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 – Information to be provided prior to consent.
- 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 is outlined in guidance note 17 – removal of gametes and embryos within the storage period.
- 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, and
 - c) taken by a person authorised by the centre to do so.
- 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:
- a) were given enough information to enable them to understand the nature, purpose and implications of the treatment or donation
 - b) were given a suitable opportunity to receive proper counselling about the implications of the proposed procedures
 - c) were given information about the procedure for varying or withdrawing consent, and
 - d) has 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. If a patient's identity is in doubt, 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 re-verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment.**
- 5.14** 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 course of treatment, or does not return with the patient for subsequent treatment, centres should take reasonable steps to find out from the patient's partner whether they still consent to their partner's treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is still valid.**
- 5.15** 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))
- 5.16** 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 22 – Research and training
 Guidance note 23 – The quality management system
 Guidance note 29 – Treating people fairly
 Consent forms

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.

- 5.17** 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.
- 5.18** 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
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.

Sperm first placed in storage before 1 August 1991 and which has been kept lawfully may legally continue without the written consent of the individual who provided the sperm for an extended period beyond the 10-year maximum storage period.

Sperm, eggs or embryos first placed in storage between 1 August 1991 and 1 October 2009 and which are being kept lawfully may legally continue without the written consent of the individual who provided the sperm, eggs or embryos for an extended period up to the provider's 55th birthday, or in the case of embryos, up to the 55th birthday of the woman being treated.

These changes do not affect sperm, eggs or embryos stored after 1 October 2009 or, if stored earlier than this, where the gamete provider subsequently provided a new consent under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009.

- 5.19** The centre should normally 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.
- 5.20** 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.
- 5.21** The gamete provider should be made aware that if they were to die or become mentally incapacitated, the gametes and embryos cannot be used in treatment unless consent to use has been provided and their partner has been named. It is therefore important that the patient updates their consent to include consent to use and the partner's name at the earliest opportunity.

See also

Guidance note 6 – Legal parenthood

Guidance note 17 – Storage of gametes and embryos

Consent forms

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

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.

5.22 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.

5.23 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.

5.24 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

Consent forms

Additional consent requirements for those participating in a benefits in kind agreement

5.25 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.

5.26 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
Consent forms

Consent to examination and treatment

5.27 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.

5.28 The centre should comply with current professional guidelines on consent.

Consent to the presence of observers

5.29 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

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).

5.30 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.

5.31 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).

5.32 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).

5.33 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
Consent forms

Cases where consent is not required for storage

Interpretation of mandatory requirements**5G**

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.

Conditions for storing the gametes of children without consent (including 16 or 17 year olds who are not competent to consent)

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 patient 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 patient 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 patient'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, 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. A registered medical practitioner must actively establish that the patient 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 patient has capacity within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991.

Condition D is that the patient 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.

Conditions for storing the gametes of persons who are 16 years and over

Paragraph 10 sets out the conditions that must be met before the gametes of a patient 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 patient 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 patient 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 patient lacks capacity to consent to their storage.

Condition D is that the patient 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 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). If the patient dies before providing this consent, the gametes can no longer remain in storage.

- 5.34** Before a centre can store a patient's gametes without their consent, the centre must ensure that it has met 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). 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 has been met.
- 5.35** 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.
- 5.36** When assessing whether it is in a child's best interests to procure and store their gametes, the centre should refer to applicable General Medical Council guidance and consider the child's short- and long-term best interests. Consent to continue storing the gametes should be sought from the child when they are competent to give consent.
- 5.37** 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.

Competence

- 5.38** 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.

5.39 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.

5.40 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 and HFEA Guide to Consent

Other legislation, professional guidelines and information

Consent to examination and treatment

[Reference Guide to Consent for Examination or Treatment \(Department of Health, April 2001\)](#)

[Consent: patients and doctors making decisions together \(General Medical Council\)](#)

[Human Tissue Authority Code of Practice 1: Consent \(Human Tissue Authority, September 2009\)](#)

[Gynaecological Examinations: Guidelines for Specialist Practice \(RCOG 2002\)](#)

Competence

[Consent: patients and doctors making decisions together \(General Medical Council, 2008\)](#)

[0-18 years: guidance for all doctors \(General Medical Council, 2007\)](#)

[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 \(Department of Health, 2004\).](#)

Legislation

[Mental Capacity Act 2005](#)

[Mental Capacity Act 2005 – Code of Practice \(2007\)](#)

[Age of Legal Capacity \(Scotland\) Act 1991](#)

[Adults with Incapacity \(Scotland\) Act 2000](#)

Copies of the relevant legislation can be found at: www.opsi.gov.uk

[Clinic Focus article: Harvesting sperm from deceased men \(October 2012\)](#)

[Chief Executive letter: CE 12 \(02\) \(May 2012\)](#)

Guidance note 6: Legal parenthood

Version 6.0

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Mandatory requirements

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

PART 2: PARENTHOOD IN CASES INVOLVING ASSISTED PRODUCTION

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 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, 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,
- (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 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, then subject to section 45(2) to (4), the other party to the civil partnership 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 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,
- (c) the other party to the civil partnership died before the placing of the embryo in the woman,
- (d) the other party to the civil partnership 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 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.

(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

- 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.

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** The centre should record the marital status of patients in the patient notes. If a patient is having treatment with their partner, the centre should record whether or not 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 or not legal parenthood consent is required.
- 6.4** 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.
- 6.5** A child's legal mother automatically has parental responsibility. The position of the father or other parent depends on factors including their marital status, what is recorded on the birth certificate, and whether the family court has made an order. 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.
- 6.6** The centre should ensure that the relevant consent to legal parenthood is complete before sperm and egg transfer, embryo transfer, or insemination takes place.
- 6.7** In cases when a centre identifies anomalies in legal parenthood consent that may impact the legal parenthood of any child born as a result of treatment, the centre should seek legal advice. They should also contact the affected patient and her partner as soon as possible and advise them of the circumstances, the options available to them and that they may wish to seek their own legal advice. The centre should inform the HFEA about any legal parenthood anomalies that it discovers.

Interpretation of mandatory requirements**6A**

Where a married woman is seeking treatment using her husband's sperm or embryos created using her husband's sperm, then 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 married woman 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, she and her husband were judicially separated, 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.

- 6.8** If a married woman 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, where applicable, 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. It may not be appropriate to contact him if he is unaware his wife is having treatment.
- 6.9** If the centre cannot obtain a written record of the husband's consent or refusal to consent, it should record the steps taken to establish whether he consents to the treatment in the medical records.
- 6.10** ~~If a~~ **A woman who is still married or in a civil partnership may wish** ~~woman wishes~~ to be treated with a new partner (with **her new partner's** ~~his~~ 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~~ **ex-partner** does not consent **to the treatment** must be obtained. ~~for the woman's new partner to be the father or parent of any child born as a result of this treatment, even if he is the biological father.~~ 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.
- 6.11** **When a woman who is married or in a civil partnership returns for subsequent treatment without her husband, 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 partner during the first treatment is still complete and correct.**

See also

HFEA Guide to consent

**Interpretation of mandatory requirements
Stating lack of consent 'as a question of fact'****6B**

To prove that the husband, 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 husband, wife or civil partner are separated and the latter is unaware of the treatment). The patient's husband, wife or civil partner may be the legal father or parent of the child if they support the treatment, for instance they help the patient to travel to receive treatment. Any consent form declaring their lack of consent will 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. For instance, evidence that the couple are about to start divorce proceedings.

Parenthood in these circumstances can be complex and case-specific, and for the family court or births registrar (or both) to decide. Clinics and couples may need to seek their own independent legal advice before proceeding with treatment.

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 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.

6.12 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 **6B**), taking into account the duty of confidentiality to the woman seeking treatment, where applicable, and
- (b) obtain a written record of the civil partner **or wife**'s consent. 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 **6B**), the centre should take all practical steps to obtain evidence of this. It may not be appropriate to contact her if she is unaware her civil partner is having treatment.

6.13 If the centre cannot obtain a written record of the civil partner **or wife**'s consent or refusal to consent, it should record the steps taken to establish whether the civil partner **or wife** consents to the treatment in the medical records.

6.14 If a woman in a civil partnership **or same-sex marriage** wishes to be treated with a new (female or male) partner, then evidence to show that her civil partner **or wife** does not consent must be obtained for the woman's new partner to be the parent/father of any child born as a result of this treatment.

Legal parenthood: unmarried male partner

Interpretation of mandatory requirements

6D

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 they do not consent to the treatment (see 6.8 and 6.11).

Where a woman is seeking treatment using her 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).

Legal parenthood: female partner who is not a civil partner **or wife**

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 they do not consent to the treatment (see as described above at 6.8 and 6.11).

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).

Parenthood after death of a man providing sperm

Interpretation of mandatory requirements

6F

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.

Parenthood after death of a partner who has not provided sperm

Interpretation of mandatory requirements

6G

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

6H

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) they were judicially separated, 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.

Stating 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 will 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 for the family court or births registrar (or both) to decide.

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/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

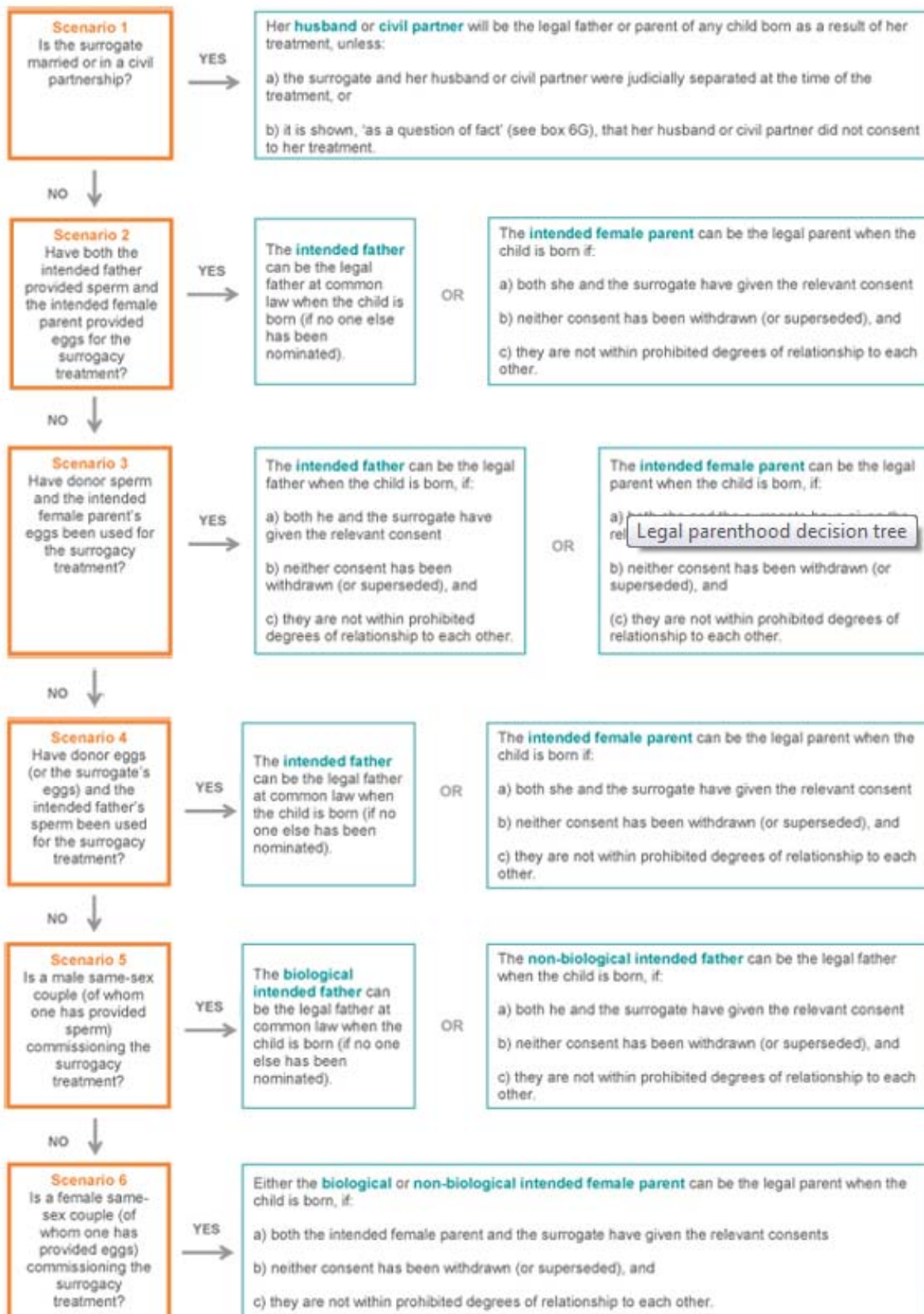
The intended parents are expected to apply to the family court for a parental order after the child is born. A parental order will make both intended parents the legal parents (with parental responsibility) and permanently extinguish the surrogate's legal motherhood. It will also trigger the re-issue 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.

Legal parenthood in surrogacy arrangements: decision tree

- 6.15** 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.



General procedures for obtaining consent

- 6.16** The centre should establish documented procedures to obtain written informed consent. The centre should retain **original** the signed consent forms and ensure that a copy is **provided to available for** those who have given consent.
- 6.17** When anyone gives, withdraws or varies consent, 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.
- 6.18** The centre should ensure that there is a written record in the medical records that information has been provided to the person giving consent in each case.
- 6.19** The centre should ensure that consent is:
- given voluntarily
 - given by a person who has the capacity to do so, and
 - taken by a person authorised by the centre to do so.
- 6.20** The centre should ensure that any person giving consent declares that:
- they were given enough information to understand the nature, purpose and implications of receiving treatment (or their partner receiving treatment) following consent
 - they were given a suitable opportunity to receive proper counselling about the implications of receiving treatment (or their partner receiving treatment) following consent
 - they were given information about the procedure for varying or withdrawing consent, and the information they have given in writing is correct and complete.
- 6.21** When obtaining consent to register the partner as the parent after their death, 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**.

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

6H

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

6I

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.

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

6J

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.

- 6.22** 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.

Guidance note 27: Adverse incidents

Version 4.0

On this page

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[Directions](#)

[HFEA guidance](#)

[Definitions](#)

[Reporting and timescales](#)

[Other legislation, professional guidelines and information](#)

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 T106 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, **issues with 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 serious 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 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.

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 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.

27.9 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 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.

- 27.10** 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

26 – Equipment and materials
32 – Obligations and reporting requirements of centres
33 – Mitochondrial donation

Other legislation, professional guidelines and information

National Patient Safety Agency – Being open: communicating patient safety incidents with patients, their families and carers

NHS Litigation Authority – Apologies and Explanations

General Medical Council – Good Medical Practice

Nursing and Midwifery Council – The code: standards of conduct, performance and ethics for nurses and midwives

CQC guidance for NHS providers on Duty of Candour

National Health Service Litigation Authority guidance on “saying sorry”

Directions 0007: Consent

Directions given under the Human Fertilisation and Embryology Act 1990 as amended

Consent

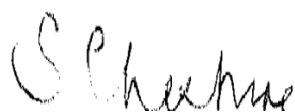
Ref: 0007

Version: 7

These Directions are:	GENERAL DIRECTIONS
Sections of the Act providing for these Directions:	Sections 12 (1) (d) and (g), 13 (2) (f), 14 (1) (d) and 15 (2)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version issued on:	1 April 2017

1. Licensed centres must record any consent of a person whose consent is required under:
 - (a) Schedule 3 and Section 33B of the Human Fertilisation and Embryology Act 1990 as amended; and
 - (b) Sections 37 (1) and 44 (1) of Part 2 of the Human Fertilisation and Embryology Act 2008

in the appropriate form listed in the Schedule to these Directions.
2. Where the storage period of a person's gametes or embryos has been extended, in accordance with the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, the PR of the licensed centres at which those gametes or embryos are stored must maintain a record of evidence that the conditions for extended storage of those gametes or embryos have been fulfilled.
3. Licensed centres must maintain a record of any withdrawal of consent by a person who has previously given a consent required under Schedule 3 to the Human Fertilisation and Embryology Act 1990, as amended, or under sections 37 (1) or 44 (1) of Part 2 of the Human Fertilisation and Embryology Act 2008. This consent should be recorded in the WC form, or in the case of surrogacy, the SWC form, as listed in the Schedule to these Directions.
4. Licensed centres holding any of the records referred to in these Directions must be able to produce a copy of those records (either electronically or as a hard copy) upon request from an HFEA member or employee.
5. From 1 May 2010, anyone receiving treatment at a licensed centre must complete a 'Consent to the disclosure of identifying information form' (CD Form) if they have not already done so, regardless of when they first registered for treatment.



Sally Cheshire
Chair, Human Fertilisation and Embryology Authority

16 September 2015

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Date version 7 issued:	1 April 2017
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Schedule

Storage

- GS Your consent to the storage of your eggs or sperm
- LGS Your consent to extending the storage of your eggs or sperm beyond 10 years
- ES Your consent to extending the storage of your embryos beyond 10 years

Donation

- MD Your consent to donating your sperm
- WD Your consent to donating your eggs
- ED Your consent to donating embryos

Treatment

- WT Women's consent to treatment and storage form (IVF and ICSI)
- MT Men's consent to treatment and storage form (IVF and ICSI)
- MGI Your consent to the use of your sperm in artificial insemination
- WGI Your consent to the use of your eggs in GIFT

Surrogacy

- MSG Men's consent to the use and storage of sperm or embryos for surrogacy
- WSG Women's consent to the use and storage of eggs or embryos for surrogacy
- SPP Your consent to being the legal parent in surrogacy
- SWP Your consent (as a surrogate) nominating an intended parent to be the legal parent

Mitochondrial donation

- WMT Mitochondrial donation: women's consent to treatment and storage
- MMT Mitochondrial donation: men's consent to treatment and storage
- WDM Mitochondrial donation: consent to donating your eggs
- MD (PNT only) Mitochondrial donation: consent to sperm donation (PNT only)
- MD (including PNT) Consent to donating your sperm (including for use in pronuclear transfer)

Disclosure of information

- CD Your consent to disclosing identifying information

Parenthood

- WP Your consent to your partner being the legal parent
- PP Your consent to being the legal parent
- PBR Your consent to being the legal parent after your death**

Withdrawal or stating lack of consent

WC Withdrawing your consent

SWC Surrogacy - withdrawing your consent

LC Stating your spouse or civil partner's lack of consent

'Guide to consent' document

(NOTE: only amended sections of the 'Guide to consent' are included)

Consent forms: a guide for clinic staff

Version 3, 1 April 2017

Consent

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Introduction

Informed consent is one of the most important principles in healthcare and a fundamental feature of the Human Fertilisation and Embryology (HFE) Act 1990 (as amended). You are responsible under the act for obtaining properly informed consent from your patients.

This reference guide is designed to help you understand your legal obligations and to use the individual consent forms appropriately. It is not designed to be used by patients.

You can find the forms on the consent form page on our [website](#). Here you can also find another resource, 'How to use consent forms – for clinic staff,' which gives you:

- information on who should complete each consent form, and
- treatment scenarios and which consent forms should be completed in each case.

What are my legal obligations?

The HFE Act 1990 (as amended) requires licensed centres to ensure that consent given by patients is written and is fully informed before they store or use their eggs, sperm or embryos. The requirements and guidance regarding consent are set out in the Code of Practice (primarily [guidance note 5](#)) and in [General Direction 0007](#).

Before you ask your patients to give consent you must give them:

- enough information to enable them to understand the nature, purpose and implications of their treatment or donation
- a suitable opportunity to receive proper counselling about the implications of the steps which they are considering taking, and
- information about the procedure for varying or withdrawing any consent given and about the implications of doing so.

You should record that you have provided this information in the patient's medical notes. You may wish to use the 'Female record of information provided before obtaining consent' and 'Male record of information provided before obtaining consent,' which you can download from our [website](#). **A record of the information and counselling provision provided at the time of consent may be particularly important if the validity of the consent is ever called into question at a later date.**

Who completes the consent forms?

The person who is giving consent must fill in the consent form. Further information on who should complete each consent form is in 'How to use consent forms – for clinic staff' on our [website](#).

You should not pre-complete consent forms on behalf of the person giving consent. If the person **acknowledges that they want to provide consent but is, at the same time,** unable to sign for themselves due to physical illness, injury or disability, someone else can complete the form on their behalf **as long as it is** in the presence of the person giving consent. However, if the person is consenting to being registered as the legal parent after their death only they can sign the form.

The provisions of the Human Tissue Act 2004, which allow next of kin to provide consent to harvesting of other body tissues, do not apply to gametes. Only the gamete provider can provide effective consent to the use of gametes in treatment. Anyone who procures, stores or uses gametes without valid and

effective consent from the gamete provider may be committing an offence. For information on the limited cases where consent is not required see the HFEA Code of Practice Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information. Please note that these exemptions do not apply to cases where a person has died (including cases of brain stem death) without having prior effective consent to storage or use in place.

Should we ask patients to complete new consent forms for every treatment cycle?

It is a clinic's legal responsibility to ensure that valid and effective consent is in place before treatment commences.

We do not require patients to complete a new set of consent forms before their second or subsequent treatment cycles; however, it is very important for you to establish that any previously completed consent forms are still valid and effective. If it is not clinic practice to ask patients and their partners to complete new consent forms for subsequent treatment cycles, you must review all of the consent forms they previously completed to ensure that the patient or partner circumstances have not changed, that there were no errors in the original consent forms and that valid and effective consent is still in place before their treatment commences. This review should include the consent to legal parenthood forms where necessary.

Where patients have transferred to your clinic from another clinic and you intend to rely on the consent forms that the couple completed at the first clinic, it is particularly important that you carefully review those consent forms to ensure that all relevant forms have been provided, were properly completed and contain the correct information. You should also confirm that your patients were given an opportunity to have counselling and were provided with all relevant information. Once patients and their partners are undergoing treatment at your clinic, the legal responsibility for ensuring that valid and effective consent is in place for that treatment lies with you, not the clinic that took the original consent.

There will be some circumstances where you cannot rely on consent forms that were previously completed and it will be necessary for your patient(s) and their partner(s) to complete new consent forms. In order to help establish whether this is necessary, you should discuss with them whether there have been any changes in their personal circumstances including:

- marital status ie, has the couple separated or divorced or become married to someone else since completing the first set of consent forms
- whether unmarried couples have since separated
- whether the patient is having treatment with a different partner from her previous round of treatment
- the health of the patient and partner (eg, whether or not they might since have developed a life-threatening condition and so may wish to reconsider giving consent to posthumous use)
- the death of the patient's partner
- whether or not the partner still wishes to go ahead with treatment
- changes to the type of treatment needed eg, the patient had IUI previously and will now have IVF or the patient will now use donor sperm.

You should emphasise to your patients that they should proactively contact you if their personal circumstances change, so that both you and the patient can consider whether consent previously given is still valid or needs to be withdrawn and new consent given.

Which declarations should patients sign?

Your patients should sign the page declaration on every page of the consent form to confirm they have read the page and agree fully with the consent and information given.



Page declaration

Your signature Date

X D D M M Y Y

Your patient will need to sign a final declaration on the last page of the consent form to declare that before they completed the form, they were given an opportunity to have counselling and received information about:

- the different options set out in the form
- the implications of giving their consent
- the consequences of withdrawing this consent and how they can make changes to, or withdraw, their consent.

If you do not give patients this information before they fill in the form, their consent may be invalid. You should check that your patient has signed the page declarations, the final declaration and, where relevant, the section declarations, before accepting their consent forms.

You should also ensure that they have ticked any required boxes on forms, where relevant.

Which consent forms should transgender people complete?

If your patient is transgender or has gender dysphoria and they do not wish to complete HFEA consent forms with male or female gender references, they may complete forms from the separate suite of gender neutral forms.

Important information about legal parenthood consent

What is legal parenthood and why is consent to parenthood so important?

Legal parenthood means that someone is legally recognised as their child's parent. It affects a wide range of areas such as the child's nationality, inheritance and who has financial responsibility for the child. It is also important for a child to be clear who his or her legal parents are. A partner may only be registered on the birth certificate if he or she is the child's legal parent.

Clinics must ensure that HFEA consent forms are properly completed before licensed treatment is provided and that copies are retained in the patient's record and are also provided to the patient and partner. Meeting these requirements will ensure that the partner, who is not married or in a civil partnership with the patient when the couple are undertaking fertility treatment using donor sperm, can be the legal parent of any child born.

If consent forms are not properly completed, are not signed and dated correctly, are lost or are completed by the wrong person, the partner may not be legally recognised as the parent of the child(ren) born. Where mistakes with consent forms have been made or forms have been misplaced, some partners have needed to seek a declaration of parenthood in the family court in order for them to become the legal parent of their child. There is no guarantee that errors can be resolved, even by the courts, and this may lead to the intended parent not being recognised as the legal parent of their child.

What are examples of legal parenthood consent(s) anomalies?

The following are some examples of mistakes that may affect the validity of legal parenthood consent:

- Missing WP or PP forms ie, there is no record or only a partial record of the consent(s)
- WP or PP forms completed after treatment (ie, after egg, sperm or embryo transfer)
- WP or PP forms completed by the wrong person
- Parts of the WP or PP forms are incomplete eg, boxes not ticked, signatures, including page declarations missing or patient information not complete
- Patients and their partners were not given the required information or offered counselling before the consent was provided (before treatment)

A mistake in the consent process does not mean that a person will automatically be deprived of their status as legal parent and the outcome of any particular case will be highly dependent upon the individual circumstances.

How can we avoid problems with legal parenthood consents?

All consents are important and should be recorded appropriately by trained members of staff, however, any mistake in consent to legal parenthood can have a devastating impact on families. As is the case for all consents, clinic procedures for taking informed consent to parenthood must be compliant with the HFE Act 1990 (as amended) and the Human Fertilisation and Embryology Act 2008. You should:

- ensure that you are clear about the marital status of the couple, whether they are married or in a civil partnership with one another or if either one of them is married or in a civil partnership with any other person. You should record this in the patient notes. This may affect who will be the

second legal parent of any child born following treatment and whether or not legal parenthood consent is required.

- ensure you provide your patients and their partners with the required information and opportunity for counselling before they consent
- allow enough dedicated time to provide information and counselling effectively and keep a record of the information and offer of counselling provided in the patient notes
- ensure your patients understand the implications of their consent
- the clinic should have a documented assurance process to ensure that the appropriate consent forms have been completed and that the completed forms contain the correct information, prior to treatment
- check consent is in place, valid and effective at each stage of a patient's treatment
- ensure forms are completed in a clinic and that patients are guided through the process
- ensure forms are completed fully and stored correctly.

What should we do if we find an anomaly with legal parenthood consents?

If you have any doubt about the validity or effectiveness of legal parenthood consents you should seek your own legal advice. You should act in a way that promotes openness and honesty with your patients and must inform the affected patients and their partners at the earliest opportunity in a compassionate and supportive manner. The disclosure to a patient and their partner that the partner may not be the legal parent of their child may be unexpected, upsetting and shocking, the clinic should consider the most appropriate way to break this news to the couple.

You should:

- fully disclose all relevant facts and documents related to the couples' case to them
- offer to financially support the patient(s) and their partner(s) to access legal advice
- provide the patient and their partner with all information as is necessary for the speedy resolution of their case if they choose to seek a declaration of parentage in the family court
- provide other support to the patient and their partner as appropriate, including counselling
- notify your HFEA inspector about what has happened and the clinic's approach
- report any anomaly resulting in harm to patients as an adverse incident using the HFEAs incidents process

Your consent to the storage of your eggs or sperm (GS form)

Purpose of this form

By law (the Human Fertilisation and Embryology Act 1990 (as amended)), your patient needs to give their written consent if they want their eggs or sperm to be stored. They must also state in writing how long they consent to their eggs or sperm remaining in storage.

Your patient is also legally required to record what they would like to happen to their eggs or sperm if they were to die or lose the ability to decide for themselves (become mentally incapacitated). While this is perhaps not something they have considered, you need to know this so you only use their eggs or sperm according to their wishes if this were to happen. Their eggs or sperm can only be used in accordance with their consent so if their wishes are not recorded properly it can have serious consequences.

This form allows your patient to consent to storage only. If they want to consent to treatment, they must complete an additional form (eg, the **MT**, **WT** or **MGI** form). This includes if a male patient wants to consent to his partner using his sperm in treatment if he was to die or become mentally incapacitated.

Section 2 – Storing eggs or sperm

Your patient must provide consent for their eggs or sperm to be stored. They can do this by ticking the yes box at 2.1.

2.1 Do you consent to your eggs or sperm being stored?

You must consent by ticking the yes box below for your sperm or eggs to be stored.

Yes

How long can eggs or sperm be stored for?

If your patient ticked yes at 2.1, they will then need to state how long they consent to store their eggs or sperm. The law permits patients to store for any period up to 10 years, but in cases where they or their partner is prematurely infertile, or likely to become prematurely infertile, they may consent to store for longer, up to 55 years. This allows people who have a medical condition (such as early menopause), or who have had treatment that has rendered them completely infertile (such as chemotherapy), to be able to extend their storage.

You should know whether your patient satisfies the criteria for premature infertility and before giving them this form you should tell them whether this is the case. If they are eligible to consent to store for 55 years, this should be clearly explained and the provision of information about this option should be clearly documented.

2.2 Have you, or your partner, been diagnosed as prematurely infertile or likely to become prematurely infertile?

Causes of premature infertility can include chemotherapy treatment and early menopause. Please speak to your clinic if you are unsure. If your circumstances change and either you or your partner become prematurely infertile, or are likely to become premature infertile, you and your partner can change your consent to store your sperm or eggs for up to 55 years.

- No ► after signing the page declaration below, continue to 2.3.
 Yes ► after signing the page declaration below, go straight to 2.4.

If your patient ticks no to premature infertility, they should go to section 2.3. The maximum period they can consent to store for is 10 years.

2.3 For how long do you consent to store your eggs or sperm?

You can consent to store your eggs or sperm for up to 10 years.

For 10 years

For a specific period (up to a maximum of 10 years) ▶ specify the number of years:

years

If your patient ticks yes to premature infertility, they should go to section 2.4.

For how long do you consent to store your eggs or sperm?

Please specify the number of years you consent to store your eggs or sperm for (up to a maximum of 55): years.

Clinic staff: please attach all relevant medical practitioners' statements to this form.

What do I need to do if my patient is storing for longer than 10 years?

Although your patient can consent to store for up to a maximum of 55 years on this form, before the expiry of the first 10 years you will need to arrange for a medical practitioner to certify in writing that the medical criteria for premature infertility have been met for storage to continue for more than 10 years. If your patient has consented to store for longer than 20 years, you should repeat this process before every 10-year period ends (up to a maximum of 55 years). For example, if your patient has consented to store for 23 years, you would need to seek a medical practitioner's statement twice over the 23-year period – one for 10-20 years and one to cover the additional three years.

Provided your patient has consented for the maximum of 55 years, they do not need to complete the consent form again, but you should attach the relevant medical practitioner's statement to this form.

You should seek the written medical opinion whilst your patient is alive. However, if your patient dies before a medical opinion can be sought, based on evidence that they would have satisfied the premature infertility criteria when they were alive, you may seek the written medical opinion after death.

Should we link how long a patient consents to store for with their funding or payment plans?

You should not direct your patient to consent to store for less time to tie in with funding or payment plans. Any practical arrangements should be kept separate to consent. If your clinic has a separate contractual arrangement, you should draw the terms of the contract to the patient's attention. You should explain the implications if they fail to pay their storage fees or if funding ends eg, that storage may not continue for the period they have specified in this form.

Section 3 – In the event of your death or mental incapacity

Your patient is legally required to record what they would like to happen to their eggs or sperm if they were to die or lose the ability to decide for themselves (become mentally incapacitated).

Section 3.1 asks your patient whether they have already stated on another consent form (eg, **WT** or **MT** form) how they want their eggs or sperm to be used in the event of their death or mental incapacity. If your patient ticks yes, they should move onto section four. You should make sure your patient is aware of what they consented to on the other form and that they do not wish to change their consent.

If your patient answers no, this form enables them to consent to storing their eggs or sperm and allowing them to be used for training purposes if they die or become mentally incapacitated.

Your patient will need to complete an additional form (eg, the **MT** or **WT** form) if they want their eggs or sperm to be used by their partner or another person if this were to happen. If your patient does not give their consent, their eggs or sperm must be allowed to perish in the event of their death or mental incapacity. This is an important issue to highlight to your patient, especially if they are seriously ill or have been diagnosed with a life-threatening condition.

3.1 Have you already stated how you want your eggs or sperm to be used in the event of your death or mental incapacity on another consent form?

Yes ▶ go straight to section four.

No ▶ your eggs or sperm can remain in storage in the event of your death or mental incapacity for the purposes outlined below:

- **In the treatment of a partner** ▶ If you wish your sperm to be used for this purpose, you will need to complete 'Men's consent to treatment and storage (IVF and ICSI)' (MT form). Your sperm will only be able to be used for the treatment of the person named on this form. You can make changes to the details you provide on this form at any time by completing a new MT form – contact your clinic to do this.
- **In the treatment of others** ▶ If you wish your eggs or sperm to be used for this purpose, if you are female (including if you wish your eggs to be used by your female partner), please complete 'Your consent to donating your eggs' (WD form). If you are a male, please complete 'Your consent to donating your sperm' (MD form).
- **For training purposes** ▶ This allows healthcare professionals to learn about, and practice, the techniques involved in fertility treatment. You can consent to this on this form (see section 3.2 below).

3.2 Do you consent to your eggs and sperm being used for training purposes?
(See above for more information).

If you die

Yes No

If you become mentally incapacitated

Yes No

⚠ What can happen if the forms are not completed properly

A single man consents to store his sperm before receiving cancer treatment. He later marries and does not realise that he must return to the clinic to amend his consent ie, to provide consent to posthumous use and to include his partner's name. He later dies and because he did not amend his consent, she cannot use his sperm.

Your consent to being the legal parent in surrogacy (SPP form)

Purpose of this form

By law (the Human Fertilisation and Embryology Act 2008), someone other than the biological father can be nominated as the second legal parent of any child born from surrogacy – as long as both the nominated intended parent and the surrogate give notices consenting to this in writing before sperm, egg or embryo transfer. The nominated intended parent can do this on this form and the surrogate can do this on the **SWP** form.

Your patient This form should not be completed **this form** if:

- the surrogate is married or in a civil partnership and her spouse or civil partner consents to the treatment (the surrogate's spouse or civil partner will be the other legal parent)
- the **intended parent** is the biological father (since in common law he will automatically be the legal parent if the surrogate is not married or in a civil partnership and no-one else has been nominated as a parent).

Section 3 – Your notice of consent to being the legal parent

Your patient The **nominated intended parent** must tick the box at 3.1 to consent to being the legal parent of any child born from the surrogate's treatment. **Your patient** They should name the surrogate in section two of the form.

3	Your notice of consent to being the legal parent
3.1	Please tick the box next to the statement below to confirm your consent. <input type="checkbox"/> I consent to being the legal parent of any child born from the surrogate's treatment (named in section two).

You should **strongly** advise **all parties involved** **I the surrogacy arrangement** **your patient that they are strongly advised** to seek their own legal advice before entering into a surrogacy arrangement.

Section 4 – In the event of your death

Your patient The **nominated intended parent** may also wish to decide whether, in the event of their death, they would like to be registered as the legal parent of any child born from surrogacy treatment (with embryos created before their death and provided to the surrogate after their death).

Please note that the law concerning posthumous conception and surrogacy is complex and if they are registered as the legal parent after their death, it may not be straightforward for their surviving partner to pursue a parental order.

Consent to birth registration

If **your patient** the **nominated intended parent** has given consent to embryos created before their death being transferred to the surrogate after their death, they may also wish to consent to being registered as the legal parent of any child that is born as a result of treatment. This will mean that their name, place of birth and occupation can be entered on the register of births as the legal parent. They can do this by ticking yes at 4.1. For more information about this, the patient should seek their own legal advice.

Your consent to your partner being the legal parent (WP form)

Purpose of this form

By law (the Human Fertilisation and Embryology Act 2008), the partner of a woman receiving treatment using donor sperm, or embryos created with donor sperm, can be the legal parent of any child born from the treatment – as long as both the patient and her partner give their written consent to this before sperm, egg or embryo transfer. The **WP** form allows your patient to do this. Her partner should complete **‘Your consent to being the legal parent’ (PP form)** if they are not married or in a civil partnership. **Your patient does not need to complete the WP form if she is married or in a civil partnership with the partner with whom she is receiving treatment as her partner will automatically be the legal parent. However, her partner should complete the ‘Your consent to being registered as the legal parent in the event of your death’ (PBR form) in order to be registered as the legal parent of any child born when embryos created with donor sperm before their death are transferred to their partner after their death.**

A woman should complete this form if she:

- is receiving treatment using donor sperm, or embryos created in vitro with donor sperm
- wishes her partner to become the legal parent of any child born as a result of her treatment, **and**
- is not married to, or in a civil partnership with, her partner.

Section 3 – Your consent

Your patient must tick the box at 3.1 to consent to her partner being the legal parent. Her partner should be named in section two of the form.

3	Your consent
3.1	Your consent to your partner being the legal parent
	Please tick the box next to the statement below to confirm your consent.
	<input type="checkbox"/> I consent to my partner (named in section two) being the legal parent of any child born from my treatment.

What can happen if the forms are not completed

A woman received treatment using donor sperm. She is in a long-term relationship with her female partner who, together with the birth mother, wished to be the legal parent of the child born following the treatment. They assumed that because they are living together, and her partner put her name on the birth certificate, that she is the legal parent. Both were unaware that they should have provided consent on the WP and PP forms before treatment took place. As a result, her partner may not be legally recognised as the child’s legal parent.

Your consent to being the legal parent (PP form)

Purpose of this form

By law (the Human Fertilisation and Embryology Act 2008), the partner of a woman receiving treatment using donor sperm, or embryos created with donor sperm, can be the legal parent of any child born from their treatment – as long as both the patient and her partner give their written consent to this before sperm, egg or embryo transfer. The PP form allows your patient's partner to do this. Your patient should complete **'Your consent to your partner being the legal parent (WP form) if she and her partner are not married or in a civil partnership.** Your patient's partner does not need to complete the PP form if they are married or in a civil partnership with your patient, with whom they are receiving treatment, as they will automatically be the legal parent. However, they should complete the **'Your consent to being registered as the legal parent in the event of your death' (PBR form)** in order to be registered as the legal parent of any child born when embryos created with donor sperm before their death are transferred to their partner after their death.

If your patient and her partner are not married nor in a civil partnership, the partner **must** sign this form to be recognised as the legal parent of any child born from their partner's treatment.

Section 3 – Your consent

Your patient's partner must tick the box at 3.1 to consent to being the legal parent of any child born from their partner's treatment. Your patient should be named in section two of the form.

3	Your consent
3.1	Your consent to being the legal parent
	Please tick the box next to the statement below to confirm your consent.
<input type="checkbox"/>	I consent to being the legal parent of any child born from my partner's treatment (named in section two).

Section 4 – In the event of your death

At section 4.1, your patient's partner can say whether, in the event of their death, they would like to be registered as the legal parent of any child born from treatment (with embryos created before your patient's death and provided to their partner after their death). This will mean that their name, place of birth and occupation can be entered on the register of births as the legal parent. For more information about this, they should seek their own legal advice.

Your consent to being registered as the legal parent in the event of your death (PBR form)

Purpose of this form

By law (the Human Fertilisation and Embryology Act 2008), the partner who is married or in a civil partnership with a woman receiving treatment using donor sperm, or embryos created with donor sperm, will automatically be the legal parent of any child born from their treatment. This form has been designed to allow the partner of a woman undergoing treatment using donor sperm to consent to being registered as the legal parent in the event of their death. This process is known as posthumous birth registration. This only applies in cases where embryos (that were created whilst the partner was still alive) are transferred to the partner after their death. If the partner is married or in a civil partnership to the woman having treatment they should complete this form.

If your patient and their partner are using donor sperm but are not married or in a civil partnership the partner should complete the HFEA 'Your consent to being the legal parent' (PP form) and not this form.

A partner (male or female) should complete this form if:

- they are married or in a civil partnership with their partner
- your partner is receiving treatment using embryos created outside the body (in vitro) using donor sperm and either her own or donor eggs, and
- they wish to be registered as the legal parent to any child born if they die before embryos (that were created before their death) are transferred to their partner.

This consent only applies to embryos created with donor sperm before the partner's death. If embryos are created with donor sperm after their death, it is not possible for them to be named as the father or second legal parent, even if they have given their consent.

Your patient's partner **must** sign the form themselves. They **may not** direct someone else to complete and sign the form for them.

The partner may change their consent at any time by submitting a new copy of the consent form to change their consent. You should record in the patient notes where a person has changed their consent.

Section 3 – Your consent

At section 3.1, your patient's partner can say whether, in the event of their death, they would like to be registered as the legal parent of any child born from treatment (with embryos created before your patient's death and provided to their partner after their death). This will mean that their name, place of birth and occupation can be entered on the register of births as the legal parent. For more information about this, they should seek their own legal advice.

'How to use consent forms' document

How to use HFEA consent forms – for clinic staff

This document should be used in conjunction with 'Consent forms: a guide for clinic staff,' which is available on our [website](#). Table one lists all of our consent forms and outlines who should complete them. The forms are colour-coded: the **male forms are green**, the **female forms are purple**, the forms for **both women and men are orange** and **surrogacy forms are blue**. You can find all of these on our [website](#). Table two outlines a number of treatment scenarios and which consent forms should be completed in each case. This is for illustrative purposes only, it does not cover all treatment scenarios and you should consider each patient's individual situation before deciding which consent forms should be completed.

Table 1

Form type	Name of form	Abbreviation	Who should complete this form?
Treatment	Women's consent to treatment and storage form (IVF and ICSI)	WT	Women who are having fertility treatment using embryos created in vitro with their own eggs. This may be IVF or ICSI.
	Men's consent to treatment and storage form (IVF and ICSI)	MT	Men whose partner is having fertility treatment using embryos created in vitro with their sperm.
	Your consent to the use of your sperm in artificial insemination	MGI	Men whose partner is having artificial insemination. This may be IUI or GIFT using their sperm.
	Your consent to the use of your eggs in GIFT	WGI	Women having GIFT using their own eggs.
Storage	Your consent to the storage of your eggs or sperm	GS	Women and men who want to store their eggs or sperm. They will need to complete a treatment form if they want to use their eggs or sperm for treatment.
	Your consent to extending the storage of your eggs or sperm beyond 10 years	LGS	Women and men who want to extend the storage period of their eggs or sperm for longer than 10 years (up to 55 years). It is not for patients storing for the first time; the GS form should instead be completed.*
	Your consent to extending the storage of your embryos beyond 10 years	ES	Women and men who already have embryos in storage and who wish to extend their current storage period beyond 10 years. It should not be filled in if they are storing embryos for the first time; the WT or MT form should

Form type	Name of form	Abbreviation	Who should complete this form?
			instead be completed.*
Donation	Your consent to donating your sperm	MD	Men donating sperm for the treatment of others, including for use in a surrogacy arrangement where the donor is not the intended father, or for training purposes.
	Your consent to donating your eggs	WD	Women donating eggs for the treatment of others including for use in a surrogacy arrangement where the donor is neither the surrogate nor intended parent, or for training purposes.
	Your consent to donating embryos	ED	People (male or female) who are donating embryos for the treatment of others or for training purposes.
Surrogacy	Men's consent to the use and storage of sperm or embryos for surrogacy	MSG	Men commissioning a surrogacy arrangement who are providing sperm or embryos (created in vitro with their sperm) to a surrogate.
	Women's consent to the use and storage of eggs or embryos for surrogacy	WSG	Women commissioning a surrogacy arrangement who are providing their eggs or embryos (created in vitro with their eggs) to the surrogate.
	Your consent to being the legal parent in surrogacy	SPP	People (male or female) commissioning a surrogacy arrangement who wish to be nominated as the other legal parent of the child, together with their surrogate. Your patient can only complete this form if: he is the intended father but is not the biological father eg, an intended father using donor sperm (or embryos created using donor sperm); he is the male partner of the biological father; or she is an intended female parent.
	Your consent (as a surrogate) nominating an intended parent to be the legal parent	SWP	Surrogates who wish to nominate one of the intended parents commissioning the surrogacy arrangement (other than the biological father) to be the legal parent of any child born as a result of treatment. The surrogate should not be married or in a civil partnership (unless their spouse or civil partner does not consent to their treatment).
Disclosure of information	Your consent to disclosing identifying information (full version, part one – general purposes and part two – research purposes)	CD	Patients (and their partners, if relevant) receiving fertility treatment, egg, sperm and embryo donors, and patients who are storing their eggs, sperm or embryos for their treatment or their partner's future treatment.
Parenthood	Your consent to your partner being the legal parent	WP	Women receiving treatment using donor sperm, or embryos created in vitro with donor sperm, who want their partner to become the legal parent of any child born as a result of treatment. They should not be married to, or in a civil partnership with, their partner.

Form type	Name of form	Abbreviation	Who should complete this form?
Withdrawal/ stating lack of consent	Your consent to being the legal parent	PP	People (male or female) whose partner is receiving treatment using donor sperm, or embryos created in vitro using donor sperm, and they wish to be the legal parent of any child born from their partner's treatment.
	Your consent to being registered as the legal parent in the event of your death	PBR	Married or civil partnered people (male or female) whose partner is receiving treatment using embryos created in vitro using donor sperm and either her own or donor eggs, who wish to be registered as the legal parent to any child born if they die before embryos (that were created before their death) are transferred to their partner.
	Withdrawing your consent	WC	People who wish to withdraw their consent to the use or storage of their eggs, sperm or embryos. It can also be used by patients withdrawing their consent to their partner being the legal parent of any child born as a result of treatment, or by the patient's partner to withdraw their consent to being the legal parent of any child born as a result of their partner's treatment. Withdrawing consent to legal parenthood can only happen if donor sperm or embryos are being used and the couple are not married or in a civil partnership.
Withdrawal/ stating lack of consent	Surrogacy – withdrawing your consent	SWC	People commissioning a surrogacy arrangement, surrogates, or partners of surrogates, who wish to withdraw their consent to: the use or storage of their eggs, sperm or embryos; being nominated as the legal parent of any child born as a result of the surrogacy treatment; or the intended parent commissioning the surrogacy being the nominated legal parent of any child born as a result of treatment.
	Stating your spouse or civil partner's lack of consent	LC	Women having fertility treatment with donor sperm or embryos who do not want their spouse or civil partner to be treated as the legal parent of any child born from their treatment because they do not consent to their treatment (a lack of consent).

* The LGS and ES forms are also not for patients who are changing the period of time they consent to store their gametes or embryos within the first 10-year standard storage period. Instead they should revise the storage period on the original form they completed (eg, GS/MT/WT) by completing another copy of that form.

Table 2

Scenario	Type of form																				
	Treatment				Storage			Donation			Surrogacy				Parenthood			Withdrawal of consent			
	WT	MT	MG I	WG I	GS	LG S	ES	MD	WD	ED	MS G	WS G	SP P	SW P	CD	WP	PP	PB R	WC	SW C	LC
1. Married man and woman seeking IVF/ICSI treatment using their own gametes.	✓	✓													✓						
2. Married man and woman seeking IVF/ICSI treatment using own eggs and donor sperm.	✓							✓ _D							✓			✓			
3. Unmarried man and woman seeking IVF/ICSI treatment using own eggs and donor sperm.	✓							✓ _D							✓	✓	✓				
4. Unmarried/ not in a civil partnership female same sex couple seeking IVF/ICSI treatment using own eggs and donor sperm.	✓							✓ _D							✓	✓	✓				
5. Married/civil partnered female same sex couple seeking IVF/ICSI treatment using own eggs and donor sperm.	✓							✓ _D							✓			✓			
6. Married/civil partnered female same sex couple								✓ _D	✓						✓			✓			

	Type of form																	
	Treatment			Storage			Donation			Surrogacy			Parenthood			Withdrawal of consent		
seeking IVF/ICSI treatment using donor sperm. Woman wishes to donate her eggs to her partner.																		
7. Man storing sperm before undergoing chemotherapy. He only wishes to store sperm, not to consent to treatment. He has no partner.				✓										✓				
8. Woman is prematurely infertile following chemotherapy; originally consented to store her eggs for five years, now wishes to extend storage for another 10 years (15 years in total).					✓													
9. Man and woman commissioning a surrogacy arrangement using their own gametes. The commissioning woman wants to be the second legal parent of the child when born. The surrogate is single.										✓	✓	✓	✓s	✓				
10. Man and woman have embryos in storage. The man, woman, or both, wish to withdraw consent to their use and storage.																	✓	
11. Man donating sperm for the treatment of others in IVF.							✓							✓				

	Type of form																				
	Treatment				Storage			Donation			Surrogacy				Parenthood			Withdrawal of consent			
12. Married man and woman seeking GIFT treatment using their own gametes.			✓	✓											✓						
13. A man commissioning a surrogacy arrangement withdrawing consent to the use of his sperm.																					✓
14. A woman who is separated (but not yet divorced) from her husband and seeking IVF treatment with sperm from her new partner. The husband is uncontactable and she wishes to demonstrate his lack of consent to her treatment ▲	✓	✓													✓						✓
15. A married couple commissions a surrogacy arrangement. The embryo is created using a donor egg and sperm provided by the husband commissioning the surrogacy arrangement. The surrogate is single.									✓		✓			✓	✓						

D The gamete donor to complete; **S** The surrogate to complete

* Only 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 married couple will need to decide who will be nominated as the second legal parent when the child is born and consequently who fills in the SPP form. If the intended father who has provided sperm wishes to be the second legal parent neither he nor the surrogate needs to consent to this as he will automatically be recognised as the legal father under common law (as long as the surrogate is not married or in a civil partnership to someone else). If the couple decide that the intended mother wishes to be nominated as the second legal parent both the intended mother and surrogate will need to consent to this.

▲ The fact that your patient has completed this form may not necessarily mean that her estranged husband will not be the legal father. If a dispute arose, the woman could use this form to help demonstrate her husband's lack of consent at the time of her treatment. If your patient is completing this form, you should strongly advise her to seek legal advice about parenthood before undergoing treatment.

Your consent to being registered as the legal parent in the event of your death

About this form

This form is produced by the Human Fertilisation and Embryology Authority (HFEA), the UK's independent regulator of fertility treatment and human embryo research. For more information about us, visit www.hfea.gov.uk.

Who should fill in this form?

Fill in this form if you are:

- married or in a civil partnership with your partner who is undergoing treatment, and
- your partner is receiving treatment using embryos created outside the body (in vitro) using donor sperm and either her own or donor eggs, and
- you wish to be registered as the legal parent to any child born if you die before embryos (that were created before your death) are transferred to your partner.

You **must** sign the form yourself. You **may not** direct someone else to complete and sign the form for you.

If you are using donor sperm but are not married or in a civil partnership you should complete the HFEA consent to legal parenthood (PP) form and not this form.

Why do I have to fill in this form?

If an embryo is transferred to your partner while you are alive then as long as you and your partner are married or in a civil partnership you will automatically be the legal parent of any child born. However, this would not be the case in the unfortunate event that you died before embryo transfer took place. By law, you **must** give your written consent if you want to be registered as the legal parent of any child born from embryos that have been created before your death that are transferred to your partner after your death. That's what this form is for.

While it may be something you prefer not to think about, it's important that you do. It's not something that happens very often, but it can happen.

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HFEA centre reference

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Other relevant forms

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Patient number

What do I need to know before filling in this form?

Make sure that your clinic has given you all the relevant information you need to make fully informed decisions. This includes:

- information about:
 - the implications of giving your consent
 - the consequences of making changes to this consent, and
 - how and when you can make changes to your consent,
- an opportunity to have counselling.

This is a complex subject, if you are unsure about anything, or think that you have not been given all of this information, please speak to your clinic. There is a declaration at the end of this form which you must sign to confirm you have received this information. If you do not receive this information before filling in this form, your consent may be invalid.

This consent only applies to embryos created with donor sperm before your death. If embryos are created with donor sperm after your death, it is not possible for you to be named as the father or second legal parent, even if you have given your consent.

When filling in this form, make sure you sign the declaration on every page to confirm you have read the page and fully agree with the consent and information given. Also ensure that you have ticked all the boxes relevant to you. When you have completed the form you may request a copy of it from your clinic.

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Patient number

12. About you

First name(s)

Surname

Date of birth

NHS/CHI/HCN/passport number (please circle)

13. About your partner

Your partner's first name(s)

Your partner's surname

Your partner's date of birth

Your partner's NHS/CHI/HCN/passport number

14. Birth registration in the event of your death

If you die after embryos have been created using donor sperm for your partner's treatment, but before your partner has the embryos transferred, then you are only able to be registered as the parent of the resulting child if you have consented to this in writing. This is known as posthumous birth registration.

14.1. Do you consent to embryos created before your death being transferred to your partner after your death, and to being registered as the legal parent of any child born from your partner's treatment after your death (ie, posthumous birth registration)?

By ticking yes, you consent to the following:

- I consent to my name, place of birth and occupation being entered on the register of births as the legal parent of any child born from my partner's treatment.

The register is kept under the Birth and Deaths Registration Act 1953, or the Births and Deaths Registration (Northern Ireland) Order 1976, or the Registration of Births, Deaths and Marriages (Scotland) Act 1965.

- I also consent to my information (relating to my partner's treatment) being disclosed to one of the following registrars:
 - the Registrar General for England and Wales
 - the Registrar General for Scotland
 - the Registrar for Northern Ireland.

Please note that being recorded in the register of births as the legal parent of a child born from your partner's treatment does not transfer any inheritance or other legal rights to the child.

Yes

No

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Patient number

15. Declaration

Please sign and date the declaration.

- I declare that I am the person named in section one of this form.
- I declare that:
 - before I completed this form, I was given information about the different options set out in this form, and I was given an opportunity to have counselling
 - the implications of giving my consent, and the consequences of changing this consent, have been fully explained to me, and
 - I understand that I can make changes to my consent at any point until the time of embryo transfer.
- I declare that the information I have given on this form is correct and complete.
- I understand that information on this form may be processed and shared for the purposes of, and in connection with, the conduct of licensable activities under the Human Fertilisation and Embryology Act 1990 (as amended) in accordance with the provisions of that act.

Your signature

Date

Annex B – Amendments to the Code of Practice related to egg sharing requirements

NOTE: Changes related to egg sharing requirements are highlighted in red; deletions are highlighted in yellow.

Guidance note 12: Egg sharing arrangements

Version 5.0

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Mandatory requirements

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

- 12 (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

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.

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:
- care is taken when selecting egg and sperm providers donating for benefits in kind
 - egg and sperm providers are fully assessed and medically suitable, and
 - 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 mitochondrial donor), they should be given in connection with the cycle in which eggs are supplied for a recipient's treatment unless **there is a clinical reason to defer those benefits 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 latter circumstances only, 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 a lower number of eggs have been collected than is needed for a benefits in kind arrangement.**

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.

See also

Guidance note 11 – Donor recruitment, assessment and screening

Information

- 12.6** 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:
- the criteria for selecting people providing and receiving gametes in exchange for benefits in kind
 - 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, and
- (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

12.7 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.

12.8 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.

12.9 The gamete provider should be given enough time to consider the implications of donating, before the donation is used.

12.10 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
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.

12.11 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

12.12 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

12.13 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

12.14 When drawing up agreements between the centre and gamete providers, centres should seek legal advice.

12.15 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.

12.16 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.

12.17 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.

12.18 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 about the implications of the treatment, and
- (e) 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

12.19 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.

12.20 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.

12.21 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) how the gametes will be distributed between the provider and recipient(s).

Agreement between a licensed centre and a recipient

12.22 When drawing up agreements between the centre and recipient, centres should seek legal advice.

12.23 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.

12.24 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.

12.25 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.

12.26 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 about the implications of the treatment, and
- (e) 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

12.27 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.

12.28 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.

12.29 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) how the eggs or sperm will be allocated between the provider and recipient(s).

Benefits in kind for research

12.30 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.

12.31 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.

12.32 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

[BICA Guidelines for Good Practice in Infertility Counselling \(2008\)](#)

[Clinic Focus article: Guidance on egg giving \(March 2016\)](#)

Annex C – Amendments to the Code of Practice relating to instances where consent to storage is not required

NOTE: Changes related to instances where consent to storage is not required are highlighted in red; deletions are highlighted in yellow.

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

Version 9.0

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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(2ZA) 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.

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.

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 (3ZB) 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.

Interpretation

- 16 (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.

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

Regulations

- The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991
The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

HFEA guidance

Consent to use and storage of gametes and embryos

Interpretation of mandatory requirements

5A

~~If no consent is in place, because the person is unable in law to provide it, or is deceased, then the gametes must not be procured, stored or used. The provisions in the Human Tissue Act 2004 which allow next of kin to provide consent to harvesting of other body tissues do not apply to gametes.~~

It is unlawful to procure, store or use gametes without written, effective consent from the gamete provider. There are, however, limited circumstances in which it may be possible to store a person's gametes without consent, provided that certain legal requirements are met. These are set out in paragraphs 9 and 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) (see 5G). These exemptions do not include where a person has died (including cases of brain stem death) without providing effective consent to the storage and use of their gametes, or where the gamete provider lacks capacity to give consent and is not expected to gain or regain it. The provisions of the Human Tissue Act 2004, which allow next of kin to give consent to procure, store or use other body tissues of the deceased, do not apply to gametes.

Anyone who procures, stores or uses gametes without valid and effective consent from the gamete provider may be committing an 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 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.~~

The law requires the centre to obtain written informed consent from a person before it performs the following procedures:

- a) storing ~~that person's~~ ~~their~~ gametes (exemptions are outlined ~~in paragraphs 9 or 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) in the HFE (Special Exemptions) Regulations 1994~~)
- b) using ~~that person's~~ ~~their~~ gametes or mitochondria for the treatment of others or for nonmedical fertility services
- c) creating embryos in vitro with ~~that person's~~ ~~their~~ gametes
- d) storing embryos created with ~~that person's~~ ~~their~~ gametes
- e) using embryos created with ~~that person's~~ ~~their~~ gametes for their own treatment, treatment of a partner or treatment of others
- f) using embryos created with ~~that person's~~ ~~their~~ gametes for training people in embryo biopsy, embryo storage or other embryological techniques
- g) using embryos created with ~~that person's~~ ~~their~~ gametes for any research project
- h) using ~~that person's~~ ~~their~~ cells to create embryos for research, or
- i) creating human admixed embryos with ~~that person's~~ ~~their~~ gametes or cells.

~~The centre must ensure it obtains written informed consent from a person before procuring their gametes. If gametes are collected without proper consent, it may be considered assault. Gametes should not be taken from a person if written, informed consent to storage has not been obtained.~~

~~The law requires that gametes stored without consent cannot be used, unless the gamete provider becomes competent and consents to such use.~~

If gametes or embryos are to be transferred to a centre outside the UK, the UK centre must **be satisfied that the requirements set out in General Directions 0006 are met.** These include obtaining the consent of the gamete provider(s) to their export 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 person responsible for the UK centre must be satisfied that **the requirements set out in General Directions 0006 are met.** These include the requirement that the provider has given written consent to the transfer of the gametes or embryos to the UK, and has not withdrawn that consent.

If the provisions of General Directions 0006 cannot be met, the UK centre may need to consider apply for a special direction to permit import or export.

Further requirements and the exemptions regarding obtaining consent to the use of gametes, cells and embryos for research (including for the creation of admixed embryos), and the exemptions, are outlined in guidance note 22 – Research and training.

Requirements regarding consent to parenthood are outlined in guidance note 6 – Legal parenthood, and [General Directions 0006](#).

- 5.1** The centre should obtain written informed 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 the appropriate consent forms have been completed and that the completed forms contain the correct information, prior to treatment.
- 5.4** If, following treatment, the centre discovers errors in the consent provided by a patient or their partner, particularly in relation to legal parenthood, the centre should take all reasonable steps to notify the affected patient at the earliest opportunity. The centre should assess the error and the potential impact of this and then consider what remedial actions should be taken. The centre should 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 notify the HFEA as soon as it becomes aware of this.
- 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 15 – Procuring, processing and transporting gametes and embryos

Guidance Note 6 – Legal Parenthood

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 – Information to be provided prior to consent.
- 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 is outlined in guidance note 17 – removal of gametes and embryos within the storage period.
- 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, as defined by 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
 - c) taken by a person authorised by the centre to do so.

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 ~~declares that:~~
- a) ~~they~~ were given enough information to enable them to understand the nature, purpose and implications of the treatment or donation
 - b) ~~they~~ were given a suitable opportunity to receive proper counselling about the implications of the proposed procedures
 - c) ~~they~~ were given information about the procedure for varying or withdrawing consent, and
 - d) ~~the information they have~~ has 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. If a patient's identity is in doubt, 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 re-verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment.
- 5.14** 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 their treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is therefore still valid.
- 5.15** 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))
- 5.16** 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 22 – Research and training
 Guidance note 23 – The quality management system
 Guidance note 29 – Treating people fairly
 Consent forms

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.

- 5.17 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.
- 5.18 The centre should ensure that it documents in the medical records that:
- relevant information, as outlined in guidance note 4, has been provided to the person, and
 - 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
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:

- specify the maximum period of storage (if less than the statutory storage period), and
- 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.

Sperm first placed in storage before 1 August 1991 and which has been kept lawfully may legally continue without the written consent of the individual who provided the sperm for an extended period beyond the 10-year maximum storage period.

Sperm, eggs or embryos first placed in storage between 1 August 1991 and 1 October 2009 and which are being kept lawfully may legally continue without the written consent of the individual who provided the sperm, eggs or embryos for an extended period up to the provider's 55th birthday, or in the case of embryos, up to the 55th birthday of the woman being treated.

These changes do not affect sperm, eggs or embryos stored after 1 October 2009 or, if stored earlier than this, where the gamete provider subsequently provided a new consent under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009.

- 5.19 The centre should normally 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.

- 5.20** 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.
- 5.21** The gamete provider should be made aware that if they were to die or become mentally incapacitated, the gametes and embryos cannot be used in treatment unless consent to use has been provided and their partner has been named. It is therefore important that the patient updates their consent to include consent to use and the partner's name at the earliest opportunity.

See also

Guidance note 6 – Legal parenthood

Guidance note 17 – Storage of gametes and embryos

Consent forms

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

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.

- 5.22** 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.
- 5.23** 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.
- 5.24** 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
Consent forms

Additional consent requirements for those participating in a benefits in kind agreement

5.25 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.

5.26 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
Consent forms

Consent to examination and treatment

5.27 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.

5.28 The centre should comply with current professional guidelines on consent.

Consent to the presence of observers

5.29 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).

5.30 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.

5.31 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).

5.32 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).

5.33 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
Consent forms

Cases where consent is not required for storage

Mandatory requirements

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

Schedule 3

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 of mandatory requirements

5G

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

Conditions for storing the gametes of children without consent (including 16 or 17 year olds who are not competent to consent)

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 patient 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 patient 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 patient'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, 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. A registered medical practitioner must actively establish that the patient 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 patient has capacity within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991.

Condition D is that the patient 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.

Conditions for storing the gametes of persons who are 16 years and over

Paragraph 10 sets out the conditions that must be met before the gametes of a patient 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 patient 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 patient 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 patient lacks capacity to consent to their storage.

Condition D is that the patient 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 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). If the patient dies before providing this consent, the gametes can no longer remain in storage.

- 5.34** Before a centre can store ~~ing~~ a patient's ~~someone's~~ gametes without their consent, the centre must ~~should~~ ensure that it has met 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). 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 has been met. ~~judge that the person is not competent to consent to the storage of gametes.~~
- 5.35** When assessing a patient's ~~the~~ competence ~~of children and adults~~ to consent, the centre should follow current guidance produced by the Department of Health, the General Medical Council and other professional bodies.
- 5.36** ~~The centre should presume that it is in the child's best interests to store gametes unless circumstances suggest otherwise.~~ When assessing whether it is in a child's best interests to procure and store their gametes, the centre should refer to ~~applicable the~~ General Medical Council guidance ~~'0-18 years: guidance for all doctors'~~ and consider the child's short- and long-term best interests. Consent ~~to continue storing the gametes~~ should be sought from the child when they ~~are competent to give consent~~ ~~reach competence.~~
- 5.37** 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.

Competence

5.38 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.

- 5.39** 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.
- 5.40** 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 and HFEA Guide to Consent

Other legislation, professional guidelines and information

Consent to examination and treatment

[Reference Guide to Consent for Examination or Treatment \(Department of Health, April 2001\)](#)

[Consent: patients and doctors making decisions together \(General Medical Council\)](#)

[Human Tissue Authority Code of Practice 1: Consent \(Human Tissue Authority, September 2009\)](#)

[Gynaecological Examinations: Guidelines for Specialist Practice \(RCOG 2002\)](#)

Competence

[Consent: patients and doctors making decisions together \(General Medical Council, 2008\)](#)

[0-18 years: guidance for all doctors \(General Medical Council, 2007\)](#)

[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 \(Department of Health, 2004\).](#)

Legislation

[Mental Capacity Act 2005](#)

[Mental Capacity Act 2005 – Code of Practice \(2007\)](#)

[Age of Legal Capacity \(Scotland\) Act 1991](#)

[Adults with Incapacity \(Scotland\) Act 2000](#)

Copies of the relevant legislation can be found at: www.opsi.gov.uk

[Clinic Focus article: Harvesting sperm from deceased men \(October 2012\)](#)

[Chief Executive letter: CE 12 \(02\) \(May 2012\)](#)

Annex D – Amendments to the Code of Practice relating to consent to storage periods for eggs, sperm and embryos

NOTE: Changes related to consent periods are highlighted in red; deletions are highlighted in yellow.

Enclosed within Annex D

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

Guidance note 17: Storage of gametes and embryos

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

Version 9.0

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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(2ZA) 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.

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.

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 (3ZB) 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.

Interpretation

- 16
- (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.

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

Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991
The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

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 without written, effective consent from the gamete provider. There are, however, limited circumstances in which it may be possible to store a person's gametes without consent, provided that certain legal requirements are met. These are set out in paragraphs 9 and 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) (see 5G). These exemptions do not include where a person has died (including cases of brain stem death) without providing effective consent to the storage and use of their gametes, or where the gamete provider lacks capacity to give consent and is not expected to gain or regain it. The provisions of the Human Tissue Act 2004, which allow next of kin to give consent to procure, store or use other body tissues of the deceased, do not apply to gametes.

Anyone who procures, stores or uses gametes without valid and effective consent from the gamete provider may be committing an 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 informed 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 or mitochondria 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 UK centre must be satisfied that the requirements set out in General Directions 0006 are met. These include obtaining the consent of

the gamete provider(s) to their export 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 person responsible for the UK centre must be satisfied that the requirements set out in General Directions 0006 are met. These include the requirement that the provider has given written consent to the transfer of the gametes or embryos to the UK, and has not withdrawn that consent.

If the provisions of General Directions 0006 cannot be met, the UK centre may need to consider apply for a special direction to permit import or export.

Further requirements and the exemptions regarding obtaining consent to the use of gametes, cells and embryos for research (including for the creation of admixed embryos), and the exemptions, are outlined in guidance note 22 – Research and training.

Requirements regarding consent to parenthood are outlined in guidance note 6 – Legal parenthood, and General Directions 0006.

- 5.1** The centre should obtain written informed 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 the appropriate consent forms have been completed and that the completed forms contain the correct information, prior to treatment.
- 5.4** If, following treatment, the centre discovers errors in the consent provided by a patient or their partner, particularly in relation to legal parenthood, 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.
- 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 15 – Procuring, processing and transporting gametes and embryos
Guidance Note 6 – Legal Parenthood

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 – Information to be provided prior to consent.
- 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 is outlined in guidance note 17 – removal of gametes and embryos within the storage period.
- 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, and
 - c) taken by a person authorised by the centre to do so.

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:
- a) were given enough information to enable them to understand the nature, purpose and implications of the treatment or donation

- b) were given a suitable opportunity to receive proper counselling about the implications of the proposed procedures
- c) were given information about the procedure for varying or withdrawing consent, and
- d) has 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. If a patient's identity is in doubt, 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 re-verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment.
- 5.14** 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 course of treatment, or does not return with the patient for subsequent treatment, centres should take reasonable steps to find out from the patient's partner whether they still consent to their partner's treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is still valid.
- 5.15** 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))
- 5.16** 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 22 – Research and training
Guidance note 23 – The quality management system
Guidance note 29 – Treating people fairly
Consent forms

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.

- 5.17** 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.
- 5.18** The centre should ensure that it documents in the medical records that:
- relevant information, as outlined in guidance note 4, has been provided to the person, and
 - 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
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:

- specify the maximum period of storage (if less than the statutory storage period), and
- 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.

~~If sperm was in storage on 1 August 1991, storage may legally continue without the written consent of the individual who provided the sperm.~~

~~The 1991 Human Fertilisation and Embryology (Statutory Storage Period) Regulations allowed the 10-year statutory storage period for such gametes to be extended up to the gamete provider's 55th birthday without written consent, subject to certain conditions. If those conditions were not met, the gametes should have been allowed to perish on 31 July 2001, as the statutory storage period for gametes first placed into storage before the Act came into force is deemed to have started on 1 August 1991.~~

~~The 2009 Human Fertilisation and Embryology (Statutory Storage Period) Regulations provide a mechanism for successive 10-year extensions of storage, up to a maximum of 55 years. If gametes were being stored for an extended period (ie, under the 1991 Regulations) and that storage period had not expired by 1 October 2009, then the gametes may remain in storage for the balance of the period (as permitted by the schedule to the 1991 Regulations), or for the period stated in the 2009 Regulations.~~

Sperm first placed in storage before 1 August 1991 and which has been kept lawfully may legally continue without the written consent of the individual who provided the sperm for an extended period beyond the 10-year maximum storage period.

Sperm, eggs or embryos first placed in storage between 1 August 1991 and 1 October 2009 and which are being kept lawfully may legally continue without the written consent of the individual who provided the

sperm, eggs or embryos for an extended period up to the provider's 55th birthday, or in the case of embryos, up to the 55th birthday of the woman being treated.

These changes do not affect sperm, eggs or embryos stored after 1 October 2009 or, if stored earlier than this, where the gamete provider subsequently provided a new consent under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009.

- 5.19** The centre should normally 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.
- 5.20** 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.
- 5.21** The gamete provider should be made aware that if they were to die or become mentally incapacitated, the gametes and embryos cannot be used in treatment unless consent to use has been provided and their partner has been named. It is therefore important that the patient updates their consent to include consent to use and the partner's name at the earliest opportunity.

See also

Guidance note 6 – Legal parenthood

Guidance note 17 – Storage of gametes and embryos

Consent forms

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

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.

- 5.22** 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.
- 5.23** 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.

- 5.24** 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
Consent forms

Additional consent requirements for those participating in a benefits in kind agreement

- 5.25** 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.

- 5.26** 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
Consent forms

Consent to examination and treatment

5.27 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.

5.28 The centre should comply with current professional guidelines on consent.

Consent to the presence of observers

5.29 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).

5.30 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.

5.31 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).

5.32 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).

5.33 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
Consent forms

Cases where consent is not required for storage

Interpretation of mandatory requirements

5G

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.

Conditions for storing the gametes of children without consent (including 16 or 17 year olds who are not competent to consent)

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 patient 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 patient 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 patient'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, 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. A registered medical practitioner must actively establish that the patient 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 patient has capacity within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991.

Condition D is that the patient 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.

Conditions for storing the gametes of persons who are 16 years and over

Paragraph 10 sets out the conditions that must be met before the gametes of a patient 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 patient 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 patient 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 patient lacks capacity to consent to their storage.

Condition D is that the patient 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 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). If the patient dies before providing this consent, the gametes can no longer remain in storage.

- 5.34** Before a centre can store a patient's gametes without their consent, the centre must ensure that it has met 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). 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 has been met.
- 5.35** 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.
- 5.36** When assessing whether it is in a child's best interests to procure and store their gametes, the centre should refer to applicable General Medical Council guidance and consider the child's short- and long-term best interests. Consent to continue storing the gametes should be sought from the child when they are competent to give consent.

- 5.37** 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.

Competence

- 5.38** 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.

- 5.39** 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.
- 5.40** 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 and HFEA Guide to Consent

Other legislation, professional guidelines and information

Consent to examination and treatment

[Reference Guide to Consent for Examination or Treatment \(Department of Health, April 2001\)](#)

[Consent: patients and doctors making decisions together \(General Medical Council\)](#)

[Human Tissue Authority Code of Practice 1: Consent \(Human Tissue Authority, September 2009\)](#)

[Gynaecological Examinations: Guidelines for Specialist Practice \(RCOG 2002\)](#)

Competence

[Consent: patients and doctors making decisions together \(General Medical Council, 2008\)](#)

[0-18 years: guidance for all doctors \(General Medical Council, 2007\)](#)

[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 \(Department of Health, 2004\).](#)

Legislation

[Mental Capacity Act 2005](#)

[Mental Capacity Act 2005 – Code of Practice \(2007\)](#)

[Age of Legal Capacity \(Scotland\) Act 1991](#)

[Adults with Incapacity \(Scotland\) Act 2000](#)

Copies of the relevant legislation can be found at: www.opsi.gov.uk

[Clinic Focus article: Harvesting sperm from deceased men \(October 2012\)](#)

[Chief Executive letter: CE 12 \(02\) \(May 2012\)](#)

Guidance note 17: Storage of gametes and embryos

Version 8.0

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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.

(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 embryo shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, should 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 should 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 should 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

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

Regulations

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991
The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

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.

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.

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.

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).

~~If sperm was in storage on 1 August 1991, storage may legally continue without the written consent of the individual who provided the sperm.~~

~~The 1991 Human Fertilisation and Embryology (Statutory Storage Period) Regulations allowed the 10-year statutory storage period for such gametes to be extended up to the gamete provider's 55th birthday without written consent, subject to compliance with certain conditions. If those conditions were not met, the gametes should have been allowed to perish on 31 July 2001, as the statutory storage period for gametes first placed into storage before the Act came into force is deemed to have started on 1 August 1991.~~

~~The 2009 Human Fertilisation and Embryology (Statutory Storage Period) Regulations provide a mechanism for successive 10-year extensions of storage, up to a maximum of 55 years. If gametes were being stored for an extended period (ie, under the 1991 Regulations) and that storage period had not expired by 1 October 2009, then the gametes may remain in storage for the balance of the period (as permitted by the schedule to the 1991 Regulations) or for the period stated in the 2009 Regulations.~~

Sperm first placed in storage before 1 August 1991 and which has been kept lawfully may legally continue without the written consent of the individual who provided the sperm for an extended period beyond the 10-year maximum storage period.

Sperm, eggs or embryos first placed in storage between 1 August 1991 and 1 October 2009 and which are being kept lawfully may legally continue without the written consent of the individual who provided the sperm, eggs or embryos for an extended period up to the provider's 55th birthday, or in the case of embryos, up to the 55th birthday of the woman being treated.

These changes do not affect sperm, eggs or embryos stored after 1 October 2009 or, if stored earlier than this, where the gamete provider subsequently provided a new consent under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009.

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

2009 ('the 2009 regulations') allows gametes or embryos to be stored for longer than the 10 year standard storage period, for any period up to 55 years, if one of the gamete providers, their partner, or the person who the gametes or embryos have been allocated to, meet(s) the medical criteria for premature infertility.

To store gametes or embryos for an extended period, the centre must obtain the gamete provider's written consent to extended storage beyond 10 years and a written statement from a registered medical practitioner that one of the gamete providers, their partner, or the person who the gametes or embryos have been allocated to, is prematurely infertile or likely to become prematurely infertile. 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 the medical criteria for extended storage, including the 2009 regulations and how these regulations are satisfied. Patients should be aware that, if they satisfy the regulations, they can provide consent to extended storage when their gametes or embryos are first placed in storage or at a later date in the first 10 years.
- 17.17** To satisfy the regulations for extended storage periods, the centre should seek a written medical opinion towards the end of the 10 year standard storage period to certify that one of the gamete providers, their partner, or the person who the gametes or embryos have been allocated to, is prematurely infertile or likely to become prematurely infertile.
- 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.
- 17.19** When the criteria for extended storage 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.

Storage review

17.20 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.

- 17.21** 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 legal maximum storage period, or the period specified when the embryos or gametes were stored if shorter. Storing embryos or gametes beyond the relevant period is a criminal offence, punishable by a prison sentence, fine or both.

- 17.22** 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.
- 17.23** 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. 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

BFS/BAS/RCOG – UK Guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008)

The Human Tissue Authority

Department of Health- A Code of Practice for Tissue Banks Providing Tissues of Human Origin For Therapeutic Purposes

Department of Health- Guidance on the Microbiological Safety of Human Organs (2011)

Information on HTLV screening, issued in Clinic Focus, November 2010

Annex E – Corrections and minor clarifications to Code of Practice guidance

NOTE: Corrections and minor clarifications to Code of Practice guidance are highlighted in red; deletions are highlighted in yellow.

Enclosed within Annex E

Guidance note 27: Adverse incidents

Guidance note 16: Imports and exports

Guidance note 30: Confidentiality and privacy

Guidance note 27: Adverse incidents

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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 T106 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

27.11 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, issues with consent and ovarian hyperstimulation syndrome (OHSS) which requires a hospital admission and has a severity grading of severe or critical.

27.12 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'.

27.13 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’.

27.14 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 **serious** adverse incidents to the HFEA by telephone within 12 working hours of their identification. This verbal notification must include the:

- i) centre’s name
- j) HFEA centre identification number
- k) contact details of the person responsible
- l) date of the initial notification or report
- m) name of any individual affected
- n) date and time of the serious adverse event or reaction
- o) details of gametes or embryos involved in the incident, and
- p) type of incident, including any transmission of infectious agents.

In addition, the centre must inform the HFEA in writing of all adverse incidents 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.

The centre must email the completed form to incident.reporting@hfea.gov.uk within 24 working hours of discovering the incident.

27.15 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.

27.16 If an adverse incident or near miss occurs, centres are expected to:

- c) review relevant procedures to minimise the risk of the incident happening again, and
- d) inform the HFEA of the revised procedures.

27.17 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:

- g) management of resources
- h) training and competence of staff
- i) equipment
- j) materials
- k) information systems, and
- l) control of environment.

A copy of the investigation report should be submitted to the HFEA.

- 27.18** 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.
- 27.19** 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 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.
- 27.20** 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

- 26 – Equipment and materials
- 32 – Obligations and reporting requirements of centres
- 33 – Mitochondrial donation

Other legislation, professional guidelines and information

National Patient Safety Agency – Being open: communicating patient safety incidents with patients, their families and carers

NHS Litigation Authority – Apologies and Explanations

General Medical Council – Good Medical Practice

Nursing and Midwifery Council – The code: standards of conduct, performance and ethics for nurses and midwives

CQC guidance for NHS providers on Duty of Candour

National Health Service Litigation Authority guidance on “saying sorry”

Guidance note 16: Imports and exports

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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 import into the United Kingdom from a country which is not an EEA state, or to export from the United Kingdom to such a 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 imports or exports meet standards of quality and safety equivalent to those laid down in the Act, and
- (b) have regard to ensuring traceability.

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.

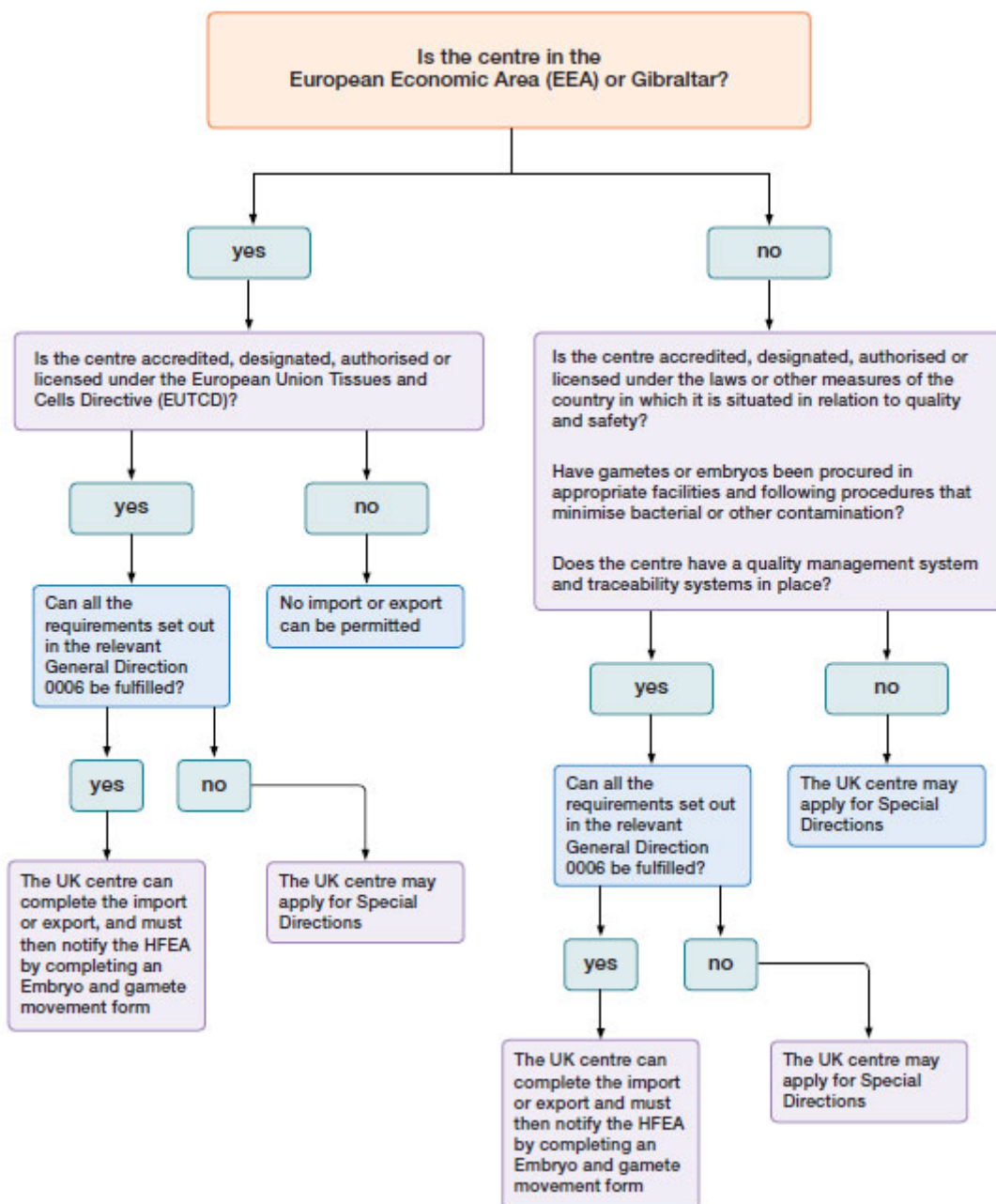
Information for patients and donors

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.



[Download the decision tree \(92 KB PDF\)](#)

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.

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 compliance with the other conditions 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.

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 **five** ~~ten~~ 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

For information on EEA countries and the relevant competent authorities there, you may find the following links useful:

[EEA countries](#)

Directions 0006: Import and export of gametes and embryos

Directions given under the Human Fertilisation and Embryology Act 1990 as amended

Import and export of gametes and embryos

Ref: 0006
Version: 5

These Directions are:	GENERAL DIRECTIONS
Sections of the Act providing for these Directions:	Sections 12 (1) (d) and (g); 24 (4) and (4A)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version issued on:	1 April 2017

1. Licensed centres may receive gametes or embryos from another centre in Gibraltar or in a European Economic Area (EEA) state other than the United Kingdom, if the conditions in Schedule 1 to these Directions are satisfied.
2. Licensed centres may send gametes and embryos outside the United Kingdom to another centre in Gibraltar or in a European Economic Area (EEA) state other than the United Kingdom, if the conditions in Schedule 2 to these Directions are satisfied.
3. Licensed centres may receive gametes or embryos from another centre in a non-European Economic Area (EEA) state other than Gibraltar, if the conditions in Schedule 3 to these Directions are satisfied.
4. Licensed centres may send gametes or embryos outside the United Kingdom to another centre outside of the European Economic Area (EEA) and Gibraltar, if the conditions in Schedule 4 to these Directions are satisfied.



Dr Andy Greenfield, HFEA member

21 October 2015

In accordance with the powers delegated by the Authority on 16 September 2015, under Section 6.6 of the Standing Orders.

Version control

Directions name:	Import and export of gametes and embryos
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Reference number:	0006
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Date version 1 issued:	1 October 2009
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Date version 7 issued:	1 April 2017
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Chair's letter reference:	CH(17)XX
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Schedule 1**Import of gametes and embryos from Gibraltar and the European Economic Area (EEA)**

1. Licensed centres may only receive gametes or embryos from another centre in Gibraltar or in a European Economic Area (EEA) state other than the United Kingdom if the following conditions are satisfied*:
 - (a) the centre from which the gametes or embryos are to be imported (the supplying centre) is accredited, designated, authorised or licensed under the laws or other measures of Gibraltar or the EEA state concerned, in accordance with the first, second and third Directives (2004/23/EC, 2006/17/EC and 2006/86/EC);
 - (b) the person who provided the gametes is (and in the case of an embryo, both persons who provided the gametes from which the embryo was created are) identifiable;
 - (c) the person who provided the gametes has (and in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being imported into the United Kingdom;
 - (d) before giving consent, the person(s) referred to in paragraph (c) has been given written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes or embryos are to be imported, and they have been given any further information which they may require;
 - (e) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits;
 - (f) the purpose of importing the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future; and
 - (g) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice that is currently in force.
2. Before any gametes or embryos are imported, the receiving centre must obtain written confirmation from the supplying centre or appropriate Competent Authority that the centre meets the requirements set out in paragraph 1 a) of this schedule. The receiving centre must also obtain written confirmation from the supplying centre that the requirements of paragraphs 1 (b), (c), (d), (e), (f) and (g) of this schedule have been met in relation to the gametes or embryos concerned. The written confirmation must be retained by the receiving centre for a period of three years and a copy provided to the Authority on request.
3. Whenever gametes or embryos are imported in accordance with these Directions, the Person Responsible of the receiving centre must ensure that the following information is submitted to the Authority using the Electronic Data Interchange (EDI) system, no later than **5** 10 working days after the import has taken place:
 - (a) the Donor Information form for each gamete donor (where donated gametes or embryos are imported);

- (b) the Patient and Partner Registration forms (where own gametes or embryos are imported); and
- (c) a notification of the import using the relevant Embryo and Gamete Movement – In (GI) form.

Schedule 2**Export of gametes and embryos to Gibraltar and the European Economic Area (EEA)**

1. Licensed centres may only send gametes and embryos outside the United Kingdom to another centre in Gibraltar or in an EEA state other than the United Kingdom (“the receiving centre”) if the following conditions are satisfied:
 - (a) the centre to which the gametes or embryos are to be exported is accredited, designated, authorised or licensed under the laws or other measure of Gibraltar or the EEA state concerned, in accordance with the first, second and third Directives (2004/23/EC, 2006/17/EC and 2006/86/EC) and in those cases where a centre wishes to export eggs or embryos created using either pronuclear transfer or maternal spindle transfer, the centre to which the eggs or embryos are to be exported is accredited, designated, authorised or licensed to undertake mitochondrial donation for the purpose of avoiding serious mitochondrial disease;
 - (b) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being exported to the country in which the receiving centre is situated;
 - (c) before giving consent, the person(s) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country to which the gametes or embryos are to be exported as it is in the United Kingdom, and they have been given any further information which they may require;
 - (d) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits;
 - (e) the purpose of exporting the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman carry a child or to be stored for such a purpose in the future;
 - (f) the gametes or embryos are not exported if they cannot be lawfully used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre; and
 - (g) the remaining term of the relevant storage period for the gametes or embryos, as provided for in section 15 (3) or (4) or by Regulations made under section 15 (5) of the Human Fertilisation and Embryology Act 1990 as amended, and the period for which the gametes and embryos may remain in storage in accordance with the consent(s) of the relevant gamete provider(s), are not less than 6 months from the date on which they are to be exported.
2. Before any gametes or embryos are exported, the supplying centre must obtain from the receiving centre or appropriate Competent Authority written confirmation that the receiving centre meets the requirements of paragraphs 1 (a). The written confirmation must be retained by the supplying centre for a period of 3 years and a copy provided to the Authority on request.

3. Whenever gametes or embryos are exported in accordance with these Directions, the Person Responsible of the supplying centre must ensure that the Embryo and Gamete Movement – Out (GO) form on the Electronic Data Interchange (EDI) system is completed and submitted to the HFEA no later than **5 10** working days after the export has taken place.
4. The supplying centre must keep all original records which it is required to maintain under its licence for the periods specified in Directions 0005 (Collecting and recording information for HFEA), but copies of the following documentation must accompany the gametes or embryos to the recipient centre:
 - (a) a copy of the consent form signed by each gamete provider;
 - (b) a copy of the Donor Information form for each gamete donor (where donated gametes or embryos are exported);
 - (c) a copy of the Patient and Partner registration forms (where own gametes or embryos are exported); and
 - (d) a copy of the relevant Embryo and Gamete Movement – Out (GO) form.

The supplying centre must notify the receiving centres and the HFEA if there are any changes to the information supplied.

Schedule 3**Import of gametes and embryos from outside of the European Economic Area (EEA) and Gibraltar**

1. Licensed centres may receive gametes or embryos from another centre in a non-EEA state other than Gibraltar, if the following conditions are satisfied*:
 - (a) the centre from which the gametes or embryos are to be imported (the supplying centre) is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated;
 - (b) the supplying centre has a quality management system in place which has been certified by an internationally recognised body;
 - (c) the supplying centre has a traceability system in place which ensures that all gametes and embryos are traceable from procurement of gametes to patient treatment and vice versa. The centre's traceability procedures should also include all materials or equipment that could have an impact on the quality or safety of the gametes or embryos;
 - (d) the procurement and processing of the gametes or embryos has taken place in appropriate facilities and following procedures that minimise bacterial or other contamination;
 - (e) the person who provided the gametes is (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, are) identifiable;
 - (f) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being imported into the United Kingdom;
 - (g) before giving consent, the person(s) referred to in paragraph (f) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes or embryos are to be imported, and have been given further information which they may require;
 - (h) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefits paid or received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits;
 - (i) the purpose of importing the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future; and
 - (j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice that is currently in force.

2. Before any gametes or embryos are imported, the receiving centre must obtain written confirmation from the supplying centre that the centre meets the requirements of paragraphs 1 (a), (b), (c) and (d) of this schedule. The receiving centre must also obtain written confirmation from the supplying centre that the requirements of paragraphs 1 (e), (f), (g), (h), (i) and (j) of this schedule will be complied with in relation to the gametes or embryos concerned. The written confirmation must be retained by the receiving centre for a period of 3 years and a copy provided to the Authority upon request.
3. Whenever gametes or embryos are imported in accordance with these Directions, the Person Responsible of the receiving centre must ensure that the following information is submitted to the Authority using the Electronic Data Interchange (EDI) system, no later than **5** 10 working days after the import has taken place:
 - (a) the Donor Information form for each gamete donor (where donated gametes or embryos are imported);
 - (b) the Patient and Partner Registration forms (where own gametes or embryos imported); and
 - (c) a notification of the import using the relevant Embryo and Gamete Movement – In (GI) form.

Schedule 4**Export of gametes and embryos outside of the European Economic Area (EEA)**

1. Licensed centres may send gametes or embryos outside the United Kingdom to another centre outside of the EEA and Gibraltar (“the receiving centre”) if the following conditions are satisfied:
 - (a) the receiving centre is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated and in those cases where a centre wishes to export eggs or embryos created using either pronuclear transfer or maternal spindle transfer, the centre to which the eggs or embryos are to be exported is accredited, designated, authorised or licensed to undertake mitochondrial donation for the purpose of avoiding serious mitochondrial disease;
 - (b) the receiving centre has a quality management system in place which has been certified by an internationally recognised body;
 - (c) the receiving centre has a traceability system in place which ensures that all gametes and embryos are traceable from procurement of gametes to patient treatment and vice versa. The centre’s traceability procedures should also encompass all materials or equipment that could have an impact on the quality or safety of the gametes and embryos;
 - (d) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being exported to the country in which the receiving centre is situated;
 - (e) before giving consent, the person(s) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country in which the receiving centre is situated as it is in the United Kingdom, and they have been given any further information which they may require;
 - (f) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with the Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving of money or other benefits;
 - (g) the purpose of exporting the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future;
 - (h) the gametes or embryos are not exported if they could not lawfully be used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre; and
 - (i) the remaining term of the relevant storage period for the gametes or embryos, as provided for in section 15 (3) or (4) or by Regulations made under section 15 (5) of the HFE Act 1990 amended, and the period for which the gametes and embryos may remain stored in accordance with the

consent(s) of the relevant gamete provider(s), are not less than 6 months from the date on which they are to be exported.

2. Before any gametes or embryos are exported the supplying centre must obtain from the receiving centre written confirmation that the receiving centre meets the requirements of paragraph 1 (a), 1 (b) and 1 (c) of this schedule. The written confirmation must be retained by the supplying centre for a period of three years and a copy provided to the Authority upon request.
3. Whenever gametes or embryos are exported in accordance with these Directions, the Person Responsible of the supplying centre must ensure that the Embryo and Gamete Movement – Out (GO) form on the Electronic Data Interchange (EDI) system is completed and submitted to the HFEA no later than **5 10** working days after the export has taken place.
4. The supplying centre should keep all original records which it is required to maintain under its licence for the periods specified in Directions 0005 (Collecting and recording information for the HFEA), but copies of the following documentation must accompany the gametes or embryos to the recipient centre:
 - a) a copy of the consent form signed by each gamete provider;
 - b) a copy of the Donor Information form for each gamete donor (where donated gametes or embryos are exported);
 - c) a copy of the Patient and Partner Registration forms (where own gametes or embryos are exported); and
 - d) a copy of the relevant Embryo and Gamete Movement – Out (GO) form.

The supplying centre must notify the receiving centres and the HFEA if there are any changes to the information supplied.

Guidance note 30: Confidentiality and privacy

Version 5.0

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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.

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 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.

30.2 If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

Breach of confidentiality

30.3 If confidentiality is breached, the centre should investigate, deal with the breach, and submit a full explanation to the HFEA. If it appears that a criminal offence has been committed, the centre should inform the police.

Access to medical records

- 30.4** 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.
- 30.5** The centre must establish a documented procedure for controlling access to medical records. This should ensure that arrangements are in place for:
- properly identifying applicants
 - promptly considering and responding to applications for access to confidential records
 - a designated individual in the centre being responsible for receiving, checking and arranging authorised access to confidential records
 - notifying the Information Commissioner in line with the Data Protection Act 1998
 - giving all individual donors and recipients who provide information about themselves access to their own individual records of that information and an opportunity to correct it
 - ensuring proper procedures are in place to maintain confidentiality when records are stored off site, and
 - ensuring that individuals are aware of their rights under the Data Protection Act 1998 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.
- 30.6** 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.
- 30.7** To mitigate the risks of unauthorised people inadvertently gaining access to patient-identifying information through electronic records, the centre should:
- ensure that such information cannot be transferred to portable media-storage devices
 - ensure that when hardware is removed from the premises, identifying information has been removed
 - 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
 - record and audit potential access to identifying information
 - 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)
 - know what software is installed on centre systems and what it allows
 - ensure agreements/contracts with the relevant providers set out expectations.
- 30.8** 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.
- 30.9** 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.

Requests under the Data Protection Act 1998

- 30.10** The centre should comply promptly with ‘subject access requests’ made under the Data Protection Act 1998. 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 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.
- 30.11** When proof of identity and payment has been received, the centre has 40 calendar days 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).
- 30.12** The centre should take into account any other exceptions and modifications to the Data Protection Act 1998 before giving access.

Disclosing non-identifying information: general

- 30.13** 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.

- 30.14** 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.

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.

- 30.15** 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 not give the donor any information about the person making the application.

Disclosing information to recipients of donated gametes and embryos

- 30.16** 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.
- 30.17** The HFEA may also disclose the information that centres may disclose in these circumstances, if that information is contained on its Register.
- 30.18** The centre should:
- reassure donors and potential donors that they may ask at any time how many children have resulted from their donation
 - reassure identifiable donors that attempts will be made to contact them before their identity is disclosed to a donor-conceived person
 - encourage identifiable donors to provide up-to-date contact details to help this, and
 - 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).

- 30.19** 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.
- 30.20** 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).
- 30.21** 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).
- 30.22** 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.

Other legislation, professional guidelines and information

Legislation

Human Rights Act 1998

European Convention for the Protection of Human Rights and Fundamental Freedoms

Data Protection Act 1998

The Data Protection (Subject Access Modification) (Health) Order 2000

Access to Health Records Act 1990

Access to Health Records (Northern Ireland) Order 1993

Professional guidelines

Care Quality Commission - Code of Practice on confidential personal information (2010) Confidentiality:

NHS Code of Practice (2003)

Records Management: NHS Code of Practice (2006)

General Medical Council – Confidentiality guidance: Protecting information (2004) Guidance from the Information Commissioner