

# Authority meeting – agenda

**11 September 2019**

**ETC.venues Victoria, 1 Drummond Gate  
SW1V 2QQ**

| Agenda item   | Time    |
|---|---------|
| 1. Welcome, apologies and declaration of interests  | 12.45pm |
| 2. Minutes of 03 July 2019 Authority meeting<br><b>HFEA (11/09/19) 923</b><br>For decision  | 12.50pm |
| 3. Chair's report (verbal)  | 12.55pm |
| 4. Chief Executive's report (verbal)  | 1.00pm  |
| 5. Committee chairs' reports (verbal)<br>Licensing activity report (paper)<br><b>HFEA (11/09/19) 924</b><br>For comment   | 1.05pm  |
| 6. Performance report<br><b>HFEA (11/09/19) 925</b><br>For information  | 1.15pm  |
| 7. EU Exit<br><b>Verbal update</b><br>For decision  | 1.25pm  |
| 8. Business planning for 2020-2023<br><b>HFEA (11/09/19) 926</b><br>For decision  | 1.35pm  |
| <b>Break</b>  | 2.00pm  |
| 9. Treatment add-ons<br><b>HFEA (11/09/19) 927</b><br>For decision  | 2.15pm  |
| 10. DNA testing update<br><b>HFEA (11/09/19) 928</b><br>For comment   | 2.45pm  |
| 11. Update on other strategic priorities <ul style="list-style-type: none"> <li>• Leadership</li> <li>• Patient support</li> </ul> <b>Presentation</b><br>For comment | 3.05pm  |
| 12. Any other business  | 3.25pm  |
| 13. Close   | 3.30pm  |

# Minutes of Authority meeting 3 July 2019

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

## Details:

|              |                                    |
|--------------|------------------------------------|
| Meeting      | Authority                          |
| Agenda item  | 2                                  |
| Paper number | HFEA (11/09/19) 923                |
| Meeting date | 11 September 2019                  |
| Author       | Debbie Okutubo, Governance Manager |

## Output:

|                              |   |
|------------------------------|---|
| For information or decision? | For decision  |
| Recommendation               | Members are asked to confirm the minutes as a true record of the meeting                              |
| Resource implications        |   |
| Implementation date          |   |
| Communication(s)             |   |
| Organisational risk          | <input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High |

Annexes

## Minutes of the Authority meeting on 03 July 2019 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

|                     |   |   |
|---------------------|---|---|
| Members present     | Sally Cheshire<br>Margaret Gilmore<br>Anita Bharucha<br>Anthony Rutherford<br>Emma Cave<br>Rachel Cutting | Bobbie Farsides<br>Jonathan Herring<br>Gudrun Moore<br>Ruth Wilde<br>Yacoub Khalaf<br>Ermal Kirby |
| Apologies           | Anne Lampe<br>Kate Brian  |   |
| Observers           | Steve Pugh<br>Dafni Moschidou<br>(Department of Health and Social<br>Care - DHSC)                         |   |
| Staff in attendance | Peter Thompson<br>Clare Ettinghausen<br>Richard Sydee<br>Catherine Drennan                                | Laura Riley<br>Paula Robinson<br>Debbie Okutubo   |

### Members

There were 12 members at the meeting – eight lay members and four professional members.

## 1. Welcome, apologies and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present. She stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not at the meeting to listen to deliberations.
- 1.2. There were two apologies for absence, Anne Lampe and Kate Brian.
- 1.3. Declarations of interest were made by;
  - Rachel Cutting (Person Responsible (PR) at a licensed centre)
  - Yacoub Khalaf (PR at a licensed clinic)
  - Anthony Rutherford (Clinician at a licensed clinic)

## 2. Minutes of Authority meeting held on 8 May 2019

- 2.1. Members agreed that the minutes of the meeting held on 8 May 2019 be signed by the Chair subject to corrections handed in before the meeting.

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### 3. Chair's report

- 3.1.** On 29 May, the Chair met Michael Johnson-Ellis from twodaddies.co.uk, to discuss how they could work together to help couples from the LGBT community.
- 3.2.** The Chair and Chief Executive (CE) later that day had the Annual Accountability meeting with the Department of Health and Social Care (DHSC). The Chair described it as a positive meeting and explained that the DHSC recognised our achievements and performance for the past year.
- 3.3.** On 12 June, the Director of Strategy and Corporate Affairs, CE and the Chair met Jane Denton to discuss possible next steps on reducing multiple births and a range of other strategic issues.
- 3.4.** Later that day the Chair and CE went to the House of Lords to attend the 20th Anniversary celebrations of the National Institute of Health and Care Excellence (NICE).
- 3.5.** The Chair thanked members and staff involved in the HFEA Conference on 13 June for helping to make it such a success. She noted that the fact that we reached capacity early and had a waiting list showed just how sought-after places were. She further commented that this year we focused on providing learning opportunities, with four workshops running three times in the day. Early indications were that the day was very well received. Feedback was being analysed and the Chair had written to thank all speakers.
- 3.6.** On 28 June the Chair met Jane Stewart, the Chair of the British Fertility Society (BFS), in York.
- 3.7.** Lastly, it was noted that the annual ESHRE conference was held in Vienna and members of the HFEA's Scientific and Clinical Advances Advisory Committee (SCAAC) had hosted the annual horizon scanning meeting with international colleagues.

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### 4. Chief Executive's report

- 4.1.** On 14 May, the CE gave a presentation on regulation and innovation to the Regulators Innovation Network seminar organised by the Department of Business, Energy and Industrial Strategy. The CE commented that the Government's recent publication on regulation and the 'fourth industrial revolution' (artificial intelligence etc.) featured a case study of our work on mitochondrial donation.
- 4.2.** On 21 May the CE had a visit from Osamu Ishihara MD, Professor and Chair from the Department of Obstetrics and Gynaecology at Saitama Medical University, who was reviewing the regulatory scheme in Japan and wanted to see how we did things.
- 4.3.** On 23 May the CE met with Kazuto Kato, Professor and Chair of the Department of Biomedical Ethics and Public Policy School of Medicine, Osaka University.
- 4.4.** Later that day the CE had a meeting with Michael Morrison from the University of Oxford, who is working on a research project looking at the regulation of new technologies in ART, and another meeting proposed with Joyce Harper, one of the SCAAC advisers.
- 4.5.** On 29 May the CE attended the Licenced Centres Panel meeting.

- 4.6.** On 30 May Professor Nick Macklon and Dr Kamal Ahuja from London Woman's Clinic had a meeting with the CE to discuss the rules relating to the import and export of donated material in the UK.
- 4.7.** On 4 June the CE had a meeting with Denise Kaye and Julie Ounaha from the Department for International Trade, to discuss how best they could support us in providing advice to overseas' governments in relation to health and social care.
- 4.8.** On 7 June the CE attended an Association of Chief Executives (ACE) seminar on Brexit, devolution and the impact on public services and another ACE event on 27 June on the role of public bodies in the government's industrial strategy.
- 4.9.** On 13 June the CE attended our Annual Conference. He expressed his thanks to staff and members for their contribution to making the day such a success. Looking ahead the plan was to step back and review our stakeholder engagement activities in the round, to see what role future conferences could play.
- 4.10.** On the same day, the CE had a meeting with Louise Johnson, CEO of VARTA, the regulatory body for ART in Victoria, Australia. He noted that challenges faced by VARTA and the HFEA were very similar and included developments in DNA testing and treatment add-ons.
- 4.11.** On 19 June, the CE and Policy Manager gave evidence to the House of Commons' Women and Equalities Select Committee as part of their inquiry into the provision of health and social care to LGBT communities.
- 4.12.** On 20 June, the Director of Finance and Resources, Director of Strategy and Corporate Affairs and the CE met with the Competition and Markets Authority.
- 4.13.** On 25 June, the CE attended a DHSC delivery partners meeting on EU Exit. He described it as the first of many in an increase in planning activity around preparations for a potential 'no deal' EU exit on 31 October.

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## **5. Committee Chairs' reports**

### **Licence Committee**

- 5.1.** The deputy Chair of the Licence Committee reported that the committee met on 2 May 2019 and considered seven items: one initial research; one renewal research; three renewals for treatment and storage, which were all granted, and two executive updates which were noted.

### **Statutory Approvals Committee**

- 5.2.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 30 May 2019 and considered three pre-implantation genetic diagnosis (PGD) items. Two PGD applications were approved and the minutes signed. One PGD application was adjourned pending further information.
- 5.3.** On 27 June 2019 two PGD applications and two Special Direction were considered. The Chair of SAC advised that the minutes from the June meeting were still in draft.

### **Executive Licensing Panel**

- 5.4.** The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met five times since the last Authority meeting, on 1 May, 7 May, 21 May, 4 June and 25 June. The panel

considered 15 items in total: two licence renewal applications; seven interim inspection reports; five licence variation applications; and one application for Special Directions.

- 5.5.** The Chair of ELP also reported that 13 Licensing Officer considerations were approved: nine for EU certificates, three for changes of Licence Holder and one for a change of centre name.

### **Audit and Governance Committee (AGC)**

- 5.6.** The Chair of the Audit and Governance Committee (AGC) reported that the committee met on 18 June and aside from the usual standing items and updates from the internal and external auditors, the committee also received reports on:
- responding to organisational capability, staff opinion and turnover and ongoing work around corporate values
  - an update on the office move, which is on the agenda for this Authority meeting
  - an update from the digital programme on progress relating to system development, data migration and the implementation of the new register
  - updates on resilience, business continuity management and cyber security
  - The Cabinet Office revised Functional Standards for Counter Fraud, which provided the committee with a benchmark against which they would assess our counter fraud activities and approach
  - the strategic risk register
  - existing contracts
  - the draft annual report and accounts.

### **Scientific and Clinical Advances Advisory Committee**

- 5.7.** The Chair of the SCAAC welcomed five new members at the June meeting, including Erial Kirby and four new external advisers. SCAAC is now made up of five Authority Members and 11 external advisers.
- 5.8.** Topics discussed at the meeting were Artificial Intelligence (AI), the new 2020 – 2023 HFEA Strategy, Fertility trends, Embryo culture media. Topics for the annual HFEA horizon scanning meeting that took place during the ESHRE conference were also discussed and would be integrated as appropriate into their workplan.

### **Decision**

- 5.9.** Members noted the Committee chairs' reports.

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## **6. Licensing and approvals activity report**

- 6.1.** A new report, to garner Authority members' views on its usefulness, was presented by the Head of Planning and Governance.
- 6.2.** The Head of Planning and Governance suggested that the intention of the report was to enhance the current way of reporting, making the information easier to digest and more informative for members, by providing it in paper form and giving some longer-term trends alongside the recent picture, for context and interest.

- 6.3.** Members were invited to comment. Members noted that it was useful to see trends and know that it could help towards better planning. It also reflected the volume and complexity of work carried out by inspectors and the licensing team, as well as the committees themselves.
- 6.4.** Members suggested that should this format of reporting licensing information be taken forward, that it would still need to maintain transparency by including previous committee decisions.
- 6.5.** Members agreed that this report needed to measure and discuss issues that were different from the State of the Sector report on compliance provided to Authority on an annual basis.

## Decision

- 6.6.** Authority members agreed to receive further reports to note, and that the Head of Planning and Governance should review the measures and data included over time.

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## 7. Audit and Governance Committee annual report

- 7.1.** The Chair of the Audit and Governance Committee (AGC) presented the annual report summarising the AGC's activity during the year and gave the Committee's opinion on HFEA's risk management and internal control arrangements.
- 7.2.** She commented that the Committee remained satisfied with the arrangements for risk management and the assurance processes and that the report formed part of the assurance process which supported the Accounting Officer's Annual Governance Statement.
- 7.3.** The AGC Chair also stated that the issue of proportionality played a key role. The size of the organisation determined what recommendations could be taken on and to what extent. It was noted that during the review of committee effectiveness this was also highlighted.
- 7.4.** There was some discussion about the role of the AGC. In response to a question, the Director of Finance and Resources commented that the Authority delegated responsibility to the AGC in relation to the annual report and accounts and the AGC then hold the Executive to account. The CE in his capacity as the Accounting Officer signs off the accounts if there are no material changes following the AGC meeting.
- 7.5.** The Chair of the Authority commented that we needed to feel assured because as an organisation we take audit and governance very seriously and this puts the Authority and the organisation in a good position for such a small organisation. She further thanked the four AGC members for their robust scrutiny.

## Decision

- 7.6.** Authority members noted that the HFEA's governance systems was well established and there was a commitment to making continuous improvements to them.
- 7.7.** They also noted that the AGC was satisfied with the arrangements for risk management and the assurance processes.
- 7.8.** Lastly that the CE in his capacity as the Accounting Officer would sign off the annual accounts.

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## 8. Performance report

- 8.1. A report summarising performance data up to the end of May 2019 was presented to the Authority.
- 8.2. The Director of Strategy and Corporate Affairs commented that a range of initiatives and events had either taken place or were scheduled to take place during and after the summer, including the Law Commission's consultation on surrogacy, following up on changes to the Code of Practice from last year and looking forward to the leadership event for PRs in the autumn. Members were thanked for their support on particular areas of work such as patient support and clinic leadership.
- 8.3. The Director of Strategy and Corporate Affairs would be attending the next meeting of the Women's Health Taskforce with Kate Brian.
- 8.4. The Authority's ambition to enhance the use of our data was starting to be realised with a record amount of interest in using our data. Further information would be brought to Authority later in the year in a report on the Register Research Panel.
- 8.5. Members suggested that the Executive could make better use of Clinic Focus to disseminate information and that it would also assist in the coverage of debates and enable better collaboration.
- 8.6. The Director of Finance and Resources provided an overview of ??? and income issues and stated that at the end of the first quarter, we would take a critical look at financial requirements across all directorates and review our income expectations.
- 8.7. The CE (in the absence of a Director of Compliance and Information) commented that the director appointment process was ongoing and interviews were set to be held later in the month. The CE thanked the inspection team for covering the management gap.
- 8.8. Lastly, the CE commented that the team were preparing for the new State of the Sector report in the Autumn and that there was progress on international work including in the United Arab Emirates (UAE) and possibly Costa Rica.

## Decision

- 8.9. Members noted the latest performance report.

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## 9. Code of Practice

- 9.1. The proposed changes to the Code of Practice were presented to the Authority.
- 9.2. The Human Fertilisation and Embryology Act 1990 (as amended) (the Act) covered the use and storage of sperm, eggs and embryos for human application, as well as all research involving the use of human and admixed embryos.
- 9.3. It was noted that one of the purposes of the Code of Practice was to support licensed clinics to comply with the Act and relevant legislation by regularly reviewing, updating and publishing the Code, as it provided guidance on licensed activities for professionals that performed them.



- 9.4.** The Code also serves as a useful reference for patients, donors, donor-conceived people and researchers.
- 9.5.** Authority decisions on changes to the Code were needed in relation to:
- Updated sperm screening requirements
  - Direct-to-consumer DNA testing and matching services and the potential impact on donor anonymity
  - Definition of 'failed to fertilise eggs'.
- 9.6.** In addition there were other minor changes to provide clarification or incorporate statutory changes.
- 9.7.** Members were invited to comment on and approve the proposed changes.
- 9.8.** There was some discussion on reasonable expenses and good quality counselling for donors.
- 9.9.** The Executive advised that at s.15.4 the current Code already provides that sperm should be supplied for insemination at home (or another unlicensed site) in exceptional circumstances. The proposed addition is about clarifying that if home insemination does take place, clinics should make sure all other requirements have been met in the same way as if insemination had taken place at the treatment centre; including around the provision of information, offer of counselling and obtaining all relevant consents.
- 9.10.** Members had concerns that it could not be guaranteed that home insemination would be genuinely used as there was room for abuse.
- 9.11.** Members suggested that for greater oversight the wording might be changed to require home insemination only 'under clinical supervision'.

## Decision

- 9.12.** Members agreed the changes to:
- surrogacy and parental orders for single people.
  - sperm screening requirements
  - direct-to-consumer DNA testing and matching services
  - the definition to the phrase 'failed to fertilise eggs'
- 9.13.** Members asked the Executive to consider the new wording on:
- Compensation for donors and
  - Home insemination
- 9.14.** with a consideration also to be made of the alternative or additional wording proposed by members within the discussion on these topics. Members asked to be updated at a future meeting with further information around the current policy positions on these topics and their origins.
- 9.15.** Lastly, the Executive were asked to ensure that consistency of language on the counselling offer is used throughout the proposed additions to the Code.

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## 10. Estates update - business case

- 10.1.** The Director of Finance and Resources presented this item to the Authority. It was noted that the HFEA's lease on its current office accommodation, 10 Spring Gardens, would expire at the end of November 2020.
- 10.2.** The Department of Health and Social Care (DHSC) initiated a programme in mid-2018 to move the majority of its central London Arms-Length Boards (ALBs) estate to 'zone 2' locations in line with the wider hub strategy for the Government's London estate. The proposal is that the HFEA moves to new offices in Stratford, east London along with several other Health ALBs
- 10.3.** The DHSC will fund the project and programme support and the cost of physical relocation of organisations to the new accommodation.
- 10.4.** Overall cost would be dependent on final space allocation, in particular the approach taken for shared areas, meeting space and the conference facilities which would be finalised over coming weeks and ahead of signing contracts.
- 10.5.** The Director of Finance and Resources stated that an office move focus group was established in March 2019 to directly involve staff across the organisation in the finalisation of designs and new ways of working in the new accommodation.
- 10.6.** In response to a question, it was noted that feedback regarding the proposed new office layout was positive and the new facilities could provide a significant improvement on the existing accommodation.
- 10.7.** Inevitably the new location would present commuting issues for some employees, but as we move forward with the project the initial focus will be on considering how to mitigate the impact of the move for staff. This would include review of existing home and flexible working policies as well as the provision of excess fares where appropriate.
- 10.8.** It had been added to the strategic risk register as a number of areas had been identified in which the office relocation could impact on the delivery of operational and strategic goals. These include, but not limited to:
- Move to Stratford leading to increased staff turnover
  - Staff resource diverted to relocation activity, negatively impacting on operational delivery
  - Post move facilities not meeting all HFEA requirements – including hosting of meetings.
- 10.9.** In response to a question, it was noted that the floor plan will be shared with Authority members in due course. Members further noted that there were benefits of co-location but the move towards home working needed to be properly managed to avoid fragmentation of teams.

## Decision

- 10.10.** The Authority approved the intent to proceed with the move to Stratford subject to affordability and formal contractual commitment to the move.
- 10.11.** Members delegated sign off of the office move to the Executive.

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## 11. Strategy consultation update

- 11.1. The Head of Planning and Governance gave an update on the strategy consultation. It was noted that she had focussed on the stakeholder engagement events to date and had drawn on the key themes from their feedback.
- 11.2. There had been positive feedback. The full draft strategy and a summary of all consultation feedback will be presented at the November 2019 Authority meeting.
- 11.3. Members suggested that individual letters could be sent to PRs to encourage them to complete the consultation survey.

### Decision

- 11.4. Members noted the update.

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## 12. Any other business

- 12.1. There was no other business.

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## 13. Chair's signature

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

Signature

Chair: **Sally Cheshire**

Date: 11 September 2019

# Licensing activity report

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

## Details:

Meeting Authority

Agenda item 5

Paper number HFEA (11/09/2019) 924

Meeting date 11 September 2019

Author Paula Robinson, Head of Planning and Governance

## Output:

For information or decision? For information

Recommendation The Authority is invited to note the latest licensing activity report.

Resource implications -

Implementation date -

Communication(s) -

Organisational risk  Low  Medium  High

Annexes Annex 1: Licensing activity report

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## 1. Introduction

- 1.1. The attached report sets out information about licensing throughput and outcomes in June and July 2019.
- 1.2. Over time, we will continue to keep this recently introduced report under review. Some elements may benefit from a year to year comparison, rather than being shown each time.
- 1.3. At the last meeting, we agreed to avoid overlap with the annual state of the sector report on compliance and inspection activities. Therefore, information about the current licence lengths of centres has not been added to this report, since that is an outcome of regulatory performance.

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## 2. Recommendation

- 2.1. Authority members are invited to note this report.

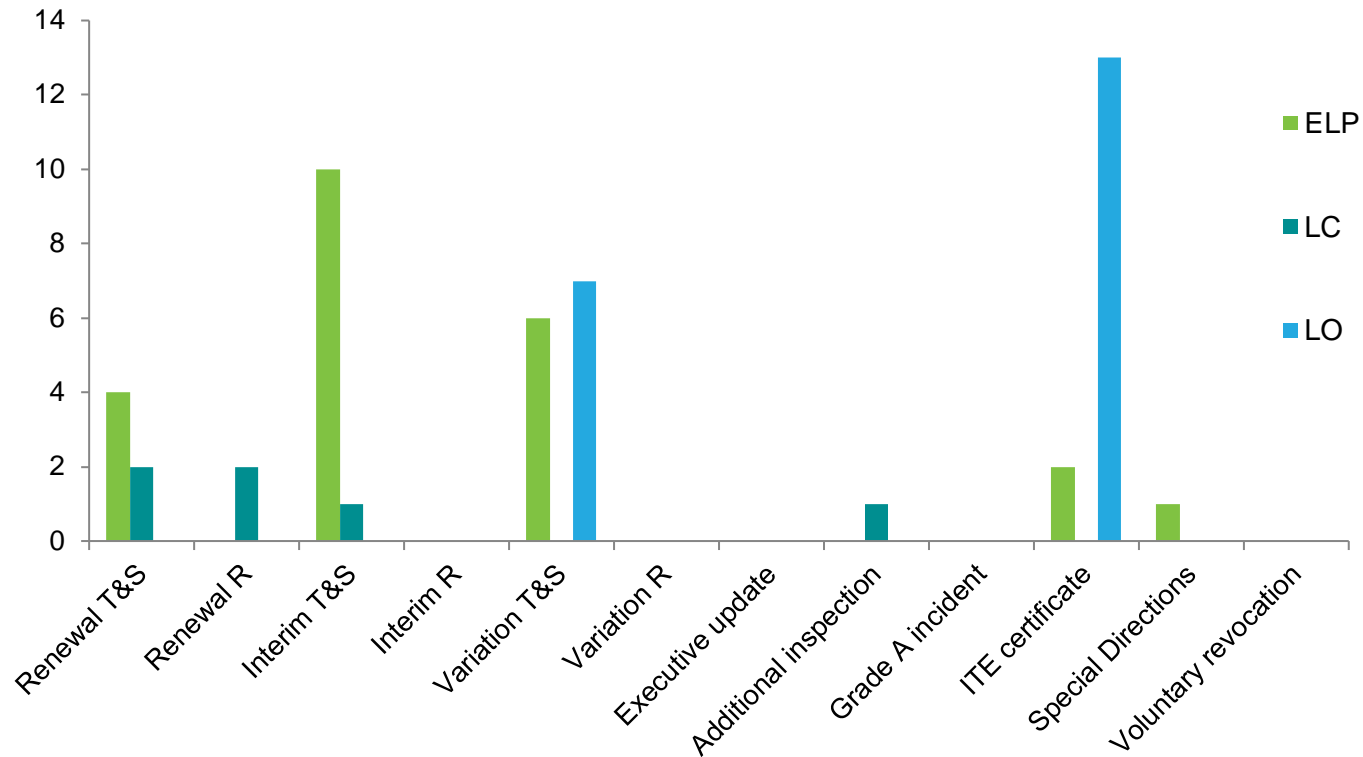
## Annex 1 - Licensing activity report for 1 June 2019 to 31 July 2019

### Outcomes of recent items by committee: 1 June – 31 July

| Committee <sup>1</sup> | Granted | Other | Not yet confirmed | Comments   |
|------------------------|---------|-------|-------------------|--|
| <b>LC</b>              | 6       | 0     | 0                 | There were some complex judgements to be made concerning certain licence renewals where there were concerns about compliance based on inspection findings. The Committee has also begun to approve renewals of importing tissue establishment (ITE) certificates alongside licence renewals, as these are now renewed at the time of inspection. |
| <b>ELP</b>             | 18      | 1     | 0                 | The majority of items were straightforward interims, renewals and licence variations. One item was referred to Licence Committee (based on the range of non-compliances found on inspection) and required special directions to be issued, to ensure the licence does not run out.   |
| <b>LO</b>              | 18      | 0     | 0                 | The majority of items (12) are still ITE certificates, but in addition the number of variations of Licence Holder and centre name were higher than usual (six) in June and July.   |
| <b>SAC</b>             | 8       | 0     | 0                 | Agendas remained smaller than has been typical at this time in previous years. The number of similar PGD (preimplantation genetic diagnosis) condition types considered ranged between one and 15 per item. Two special directions for export were also considered and approved in June.   |

<sup>1</sup> LC = Licence Committee ELP = Executive Licensing Panel LO = Licensing Officer SAC = Statutory Approvals Committee

## Decisions made by LC, ELP and LO



### Commentary

ITE certificate granting via the LO continues to be relatively high, but is lower than the last period. The remainder shows a typical pattern of ELP and LC item types. The overall volume of items is slightly higher than in the same period in 2018.

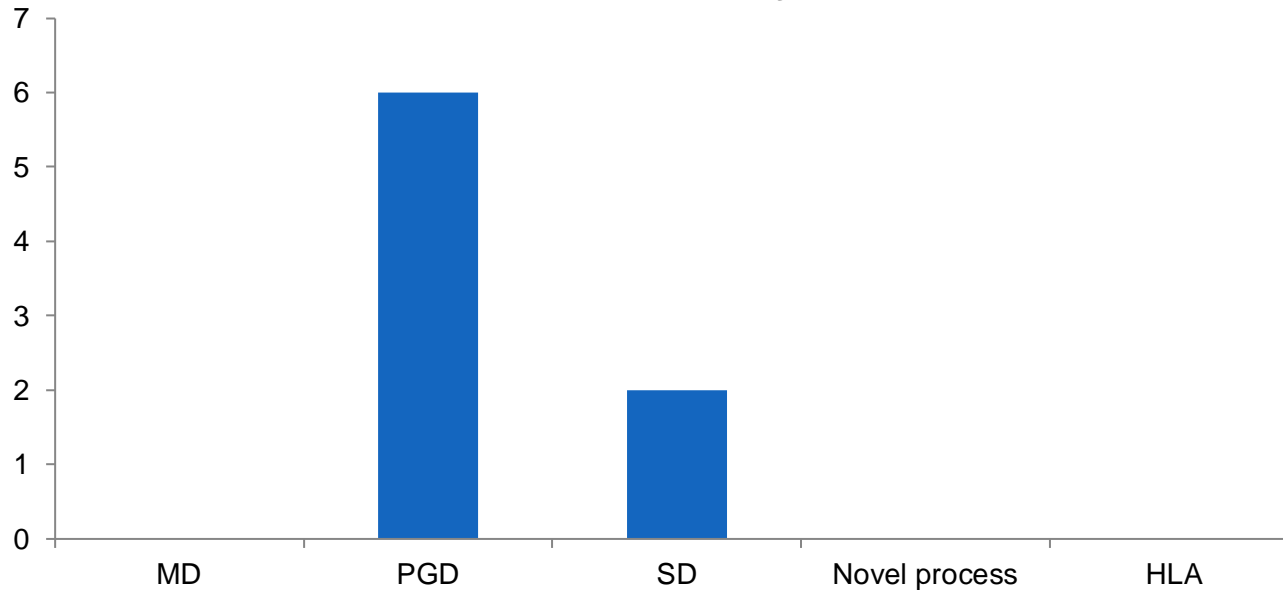
### Key:

T&S = treatment and storage

R = research

ITE = importing tissue establishment

## Decisions made by SAC



### Commentary

The pattern so far this calendar year has been different from previous years as the volume of items has been lower. Most items are PGD applications. There is continuing variation in the number of types considered under each application (from one to 15 in this period).

There have been no new mitochondrial donation items since January 2019.

### Key:

MD = mitochondrial donation

PGD = preimplantation genetic diagnosis

SD = special directions for import or export

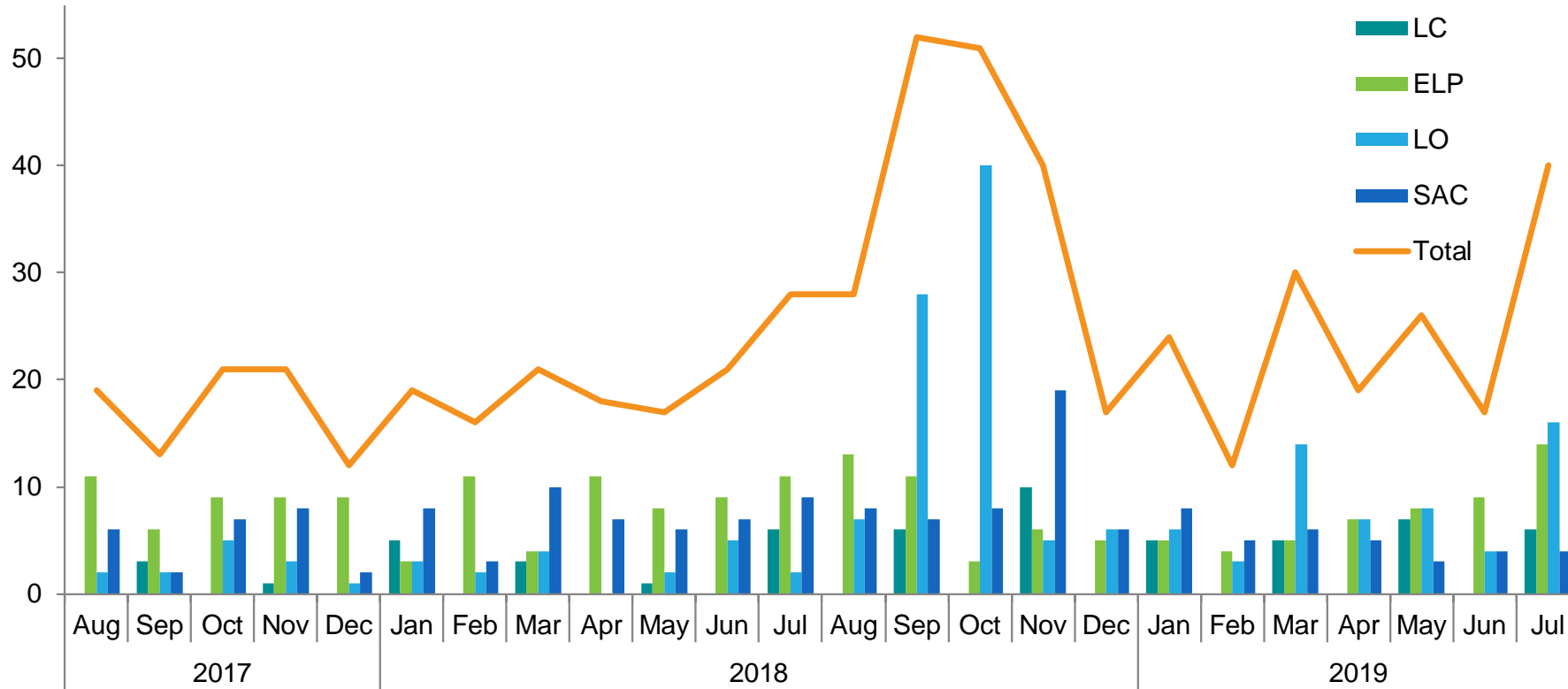
HLA = human leucocyte antigen



## Longer term trends – two year rolling report

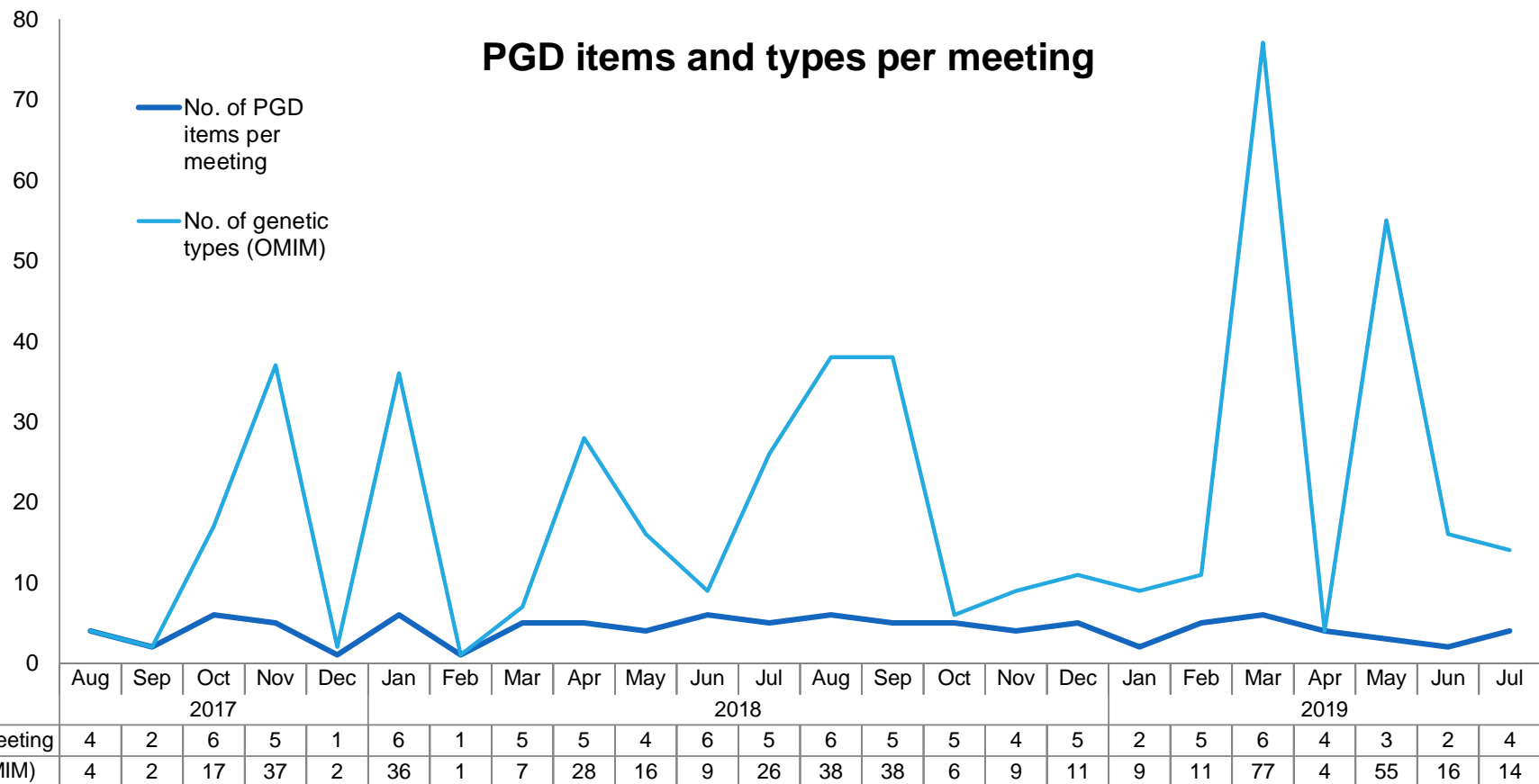
Item numbers per committee across the last two years (rolling picture) – all committees

### Number of items - August 2017- July 2019



We will continue to monitor for trends.

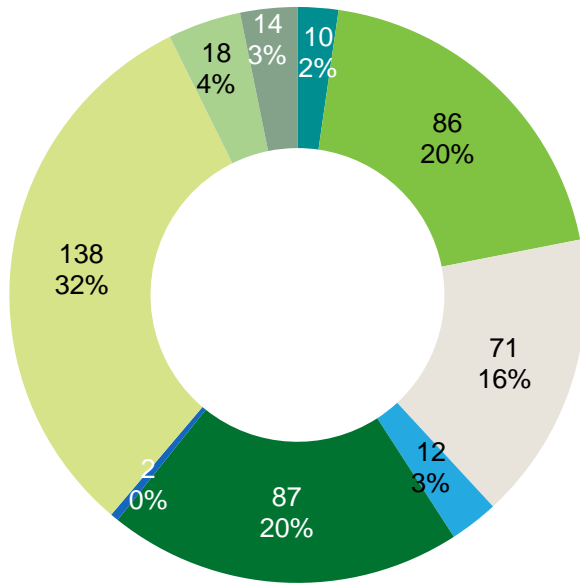
PGD types considered – trend over time: August 2017 – July 2019



There is continuing variation in the number of similar types considered with any given PGD application. We will continue to monitor this. The number of PGD applications considered at each meeting continues to vary between one and six. Special directions for import and export are generally more complex in practice (even compared to PGD items with a large number of similar types to consider) as each scenario is unique.

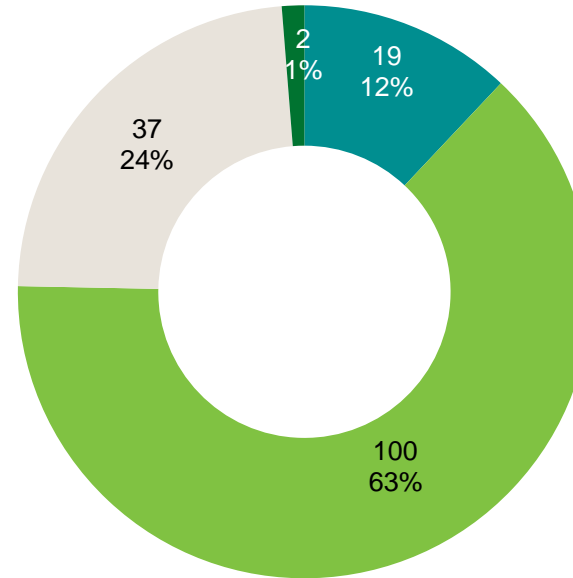
Item types – August 2017 – July 2019

Licensing item types  
- two years (rolling)



- Initials
- Renewals
- Interims
- Revocations
- Variations
- HLA (ELP)
- ITE import certificate
- Executive updates
- Other

SAC item types  
- two years (rolling)



- MD
- PGD
- SD (import/export)
- Novel process
- HLA (SAC)

This picture is very similar to that presented at the July meeting. We propose to include an annual comparison in future (when this report has been in existence for a year), to show any long-term growth or shrinkage in particular item types.

# Performance report

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

## Details:

Meeting Authority

Agenda item 6

Paper number HFEA (11/09/2019) 925

Meeting date 11 September 2019

Author Helen Crutcher, Risk and Business Planning Manager

## Output:

For information or decision? For information

Recommendation The Authority is asked to note and comment on the latest performance report.

Resource implications In budget

Implementation date Ongoing

Communication(s) The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper.

The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting.

The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).

Organisational risk  Low  Medium  High

Annexes Annex 1: HFEA performance scorecard

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## **1. Introduction**

- 1.1.** The attached paper summarises our performance up to the end of July 2019.
- 1.2.** Further updates on performance and trends since this point will be provided verbally in the meeting.

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## **2. Reviewing performance**

- 2.1.** SMT reviewed July performance data at its 2 September 2019 meeting.
- 2.2.** Overall performance is good. Four indicators are currently classified as red. There is a full discussion of these in the performance report, provided in the annex to this paper.

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## **3. Recommendation**

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

# HFEA performance scorecard

## Dashboard – July data

### Overall performance – RAG status (all indicators)



### People – capacity

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

↓  
Leavers: 2  
(26.8%)

### Engagement – Website traffic

Website sessions this month  
Arrow tracks performance since last month

↑  
56,400

### Licensing end-to-end

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

★  
50 working days

## Summary Financial Position - July 2019

|                                  | Year to Date    |                 |                   | Full Year         |                 |                   |
|----------------------------------|-----------------|-----------------|-------------------|-------------------|-----------------|-------------------|
|                                  | Actual<br>£'000 | Budget<br>£'000 | Variance<br>£'000 | Forecast<br>£'000 | Budget<br>£'000 | Variance<br>£'000 |
| Income                           | 2,223           | 2,263           | 41                | 7,089             | 7,063           | (26)              |
| Expenditure                      | 2,345           | 2,505           | 160               | 7,137             | 7,067           | (70)              |
| <b>TOTAL Surplus / (Deficit)</b> | <b>(122)</b>    | <b>(242)</b>    | <b>120</b>        | <b>(48)</b>       | <b>(4)</b>      | <b>(44)</b>       |

### Commentary

As at 31 July shows a favourable variance against budget of **£120k**. This is mainly due to reduced spending against the legal budget over the first four months of the year.

We have undertaken a detailed review of planned expenditure over the remainder of the financial year and our forecast has identified a small pressure relating to temporary staff costs, we expect to make necessary adjustments across our spend profile to bring this down by year end.

## Overall performance – July 2019

SMT reviewed the overall performance picture on 2 September. There were four red indicators. Overall, July performance was generally good.

In July we launched DocuSign, an online way of submitting OTR requests. This resulted in a significant increase in applications being submitted and processed in the month. This is being monitored and more information on OTR generally will come to the Authority in November.

### Red indicators

The 4 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

#### People

- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% headcount turnover for the year. Performance in July was 26.8%. The overall planned and unplanned leavers for the year is 28.3%. This was a slight decrease from June.

#### Information requests

- Percentage of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests responded to within statutory deadlines. Our target is 100% but in July, we managed 80% as one of the five FOI requests missed the deadline.

#### PGD processing

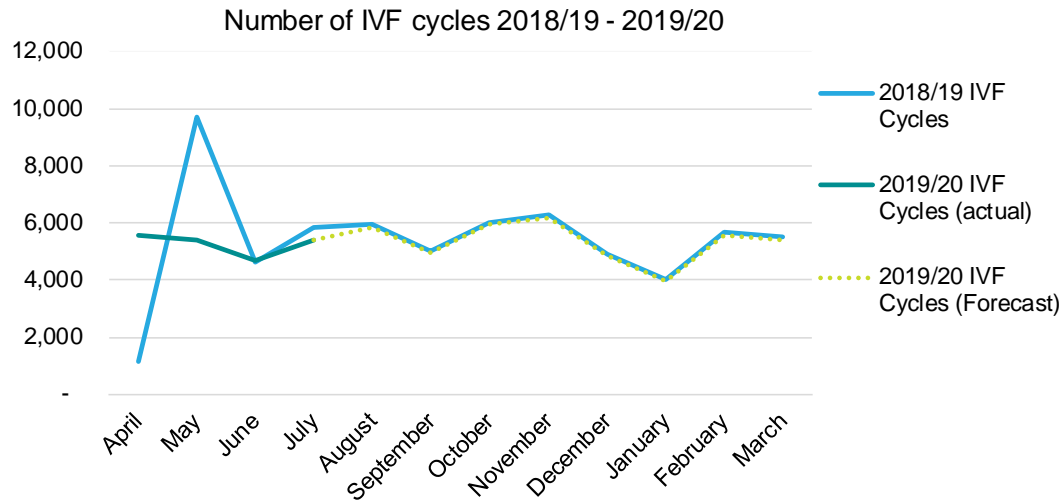
- 3 month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is 100% within 66 working days. In July we achieved 36% (four of the 11 due for completion were done on time), with an average processing time for those that had been completed of just over the target at 70 working days.

#### Debt processing

- % debts collected within 60 days. Our target is for 85% of debts collected in the month to be within 60 calendar days from billing. In July 78% of debts (81/104) were collected within this timeframe.

# Budget status – July data

## 2019/20 Income

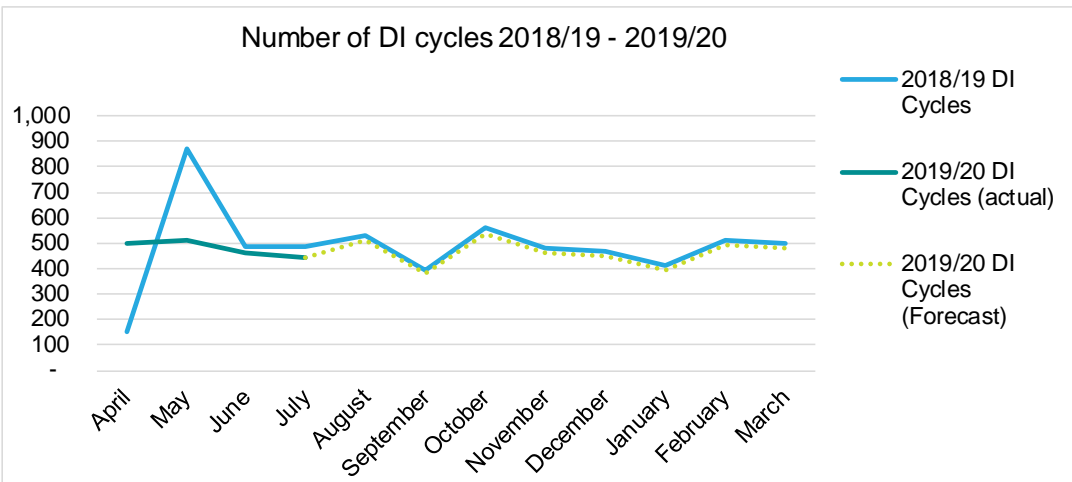


### IVF Cycles

|                    | YTD    |           | YE Position |           |
|--------------------|--------|-----------|-------------|-----------|
|                    | Volume | £         | Volume      | £         |
| 2018/19 IVF Cycles | 21,354 | 1,708,320 | 64,720      | 5,177,600 |
| 2019/20 IVF Cycles | 21,030 | 1,682,400 | 63,738      | 5,099,041 |
| Variance           | 324    | 25,920    | 982         | 78,559    |

At the end of July, the number of billable IVF treatments is slightly lower than the 2018/19 figures. If this trend is maintained, we could see reduction in income of c£78k compared to our initial budgeted figure.

The £ value shown in the management commentary does not translate to the volumes shown due to an adjustment to the calculation we use to estimate missing treatments. The effect will be rectified by the next quarter.



### DI Cycles

|                   | YTD    |        | YE / Forecast |         |
|-------------------|--------|--------|---------------|---------|
|                   | Volume | £      | Volume        | £       |
| 2018/19 DI Cycles | 1,994  | 74,775 | 5,845         | 219,188 |
| 2019/20 DI Cycles | 1,918  | 71,925 | 5,622         | 210,833 |
| Variance          | 76     | 2,850  | 223           | 8,354   |

There is a small drop in volumes compared to 2018/19, however current forecast suggests that we should still achieve our budget.



# HFEA Income & Expenditure

## Jul-2019

|                                    | Year to Date |              |            |            | Full Year    |              |             |
|------------------------------------|--------------|--------------|------------|------------|--------------|--------------|-------------|
|                                    | Actual       | Budget       | Variance   | Variance   | Forecast     | Budget       | Variance    |
|                                    | £'000        | £'000        | £'000      | %          | £'000        | £'000        | £'000       |
| <b>Income</b>                      |              |              |            |            |              |              |             |
| Grant-in-aid                       | 233          | 233          | -          | 0%         | 934          | 934          | -           |
| Non-cash (Ring-fenced RDEL)        | 168          | 168          | -          | 0%         | 504          | 504          | -           |
| Grant-in-aid - PCSPS contribution  | 33           | 33           | 0          | 0%         | 100          | 100          | -           |
| Licence Fees                       | 1,735        | 1,791        | 56         | 3          | 5,400        | 5,374        | (26)        |
| Other Income                       | 5            | 3            | (2)        | (90)       | 10           | 10           | -           |
| Ring-fenced and seconded income    | 49           | 35           | (13)       |            | 142          | 142          | -           |
| <b>Total Income</b>                | <b>2,223</b> | <b>2,263</b> | <b>41</b>  | <b>2</b>   | <b>7,089</b> | <b>7,063</b> | <b>(26)</b> |
| <b>Revenue Costs</b>               |              |              |            |            |              |              |             |
| Salaries (excluding Authority)     | 1,498        | 1,457        | (41)       | 3          | 4,372        | 4,343        | (28)        |
| Staff Travel & Subsistence         | 60           | 50           | (10)       | 19         | 143          | 144          | 1           |
| Other Staff Costs                  | 105          | 47           | (59)       | 126        | 148          | 101          | (47)        |
| Authority & Other Committees costs | 93           | 93           | 0          | (0)        | 269          | 270          | 1           |
| Facilities Costs incl non-cash     | 224          | 296          | 72         | (24)       | 900          | 889          | (12)        |
| IT Costs                           | 212          | 238          | 26         | (11)       | 669          | 669          | -           |
| Legal / Professional Fees          | 65           | 189          | 123        | (65)       | 402          | 402          | 0           |
| Other Costs                        | 87           | 135          | 48         | (36)       | 234          | 249          | 15          |
| <b>Total Revenue Costs</b>         | <b>2,345</b> | <b>2,505</b> | <b>160</b> | <b>(6)</b> | <b>7,137</b> | <b>7,067</b> | <b>(70)</b> |
| <b>TOTAL Surplus / (Deficit)</b>   | <b>(122)</b> | <b>(242)</b> | <b>120</b> | <b>49</b>  | <b>(48)</b>  | <b>(4)</b>   | <b>(44)</b> |

### Management commentary

#### Income.

Our Licence fee income year to date is below budget by **£56k**. This is mainly due to adjustments at year end and during the month of June to correct the calculation we use to estimate missing treatments that has affected the year-to-date figures.

#### Expenditure.

Expenditure for the first four months of the financial year shows an underspend against budget of **£160k**. The profiling of the budget currently does not reflect expenditure activity. By exception:

**Staff costs** - are showing an overspend against budget of **£41k**. This cost line includes Temporary Staff costs, which are over budget by £181k, this is partly off-set by underspends within salaries but is in the main related to work underway to complete the PRISM project. A reforecast has been completed and takes account of known costs and plans for future development work on PRISM. Of all costs, the expenditure on Temporary staff is being closely scrutinized.

**Staff Travel and Subsistence and Other staff costs** - are over budget by **£10k** and **£59k** respectively. Staff Travel is over budget by £10k due to inclusion of home to office costs for the previous quarter. Other staff costs are over budget due to in funding for essential staff training

**Facilities incl non-cash** is under budget due to the delay in capitalisation of PRISM.

**IT costs** - are significantly under budget. This is largely due to limited use of the support contract in quarter 1 therefore incurring limited charges. It is expected that activity across the remainder of the year will utilise the available budget.

**Legal and Professional costs** - are underspent by **£123k** is largely due to a welcome lack of legal activity., however this may change as the year progresses

#### Forecast

We are forecasting a small overspend against budget, however this position will change over the next quarter if income remains on it's current trajectory.

## People – key performance and volume indicators

| Indicator   | Score | RAG | Recent trend <sup>1</sup> | Notes  |
|---|-------|-----|---------------------------|--|
| <b>Current headcount by month</b><br>Staff in post/headcount  | 66/68 | ↑   |                           | Overall volume (capacity) indicator.   |
| <b>Turnover: Establishment ('unplanned') leavers</b><br>(% establishment turnover for the year). This is done monthly for the rolling year to date. | 26.8% | ↓   |                           | KPI range: 5-15% turnover for the rolling year<br><br>The public-sector average is 10.9% (Xpert HR 2017) on which we base our target.                  |
| <b>Staff sickness absence rate (%) per month.</b>   | 2.47% | ★   |                           | KPI: Absence rate of ≤ 2.5%.<br><br>Average rate of public sector sickness absence is 2.6% versus 1.7% for the private sector. (Source: ONS data 2017) |

## Information – key performance and volume indicators

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

| Indicator  | Score         | RAG                  | Recent trend  | Notes |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
|--|---------------|----------------------|---|-------|---------------|----------------------|--------|------|-----|--------|------|-----|--------|------|-----|--------|------|-----|--------|------|-----|---|
| Number of emailed public enquiries received (compared with same month last year) | 131           | ↑                    | <table border="1"> <caption>Emailed public enquiries received</caption> <thead> <tr> <th>Month</th> <th>This year</th> <th>Last year</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>198</td> <td>170</td> </tr> <tr> <td>Apr</td> <td>186</td> <td>164</td> </tr> <tr> <td>May</td> <td>173</td> <td>159</td> </tr> <tr> <td>June</td> <td>138</td> <td>103</td> </tr> <tr> <td>Jul</td> <td>143</td> <td>131</td> </tr> </tbody> </table>   | Month | This year     | Last year            | Mar    | 198  | 170 | Apr    | 186  | 164 | May    | 173  | 159 | June   | 138  | 103 | Jul    | 143  | 131 | Volume indicator.   |
| Month  | This year     | Last year            |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Mar  | 198           | 170                  |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Apr  | 186           | 164                  |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| May  | 173           | 159                  |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| June   | 138           | 103                  |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Jul  | 143           | 131                  |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Percentage of Opening the Register requests responded to within 20 working days  | 100%          | ★                    | <table border="1"> <caption>Opening the Register requests responded to within 20 working days</caption> <thead> <tr> <th>Month</th> <th>Percentage</th> <th>Number of requests</th> </tr> </thead> <tbody> <tr> <td>Mar-19</td> <td>100%</td> <td>27</td> </tr> <tr> <td>Apr-19</td> <td>100%</td> <td>34</td> </tr> <tr> <td>May-19</td> <td>100%</td> <td>28</td> </tr> <tr> <td>Jun-19</td> <td>100%</td> <td>27</td> </tr> <tr> <td>Jul-19</td> <td>100%</td> <td>28</td> </tr> </tbody> </table> | Month | Percentage    | Number of requests   | Mar-19 | 100% | 27  | Apr-19 | 100% | 34  | May-19 | 100% | 28  | Jun-19 | 100% | 27  | Jul-19 | 100% | 28  | <p>KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)</p> <p>The increase in applications in July will appear in August data, when they were due to be closed.</p> |
| Month  | Percentage    | Number of requests   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Mar-19   | 100%          | 27                   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Apr-19   | 100%          | 34                   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| May-19   | 100%          | 28                   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Jun-19   | 100%          | 27                   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Jul-19   | 100%          | 28                   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Number of requests for contributions to Parliamentary questions                  | 1             | ↓                    | <table border="1"> <caption>Requests for contributions to Parliamentary questions</caption> <thead> <tr> <th>Month</th> <th>PQs answered</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>0</td> <td>17</td> </tr> <tr> <td>Apr</td> <td>5</td> <td>2</td> </tr> <tr> <td>May</td> <td>0</td> <td>1</td> </tr> <tr> <td>Jun</td> <td>2</td> <td>15</td> </tr> <tr> <td>Jul</td> <td>2</td> <td>1</td> </tr> </tbody> </table>  | Month | PQs answered  | Same month last year | Mar    | 0    | 17  | Apr    | 5    | 2   | May    | 0    | 1   | Jun    | 2    | 15  | Jul    | 2    | 1   | Volume indicator.   |
| Month  | PQs answered  | Same month last year |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Mar  | 0             | 17                   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Apr  | 5             | 2                    |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| May  | 0             | 1                    |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Jun  | 2             | 15                   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Jul  | 2             | 1                    |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Number of Freedom of Information (FOI) requests                                  | 4             | ↔                    | <table border="1"> <caption>Freedom of Information (FOI) requests</caption> <thead> <tr> <th>Month</th> <th>FOIs answered</th> <th>Same month last year</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>2</td> <td>6</td> </tr> <tr> <td>Apr</td> <td>2</td> <td>8</td> </tr> <tr> <td>May</td> <td>2</td> <td>11</td> </tr> <tr> <td>Jun</td> <td>4</td> <td>3</td> </tr> <tr> <td>Jul</td> <td>4</td> <td>6</td> </tr> </tbody> </table>  | Month | FOIs answered | Same month last year | Mar    | 2    | 6   | Apr    | 2    | 8   | May    | 2    | 11  | Jun    | 4    | 3   | Jul    | 4    | 6   | Volume indicator.   |
| Month  | FOIs answered | Same month last year |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Mar  | 2             | 6                    |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Apr  | 2             | 8                    |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| May  | 2             | 11                   |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Jun  | 4             | 3                    |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |
| Jul  | 4             | 6                    |   |       |               |                      |        |      |     |        |      |     |        |      |     |        |      |     |        |      |     |   |

## Inspection and licensing process – key performance and volume indicators

| Indicator  | Score        | RAG | Recent trend <sup>2</sup>  | Notes |              |     |     |     |    |     |     |     |    |     |      |   |
|--|--------------|-----|--|-------|--------------|-----|-----|-----|----|-----|-----|-----|----|-----|------|---|
| Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair) | 50           | ★   | <table border="1"> <caption>Working days (KPI: Less than or equal to 70 working days)</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>60</td> </tr> <tr> <td>Apr</td> <td>55</td> </tr> <tr> <td>May</td> <td>38</td> </tr> <tr> <td>Jun</td> <td>50</td> </tr> <tr> <td>Jul</td> <td>50</td> </tr> </tbody> </table> | Month | Working days | Mar | 60  | Apr | 55 | May | 38  | Jun | 50 | Jul | 50   | KPI: Less than or equal to 70 working days.   |
| Month  | Working days |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Mar  | 60           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Apr  | 55           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| May  | 38           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Jun  | 50           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Jul  | 50           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Monthly percentage of PGD applications processed within three months (66 working days).  | 100% (2/2)   | ★   | <table border="1"> <caption>Performance (KPI: 100% processed within three months)</caption> <thead> <tr> <th>Month</th> <th>Performance</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>71%</td> </tr> <tr> <td>Apr</td> <td>0%</td> </tr> <tr> <td>May</td> <td>29%</td> </tr> <tr> <td>Jun</td> <td>0%</td> </tr> <tr> <td>Jul</td> <td>100%</td> </tr> </tbody> </table>  | Month | Performance  | Mar | 71% | Apr | 0% | May | 29% | Jun | 0% | Jul | 100% | KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application. |
| Month  | Performance  |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Mar  | 71%          |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Apr  | 0%           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| May  | 29%          |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Jun  | 0%           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Jul  | 100%         |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Average number of working days taken (in the month).   | 66           | ★   | <table border="1"> <caption>Working days (KPI: 66 working days)</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>67</td> </tr> <tr> <td>Apr</td> <td>77</td> </tr> <tr> <td>May</td> <td>66</td> </tr> <tr> <td>Jun</td> <td>77</td> </tr> <tr> <td>Jul</td> <td>66</td> </tr> </tbody> </table>                       | Month | Working days | Mar | 67  | Apr | 77 | May | 66  | Jun | 77 | Jul | 66   |   |
| Month  | Working days |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Mar  | 67           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Apr  | 77           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| May  | 66           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Jun  | 77           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |
| Jul  | 66           |     |  |       |              |     |     |     |    |     |     |     |    |     |      |   |

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

| Indicator  | Score           | RAG | Recent trend <sup>2</sup>   | Notes |                 |     |     |     |     |     |     |     |     |     |     |                |
|--|-----------------|-----|---|-------|-----------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----------------|
| Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days) | 36%<br>(4/11)   | ↑   | <table border="1"> <caption>Performance Data</caption> <thead> <tr> <th>Month</th> <th>Performance (%)</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>56%</td> </tr> <tr> <td>Apr</td> <td>45%</td> </tr> <tr> <td>May</td> <td>47%</td> </tr> <tr> <td>Jun</td> <td>18%</td> </tr> <tr> <td>Jul</td> <td>36%</td> </tr> </tbody> </table> | Month | Performance (%) | Mar | 56% | Apr | 45% | May | 47% | Jun | 18% | Jul | 36% | KPI: As above. |
| Month  | Performance (%) |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Mar  | 56%             |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Apr  | 45%             |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| May  | 47%             |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Jun  | 18%             |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Jul  | 36%             |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Average number of working days taken (cumulative 3 month picture).   | 70              | ↓   | <table border="1"> <caption>Working days Data</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Mar</td> <td>68</td> </tr> <tr> <td>Apr</td> <td>70</td> </tr> <tr> <td>May</td> <td>68</td> </tr> <tr> <td>Jun</td> <td>72</td> </tr> <tr> <td>Jul</td> <td>70</td> </tr> </tbody> </table>        | Month | Working days    | Mar | 68  | Apr | 70  | May | 68  | Jun | 72  | Jul | 70  |                |
| Month  | Working days    |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Mar  | 68              |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Apr  | 70              |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| May  | 68              |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Jun  | 72              |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |
| Jul  | 70              |     |   |       |                 |     |     |     |     |     |     |     |     |     |     |                |

# Business planning for 2020-2023

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

## Details:

|              |   |
|--------------|---|
| Meeting      | Authority                                       |
| Agenda item  | 8   |
| Paper number | HFEA (11/09/2019) 926                           |
| Meeting date | 11 September 2019                               |
| Author       | Paula Robinson, Head of Planning and Governance |

## Output:

|                              |   |
|------------------------------|---|
| For information or decision? | For decision  |
| Recommendation               | The Authority is asked to note and comment on the draft three year plan for strategy delivery in 2020-2023, and in particular to approve the proposed activities for inclusion in the first draft of the business plan for 2020/21. |
| Resource implications        | In budget   |
| Implementation date          | Strategic period 2020-2023  |
| Communication(s)             | The strategy and business plans, once agreed, will be published on our website.   |
| Organisational risk          | <input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High   |
| Annexes                      | Annex 1: Three year delivery programme – 2020-2023  |

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## 1. Introduction

- 1.1. Every September, the Authority is asked to approve outline content for the following year's business plan, so that it can be developed over the coming months. A draft is approved at the November meeting. This timetable allows us to meet the Department's requirement for a near final draft business plan in the new year.
- 1.2. This year the process is made more complex as we are simultaneously in the process of developing our new strategy for 2020-2023. The Authority will receive a full draft of the strategy for consideration in November, alongside consultation feedback. Although the timing is not ideal the draft strategy outline has received positive support from stakeholders, which gives us a good basis to proceed with our planning.
- 1.3. With this in mind, the Corporate Management Group (CMG) has started to consider how to deliver the strategy across the next three business plans.
- 1.4. This paper presents a draft three year delivery plan, and highlights in particular work that could be done in the 2020/21 business year. This will form the basis for drafting the next business plan, although it should be noted that some of the detail is likely to change for the reasons set out above.

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## 2. Business planning for the new strategy

- 2.1. At the beginning of a new strategy, it is important to give some thought to delivery. Some pieces of work will have a natural order to them. Some will fit in a single business year, while others may stretch across two or three years.
- 2.2. At Annex A, there is an early draft outline delivery plan. This may be adjusted later on, especially if elements of the strategy change while we are finalising it. We will hold further planning discussions, focusing on scope, scale and resources. These conversations will assist teams to produce realistic service delivery plans for the coming year, and will also help us to develop a new people strategy to sit alongside the main strategy document.
- 2.3. For the next business year, 2020/21, the following is a summary of the proposed strategic content, which would be in addition to our normal range of core regulatory work.

### Best care

- Evaluation of information and traffic-lights for add-ons
- Project to establish a data review board for considering additions to the Register
- Work to build on success rates work from this year
- Work on supporting and encouraging research
- Review of compliance regime to ensure that it aligns with the Authority's strategic aims

### Right information

- Partnership working to facilitate the provision of key information to primary care professionals

- Better positioning and promoting our existing information
- Developing more information specifically for partners and donors
- Developing new information about any new treatments (including add-ons) or evidence that arise
- Possible review of consent issues (following paper that will come to Authority in November)
- Clinic portal and website upgrades

## Shaping the future

- Following scoping this year (2019/20), ensure we are organisationally ready for an increase in our OTR operations
- Policy work (in all three years) to prepare for any changes related to new technologies, etc.
- Fee review
- Office move.

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## 3. Next steps

- 3.1.** As noted above, in November the Authority will receive feedback on the strategy consultation, and a full draft of the strategy for approval. This gives us sufficient time for any editorial processes to take place prior to design and publication.
- 3.2.** At the same meeting, the Authority will receive the first full draft of the business plan for 2020/21. This could be amended if necessary, based on the discussion about the strategy.
- 3.3.** Again as noted above, the Department's deadline for receiving a first draft and proceeding with budget discussions is usually some time in January.
- 3.4.** Both the business plan and the new strategy should be ready for publication in early April 2020.

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## 4. Recommendations

- 4.1.** The Authority is asked to:
  - Note and comment on the draft three year delivery programme for the new strategy
  - Note that staff will continue to discuss the delivery plan, including resourcing, to ensure that all teams have realistic service delivery plans in place and that the scope and scale of individual pieces of work is clear
  - Approve in principle the draft outline business plan activities for 2020/21, as the basis for developing a full draft for November Authority.



## Annex A (Three year delivery programme – 2020-2023)

### Business planning for strategic delivery

**Table: Outline delivery plan for 2020-2023**

Key: S=Small M=Medium L=Large XL=Extra large

| Strategic aim and objective  | Strategic outcome   | Work packages  | Business plan year |         |         |
|--|---|--|--------------------|---------|---------|
|  |   |  | 2020/21            | 2021/22 | 2022/23 |
| <b>The best care</b>   |   |  |                    |         |         |
| <p>Aim:<br/>That patients, partners and donors receive evidence-based high-quality care.</p> <p>Objective:<br/>Treatment that is ethically and scientifically robust</p> | Individualised care that is safe, responsible, consistent and based on clear values.                          | Review of compliance regime  | L                  | L       |         |
|  |   | Review of donation   |                    | L       |         |
|  | A transparent and accurate evidence base, to ensure that patients make informed choices about their treatment | Evaluation of information and traffic-lights for add-ons                               | M                  |         |         |
|  |   | Project to establish a data review board for considering additions to the Register     | S                  |         |         |
|  |   | Patient survey   |                    | M       |         |
|  | Clinics that are well led and see compliance as good business and part of high-quality care.                  | Improved tools to better utilise our new Register data to inform good clinic practices |                    | M       |         |
|  |   | Work to build on success rates work from 2019/20                                       | S                  |         |         |
|  | More research and innovation to improve outcomes.   | Work on supporting and encouraging research  | S                  |         |         |
| Review of processes around granting and approval of research (clinical and data)   |   |  | M                  |         |         |

| Strategic aim and objective  | Strategic outcome   | Work packages   | Business plan year |         |         |
|--|---|---|--------------------|---------|---------|
|  |   |   | 2020/21            | 2021/22 | 2022/23 |
| <p>Aim:<br/>That patients, partners and donors receive evidence-based high-quality care.</p> <p>Objective:<br/>Improved recognition of partners' importance in the care process, whether they are from the same or the opposite sex.</p> | Partners to be involved in care and treatment choices throughout the process, on an equal footing with patients.          | Development of guidance and website/portal information for clinics. |                    | M-L     |         |
|  | Clinics to recognise that partner care is a core part of the service they provide.  |   |                    |         |         |
|  | Provide information about male fertility issues.  | Reciprocal signposting to websites that hold valid information.     |                    | M       |         |
| Underpinning core work supporting this aim:  | Regulation of clinics   |   | XL                 | XL      | XL      |
|  | Good governance of licensing decisions  |   | L                  | L       | L       |
|  | Processing applications for PGD and mitochondrial donation  |   | M                  | M       | M       |
|  | Revision of the Code of Practice when required  |   | M                  | M       | M       |
|  | Annual horizon scanning and Scientific and Clinical Advances Advisory Committee work, including ongoing review of add-ons |   | S                  | S       | S       |

## The right information

|  |  |  |   |     |  |
|--|--|--|---|-----|--|
| <p>Aim:<br/>To ensure that people can access the right information at the right time.</p> <p>Objective:<br/>Improved access to information at the earliest stage of the treatment journey.</p> | Right-moment information provision for patients and partners.  | Partnership working to facilitate the provision of key information to primary care professionals | L | L/M |  |
|  | People to be supported all the way through their journey and their choices, including at the very beginning. |  |   |     |  |
|  | Information about accessing fertility services to be transparent at the outset.                              | Project to scope, develop and user-test materials for people at the beginning of their journey.  |   | M   |  |

| Strategic aim and objective  | Strategic outcome   | Work packages   | Business plan year |         |         |
|--|---|---|--------------------|---------|---------|
|  |   |   | 2020/21            | 2021/22 | 2022/23 |
| <p>Aim:<br/>To ensure that people can access the right information at the right time.</p> <p>Objective:<br/>Patients, partners, professionals, donors, donor-conceived people, their families and the wider public to have access to high quality information.</p> | Patients to have the right information to support them in making choices. | Positioning and promoting our existing information through various channels | S                  | S       | S       |
|  | Others to have access to useful and impartial information.                | Developing more information specifically for partners and donors            | S                  | S       | S       |
|  |   | Developing new information about any new treatments or evidence that arise  | S                  | S       | S       |
|  | Patients to feel supported to make difficult treatment decisions.         | Clinic portal and website upgrades  | M                  |         |         |
|  |   | Ensure we focus on support at all stages of treatment and decision making,  |                    | M       |         |
| Possible review of consent issues  | L   |   |                    |         |         |
| <p>Underpinning core work supporting this aim:</p>   | Maintain up to date information and advice on website                     |   | S                  | S       | S       |
|  | Responding to media reports etc.  |   | M                  | M       | M       |
|  | Information for researchers   |   | L                  | L       | L       |
|  | FOI, PQ, DPA requests   |   | L                  | L       | L       |
|  | OTR & counselling service   |   | M                  | M       | M       |
|  | Regular updates of CaFC data  |   | M                  | M       | M       |
|  | Publish regular reports eg Fertility trends                               |   | M                  | M       | M       |
|  | Enquiries handling  |   | S                  | S       | S       |
|  | Analysis of patient feedback  |   | M                  | M       | M       |

## Shaping the future

|  |  |  |  |   |   |
|--|--|--|--|---|---|
| <p>Aim:<br/>To be ready for any changes in law, science and society.</p> | To ensure the HFEA and the sector are prepared for future changes in the fertility field, and for any legislative change | Respond to any decisions of government                     |  | ? | ? |
|  |  | Implement any legislative changes relating to surrogacy or |  | L | L |

| Strategic aim and objective  | Strategic outcome  | Work packages  | Business plan year |         |         |
|--|--|--|--------------------|---------|---------|
|  |  |  | 2020/21            | 2021/22 | 2022/23 |
| Objective:<br>Preparing for future legislative and operational changes.  | To be prepared for a growth in donor-conceived people eligible to make 'opening the register' (OTR) requests from 2021 and 2023  | storage limits (for example)   |                    |         |         |
|  |  | Following scoping this year, ensure we are organisationally ready for any increase in our OTR operations   | L-XL               | L       | M       |
| Aim:<br>To be ready for any changes in law, science and society.   | Patients to have information that is up to date and relevant on developments such as genome research and editing, DNA tests and screening, home genetic testing and AI | Policy work to prepare for any changes related to new technologies, etc.   | L                  | L       | L       |
|  |  | Investigative work being started now into the 'known unknowns' around PGD testing will inform our work. Project focusing on new types of patient and family, to integrate recognition of scientific and societal changes into our work and the information we publish. |                    | M       |         |
| Objective:<br>Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). | Annual horizon scanning  |  | S                  | S       | S       |
|  | Office move  |  | L                  |         |         |
|  | Maintaining the register   |  | M                  | M       | M       |
|  | Managing capacity/capability   |  | M                  | M       | M       |
|  | Records management and information governance  |  | M                  | M       | M       |
|  | Fee review   |  | M                  |         |         |
|  | Collaboration and partnering   |  | M                  | M       | M       |
| Underpinning core work supporting this aim:  |  |  |                    |         |         |

# Treatment add-ons – next steps

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

## Details:

Meeting Authority

Agenda item 9

Paper number HFEA (11/09/2019) 927

Meeting date 11 September 2019

Author Dina Halai, Scientific Policy Manager

## Output:

For information or decision? For decision

Recommendation The Authority are asked to consider and to agree:

- The proposed aims for our work on add-ons as outlined in section 3.
- The proposed criteria for add-ons as outlined in section 4.
- The proposed direction of travel to continue addressing issues associated with the supply and demand of add-ons as outlined in section 5.

Resource implications Within budget

Implementation date With immediate effect

Communication(s) Code of Practice updates, clinic focus articles and website updates and wider media and patient-focused activities where necessary

Organisational risk  Low  Medium  High

Annexes Annex A: Summary of findings from clinic website review of add-ons offered and their costs

## 1. Introduction

- 1.1.** Treatment add-ons are optional extras that claim to improve patients' chances of having a baby. They are a growing feature of UK treatment. Add-ons can be a sign of healthy innovation; however, many are concerned about the way in which they are offered to patients. The evidence base for many add-ons is weak; there are few (if any) randomised controlled trials (RCT, the gold standard of clinical effectiveness) and few high-powered retrospective studies of effectiveness either. Yet despite this, add-ons are frequently being offered to patients at a charge.
- 1.2.** The potential regulation of add-ons in the UK is complex. In large part this reflects the variety of the treatments offered – there is no agreed definition of what constitutes a treatment add-on and some commonly offered add-ons are drugs, others surgical interventions, and some are technologies or equipment. Some believe that complementary therapies should be classified as add-ons, others do not. The HFEA does not have explicit regulatory powers that would allow it to control the introduction and uptake of treatment add-ons. We do, however, have powers that relate to the information that clinics must provide to patients so that they can make an informed choice, we also have some limited powers over the introduction of novel treatments and we can work with other regulatory bodies in respect of drugs, medical devices and advertising.
- 1.3.** The regulation of add-ons is made more complex still by the fact that this is a problem of both supply and demand. Clinics are increasingly offering add-ons. Yet we also need to recognise that patients are also requesting add-ons, often having read about their supposed effectiveness online. In their desire to have a baby, many patients have indicated that they are prepared to try almost anything if there is some evidence that a particular add-on might make a difference, however small the evidence is or high the additional cost may be.
- 1.4.** The HFEA has been concerned about treatment add-ons for some time and made two early policy interventions, in 2017 and 2019. The first was concerned to improve the quality of the public information available on the evidence base. The HFEA sought advice from the [Science and Clinical Advances Advisory Committee \(SCAAC\)](#) and introduced a 'traffic light' system which categorises add-ons according to the available evidence. The traffic light assessment is on our [website](#) and currently covers 11 commonly offered add-ons and will be updated annually following a review by SCAAC. The aim is to provide patients with an independent expert reference point against which to assess many of the claims made by others.
- 1.5.** The second policy intervention was designed to build consensus among professional and patient groups about the way in which add-ons are offered in clinics. To that end the HFEA convened a working group in March 2018 which resulted in a [consensus statement](#) signed by 11 bodies<sup>1</sup> that set out a number of principles on offering of add-ons and aimed to make clear the roles and responsibilities of different stakeholders. The aim of the consensus statement is to bring about a culture change in the sector towards more responsible innovation. It was always recognised that

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<sup>1</sup>Association of Biomedical Andrologists (ABA), Association of Clinical Embryologists (ACE), British Andrology Society, British Fertility Society (BFS), British Infertility Counselling Association (BICA), European Society of Human Reproduction and Embryology (ESHRE), Fertility Network UK (FNUK), Human Fertilisation and Embryology Authority (HFEA), Royal College of Nursing (RCN), Royal College of Obstetricians and Gynaecologists (RCOG) and Senior Infertility Nurses Group (SING)

such culture change would take time and the HFEA will continue to work with the signatory bodies to evaluate the success of this consensus approach over time.

**1.6.** This paper reflects on the progress made on add-ons and suggest next steps, as follows:

- Section 2 of the paper summarises the considerable activity that has taken place and what has been achieved to date.
- Section 3 sets out some strategic aims for our work on add-ons - this is not straightforward as unlike our work on multiple births there is no simple target to aim at.
- Section 4 then moves on to the contested issue of what constitutes an add-on.
- Finally, section 5, sets out a range of suggested policy actions to address both the supply and demand sides of this issue. At this stage all we are looking for is a steer from the Authority about our suggested direction of travel.

**1.7.** Depending on the discussion we will wish to return to the Authority with more worked up proposals. Whatever decisions are taken, tackling treatment add-ons will be a key feature of our future strategy 2020-23.

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## 2. What we have done so far

**2.1.** It's early days but evidence shows that we're making progress. HFEA inspections reveal that strengthened information on add-ons is being provided at clinics.

**2.2.** The following provides a summary of activities undertaken, working with the sector, to embed the principles outlined within the consensus statement:

- New rules - In January 2019, we updated our Code of Practice to require clinics to give patients information, in a lay format, about any treatment add-ons which may be offered and the evidence of effectiveness supporting their use; that any information should explain that treatment add-ons refers to the technologies and treatments listed on the [treatment add-ons page](#) of the HFEA website. We consider this a key contribution towards supporting patient information to inform patient choice
- Media coverage - Our press release in January 2019 gathered significant national coverage, with supporting comment from ACE and the General Medical Council (GMC), and BBC's The One Show broadcasted a pre-recorded interview with the HFEA Chair, Sally Cheshire
- Speaking to the sector - HFEA spoke about add-ons at the RCN Fertility Nursing Forum Conference in March 2019. A workshop was held on the importance of sharing information on add-ons, both with patients and between clinics, at the HFEA's Annual Conference in June 2019. Add-ons were discussed at the July 2018 and June 2019 Horizon scanning meetings held at ESHRE with international experts attending.
- Follow up with consensus statement signatories - In May 2019, three months after the consensus statement was published, we contacted the signatories of the statement for updates on actions they had taken
- Review of clinic websites - In August 2016, the HFEA carried out a review of clinic websites to get a better understanding of which add-ons are offered to patients and how much each add-on costs. In September 2018, a second website review was carried out (see Annex A). The next website review is planned for September 2019 and we will compare findings with the previous reviews

### 2.3. A summary of activities undertaken to communicate reliable information on add-ons to patients:

- Assessing the evidence - Treatment add-ons traffic-lights information added to our [website](#), which resulted in a significant increase in views. SCAAC will annually assess the quality of evidence for treatment add-ons and make recommendations to the Authority for the traffic light ratings
- Publicity aimed at patients - HFEA leaflets for the different add-ons have been distributed to patients at The Fertility Show Manchester 2019 and The Fertility Forum at the Royal College of Obstetricians and Gynaecologists. Our treatment add-ons information and associated communications campaign, including patient involvement, has been highly commended in the 2019 BMA patient information awards and is shortlisted for the overall BMA patient information awards 2019 which will be announced in September
- Speaking at patient events - Authority members, Tony Rutherford and Yacoub Khalaf, spoke about add-ons at The Fertility Show Manchester 2019 and The Fertility Forum respectively
- Media work - HFEA continue to carry out a social media campaign (Twitter, Facebook) driven by traffic light infographics for the different add-ons. Authority member Kate Brian published a Fertility Matters blog in January 2019 titled 'Advice on treatment add-ons'

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## 3. Proposed aims for our work on add-ons

**3.1.** Having made real progress over the past two years we believe the time is right to refine the focus of our work on add-ons. To that end we ask the Authority to consider and agree our aims for next steps on treatment add-ons and make these aims available publicly, as appropriate, so that it is clear to clinics and patients what we are trying to achieve, ideally with the cooperation of some key stakeholders.

**3.2.** The proposed aims are:

- 3.2.1. to stop patients from being misled (in terms of potentially exploiting unfounded expectations) by ensuring, through inspections and our own published information, that patients are provided with information that is clear and reliable
- 3.2.2. to ensure informed consent is obtained
- 3.2.3. to ensure patient safety by investigating how outcomes and follow ups can be best assessed
- 3.2.4. to encourage research to assess whether any current or future add-ons increase success rates
- 3.2.5. to require clinics to provide costed/itemised treatment plans where the costs of treatments and add-ons are clear and to avoid costs being lost in package prices

**3.3.** The Authority are asked to consider and to agree the proposed aims as outlined in this section.

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## 4. Proposed criteria for add-ons

**4.1.** As noted above there is no agreed definition of what constitutes a treatment add-on. Our initial approach focussed on providing patient information on those treatment add-ons that we felt that patients most needed information about. At that time, it was agreed that information on techniques that are more commonly offered and were not necessarily specific to fertility treatment may be incorporated into other sections of the HFEA website without a traffic light rating. At present we provide information on:



- 4.1.1. Additional treatments (to the core treatment eg IVF or IUI), that patients need unbiased information about effectiveness and risks, that are being offered in fertility clinics;
- 4.1.2. where there is published scientific literature of a good RCT investigating the treatments ability to improve the chances of having a baby; and
- 4.1.3. where evidence on efficacy or safety for the use of the treatment in a clinical setting is lacking or absent.
- 4.2. We think these criteria are still appropriate and ask the Authority to endorse this approach.** We think these criteria should be published to the website, as appropriate, so that it is clear to clinics and patients what we define as an add-on.
- 4.3.** There have been requests to add treatments such as acupuncture, massage and nutritional therapy to the add-ons list, which are amongst the commonly purchased additional treatments for improving fertility. The advantage of opening up the criteria in this way is that patients would be provided with information on anything additional to core treatment. However, such a move would require significantly more resource to review and update information and traffic light ratings, and more problematically, a review of clinical effectiveness and designation of a traffic light rating would be difficult for additional treatments where there is no meaningful evidence. **We therefore propose that either an information page be added to the HFEA website which lists other types of additional therapies without traffic light ratings, that is separate to the main list of add-ons, or to have these more commonly offered or established treatments incorporated into other sections of the HFEA website.**

## 5. Proposed direction of travel

- 5.1.** As noted above, the problem of treatment add-ons is complex as they cover a range of interventions such as genetic tests, drugs and surgery. The problem is made more complex still by the fact that it is both a supply problem and a demand problem, although they are also clearly related.



- 5.2.** The Authority are asked to consider and to agree the proposed direction of travel, to continue addressing issues associated with the supply and demand of add-ons. As a first step we will reconvene the stakeholder working group made up of the 11 signatures of the consensus statement to build on this initiative and bottom out the specific actions and responsibilities.

## Addressing the supply problem

### 5.3. We propose:

#### 5.3.1. Work with clinicians to ensure treatments are provided in the interest of patients and with full information:

- support clinic staff on how best to discuss an add-on with a patient
- require clinicians to declare any financial interests where they may benefit from a patient opting to have a specific add-on or treatment at their place of work.
- Empower clinic staff to speak out about bad practice that they may be aware of, working in line with whistleblowing guidance set out by the GMC, the Nursing and Midwifery Council and the Medical Royal Colleges
- Ensure the costs of add-ons are clear and are not being lost in package prices (would require an update to the Code of Practice)

#### 5.3.2. Continue to highlight the importance of evidence-based practice and innovation

- Provide information for clinicians to aid to comprehension and assessment of evidence around add-ons
- Provide information for clinicians on the legal requirements for informed consent under Montgomery<sup>2</sup>
- Consider the value of different types of evidence and how evidence should be assessed
- Encourage more research and funding in the sector around identified priorities

## Addressing the demand problem

### 5.4. We propose:

#### 5.4.1. Continue providing improved information on add-ons for patients:

- Information on other therapies not listed on the main add-ons webpage
- Information for patients about what good evidence for add-ons looks like
- Patient involvement in our continued discussion of this issue via patient groups and advocates in a stakeholder group (eg the proposed pilot patient forum next year)
- Information on costs of add-ons based on clinic websites
- Evaluate and if necessary improve the information provided on the HFEA traffic lights page on the HFEA website

#### 5.4.2. Ensure patients are provided information in clinics to ensure they make an informed decision:

- Requirements around the nature of conversation before treatment eg including discussions about the potential financial and mental impact of treatment
- Consider active HFEA consent for add-ons

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<sup>2</sup> <https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf>. The Montgomery decision redefined the standard for informed consent and disclosure in the UK to a new, patient-focused standard: revolving around whether “a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.”

## Annex A

### Summary of findings from clinic website review of add-ons offered and their costs

In August 2016, the HFEA carried out a review of clinic websites to get a better understanding of which add-ons are offered to patients and how much each add-on costs. Data was collated using price lists from fertility clinic websites and information provided by Fertility Network UK. In September 2018, a second website review was carried out. A summary of findings from these reviews are as follows:

| Region  | 2016 review  | 2018 review  |
|---|--|--|
| % of add-ons offered in England   | 85%  | 86%  |
| % of these clinics situated in London                                   | 30%  | 32%  |
| Most frequently mentioned add-ons                                       | Endometrial scratching, assisted hatching and time lapse imaging | Endometrial scratching, assisted hatching and time-lapse |
| Most frequently offered add-on in privately managed centres             | Assisted Hatching  | Endometrial scratching                                   |
| Most frequently offered add-on offered privately in NHS managed centres | Endometrial scratching   | Assisted hatching  |

In addition:

- The cost of treatment add-ons are presented various ways on clinic's websites (ie the cost of the add-on alone, overall package cost or not stating the cost at all)
- Outside of England the availability of most add-ons was less common, in addition, the cost of treatment add-ons varies more within London than any other region

The findings from these reviews indicated that add-ons were widely offered in the UK. The next website review is planned for September 2019.

# DNA based matching websites

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

## Details:

|              |                               |
|--------------|-------------------------------|
| Meeting      | Authority                     |
| Agenda item  | 10                            |
| Paper number | HFEA (11/09/2019) 928         |
| Meeting date | 11 September 2019             |
| Author       | Anna Coundley, Policy Manager |

## Output:

|                              |   |
|------------------------------|---|
| For information or decision? | For information   |
| Recommendation               | To note the information in the report   |
| Resource implications        | None  |
| Implementation date          | Immediate   |
| Communication(s)             | As outlined in paper  |
| Organisational risk          | <input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High |
| Annexes                      | none  |

## 1. Background

- 1.1. At the September 2018 meeting the Authority was briefed on the wide-ranging impact of direct-to-consumer genetic testing services offering opt-in 'matching' services. DNA testing websites offer users DNA-based information for family history or ancestral ethnicity purposes, or for generalised health information. Many DNA testing websites now also offer optional additional services to help identify genetic relatedness between their users, by 'matching' them with other users in their database. The matching sites are not within the regulatory remit of the HFEA but there are important implications for our work.
- 1.2. The growth of these sites has been valuable for many people seeking information, but there is a good argument that more prominent, detailed information in relation to donor conception would better prepare users for the potential issues that might arise. In addition, more signposting to available support may be useful.
- 1.3. The Authority was asked to note:
  - the rapidly growing number of people using DNA testing websites, offering opt-in matching services
  - the implications of discovering a donor or donor-conceived person's identity through such matching services, including unexpectedly
  - the changing context in which HFEA offers managed DCR and OTR services including the offer of counselling in line with the HFE Act
  - that information is freely available on how to use DNA matching services to seek donors' or donor-conceived peoples' identifiable information
  - that there is little emotional support or advice available around responding to 'matching' information, or contacting others in relation to matches
- 1.4. Several possible HFEA responses were discussed and agreed at the 2018 meeting, as listed below.

### HFEA to raise awareness and signpost to available information and support

We proposed to raise patient and donor awareness through providing information regarding the use of DNA testing websites and the implications, via:

- information on HFEA website
- signposting to the available support (primarily peer support groups online)
- information on HFEA donor and recipient consent forms
- training for clinics
- guidance for clinics to discuss DNA matching and its implications with intended parents and donors.

### Dialogue with DNA testing websites

We proposed to have a dialogue with the larger DNA testing websites used by people in the UK, to encourage them to offer prominent information on their websites about possibly uncovering unexpected information, especially for people affected by donor-conception, including signposting to available emotional support. We noted that we do not regulate DNA testing websites.

- 1.5.** This is an update on the steps we have taken since September 2018 in relation to direct-to-consumer genetic testing and its impacts, including a summary of discussions with the main genetic testing and matching companies and the responses they have made, a summary of recent discussion with stakeholder organisations and an outline of future actions in this area.
- 1.6.** We propose to return to the Authority after the launch of the Code content and accompanying resources on this issue to inform and update them further on our activity in this area.

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## **2. Updates to HFEA Code of Practice**

- 2.1.** In July 2019, the Authority approved changes to our Code of Practice guidance related to DTC DNA testing and matching services and the amended version of the Code is due to be published late in 2019 (to be published subject to approval from the Minister or Secretary of State). The Code will now require that clinics are familiar with these sites and have a basic understanding of how they operate and how they could impact the patients and donors who come through their clinic, as well as donor conceived people.
- 2.2.** Additionally, the amended draft Code states that as part of the implications of treatment discussions that clinics already have with prospective donors and recipients, clinics should refer to the potential implications of DTC DNA matching services for donation anonymity, including the fact that they can result in donors and donor-conceived people or their close genetic relatives being made identifiable, or their identity being able to be inferred, even if these individuals are not themselves signed up to DNA testing and matching sites (providing that a close genetic relative of the individual is registered on a site and has opted into matching).
- 2.3.** The Code continues that clinics should ensure that donors understand, before giving their consent to donation, that this means there is the potential for them to become identifiable at any time (including before any child born from their donation turns 18). Likewise, clinics should ensure that, before giving their consent, recipients of donated gametes understand that any resulting child born could become identifiable at any time, including before the child reaches 18.
- 2.4.** The scope is defined such that only donors who are being asked to give consent to donate, or recipients who are being asked to give consent to receive donated gametes, will be having these implications discussions with clinics, and that historical donors and recipients and donor-conceived people will fall outside of these conversations. We will however aim to offer information for them via our website (described at the end of this paper).

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## **3. Meetings with genetic testing and matching companies**

- 3.1.** Since the September 2018 Authority meeting the Executive contacted companies offering testing and opt-in matching services with a UK user base and has held meetings with three of the larger direct-to-consumer testing and matching companies operating in the UK, 23andme, Ancestry and Living DNA. In these meetings we provided an introduction to the HFEA and to our system of managed information provision for donors and donor-conceived people, as well as to discuss:
  - The information that these companies provide (if any, currently) in relation to donor conception

- their signposting to users of their sites to further support around issues related to donor conception
  - any further information or contacts that HFEA may be able to offer to help service providers to develop their offer to customers around donor conception information and support.
- 3.2.** We encouraged companies to include more prominent information on their websites about the possibility of uncovering unexpected relatedness information including in relation to donor conception issues, and including information around donor conception, including signposting to available support.
- 3.3.** 23andme, Ancestry and Living DNA volunteered to tailor their information provision, signposting and/or phone service information support to improve their offer for people affected by donor conception who may have discovered information via their services.
- 3.4.** In follow up meetings with the companies, 23andme reported that they have revised their UK site along the lines suggested. Living DNA are still considering what actions to take. Ancestry are due to meet us later this Autumn to update us on their progress.

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## 4. Stakeholders' work on DTC DNA matching

### 4.1.

Some relevant resources are being produced in this area and we are investigating possibilities for collaboration on the production of resources or training for clinic staff related to DTC DNA testing and matching services and their impact. These include:

#### Donor Conception Network

Since the September 2018 Authority meeting, we have kept in touch with DCN (<https://www.dcnetwork.org/>) about their plans for resources around this issue.

DCN have an upcoming 'Professionals' event' in November which includes a session on DNA testing and they plan to add some information for donor conceived adults on direct-to-consumer DNA testing and matching sites on their website. DCN will also produce a film featuring donor-conceived adults, including some speaking about meeting their half-siblings and/or donors – some of whom were found through DNA matching.

DCN sees the issue of DTC DNA testing and matching services and their impact as part of a broader issue about openness and the importance of donor-conceived people having access to knowledge about their origins

DCN is supportive of any HFEA resources/ podcasting signposting to DCN. They are also potentially open to involvement with any podcasts, resources etc. produced by HFEA.

#### The SEED Trust (The Sperm, Egg and Embryo Donation Trust; formerly the National Gamete Donation Trust)

SEED Trust launched in spring 2019, with the remit of providing impartial advice, support and information to prospective donors, intended parents and surrogates and has no information on their website (<https://seedtrust.org.uk/>) about this topic. We understand that they are likely to be exploring this issue further in future.

## International Society of Genetic Genealogists (ISOGG)

ISOGG offers extensive information and practical resources aimed at anyone who has had [unexpected results](#) from a DNA test including matching results. They also offer resources for [donors, on getting ready for contact with their donor offspring](#), including where this approach comes following DTC DNA testing and matching. This also mentions the HFEA's Donor Conceived Register arrangements for anyone who donated pre-1991.

This adds to ISOGG's extensive existing guides for UK donor-conceived people searching for their donor, which refer to matching services: including country-specific resources around [DNA testing for donor-conceived people](#), and in the UK specifically, about their [legal rights](#) to access information and making contact with their donor(s) and donor-related siblings, [support and information](#) available for donor-conceived people, (both of which mention the HFEA's Opening the Register service) and also on [getting ready to search](#), and [getting ready for contact](#). We intend to contact ISOGG and ask for permission to signpost to their resources in our HFEA content.

## European Society for Human Reproduction and Embryology (ESHRE)

We are also in touch with ESHRE who are currently drafting good practice guidance for clinics aimed at clinic staff and counsellors across Europe on what clinics should be telling their prospective donors and recipients of donated embryos or gametes about DTC DNA matching, likely to be published early in 2020. We will signpost clinics to this, once it becomes available.

## The Victorian Assisted Reproductive Treatment Authority (VARTA)

VARTA is Victoria, Australia's equivalent of the HFEA.

VARTA has retrospectively completely removed donor anonymity and provides various useful resources on their site of relevance to donors, donor-conceived people and their families relating to this.

We intend to adapt relevant resources or information from VARTA (for example, [information on how historic donors can talk to their families about their donation in the new information](#); [information on how to make contact with a genetic relative you are linked to via donation](#)) in the information that we are producing for the HFEA website. These will be aimed at donor-conceived people (including those who may not have been aware that they are donor-conceived before they used a DTC DNA testing and matching service), or donors who have donated historically under donor anonymity and now find themselves effectively identifiable via DNA matching, or their family members and partners. There is very little on offer currently to support the information needs of these groups that we are aware of.

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## 5. Information and resources on HFEA website

- 5.1.** On the HFEA public-facing website, we will be publishing new information on DTC DNA testing and matching, aimed at
- people thinking of using donor-assisted conception
  - donor-conceived people and their families.
  - donors and their families (including prospective donors, current donors and historical donors who are no longer actively donating)



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- 5.2.** On the Clinic Portal, we will publish a series of accompanying podcasts (downloadable, recorded talks) aimed at clinic staff to support them in complying with our new guidance
  - 5.3.** These resources taken together will help to support the new Code requirement for clinics to be familiar with the basics of DTC DNA testing and matching services. This will help support them in confidently covering DTC testing and matching services and their potential implications with donor-conceived people and donors in the implications discussions which take place before consent is given.
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