

Authority meeting - agenda

29 January 2020

ETC.venues Victoria, 1 Drummond Gate SW1V 2QQ

Agenda item	Time
1. Welcome, apologies and declaration of interests	12.45pm
2. Minutes of 13 November 2019 Authority meeting HFEA (29/01/20) For decision	12.50pm
3. Chair's report (verbal)	12.55pm
4. Chief Executive's report incorporating EU exit (verbal)	1.00pm
5. Committee chairs' report (verbal) Licensing activity report HFEA (29/01/20) For information	1.05pm
6. Performance report HFEA (29/01/20) For information	1.20pm
7. 2020/21 Fees and budget HFEA (29/01/20) For information	1.35pm
8. Strategy and planning HFEA (29/01/20) For decision	1.50pm
Break	2.20pm
9. Communication Strategy HFEA (29/01/20) For information	2.35pm
10. Multiple births HFEA (29/01/20) Presentation	3.05pm
11. Birth rates HFEA (29/01/20) Presentation	3.25pm
12. Any other business	3.50pm
13. Close	3.55pm

Minutes of Authority meeting 13 November 2019

Details about this paper

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
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Meeting:	Authority
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Agenda item:	2
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Meeting date:	29 January 2020
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Author:	Debbie Okutubo, Governance Manager
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Annexes	
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Output from this paper

For information or decision?	For decision
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Recommendation:	
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Resource implications:	
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Implementation date:	
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Communication(s):	
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Organisational risk:	Low
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Minutes of the Authority meeting on 13 November 2019 held at ETC.venues Victoria, 1 Drummond Gate SW1V 2QQ

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Anne Lampe Kate Brian	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby
Apologies	Bobbie Farsides	
Observers	Steve Pugh (Department of Health and Social Care - DHSC) Dafni Moschidou (DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Dan Howard Sumrah Chohan	Catherine Drennan Paula Robinson Nora Cooke O'Dowd Helen Crutcher 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.** Bobbie Farsides sent her apologies. The Chair commented that today would have been Bobbie's last Authority meeting as her term of office would come to an end on 21 November. She thanked Bobbie for her contribution to the work of the Authority over the last three years. The Chair further commented that Bobbie had a national and international reputation as a leading medical ethicist and that her judgement and wisdom would be missed. The Chair stated that she had written to Bobbie on behalf of the board to express her appreciation.
- 1.3.** Declarations of interest were made by
- Yacoub Khalaf (PR at a licensed clinic)
 - Anthony Rutherford (Clinician at a licensed clinic)
 - Anne Lampe (Clinician)
 - Ruth Wilde (Counsellor at licensed clinic).

2. Minutes of Authority meeting held 11 September 2019

- 2.1.** Members agreed that the minutes of the meeting held on 11 September 2019 be signed by the Chair.
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3. Chair's report

- 3.1.** The Chair welcomed Rachel Cutting to her first meeting as the Director of Compliance and Information. With two Authority member positions vacant, the Chair commented that member appointments were a matter for the Secretary of State, and that therefore advertisements for the vacant positions would not be able to go out until after the general election to be held on 12 December 2019.
- 3.2.** On 18 September the Chair and Chief Executive (CE) had an introductory meeting with the Health Minister, Caroline Dinenage. From the meeting it was clear that the Minister was committed to our agenda and just before Parliament rose, the Minister wrote to Chairs of Clinical Commissioning Groups (CCGs) that currently offered no local fertility services to ask what their plans were.
- 3.3.** On 19 September the Chair attended the HFEA patient support event in Manchester and thanked Ruth Wilde and staff for leading the event.
- 3.4.** On 25 September the Chair and CE attended the Royal College of Obstetricians and Gynaecologists (RCOG) Steptoe and Edwards lecture.
- 3.5.** On 2 October the Chair attended our second event for PRs in London and noted that this was a worthwhile event to be run annually.
- 3.6.** On 14 October the Chair and CE attended the Scientific Clinical Advances and Advisory Committee (SCAAC) meeting.
- 3.7.** On 28 October the Chair appeared on the Victoria Derbyshire programme and Sky News to talk about the 10-year limit on egg storage.
- 3.8.** On 8 November the Chair chaired the Remuneration Committee meeting to consider the pay award for Senior Management Team (SMT) members.
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4. Chief Executive's report

- 4.1.** The CE reported back on key meetings since the last Authority meeting.
- 4.2.** On 30 September he and other HFEA colleagues had a meeting with the Law Commission to discuss their review of surrogacy.
- 4.3.** On 2 October the CE attended the PR Leadership event in London.
- 4.4.** On 7 October the CE and SMT colleagues attended the DHSC/HFEA quarterly accountability meeting.
- 4.5.** On 9 October the CE attended the Medicines and Healthcare products Regulatory Agency (MHRA) annual lecture given by Sir John Bell.
- 4.6.** On 16 October he attended the Health care leaders scheme meeting.

- 4.7.** On 22 October he represented the HFEA at the memorial service for Mary Warnock at St Margaret's, Westminster. Ermal Kirby and Gudrun Moore were also in attendance alongside several previous Authority members.
- 4.8.** The CE announced the passing of former MP Frank Dobson. He was Secretary of State for Health 1997 – 1999 and played a pivotal role in relation to HFEA.
- 4.9.** Authority members were polled by email prior to the meeting, in relation to changes required for the Code of Practice following a court ruling. In compliance with standing orders, a vote on the written resolution was passed in accordance with Standing Orders, as follows:
- 11 voted yes
 - 0 abstentions
 - 0 declines.
- 4.10.** The resulting changes to the Code of Practice were signed off by the Secretary of State just before Parliament rose.
- 4.11.** In relation to EU exit the CE discussed the current position for the Authority. He stated that in terms of readiness, this had already been assessed and we remained well placed to manage required changes come 31 January 2020, in the event of either a deal or no deal EU exit.

5. Committee Chair's report

Licence Committee

- 5.1.** The Chair of the Licence Committee reported that the committee met on 5 September 2019 and considered four items: one renewal for treatment and storage which was granted, two interim treatment and storage which were approved and one executive update on research which was noted.
- 5.2.** They also met on 7 November and considered five items: two renewals for treatment and storage, one interim treatment and storage and two executive updates on treatment and storage. The minutes were still in draft.

Statutory Approvals Committee

- 5.3.** The Chair noted that at the 29 August 2019 meeting one mitochondrial donation application and two new PGD conditions were approved and one special direction granted.
- 5.4.** At the 26 September 2019 meeting one mitochondrial donation application and five new PGD conditions were approved and one special direction was adjourned.
- 5.5.** The Committee also met on 31 October 2019 and considered five items: one mitochondrial donation application and four new PGD conditions. The minutes from the meeting were still in draft.

Executive Licensing Panel

- 5.6.** The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met five times since the last Authority meeting on 17 September, 3 October, 15 October, 29 October and 12 November. The panel considered 17 items in total: three renewals, four interims, eight variations, one executive update and one application for HLA testing. All items were approved.

- 5.7.** In addition there were 22 Licence Officer approvals: 14 EU import certificates, five changes of Licence Holders, two change of centre name and one voluntary revocation of a licence.

Audit and Governance Committee

- 5.8.** The Chair of AGC reported back to the Authority. It was noted that in addition to the standard items, there was a substantive report on capability risks which would be discussed during the item on the Strategic risk register. The Chair also noted that the external auditors attended the meeting.
- 5.9.** She continued that the annual SIRO (Senior Information Risk Officer) report was presented and they reviewed the Reserves policy and received an Estates update. She stated that updates would be received by the committee until the office move happened.
- 5.10.** Also at the meeting, she commented that the Digital programme was discussed at length and the committee will be looking at it again at their December meeting.
- 5.11.** Cyber security was discussed and they had recommended that all Authority members do their annual information security training on Civil Service Learning. It was noted that staff would send out instructions on how to log on to the site before the end of the year.
- 5.12.** Lastly, they looked at the gift and hospitality register and the counter fraud strategy.

Scientific Clinical Advances and Advisory Committee

- 5.13.** The Chair of SCAAC reported back to the Board. The committee met on 14 October 2019 and advised that they looked at treatment add-ons and their traffic light ratings.
- 5.14.** It was noted that one treatment add-on, pre-implantation genetic screening (day 5) was suggested to be demoted from an amber to a red traffic light rating. The remaining 10 treatment add-ons had no suggested change to their traffic light ratings.
- 5.15.** The committee suggested that retrospective studies of large data could not replace, but could support, randomised controlled trials (RCTs), for example identifying subgroup populations and evaluating long term patient safety outcomes.
- 5.16.** The committee also discussed consulting with the stroke national database to see what resources were required to maintain a large database that could be used to identify co-morbidities.

Remuneration Committee

- 5.17.** The Committee met on 8 November 2019 to consider the pay award for SMT members.

Decision

- 5.18.** Members noted the Committee chairs' reports and the licensing activity report.

6. Performance report

- 6.1.** A report summarising performance data up to the end of September 2019 was presented to the Authority.
- 6.2.** It was noted that there were five red key performance indicators (KPIs) shown in the overall status. The five areas were, (1) establishment leavers per year, (2) outstanding errors in the register 12 months running total, (3) average number of working days from day of inspection to the day the draft report is sent to the PR, (4) average number of working days taken for the whole process, from the day of inspection to the decision being signed by Chair, (5) average number of working days between Licence Committee date and minutes being signed by the Chair.
- 6.3.** Despite these red KPIs, overall performance was considered to be good. For the first time since June 2018 it was noted that our performance in processing PGD applications had returned to 100% for the rolling three-month period to September 2019.
- 6.4.** The CE commented that it was better that we set stretching and meaningful targets rather than non-challenging ones which could result in us regulating badly. He further thanked staff and contractors for all the work put into resolving some of the issues identified.
- 6.5.** The Director of Strategy and Corporate Affairs reported back on a range of initiatives and events that were in progress including the launch of a role description for PRs, collaborating with other regulators and responding to the Law Commission review on surrogacy.
- 6.6.** She further commented that we had a stand at the recent Fertility Show and it was very busy with people raising a range of issues. We were also in the process of planning for the next professional and patient stakeholder group meetings.
- 6.7.** Members commented that feedback about the Fertility Show indicated that the number of overseas clinics represented there outweighed UK based ones. Work therefore needed to be done to encourage UK based clinics to attend and exhibit at such events and we should consider whether our attendance was an effective use of HFEA resources.
- 6.8.** The Director of Finance and Resources reported that we were forecasting break-even against budget as the profiling of the budget currently was not fully reflective of expenditure activity. It was noted that this was being closely monitored to ensure we delivered the forecast at year end.
- 6.9.** The Director of Compliance and Information commented that she was now picking up the reins in her new role, and in the new year she would report back to the Authority on her emerging priorities.

Decision

- 6.10.** Authority members noted the performance report.

7. Strategic risk register

- 7.1.** The Risk and Business Planning Manager presented an overview of the strategic risk register. This was last reviewed by both AGC and SMT at their October meetings.
- 7.2.** This register was last brought to the Authority in May as it is presented bi-annually.
- 7.3.** The regulatory effectiveness risk was currently the only above tolerance risk. This is about our ability to take advantage of enhanced data due to ongoing delays to data migration and the launch of PRISM.

7.4. The Authority heard that the wider impact of the delay meant that we were unable to commit certain resources to other work for as long as the delay continued. This would continue to be reported to AGC, with their next meeting occurring in December 2019.

7.5. All other risks were within their tolerances.

7.6. It was noted that there was an emerging risk around the renewal of Authority members and we were liaising with the Department to ensure that the board and its committees were able to continue to function effectively. The executive committed to discussing this at the next AGC meeting.

7.7. The new estates risk captured risks relating to the office move scheduled for late 2020 and its potential to disrupt operations and strategic delivery. It was noted that there were particular capability risks arising from the office move.

Decision

7.8. The Authority noted the latest edition of the risk register.

8. HFEA strategy 2020-2023

8.1. The full draft of the new HFEA strategy for 2020-2023 was presented to the Authority following earlier Authority discussions and a period of consultation.

8.2. The main consultation points that had been addressed in the new draft strategy were:

- Greater emphasis on the word effective, in relation to treatment. Members welcomed the emphasis on effective treatment.
- Recognition of donors, donor-conceived people, surrogates and professionals (as relevant), in addition to patients.
- Clearer delineation between the two parts of the 'right information' aim.
- Clearer drafting in the 'shaping the future' section to recognise that there may be other legislative changes within the next three years, for example in relation to storage duration; and to broaden the wording of the section about our future operating environment.
- Other minor edits to improve wording, flow and clarity in response to queries and observations about our intended approach.

8.3. Members welcomed these changes and agreed that further editorial changes would be discussed with the committee chairs outside the meeting. The final version would be brought to the January 2020 Authority meeting for approval.

8.4. It was suggested that more collaboration between clinics be included into the strategy.

8.5. Members noted that the proposed new vision statement for 2020-2023 was:

Regulating for excellence: the best fertility care, support and information.

8.6. Members observed that as good as the vision was, it could be made better by being more ambitious in terms of the Authority's role in bringing future developments into current practice. As a regulator we needed to educate people to enable a better understanding of this complex area.

8.7. A revised vision statement was suggested, for further discussion after the meeting:

Evidence, support and information: regulating for excellence.

- 8.8.** It was further suggested that pre-treatment information could usefully include links to advice about lifestyle choices which could prevent or reduce infertility problems.

Decision

- 8.9.** It was agreed that committee chairs will be involved in the final editing on behalf of the board, taking into account all comments made during the discussion.

- 8.10.** The final version to be brought back to the January 2020 Authority meeting for approval.
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9. Opening the Register annual report

- 9.1.** The HFE Act requires the Authority to keep a register of information about donors and treatments involving the use of donor gametes and embryos in the UK.
- 9.2.** Improvements have been made to the Opening the Register (OTR) service during 2019, and a paper providing an overview of the changes and their impact was presented to Authority. Members noted the very high satisfaction levels of the users of the OTR service.
- 9.3.** Members were advised that the introduction of DocuSign software meant that people no longer needed to send in their original documents (by post) which could be a reason for the rise in activity in this area.
- 9.4.** In response to a question about emotional care for HFEA staff dealing with OTR enquiries from donor-conceived people, it was confirmed that there was support from line management and access to external counselling support, should it be required.
- 9.5.** Members commented that there was likely to be an increase in applications from 2021 onwards, when donor-conceived people born after the law on donor anonymity was changed (in 2005) turned 16. Staff confirmed that the workload would be monitored, and that work on the anticipated growth in OTR requests would form part of the delivery of the new strategy.

Decision

- 9.6.** Members noted:
- the update on OTR activity and performance
 - the supportive way in which OTRs are handled by the team
 - the level of applications in 2018 and the early indications of further increases received during 2019
 - the planning underway to cope with future increase in applications following donor anonymity changes in 2005.
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10. Donor Conceived Register

- 10.1.** In April 2017, at the request of the Department of Health and Social Care (DHSC), responsibility for the Donor Conceived Register (DCR), which related to treatments before the HFEA came into being, transferred from the DHSC to the HFEA. At that time the DCR was serviced by the National Gamete Donation Trust under a rolling 12-month contract. That contract ended on 31 March 2019.

- 10.2.** The DCR service comprises three main parts a) administration b) DNA testing and matching and c) counselling.
- 10.3.** Since the last Authority update in March 2018, we have successfully awarded the contract to the Hewitt Fertility Centre and we will continue to work with them.
- 10.4.** We will regularly monitor service performance and customer satisfaction to ensure the new service delivers the service standards we are seeking and meets its vision of a stable, long term and high-quality service.
- 10.5.** In response to a question, it was noted that there was ongoing engagement with the registrants panel.

Decision

- 10.6.** The Authority noted:
- the update on progress to establish a new improved Donor Conceived Register service
 - the outcome of the tender process and commencement of the new service
 - the arrangements for monitoring the new service.

11. Update on storage consent

- 11.1.** The Head of Legal set out the approach taken to address cases and steps taken to equip the sector with a better understanding of the law. The aim is to ensure that the necessary steps are taken at the appropriate time to enable patients to continue storing their gametes and embryos legally.
- 11.2.** Members were advised that where situations arise with consent, this could lead to tensions between patients' wishes and the requirements of the law and we have a statutory responsibility to uphold and promote compliance of the law.
- 11.3.** It was noted that there had been a number of cases where the Act has been breached. When HFEA inspectors became aware of such cases clinics were required to explain what actions they had taken and that this would continue to be the approach going forward.
- 11.4.** In such situations Inspectors check that clinics understand the law, that they are able to apply it correctly and that measures are in place to ensure that gaps in consent do not re-occur.
- 11.5.** Members were advised that clinics are required to ensure that there is effective consent at all times with no gaps in consent.
- 11.6.** We have sought to balance the interests of the patient with the obligations we have as the regulator.
- 11.7.** The HFEA's patient-centred stance on these issues has not been tested by a court. However, given the lengths the Courts went to in the legal parenthood cases to find a way to make the declarations that were sought, the view is that it is likely that a similar approach would be taken with storage consent cases.
- 11.8.** It was noted that going forward there will be more workshops and engagements to embed clinics' understanding of the law. The introduction of the new Person Responsible Entry Programme

(PREP) would also assist and may be a tool that clinics can use for their training for staff who deal with storage consent.

11.9. Members commented that we needed to be mindful not to stretch the law but ensure that we remained human rights compliant.

Decision

11.10. The Authority endorsed:

- the approach to storage consent as set out in the report
- the multi-pronged approach to raising awareness of the issue and improving understanding of a complex area of law.

11.11. The Authority noted that:

- the new PREP learning tool would be launched early in 2020
- the proposed new Code of Practice guidance on storage consent would be included in the next iteration of the Code which would be presented to the Authority for sign-off.

12. Register Research Panel annual report

12.1. The Head of Research and Intelligence presented the report to the Authority. The last annual report on the Register Research Panel (RRP) to the Authority was on 30 January 2019.

12.2. The Authority noted that between 2010 and 2018, 16 projects were approved in total with a maximum of two projects approved each year. In 2018 there was an increase in interest, and seven projects were approved in a single year.

12.3. In 2019 there have been 26 expressions of interest from separate research projects although none of these have yet translated into formal applications to the Register Research Panel.

12.4. The Head of Research and Intelligence commented that the larger volume of activity meant we needed to adapt our processes to meet demand. This would be done by:

- working with other public bodies on information governance
- creating a single internal log of project approvals and amendments
- seeking legal advice on contract issues around data linkages
- RRP meetings to be scheduled every other month (an increase in frequency)
- Information Governance and Records Manager to provide advice to the panel
- basing our application form on those used by the office for Data Release at Public Health England
- continuing to strengthen our processes to ensure they were transparent and well documented.

12.5. It was noted that as we expect to see further increases in interest in register data there was a proposal that we start charging fees in line with other similar organisations who ran a cost recovery model. In law, the relevant Regulations allowed for a fee to be charged.

- 12.6.** From conversations with researchers, it had emerged that researchers expected to be charged to access data and built provision for this into their funding proposals. Anonymised data and underlying data tables would still be available free of charge on our website.
- 12.7.** Members commented that it was legitimate and reasonable to charge.
- 12.8.** In response to a question, it was noted that a maximum charge of £5000 was defined in the Regulations.
- 12.9.** Members requested that the list of published research papers that had resulted from researchers' approved data requests should be published on our website.
- 12.10.** Members also noted that the HFEA would be hosting a Research Engagement day on 18 May 2020 as part of our continued efforts to encourage and support more research.

Decision

- 12.11.** Members agreed that the maximum of £5000 be charged and advised strongly that there be no exceptions.
- 12.12.** The Authority approved the introduction of the RRP fee effective from 1 April 2020.

13. Any other business

- 13.1.** There was no other business.
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14. Chair's signature

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

Signature

Chair: Sally Cheshire

Date: 29 January 2020

Licensing activity report

Details about this paper

Area(s) of strategy this paper relates to:	-
Meeting:	Authority
Agenda item:	5
Meeting date:	29 January 2020
Author:	Paula Robinson, Head of Planning and Governance
Annexes	Annex 1: Licensing activity report

Output from this paper

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

1. Introduction

- 1.1. The attached report sets out information about licensing throughput and outcomes in November and December 2019.
- 1.2. We have been tracking data to compile this report since July 2019. We will continue to monitor the data to detect any shifts in trends. We will review the document in full in July 2020, and decide then whether some aspects should be included only annually.

2. Recommendation

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

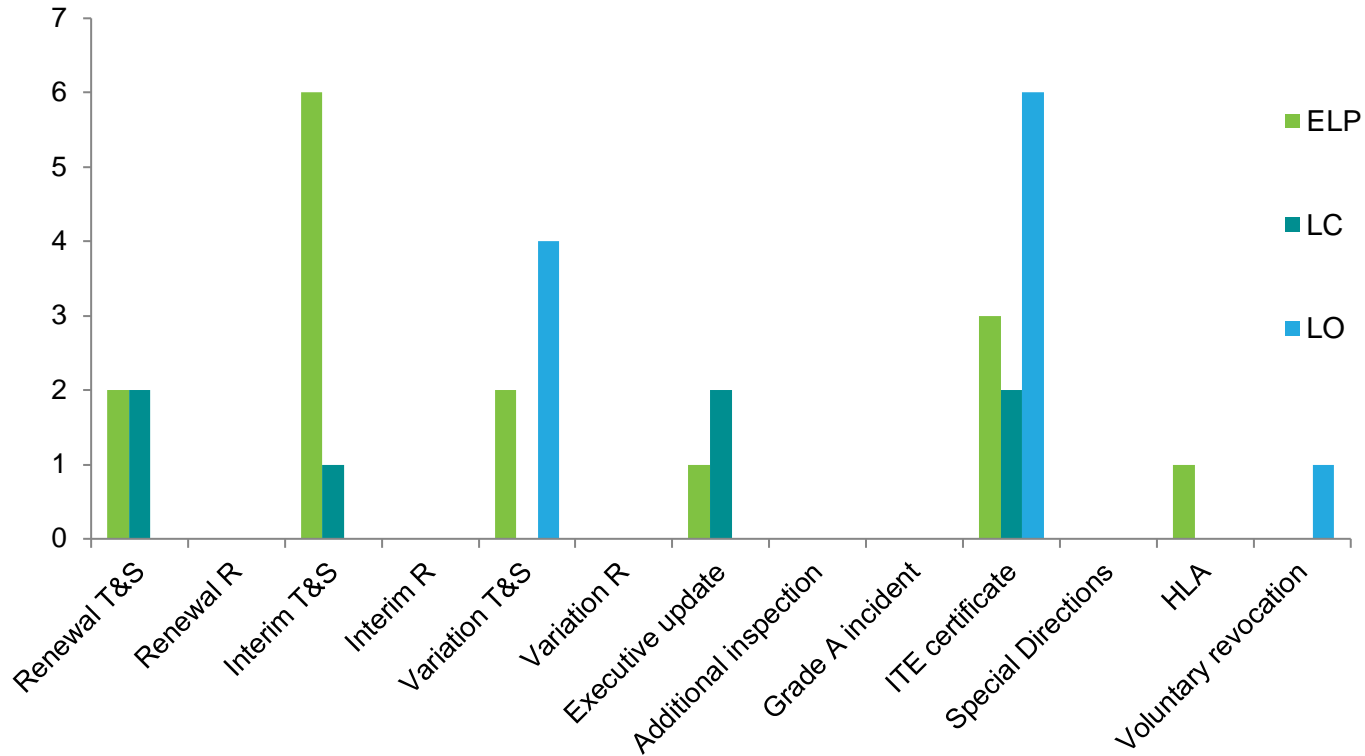
Annex A - Licensing activity report for 1 November to 31 December 2019

Outcomes of recent items by committee: 1 November – 31 December

Committee ¹	Granted	Other	Not yet confirmed	Comments
LC	3	2	0	Two executive updates were noted.
ELP	11	1	0	-
LO	10	0	0	-
SAC	9	3	0	One PGD item was authorised for one family only, and so was not added to the PGD list.

¹ LC = Licence Committee ELP = Executive Licensing Panel LO = Licensing Officer SAC = Statutory Approvals Committee

Decisions made by LC, ELP and LO



Commentary

A typical range of items, still featuring a relatively high number of ITE certificates (new certificates and renewals).

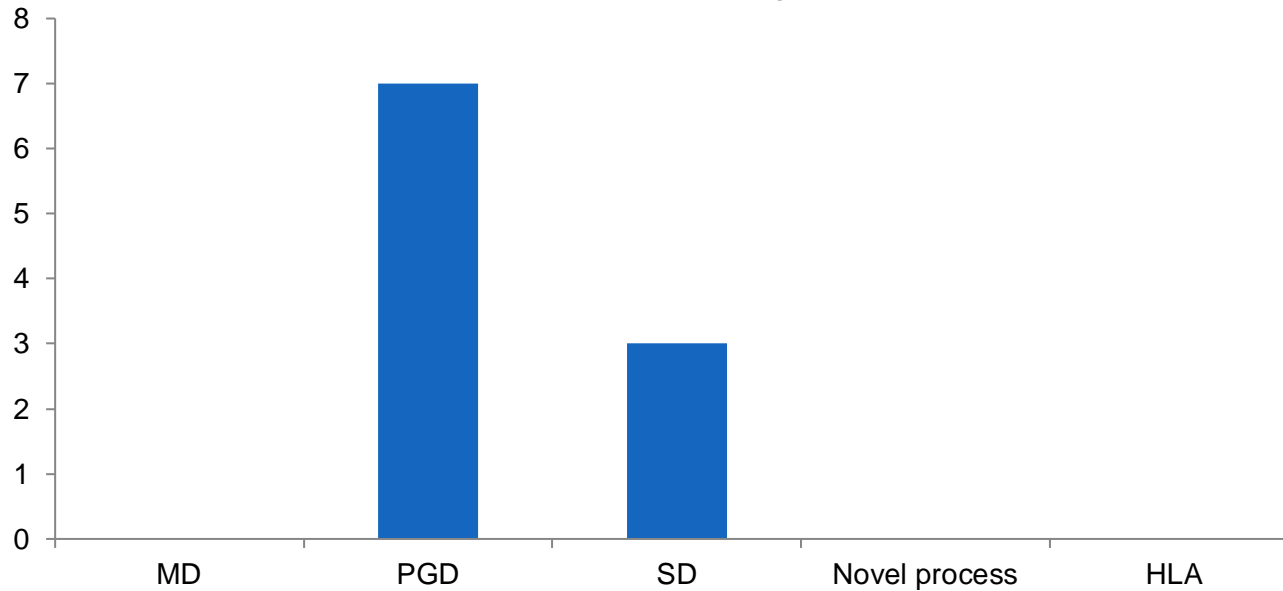
Key:

T&S = treatment and storage

R = research

ITE = importing tissue establishment

Decisions made by SAC



Commentary

There were no further mitochondrial donation items in November and December.

Key:

MD = mitochondrial donation

PGD = preimplantation genetic diagnosis

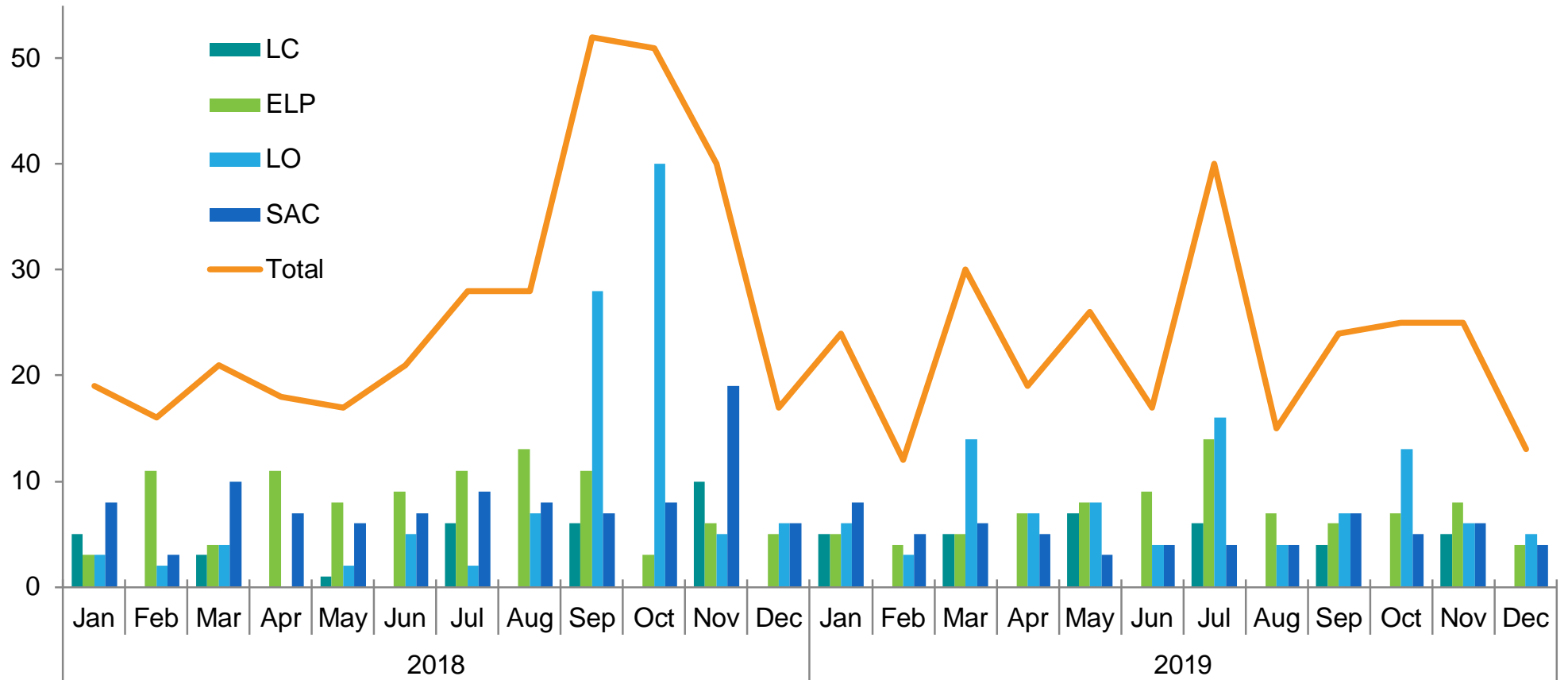
SD = special directions for import or export

HLA = human leucocyte antigen

Longer term trends – two year rolling report

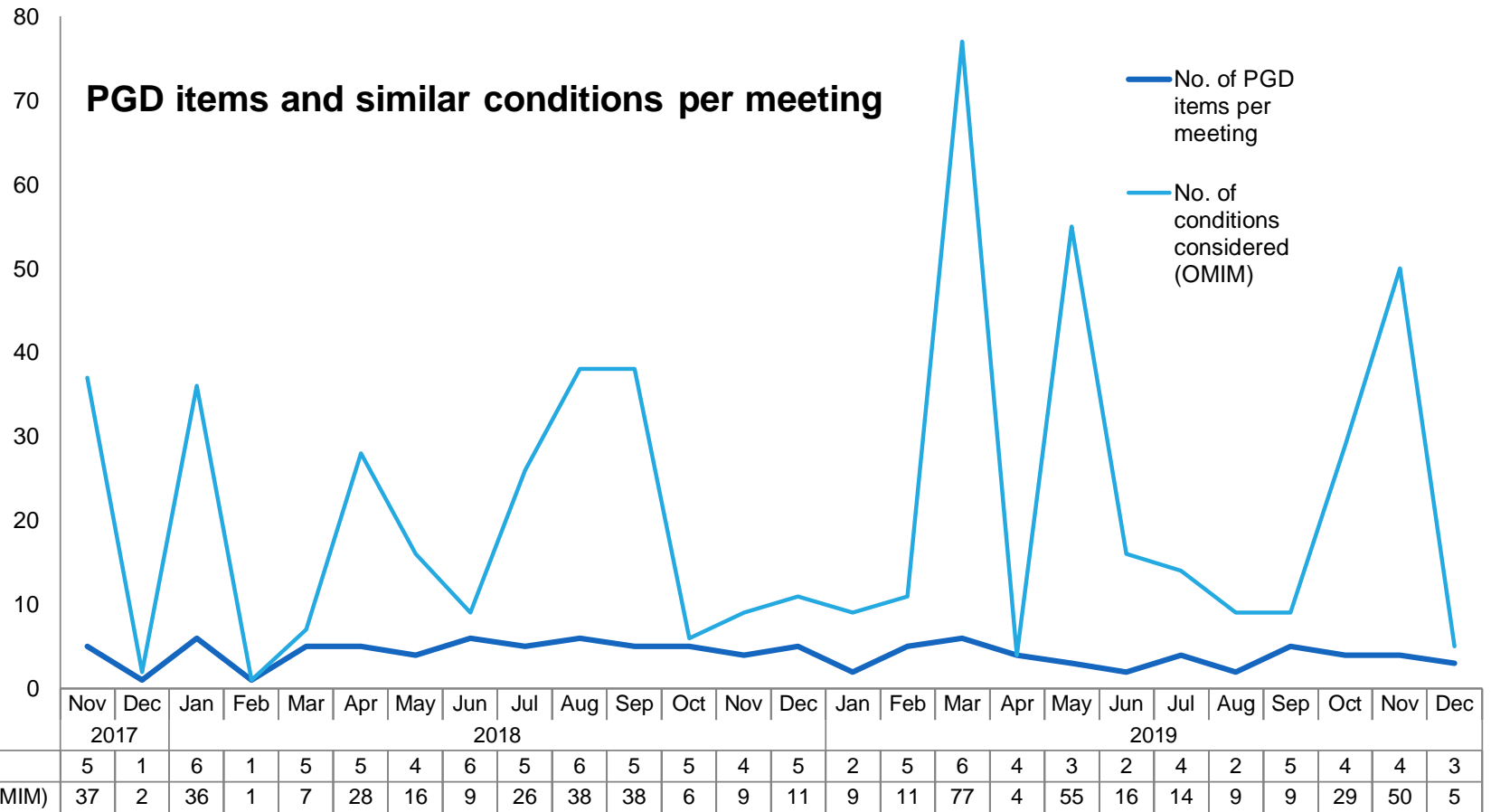
Item numbers per committee across the last two years (rolling picture) – all committees

Number of items - January 2018 - December 2019



We will continue to monitor for trends. Item volumes are typically highest between March and August.

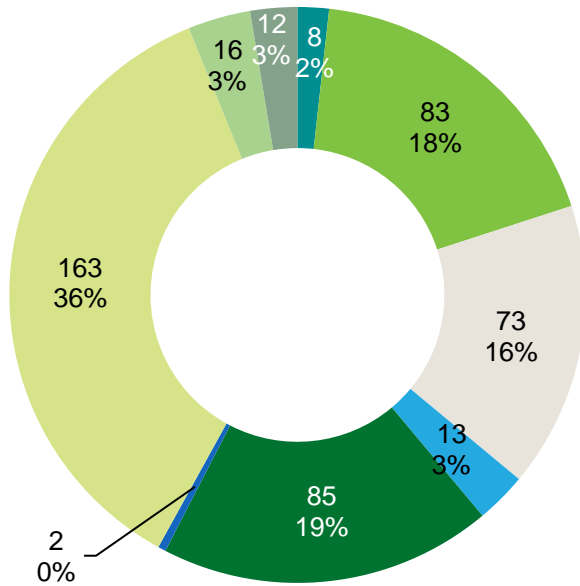
PGD conditions considered – trend over time: January 2018 – December 2019



There is continuing variation in the number of similar conditions 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 conditions to consider) as each scenario is unique.

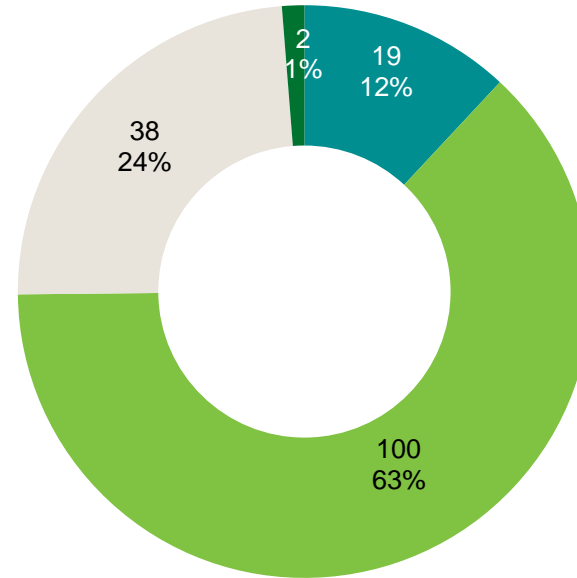
Item types – January 2018 – December 2019

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 previous meetings. 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

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	6
Meeting date:	29 January 2020
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1: HFEA performance scorecard

Output from this paper

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):	<p>The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper.</p> <p>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.</p> <p>The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).</p>
Organisational risk:	Medium

1. Introduction

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

2. Reviewing performance

- 2.1. SMT reviewed November performance data at its 6 January 2020 meeting.
- 2.2. Overall performance is good. Three indicators are currently classified as red. There is a full discussion of these in the performance report, provided in the annex to this paper.

3. Recommendation

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

Annex 1 - HFEA performance scorecard

Dashboard – November data

Overall performance – RAG status (all indicators)



People – capacity

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

↓
Leavers: 0
(17%)

Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month

↓
57,471

Licensing end-to-end

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

↑
80 working days

Summary Financial Position - November 2019

	Year to Date			Full Year		
	Actual £'000	Budget £'000	Variance £'000	Forecast £'000	Budget £'000	Variance £'000
Income	4,652	4,529	(123)	7,089	7,063	(26)
Expenditure	4,646	4,877	232	7,035	7,067	32
TOTAL Surplus / (Deficit)	6	(349)	355	54	(4)	57

Commentary

The position as at the end of November shows a favourable variance against budget of **£355k**. This is primarily due to underspends within the legal and non-cash cost lines.

We are currently forecasting to end the year with a small surplus against budget, this figure is based on continued low demand for legal expenditure and before final estimates for the extension of the PRISM project.

Overall performance – November 2019

SMT reviewed the overall performance picture on 6 January. There were 3 red indicators. Overall, November performance was generally good.

Red indicators

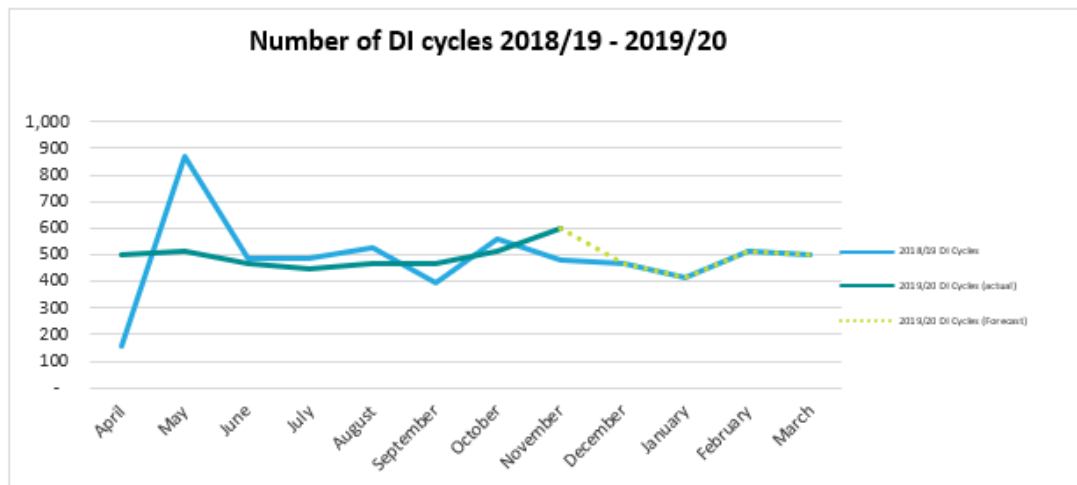
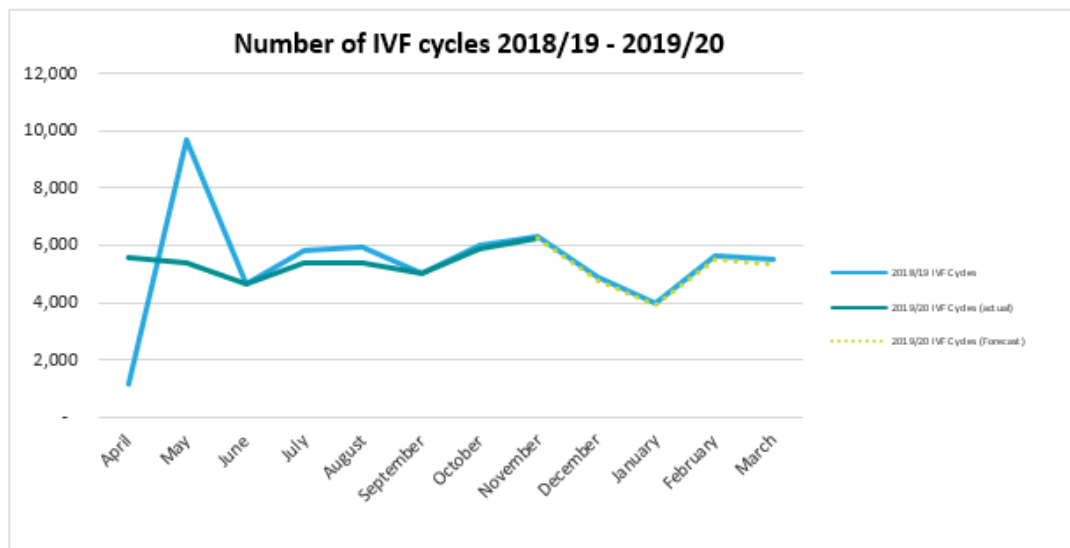
The 3 red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

Inspection and licensing processes

- Average number of working days from day of inspection to the day the draft report is sent to the PR. Our target is for 90% of these to be sent in 20 working days. In November 75% of reports (3/4) were sent in this timeframe, with an average of 30 working days. One missed the KPI due to inspection team delays because of sickness and annual leave.
- Average number of working days taken for the whole process, from the day of inspection to the decision being finalised (signed by Chair) (including only items starting with an inspection). Our target is 70 working days, but in November the average was 80. Delays were due to more complicated reports with the need for management review and delays to receiving PR responses to draft reports. The delay is not therefore structural.
- 3 month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. No PGD applications were due in November, but 70% of applications (7/10) in the rolling 3 months were processed within the KPI, the average time to process these was 61 working days. Those that missed the KPI did so by only one day.

Budget status – November data

2019/20 Income



IVF Cycles

	YTD		YE Position	
	Volume	£	Volume	£
2018/19 IVF Cycles	44,641	3,571,280	64,720	5,177,600
2019/20 IVF Cycles	43,473	3,477,840	63,027	5,042,132
Variance	1,168	93,440	1,693	135,468

At the end of November, the number of billable IVF treatments is 2.6% lower than the 2018/19 figures, this is primarily due to low activity in July and August. Should figures not recover by the end of quarter 3 we may need to consider reducing our fee income forecast, current projections indicate a short fall of around £130k compared to the last financial year

The £ value shown in the management commentary does not translate to the volumes shown due cumulative rounding differences which are not material.

DI Cycles

	YTD		YE / Forecast	
	Volume	£	Volume	£
2018/19 DI Cycles	3,958	148,425	5,845	219,188
2019/20 DI Cycles	3,960	148,500	5,848	219,298
Variance	2	75	3	111

There is a slight increase in volumes compared to 2018/19 and the current projection suggests that we should still achieve our budget.

HFEA Income & Expenditure

Nov-19

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	517	467	(50)	-11%	934	934	-
Non-cash (Ring-fenced RDEL)	336	336	-	0%	504	504	-
Grant-in-aid - PCSPS contribution	67	67	0	0%	100	100	-
Licence Fees	3,629	3,583	(45)	(1)	5,400	5,374	(26)
Other Income	9	5	(4)	(84)	10	10	-
Ring-fenced and seconded income	94	71	(24)		142	142	-
Total Income	4,652	4,529	(123)	(3)	7,089	7,063	(26)
Revenue Costs							
Salaries (excluding Authority)	2,937	2,941	5	(0)	4,281	4,343	63
Staff Travel & Subsistence	118	97	(21)	21	160	144	(15)
Other Staff Costs	127	74	(54)	73	148	101	(47)
Authority & Other Committees cos	182	178	(4)	2	267	270	3
Facilities Costs incl non-cash	453	591	139	(23)	900	889	(12)
IT Costs	527	504	(23)	4	669	669	-
Legal / Professional Fees	132	295	164	(55)	376	402	25
Other Costs	170	196	26	(13)	234	249	15
Total Revenue Costs	4,646	4,877	232	(5)	7,035	7,067	32
TOTAL Surplus / (Deficit)	6	(349)	355	102	54	(4)	57

Management commentary

Income.

Total income is above budget by **£123k** this made up of an increase in our Grant-in-aid (£50k) relating to increased pension contributions an increase in Renewal and EUTD fee income of (£45k) and a small increase in other income (£28k) of which most relates to secondment.

Expenditure.

Expenditure for the eight months of the financial year shows an underspend against budget of **£222k**.

Staff costs - are on budget year to date, however this is due to an underspend in salaries of (£244k) against an overspend on temporary staff costs of (£249k). There are pressures relating to contractors cost incurred to complete the work on PRISM. Other underspends are being utilised across the business to ensure this work is funded.

Staff Travel and Subsistence and Other staff costs - are over budget by **£21k** and **£54k** respectively. Staff Travel and subsistence is over the profiled budget due to inclusion of home to office taxation costs previously accounted for at year end. Other staff costs are over budget due to further costs for essential staff training (£46k) and external recruitment costs (£8k).

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

Legal and Professional costs - are underspent by **£164k** and is largely due to low levels of legal activity within areas such as Committee Advice, Policy and Litigation. A closer look at this area of spend is being undertaken in as part of the Quarter 3 review.

Forecast

We are forecasting a small variance against budget (**£57k**), and are monitoring our income and IT expenditure closely to ensure we deliver a balanced position at year-end.

People – key performance and volume indicators

Indicator	Score	RAG	Recent trend ¹	Notes
Current headcount by month Staff in post/headcount	66/68	↑	<p>Headcount vs establishment</p>	Overall volume (capacity) indicator.
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	17%	↓	<p>Turnover vs target range (5-15%)</p>	KPI range: 5-15% turnover for the rolling year The public-sector average is 10.9% (Xpert HR 2017) on which we base our target.
Staff sickness absence rate (%) per month.	2.5%	★	<p>Sickness absence</p>	KPI: Absence rate of ≤ 2.5%. Average rate of public sector sickness absence is 2.6% versus 1.7% for the private sector. (Source: ONS data 2017)

¹ 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.

Information – key performance and volume indicators

Indicator	Score	RAG	Recent trend	Notes																		
Number of emailed public enquiries received (compared with same month last year)	116	↓	<table border="1"> <caption>Number of emailed public enquiries received</caption> <thead> <tr> <th>Month</th> <th>Last year</th> <th>This year</th> </tr> </thead> <tbody> <tr> <td>Jul</td> <td>143</td> <td>131</td> </tr> <tr> <td>Aug</td> <td>169</td> <td>84</td> </tr> <tr> <td>Sep</td> <td>146</td> <td>74</td> </tr> <tr> <td>Oct</td> <td>218</td> <td>145</td> </tr> <tr> <td>Nov</td> <td>172</td> <td>116</td> </tr> </tbody> </table>	Month	Last year	This year	Jul	143	131	Aug	169	84	Sep	146	74	Oct	218	145	Nov	172	116	Volume indicator.
Month	Last year	This year																				
Jul	143	131																				
Aug	169	84																				
Sep	146	74																				
Oct	218	145																				
Nov	172	116																				
Percentage of Opening the Register requests responded to within 20 working days	100%	★	<table border="1"> <caption>Percentage of Opening the Register requests responded to within 20 working days</caption> <thead> <tr> <th>Month</th> <th>Number of requests</th> <th>% within 20 days</th> </tr> </thead> <tbody> <tr> <td>Jul-19</td> <td>28</td> <td>100%</td> </tr> <tr> <td>Aug-19</td> <td>58</td> <td>100%</td> </tr> <tr> <td>Sep-19</td> <td>52</td> <td>100%</td> </tr> <tr> <td>Oct-19</td> <td>50</td> <td>98%</td> </tr> <tr> <td>Nov-19</td> <td>50</td> <td>100%</td> </tr> </tbody> </table>	Month	Number of requests	% within 20 days	Jul-19	28	100%	Aug-19	58	100%	Sep-19	52	100%	Oct-19	50	98%	Nov-19	50	100%	<p>KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)</p> <p>The increase in applications received that we reported in September has continued.</p>
Month	Number of requests	% within 20 days																				
Jul-19	28	100%																				
Aug-19	58	100%																				
Sep-19	52	100%																				
Oct-19	50	98%																				
Nov-19	50	100%																				
Number of requests for contributions to Parliamentary questions	0	↔	<table border="1"> <caption>Number of 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>Jul</td> <td>1</td> <td>2</td> </tr> <tr> <td>Aug</td> <td>0</td> <td>0</td> </tr> <tr> <td>Sep</td> <td>0</td> <td>0</td> </tr> <tr> <td>Oct</td> <td>0</td> <td>29</td> </tr> <tr> <td>Nov</td> <td>0</td> <td>9</td> </tr> </tbody> </table>	Month	PQs answered	Same month last year	Jul	1	2	Aug	0	0	Sep	0	0	Oct	0	29	Nov	0	9	Volume indicator.
Month	PQs answered	Same month last year																				
Jul	1	2																				
Aug	0	0																				
Sep	0	0																				
Oct	0	29																				
Nov	0	9																				

Indicator	Score	RAG	Recent trend	Notes
Number of Freedom of Information (FOI) requests	3	↓		Volume indicator.

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend ²	Notes
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair)	80	↑		<p>KPI: Less than or equal to 70 working days.</p> <p>See above for further commentary - additional complexity meant there were delays to processing several applications in September.</p>
Monthly percentage of PGD applications processed within three months (66 working days).	N/A (none due to be completed in November)	-		<p>KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.</p> <p>No applications were due to be completed in November, so there is no data for this month.</p>

² 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 ²	Notes												
Average number of working days taken (in the month).	N/A	-	<p>Working days</p> <table border="1"> <tr><th>Month</th><td>Jul</td><td>Aug</td><td>Sep</td><td>Oct</td></tr> <tr><th>Value</th><td>66</td><td>66</td><td>56</td><td>60</td></tr> </table>	Month	Jul	Aug	Sep	Oct	Value	66	66	56	60	The fall in performance in October was due to two applications missing their KPI by just one day.		
Month	Jul	Aug	Sep	Oct												
Value	66	66	56	60												
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	70% (7/10)	↓	<p>Performance</p> <table border="1"> <tr><th>Month</th><td>Jul</td><td>Aug</td><td>Sep</td><td>Oct</td><td>Nov</td></tr> <tr><th>Value</th><td>36%</td><td>60%</td><td>100%</td><td>73%</td><td>70%</td></tr> </table>	Month	Jul	Aug	Sep	Oct	Nov	Value	36%	60%	100%	73%	70%	KPI: As above. As mentioned above, the drop in performance is due to two applications missing the deadline by one day in October.
Month	Jul	Aug	Sep	Oct	Nov											
Value	36%	60%	100%	73%	70%											
Average number of working days taken (cumulative 3 month picture).	61	★	<p>Working days</p> <table border="1"> <tr><th>Month</th><td>Jul</td><td>Aug</td><td>Sep</td><td>Oct</td><td>Nov</td></tr> <tr><th>Value</th><td>70</td><td>70</td><td>60</td><td>62</td><td>61</td></tr> </table>	Month	Jul	Aug	Sep	Oct	Nov	Value	70	70	60	62	61	
Month	Jul	Aug	Sep	Oct	Nov											
Value	70	70	60	62	61											

2020/21 Fees and budgets

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence
Meeting:	Authority
Agenda item:	7
Meeting date:	29 January 2020
Author:	Richard Sydee, Director of Finance and Resources
Annexes	

Output from this paper

For information or decision?	For decision
Recommendation:	
Resource implications:	
Implementation date:	1 April 2020
Communication(s):	
Organisational risk:	Medium

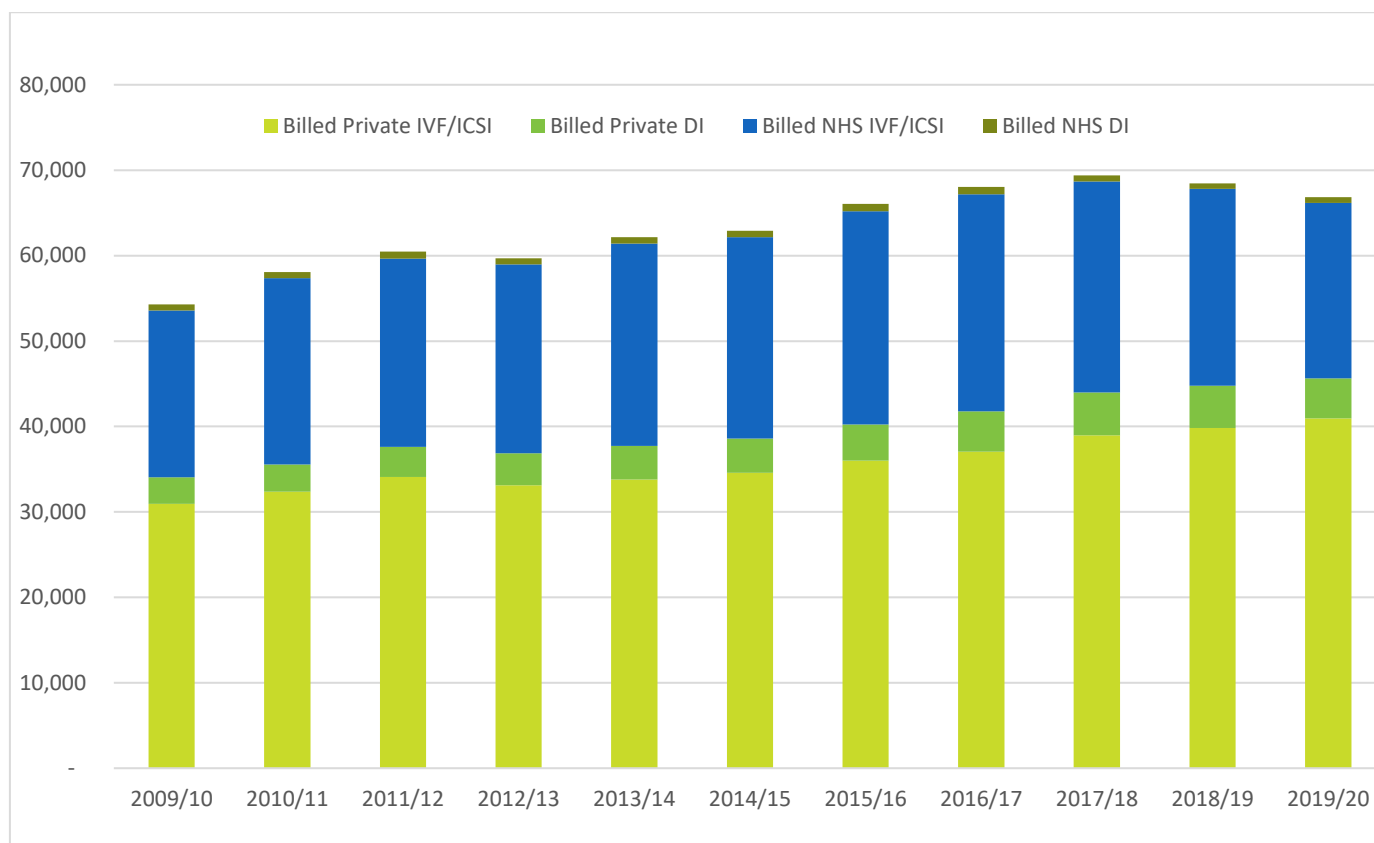
1. Background

- 1.1. The HFEA raises most of its operating funds through charging fees to licenced establishments for the cost of regulation. Although there are some small annual or application fees the majority of licence charges to establishments are based on activity, with a fee being charged to the centre for each IVF or DI cycle they perform.
- 1.2. It is important to be clear that this is a charge to licenced establishments and not patients, although some clinics choose to list this fee on patient's bills the HFEA does not make any charges to patients. Historically it has been felt the cost of regulation is evenly distributed amongst licenced establishments based on the level of activity that they undertake and that therefore a fee per cycle performed is used as proxy for an annual licence fee.
- 1.3. Until recently we have seen consistent year on year growth in treatment activity across the sector. Since the HFEA last reviewed its fees in April 2016 growth has been approximately 2% per annum, which is broadly in line with inflation across the same period. As a result, the HFEA has been able to hold fees at 2016 rates for the past 4 years.
- 1.4. As the regulator we monitor treatment activity closely, with our monthly review of billing activity a key early indicator of changes in activity levels. Since the second quarter of this financial year we have seen a reduction in the number of billable IVF cycles performed across the sector. We first reported this to the Authority in September 2019, at the end of the second quarter, and in line with the Authority's request have undertaken a detailed review of recent activity level consider if this represents an emerging trend.

2. Treatment activity

- 2.1. Our analysis of treatment activity has shown a downturn in overall activity and billable IVF activity across the sector since the start of 2019. Our actual billed activity to the end of the third quarter of this financial year is 4% below the levels reported to the same period in the 2018/19 financial year.
- 2.2. The graph below shows billable IVF and DI activity over the last 10 years. As is clear we have seen steady and continued growth throughout the last 10 years. In only one year in the previous 10 have we seen activity dip below the prior year levels, in 2012/13, although the overall trend resumed in 2013/14 and has continued to this point.
- 2.3. The graph provides a split of billable treatment activity between the NHS and Private clinics and also between DI and IVF activity. Growth over the past 10 years has been fuelled by increased activity in the private sector, with NHS treatment activity staying broadly static in terms of numbers but becoming a proportionately smaller percentage of overall activity.

Figure 1: Billed activity in the UK by stated intention of cycles, 2009/10 to 2019/20



- 2.4.** As can be seen above there has been a material reduction in billable NHS treatment activity in 2019/20, this has occurred concurrently with almost no growth in private sector IVF activity, resulting overall in a drop in billable activity this financial year.
- 2.5.** As a result of this reduced activity we have reduced our 2019/20 income forecast by £150k and have considered the implications for sector activity and HFEA licence income should this position prove to be indicative of a future trend.

3. Budget for 2020/21

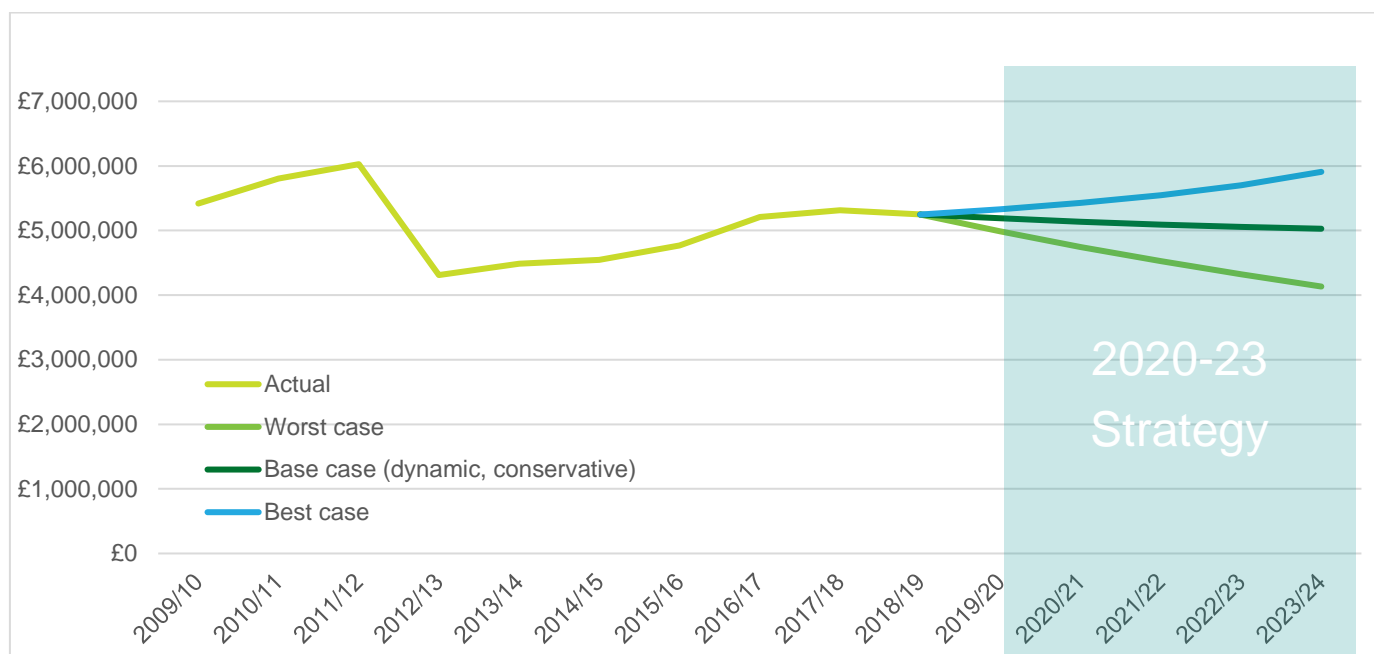
- 3.1.** The HFEA budgeting process has already commenced and high-level operational requirements have been calculated. Annual HFEA expenditure is primarily fixed, with less than 20% of the budget not tied to contractual obligations.
- 3.2.** As with most public sector organisation the HFEA looks to restrict growth in costs wherever it can. This year we set out to limit our overall budget increase to no more than 2%. The majority of cost pressures faced by the HFEA in 2020/21 are directly linked to contractual indexation, in line with the Consumer Price Index, or due to increased staff costs which have been driven by the annual pay award (2% - as per Cabinet Office guidance on Civil Service pay) and due the unfunded element of the increase in Employers pension contributions to the Civil Service Pension Scheme (2.3%).

- 3.3.** The working budget for 2020/21 is £7.20m, which represents a 1.9% increase on the 2019/20 budget of £7.06m. Our Grant in Aid, provided by the Department of Health and Social Care (DHSC), will remain at 2019/20 levels and we do not anticipate any material increases in other income sources. As a result, the HFEA will need to raise c£5.5m in licence fee income in order to achieve a balanced budget position.
- 3.4.** Given the nature of HFEA's budget, and the limited spend which is uncommitted at the start of the financial year, there are few options available to make savings that would not impact directly on the strategic aims of the HFEA in the first year of its new strategy.

4. Forecast activity projections

- 4.1.** We have modelled a number of scenarios which take account of the recent downturn in sector activity. For the purposes of income forecasting we have used three projections which provide a worst, most likely and best case scenario modelled over the next strategic period.
- 4.2.** The graph below indicates the likely income levels over the next three years for these three scenarios.

Figure 2: HFEA fee income projection (all scenarios), 2009/10 to 2023/24



- 4.3.** The Authority should note:
- The best case sees growth return quickly to historic levels and continue to grow at c2% per annum, this would provide c£5.45m in income for the 2020/21 financial year.
 - Our base case (most likely) scenario see the continuation of reduced NHS activity, leading to a reduction of c 1% per annum in total activity across the three-year period. This would lead to income of c £5.14m for 2020/21.

- Our worst-case scenario assumes private sector activity levels declining in line with the recent reduction in NHS activity. Although unlikely this would lead to year on year reductions at c 5% per annum and result in income for 2020/21 of £4.75m

4.4. Although none of these scenarios would deliver the required income of £5.5m in licence fees for 2020/21 the best-case scenario, which is in line with historic growth over the past 10 years, would deliver income that the Executive would be confident in committing to delivering all planned activity. Other scenarios result in significant shortfalls against budgets that would require significant restrictions on expenditure and that would impact on delivering strategic objectives – limiting the HFEA to our core regulatory and compliance activity.

5. Changes to licence fees

- 5.1.** The existing approach to licence fees has been in place for a considerable period of time and has been able to provide sufficient income to ensure the HFEA can perform its functions in full. Looking ahead, the simplest proposal to increase the licence fee income would be to propose an increase to the existing licence fees with no change to the current charging mechanisms.
- 5.2.** Since fees were last increased, in April 2016, the CPI rate of inflation has averaged just under 2% per annum and the index has increased by 8.3% in total between April 2016 to December 2019. If this indexation was applied to the current fees the charge per IVF cycle would increase from £80 to £86.64 and per DI cycle from £37.50 to £40.61.
- 5.3.** An increase to current charges of £5 per IVF cycle and £2.50 per DI cycle would raise approximately £325k more in fees than the current charge. This would be sufficient to cover the income shortfall identified for 2020/21 but would be insufficient to cover the gap across the three year strategic period if our base case forecast were indicative of future activity levels.
- 5.4.** Another option, which would require further analysis and work, would be to consider whether the current charging regime remains the appropriate mechanism for calculating and charging licence fees.
- 5.5.** Our analysis of activity has shown that the number of billable cycles is reducing as a proportion of overall activity in the sector. This may be indicative of changes in treatment practice and the Authority may wish to consider whether, in the medium to long term, the current licensing regime still represents an appropriate approach to recovering the cost of regulation equitably across the sector.
- 5.6.** All of this must be considered in the light of the relatively recent emergence of this activity data and whether the reduced activity we have seen over the last 6-9 months is truly indicative of a new trend. Although the HFEA would face a potential income shortfall in 2020/21 should this trend continue we might wish to obtain more certainty around both the drivers of reduced activity and the likelihood of our forecast scenarios.
- 5.7.** Either of these options would require discussions with DHSC and potentially HM Treasury. We would look to explore with DHSC colleagues the possibility of underwriting a potential shortfall in 2020/21 whilst we conduct further analysis of this data and the options for licence fee increases or more fundamental structural changes to our licence fee methodology. We would hope to provide

more certainty on options and the likely engagement and implementation timetables at the March Authority meeting.

6. Recommendations

- 6.1.** The Authority are asked to consider the budget requirement for the 2020/21 financial year and the indicative activity and income forecasts based on our most recent modelling.
- 6.2.** The Authority are asked to:
- Approve the 2020/21 budget
 - Agree that the Executive should explore options for managing the financial risk for 2020/21 with DHSC and the likely timetables for future licence fee changes
 - Agree that further work be undertaken to consider whether the existing licence fee structure remains the appropriate mechanism for recovering the cost of regulation and to identify alternative proposals that could replace the existing model
-

7. Next steps

- 7.1.** Subject to the Authority's approval we will finalise detailed Directorate budgets and plans based on the working budget maximum of £7.2m.
- 7.2.** We have already briefed DHSC colleagues on the emerging activity levels and potential impact on our licence fee income. We will meet in early February with colleagues to discuss how we might manage any initial financial pressures in the short term and agree next steps for any review of fees.
- 7.3.** Further work on options for changes to the fee structure would be undertaken once parameters and an implementation timetable is agreed with the Department.
-

Strategy and planning

Details about this paper

Area(s) of strategy this paper relates to:	Strategy 2020-2023
Meeting:	Authority
Agenda item:	8
Meeting date:	29 January 2020
Author:	Paula Robinson, Head of Planning and Governance Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1: Strategy 2020-2023 Annex 2: Business plan 2020/21 – activities section

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to approve the strategy for 2020-2023, and the draft business plan for 2020/21.
Resource implications:	In budget.
Implementation date:	1 April 2020 onwards
Communication(s):	HFEA website
Organisational risk:	Low

1. Introduction

- 1.1. This paper presents a final draft of the Authority's new strategy for 2020-2023, alongside an overview of plans and priorities for the coming business year.
- 1.2. Attached are two annexes:
 - Annex 1: Strategy 2020-2023
 - Annex 2: Draft business plan for 2020/21.

2. Finalising the strategy

- 2.1. Since the Authority's November 2019 meeting, the Committee Chairs have kindly assisted with finalising the draft strategy.
- 2.2. In November, members expressed overall approval for the draft strategy, noted that it had been well received by stakeholders, and agreed that our strategy should be ambitious, balancing current and future priorities.
- 2.3. Our vision statement has been slightly revised since November, and signals our overall ambitions for the next three years. Our proposed vision statement now reads:

Regulating for excellence: shaping the future of fertility care and treatment

- 2.4. The Authority is now asked to approve this final draft, so that design work can be completed in readiness for publication in April.

3. Delivering our strategic priorities

- 3.1. As the Authority has recognised previously, it is important that we balance delivery of our ambitious new strategic priorities with our core statutory work; but it is also the case that our core work is often a key vehicle for delivery of our strategy. With this in mind, the Corporate Management Group (CMG) has been considering, at corporate and team level, what the key planning priorities should be, particularly for year one of delivery (2020/21). We have previously presented to the Authority an early version of our assessment of delivery over the next three years, and CMG has spent further time since then considering how best to sequence, resource and prioritise the different packages of work, including our vital core work.
- 3.2. We consider the key priorities to enable strategic delivery within the 2020/21 business plan to be as follows:
 - Delivery of our core statutory functions and processes.
 - Including key delivery mechanisms for our strategic work, such as our regulatory regime, horizon scanning, reports and publications, information provision, and collaborative working with other bodies.
 - Large component of our overall work and resources. This work will need to be managed alongside an office move in autumn 2020.
 - Our range of upcoming work on add-ons, to ensure an accurate and helpful evidence base for patients, and to encourage responsible innovation. (The best care, objective 1 and Shaping the future, objective 5.)

- Medium-sized scale of work, in both year one and year two (and beyond).
 - Scoping and preparatory work to begin to prepare for the anticipated future increase in our 'Opening the Register' (OTR) operations. (Shaping the future objective 6.)
 - Medium-sized scale of work in 2020/21, growing in scale in years two and three.
 - First steps in our planned review of the compliance regime. (The best care, objective 1.)
 - Large-scale piece of work in both year one and year two, commencing with a review of the compliance and enforcement policy.
 - Commencing partnership working to facilitate the provision of key information about infertility to primary care professionals, so that people are better supported in making early decisions and understanding their options. (The right information, objective 3.)
 - Medium-sized scale of work in year one; likely to be larger-scale in year two.
 - Some technical upgrades to the clinic portal and website, to support our strategic information aims. (The right information, objective 4).
 - Small or medium-sized scale of work in year one, to enable other subsequent strategic work.
- 3.3.** Our overall aim is to ensure that our operational plans and resourcing are focused on delivering our strategic aspirations, and are well managed.
- 3.4.** CMG will continue to focus on detailed planning, and teams' service delivery plans will be shared at the next CMG meeting (in February) to ensure that plans, interdependencies and risks are considered and communicated.
- 3.5.** Editorial work on the next business plan has continued alongside these discussions, and the activities section of the business plan for 2020/21 is attached for approval at annex 2. We are not yet in a position to add the financial section of the business plan – the Authority has a separate item on the indicative budget on the agenda for this meeting.

4. Recommendations

- 4.1.** The Authority is asked to:
- Approve the strategy for 2020-2023.
 - Comment on the main planning priorities set out in paragraph 3.3 above.
 - Approve the activities section of the business plan for 2020/21.



Human
Fertilisation &
Embryology
Authority

Annex 1:

HFEA

Strategy

2020-2023

www.hfea.gov.uk

Our vision

Our vision is...




Regulating for excellence: shaping the future of fertility care and treatment

As we approach the 30th anniversary of the HFEA's creation, we continue to put everyone who uses fertility services at the heart of everything we do - patients, partners, donors, donor-conceived people and surrogates. We want them all to receive excellent care, support and information.

Their experiences differ, based on their individual circumstances. Our focus will be on providing the best, most effective care for everyone, recognising the diverse family structures in which treatment and donation take place. We want to ensure people can access the right information at the right time. As science and society advance we will shape and respond to future change, helping ensure that the translation from innovative treatment to everyday care is ethical and responsible.

As the regulator of fertility services and research involving human embryos, we aim to be effective and efficient, providing consistent oversight and advice to clinic staff and researchers.

Our ambitions for 2020-2023 are summarised in the figure below:

 The best care	 The right information	 Shaping the future
<p>Effective and ethical care that is scientifically robust, accompanied by excellent support, and provided by well-led clinics.</p>	<p>Accurate and useful information that is provided at the right time.</p>	<p>Proactively embracing new developments in the changing fields of modern family creation, genetics, and artificial intelligence.</p>
<p>A transparent evidence base so that patients can make informed choices, and more research and innovation to improve the evidence base.</p>	<p>Improved information at the earliest (pre-treatment) stage, with new information flows to support primary care professionals and patients.</p>	<p>Engaging with and facilitating debates on changes in science, law and society, integrating new developments into our work.</p>
<p>Improved recognition by clinics of partners' importance in the care process.</p>	<p>Access to relevant and impartial information for all – particularly about the evidence base, add-ons and treatment options.</p>	<p>Preparing for future legislative and operational changes, to ensure we remain a modern, effective and responsive regulator.</p>

Engagement, partnering and collaboration

As a public body, we value working collaboratively with organisations and professional bodies with whom we have shared interests.

We have well-established relationships with stakeholder groups and professional bodies, and we plan to build further partnerships with other organisations over the coming years.

Engagement with fertility clinics is about much more than satisfying the requirements of the compliance regime. We know we are most successful when we involve the sector and the professional bodies working within and around it, and when we listen to patients.

Partnership working helps us to have the most positive effect on the quality of care in clinics, and to magnify our impact, even though we work with limited resources.

Through dialogue and partnership, we want to improve the accessibility and positioning of accurate and timely information about fertility issues and treatment.

The best care



Aim: Effective and ethical care for everyone.

Objectives

Treatment that is effective, ethical and scientifically robust.

We want

Individualised treatment and care that is safe, responsible, consistent and based on clear values.

We will

Regulate effectively, transparently and consistently, and provide clinics with more comparative information about performance to encourage improved care.

Use our data to reduce variations between clinics (eg, for success rates, and levels of compliance) and collaboratively define best practices.

Clinics that are well led and see compliance and the provision of high quality care, including excellent support, as good business.

Continue our dialogue with clinic leaders, engaging with a representative cross-section of the sector (NHS and private clinics).

Continue to ensure clinics are compliant and offer good support.

A transparent and accurate evidence base, to ensure that patients can make informed choices about their treatment.

Work collaboratively to encourage and support more clinical and data research, including the usage of our Register data.

More research and innovation to improve the evidence base and outcomes.

Encourage clinics to use add-ons responsibly.

Improved recognition of partners' importance (of the same or opposite sex) in the care process.

Partners to be involved in care and treatment choices throughout the process.

Focus strongly on the care of partners and the provision of improved information for them by clinics.

Clinics to recognise that partner care is a core part of the service they provide.

Highlight accurate information and encourage dialogue about male (as well as female) fertility issues.

The right information



Aim: To ensure that people can access the right information at the right time.

Objectives

We want

We will

Improved access to information at the earliest (pre-treatment) stage.

Right-moment information provision from the outset for patients, partners, donors and surrogates.

Create new information flows to support and engage with GPs, practice nurses and patients.

Work in partnership with key organisations such as the Royal Colleges to develop or link to materials for primary care professionals to help them access key knowledge and learning to help them guide patients.

Develop materials to support people in making early decisions about treatment, donation and surrogacy.

High quality information to support decision-making during and after treatment or donation.

Patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.

Position and promote our information so it is easy to find by everyone including professionals.

Publish more information about the evidence-base for treatments and add-ons.

Keep our information up to date so that it explains new treatment options.

Shaping the future



Aim: To embrace changes in the law, science and society.

Objectives

We want

We will

Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI).

Diverse fertility service users and professionals 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.

Clinics to assess innovative treatments (including add-ons), and to encourage responsible innovation that improves current practice.

Engage with and facilitate debates within the fertility sector on emerging topics, working in partnership with relevant bodies, and providing up-to-date information.

Recognise scientific evidence and societal changes, integrate these into our work, and encourage take-up of effective new techniques into clinical practice.

Preparing for future legislative and operational changes.

To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes.

To be a modern effective regulator and continue to respond to changes in our operating environment.

Prepare to inform any future Parliamentary and public debate and implement any agreed changes.

Be responsive to the changing nature of patient and public concerns.

Work with the sector to ensure preparedness for ensuing changes.

Respond to changes such as the growth in donor-conceived people eligible to make 'opening the register' (OTR) requests from 2021 and 2023.

Annex 2:

Delivering our strategy in 2020/2021

Delivering the strategy

Our strategic vision for the three years from April 2020 to March 2023 is:

Regulating for excellence: shaping the future of fertility care and treatment

We aim to achieve our vision through delivering the following strategic objectives:

Figure 1 - Outline of our strategic objectives and aims for 2020 to 2023

In this area...	We will...
The best care	<p>1. Treatment that is effective, ethical and scientifically robust.</p> <p>Our aims:</p> <ul style="list-style-type: none"> • Individualised treatment and care that is safe, responsible, consistent and based on clear values. • Clinics that are well led and see compliance and the provision of high quality care, including excellent support, as good business. • A transparent and accurate evidence base, to ensure that patients can make informed choices about their treatment. • More research and innovation to improve the evidence base and outcomes.
	<p>2. Improved recognition of partners' importance (of the same or opposite sex) in the care process.</p> <p>Our aims:</p> <ul style="list-style-type: none"> • Partners to be involved in care and treatment choices throughout the process. • Clinics to recognise that partner care is a core part of the service they provide.

In this area...	We will...
The right information	<p>3. Improved access to information at the earliest (pre-treatment) stage.</p> <p>Our aim:</p> <ul style="list-style-type: none"> • Right-moment information provision from the outset for patients, partners, donors and surrogates.
	<p>4. High quality information to support decision-making during and after treatment or donation.</p> <p>Our aim:</p> <ul style="list-style-type: none"> • Patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.
Shaping the future	<p>5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI).</p> <p>Our aims:</p> <ul style="list-style-type: none"> • Diverse fertility service users and professionals 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. • Clinics to assess innovative treatments (including add-ons), and to encourage responsible innovation that improves current practice.
	<p>6. Preparing for future legislative and operational changes.</p> <p>Our aim:</p> <ul style="list-style-type: none"> • To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes.

Although we are a specialist regulator, there are broad priorities that will be important across the health and care system which are relevant to us and our programme of work is well aligned to these.

Activities for 2020/2021

The 2020/2021 business plan represents the first year of our 2020 - 2023 strategy.

[Further introductory text to be added prior to publication]

The activities set out over the next few pages will help us to deliver our strategic objectives in 2020/2021.

The best care

Our first aim is for effective and ethical care for everyone. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Figure 2 - Strategic objective 1. Treatment that is effective, ethical and scientifically robust. Table outlining planned activities for 2020 to 2021.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
<p>Planning for a review of the compliance regime to ensure this remains robust and able to effectively assess care against target outcomes.</p>	<ul style="list-style-type: none"> • Review of: <ul style="list-style-type: none"> – Compliance and enforcement policy – inspection priorities – our use of intelligence gained from inspection – information in reports – roll out and use of the revised PREP test. • Develop plans for quality improvements. • HFEA compliance regime is more aligned to strategic priorities. 	<p>Throughout the year</p>

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
<p>Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities.</p>	<ul style="list-style-type: none"> • All clinics and research establishments in the sector are: <ul style="list-style-type: none"> • appropriately inspected and monitored against the requirements of the act and published performance indicators, and • issued with licences for up to four years. • Assurance of consistent standards and safety for the public and other stakeholders. • Positive overall impact on quality of care, outcomes, safety, support, and information clinics publish (eg, on their websites) and provide to us. • Patients know that all clinics are safe and appropriately licensed. • Reduction in the number of critical, major and other non-compliances. 	<p>Throughout the year</p>
<p>A project to improve the provision of treatment add-ons and to encourage responsible supply of these by clinics. Including further development and publicising of patient information and traffic lights.</p>	<ul style="list-style-type: none"> • Responsible supply of add-ons by clinicians/clinics based on good evidence • Add-ons offered: <ul style="list-style-type: none"> – with full information so patients can make informed decisions – only to specific groups where there is evidence of effectiveness and safety. • General agreement within the fertility sector around the direction of travel toward best practice around add-ons. • Patients and clinics understand the risks associated with add-ons. • SCAAC annual review of add-on treatments so that patients and clinics have accessible information on sound scientific evidence 	<p>Throughout the year, with further work planned for subsequent years of this strategy delivery.</p>

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Placeholder: Work to build on success rates work from 2019/2020.	<ul style="list-style-type: none"> We use our data to understand variations between clinics and collaboratively define best practices. 	[Current findings being discussed with Authority at January 2020 meeting]
Establish a data review board for considering any proposed additions of new data fields to the Register.	<ul style="list-style-type: none"> A transparent and accurate evidence base. Clinic and researchers have up to date information about the data fields within the Register and the reasons for any changes to these. There is a clear and robust process place for assessing potential additions to the Register. We continue to maintain a robust Data Dictionary and support effective management of the Register of treatments and outcomes. 	
<p>Effective handling of and communication about:</p> <ul style="list-style-type: none"> clinical incidents and adverse events, including publication of 2019/20 'State of the Sector' report and quarterly compliance reports complaints about clinics 	<ul style="list-style-type: none"> Continued strong focus on learning in dialogue with the sector. Sector provided with useful information about learning points from incidents and adverse events. Reduction in the number of clinic incidents, owing to learning from own and others' mistakes. Learning gained, to inform future inspections. Patients' experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse events. 	Throughout the year, with the state of the sector report published in Autumn 2020
Running workshops for clinic staff	<ul style="list-style-type: none"> To provide learning opportunities, particularly in areas where there have been many/common non-compliances. 	Autumn 2020

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	<ul style="list-style-type: none"> • Ensure that licensing decisions and other approvals are well governed. • Efficient and effective decision-making is maintained. • Decisions are evidenced, transparent and consistent. • Committee governance arrangements and effectiveness reviewed annually. 	Throughout the year
Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	<ul style="list-style-type: none"> • Applications handled effectively, efficiently and transparently and processed according to performance indicator timelines. • Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment. • Mitochondrial donation and PGD approvals taken in an accountable and transparent way. 	Throughout the year
Engagement with researchers across the field of fertility research, particularly those using – or with potential uses for – HFEA Register data and those involved or interested in commencing research with human embryos.	<ul style="list-style-type: none"> • More research and innovation to improve outcomes. • Improved relations with the research community. • Promote quality research and collaboration using HFEA Register data and/or human embryos. • Researchers have access to relevant and valuable data in our Register, to inform high quality research. • We review the application process for researchers to use HFEA data, or human embryos. • Anonymised Register dataset available for researchers. • We continue to be active members of the UK health data research alliance to encourage widespread and responsible access to data 	Event for researchers in May 2020; other work throughout the year.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
<p>Ongoing review of guidance for clinics to ensure this remains fit for purpose, including:</p> <ul style="list-style-type: none"> updates to the Code of Practice including further guidance on electronic and storage consent. other clinic-facing resources such as patient support pathways. 	<ul style="list-style-type: none"> Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions. A clear Code of Practice and other guidance for clinics, that is regularly updated. 	Throughout the year
<p>Servicing the legal information needs of the HFEA including:</p> <ul style="list-style-type: none"> provision of legal advice to inform other HFEA work management of team of external legal advisers to support effective licensing processes. supporting the review of the Compliance and enforcement policy. 	<ul style="list-style-type: none"> HFEA licensing decisions are sound and based on comprehensive legal advice. HFEA policy decisions and approaches are compatible with the regulatory framework. 	Throughout the year
<p>Review of information provided on HFEA website about:</p> <ul style="list-style-type: none"> routine treatments for instance 'standard' IVF typical prices for treatment <p>including testing of this information using the pilot patient forum.</p>	<ul style="list-style-type: none"> We use our communications channels to make sure patients receive the right information at the right time. Information is reviewed on a cyclical basis to ensure that it is fit for purpose. 	Throughout the year
<p>Placeholder: EU exit (Brexit) follow on work, as this emerges.</p>	<ul style="list-style-type: none"> To update as this becomes clearer, in line with DHSC wording and requirements. 	Throughout the year

Figure 3 - Strategic objective 2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Table outlining planned activities for 2020 to 2021

Objective 2 Improved recognition of partners' importance (of the same or opposite sex) in the care process - methods and channels	Benefits and outcomes	Timescale
Nothing planned against this objective in year one - work to follow in years two and three.	<ul style="list-style-type: none">• None in year one	-

The right information

Our second aim is to ensure that people can access the right information at the right time. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Figure 4 - Strategic objective 3. Improved access to information at the earliest (pre-treatment) stage. Table outlining planned activities for 2020 to 2021

Objective 3 Improved access to information at the earliest (pre-treatment) stage - methods and channels	Benefits and outcomes	Timescale
Develop relationships with key organisations such as the Royal Colleges and work in partnership to signpost information for GPs and other primary care professionals, to help them access key knowledge to support their patients.	<ul style="list-style-type: none"> • We build effective collaborative relationships with others to design the most effective approaches for this work. To provide the basis for: <ul style="list-style-type: none"> – Right-moment information provision for patients and partners. – People to be supported all the way through their journey and their choices, including at the very beginning. – Creation of new information flows to support and engage with GPs, practice nurses and patients. – Information about accessing fertility services to be transparent at the outset. 	Throughout the year
Using social media and other channels, including the media, we will communicate relevant information to the wider general public and those who are not having fertility treatment.	<ul style="list-style-type: none"> • We communicate via a range of channels and methods so people can access the right information at the right time for them. • We will utilise our content strategy to position our information effectively. • We will raise our profile and provide the general public, not just current fertility patients, with useful information. 	Throughout the year

Figure 5 - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Table outlining planned activities for 2020 to 2021.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Work to review our compliance with accessibility requirements.	<ul style="list-style-type: none"> Stakeholders' accessibility needs are considered so that they are able to access our information. HFEA services are available to everyone that needs them. We ensure that HFEA appropriately complies with government accessibility requirements and legal obligations. 	Throughout the year
Consideration of Clinic portal and website updates to: <ul style="list-style-type: none"> increase stability enhance search functionality and ensure CaFC data can be updated from the new HFEA Register. 	<ul style="list-style-type: none"> Our systems support continued information provision and improvements. Implementation of website improvements identified by users. Updated Register outcome data presented on CaFC remains up to date to inform patient choice. 	Throughout the year
Update to the data available in CaFC.	<ul style="list-style-type: none"> Patients have access to updated data on clinic performance to inform their treatment decisions. 	March 2021
Make use of patient feedback and our pilot patient forum to ensure that information is fit for purpose.	<ul style="list-style-type: none"> Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach. We gain an insight into the patient experience in clinics and encourage good practice based on feedback. 	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Deliver the Research Engagement Day and undertake follow-up work to consider the information available to researchers.	<ul style="list-style-type: none"> • We bring researchers from a broad range of disciplines together to encourage quality research and collaboration using HFEA Register data and/or human embryos and promote use of HFEA Register data and human embryos for fertility research. • Increased use of HFEA Register data and licensed human embryo research in high quality research. • Improved relations and communication with the fertility research community. • Improved insight into current fertility research and awareness of how we can help make fertility research easier. 	May 2020
Maintain up to date and accurate information and advice on our public-facing website.	<ul style="list-style-type: none"> • Patients know where to look to get answers to their questions. • Patients see HFEA information as 'go to' impartial advice. • People understand the possibilities and the difficulties of treatment and can weigh up the options open to them. • People can easily find relevant information and signposting on our website to inform their next steps. 	Throughout the year
Responding to media reports.	<ul style="list-style-type: none"> • Balance and accuracy provided for issues the media is covering. 	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Maintaining effective Opening the Register (OTR) and counselling services.	<ul style="list-style-type: none"> • Opening the Register requests continue to be met in a sensitive manner and within required time limits. • Counselling support is offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information. • OTR applicants feel more supported and prepared to deal with the information they receive from us. 	Throughout the year
Performance management of Donor Conceived Register (DCR) services including counselling provision.	<ul style="list-style-type: none"> • The provision of the DCR is properly performance managed against agreed KPIs, to ensure that it remains fit for purpose. • Intermediary training and systems in place for dealing with identity release to donors and donor conceived people. • Intermediary services are in place for when donors and donor-conceived people meet. 	Throughout the year
We provide timely and appropriate responses to freedom of information (FOI), parliamentary question (PQ), and subject access requests.	<ul style="list-style-type: none"> • We comply with FOI, PQ and DPA requirements. • Requesters have access to accurate information in a timely fashion. <p>We actively publish information on our business activities on our website, following best practice, to be transparent in our working whilst maintaining compliance with the FOI Act.</p>	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
To publish good quality statistical and other reports, including the Fertility trends report.	<ul style="list-style-type: none"> • We provide the public, patients, clinic staff and others with up-to-date, high quality information about treatment outcomes, trends and the performance of clinics. • We provide important information to those affected by donor conception, to patients seeking treatment. • We make use of our data to help us to enhance the quality of care that patients and donors receive in clinics through our regulatory work. 	Throughout the year
Effective handling of enquiries, complaints about the HFEA and whistleblowing.	<ul style="list-style-type: none"> • These are handled efficiently and appropriately. • Learning gained and actions identified where necessary to secure improvements. 	Throughout the year
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	<ul style="list-style-type: none"> • Register data and forms continue to be processed and quality assured through liaison with clinics on errors and omissions and through validation and verification of Register entries. • High quality data available to develop patient information and respond to information requests. 	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
<p>Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.</p>	<ul style="list-style-type: none"> • Running the Register Research Panel to oversee applications for data release and ensure approved data is released effectively and securely to researchers. • Information for researchers is provided within specified timeframes. • Register information is used to best effect, to increase understanding and facilitate good research and ultimately benefit patients. • More researchers can access and use our Register data. • Increased standardisation and clarity of processes and efficient use of time and resource. • Greater knowledge about the efficacy and safety of fertility treatment. 	<p>Throughout the year</p>
<p>Ongoing compliance with government information requirements, including:</p> <ul style="list-style-type: none"> • Reporting in our annual report on the growth duty and compliance with the regulators' code. • Complying with the business impact target by identifying and reporting any 'in-scope activity'. 	<ul style="list-style-type: none"> • We respond to Government requirements and new initiatives in a manner consistent with our legal status, and proportionately within our small resource envelope, carefully recognising our duties. • Annual report published including required information. • Compliance with the business impact target for any activities that may be in scope. 	<p>Throughout the year</p>

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Effective records management and information governance.	<ul style="list-style-type: none"> • Appropriate information governance policies and processes are in place, and regularly reviewed, ensuring roles and responsibilities and correct processes are clearly set out for staff. • Good records management practice is embedded and maintained, including records retention and appropriate behaviours, to ensure access to information is maintained at all times. • Information governance arrangements comply with latest requirements. • Records management and information governance risks are managed effectively. 	Throughout the year
Responding to external consultations and reviews including from the Department of Health and Social Care, other regulators and wider public sector.	<ul style="list-style-type: none"> • HFEA is part of discussions that may affect us, relevant legislation or the wider fertility sector. 	Throughout the year
Recruitment of new Authority and other committee members.	<ul style="list-style-type: none"> • HFEA decision-making capabilities maintained. • Effective induction to ensure new members are up to speed and able to carry out effective decision-making. 	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Continued participation in the collaborative regulatory advice service for regenerative medicine, to provide advice to those working in the life sciences industry.	<ul style="list-style-type: none"> • Ensuring we're an effective collaborator and partner in the interests of the efficiency of the wider Department of Health and Social Care group of arm's length bodies (ALBs) and other health organisations. • Ability to capitalise on previously established relationships, eg, to address issues that require joint working in an efficient and coordinated way, or to establish the best approach if any new areas of regulatory overlap should arise. • Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators. 	Throughout the year
Full realisation of the benefits of our improved Register function and processes, including early support for the PRISM data submission system and ongoing engagement with and feedback from clinics.	<ul style="list-style-type: none"> • PRISM fully bedded in with clinics and Electronic Patient Record System (EPRS) providers. • Reduced transactional costs for clinics and increased satisfaction. • 'Right first time' data quality and reduction in unnecessary effort by clinics submitting the data. 	Throughout the year

Shaping the future

Our final aim is to embrace changes in the law, science and society. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Figure 6 - Strategic objective 5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). Table outlining planned activities for 2020 to 2021.

Objective 6 Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI) - methods and channels	Benefits and outcomes	Timescale
Placeholder: for policy projects under this objective.	<ul style="list-style-type: none"> TBC 	[Under discussion now]
Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	<ul style="list-style-type: none"> The Horizon Scanning Panel meets once per year. The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is facilitated by early identification of upcoming issues. 	<p>June 2019</p> <p>Throughout the year</p> <p>Throughout the year</p> <p>Throughout the year</p>

Figure 7 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for 2020 to 2021.

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Respond to any requests for consultation on possible legislative changes as these occur and consider how these will impact the HFEA.	<ul style="list-style-type: none"> • Early consideration of possible impacts of any changes on the sector and the HFEA. • To ensure the HFEA and the sector are prepared for future changes in the fertility field. 	As these occur
Project to scope future 'opening the Register' (OTR) demand and logistics.	<ul style="list-style-type: none"> • To understand, through analysis, the likely future demand on the OTR service. • To put the groundwork in place for a subsequent project to operationally prepare for a growth demand as donor-conceived people are eligible to make OTR requests from 2021 and 2023, ensuring that the OTR team can handle increasing demand. 	By March 2021
HFEA Office relocation to Stratford.	<ul style="list-style-type: none"> • Continue to implement a project to coordinate work for the HFEA to prepare for new accommodation in Stratford and engage with a wider DHSC project, managing the infrastructure and logistics of the move. • HFEA have the space and facilities needed to operate effectively within the new office and for staff working remotely. • HFEA successfully move in 2020 with minimal disruption to HFEA operations during the move. 	Autumn 2020
Ensuring that we retain and recruit the staff we need in order to operate a good quality service, and implement our People Strategy for 2020-2023.	<ul style="list-style-type: none"> • We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. • Continuing to develop our staff to ensure they have the skills they need through Civil Service Learning and other means. • Staff feel valued and motivated to deliver our strategic aims. 	Throughout the year

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Undertake a fee review informed by our income forecasting model.	<ul style="list-style-type: none">• That clinics continue to meet the cost of regulation.	TBC

Communications strategy

Area(s) of strategy this paper relates to:	Consistent outcomes and support Improving standards through intelligence
Meeting:	Authority
Agenda item:	9
Meeting date:	29 January 2020
Author:	Joanne Triggs, Head of Communications
Annexes	Annex 1: Communications strategy Annex 2: Media and social media analysis Annex 3: Digital and social media analytics Annex 4: Google key words and how we rank

Output from this paper

For information or decision?	For information
Recommendation:	
Resource implications:	The communications team and budget
Implementation date:	1 April 2020
Communication(s):	
Organisational risk:	Low

1. Introduction

- 1.1.** A new organisational strategy provides us with an opportunity to consider how we want to place the HFEA in the public domain over the next three years. This paper looks at how our organisational objectives can be supported through an ambitious programme of communications activities.
- 1.2.** The new strategy has a focus on information for all those who need it, collaboration with those best placed to provide that information, and a specific objective on being ready for any changes in law, science or medicine so we can make effective contributions to these important discussions both of public policy and of individual patient treatment.
- 1.3.** We've come a long way with our communications in the last three years and made a big impact in our work. This new strategy builds on these achievements.
- 1.4.** The main audiences for this strategy, aligned with our corporate strategy are patients, professionals and those working in the fertility sector.
- 1.5.** Our position as the fertility sector regulator provides both communication opportunities and constraints. We want to be a provider of information to patients and clinic staff, as well as researchers, the media and wider public, and our work must reach lots of different audiences.
- 1.6.** As the regulator, we also need to maintain a level of separation from specific medical advice and keep in mind that we do not directly deliver fertility services. However, we can regularly be an advocate, an intermediary between patients and complex information; and between the media and the public, we can support as well as regulate clinic activity and through our communication activities engage a wide audience with the issues we cover.
- 1.7.** The proposed outline three-year communications strategy can be found in Annex 1. The key questions that need to be addressed can be found in section 7 below.

2. Our communications work 2017-20

- 2.1.** We have good foundations to build on including qualitative and quantitative data, which means we know what has worked and what hasn't and will help drive our communications forward.
- 2.2.** In the last three years we have:
 - Implemented a new patient-focused website and evaluated its effectiveness as an information source for patients.
 - introduced rich media to provide another visual element to our communications including patient videos, podcasts and a video animation.
 - increased our social media activity, including launching a new Facebook page and using infographics to increase our reach and get our messages across
 - run more campaigns (used in the sense of linked communications over time on a given policy topic or theme) – examples include the 40th anniversary of IVF in 2018 and most recently treatment add-ons
 - redesigned our clinic communications including the Clinic Focus newsletter and the knowledge base of the Clinic Portal

- considered our approach to the media to manage our reputation as a robust regulator but also to show we are knowledgeable and insightful of the sector we regulate.
 - developed a content strategy for our website to increase our ranking on google making it easier for patients to find our information
 - run more events for clinic staff to improve engagement including the annual conference, PR event and topic specific workshops.
- 2.3.** We obtained the information standard accreditation for our print and digital patient information, so that the content we produce goes through a process that ensures it's accurate, relevant and tested with users.
- 2.4.** We were highly commended in the 2019 BMA patient information awards for our 'treatment add-ons' resource. Our submission detailed the objectives of the treatment add-ons resource, the involvement of appropriate experts, how users/patients were involved in developing the resource, how the resource was disseminated and how we've evaluated the impact.

3. What the numbers tell us

- 3.1.** We now have access to more metrics and feedback to give us greater insight into the performance of our communications. These include the national patient survey, social media and google analytics, in-page patient ratings, and the website user testing.
- 3.2.** These numbers tell us a lot about our communications and if we need to make any changes to make them more effective. This includes:
- 71% of patients who answered the patient survey are aware of the HFEA.
 - averaging over 30K users and 50K sessions on our website each month
 - increasing our Twitter followers by over 40% in the last two years resulting in 6000 followers at the beginning of 2020.
 - a content strategy that indicates we appear high in google searches for common terms including IVF (where we are ranked 2) and treatment add ons (where we are ranked 1).
 - over 1100 clinic staff regularly using the clinic portal each month.
 - running an annual conference and workshops for clinic staff, each receiving positive feedback.
 - increasing the volume of media mentions by 32% from 2,072 media mentions in 2018, to 2,750 in 2019.

4. Our strengths and weaknesses

- 4.1.** We have made good progress with our communications over the last three years and have put the foundations in place to deliver the new strategy. A SWOT analysis tells us where we currently are with our communications.

Strengths

- Worldwide reputation as a robust regulator.
- Well-established website with credible content

Weaknesses

- Lack of engagement with primary care.
- No day to day contact with patients.

<p>tested on real users.</p> <ul style="list-style-type: none"> • Effective social media channels. • A good understanding of the needs of our audiences and how we can adapt our information accordingly. • Good relationships with the media resulting in many approaches for comment/interview. • A good understanding of the fertility sector and the communications opportunities in it. • Good engagement with patient and professional stakeholder groups. • Good partnership working with colleagues in the sector and wider healthcare sector. • Access to a wealth of fertility data. • Ability to produce interesting infographics. 	<ul style="list-style-type: none"> • Limited access to an IT developer to make changes to the website/portal.
Opportunities	Threats
<ul style="list-style-type: none"> • Ability to produce and use rich media content. • Better partnership working. • Increased use of social media channels. • New patient involvement channels. • New campaigns. • More media opportunities generated from our data and being more proactive. 	<ul style="list-style-type: none"> • Negative fertility stories in the media. • New companies producing patient information. • New companies offering online services to help patients choose a fertility clinic. • Changes in Government policy. • New accessibility rules for our digital channels

- 4.2.** This analysis indicates there are many strengths and opportunities for our communications and very few weaknesses. This new strategy will build on these, together with making the most of the opportunities available to us, whilst being mindful of the threats.
- 4.3.** New regulations mean public sector organisations will soon have a legal duty to make sure websites and apps meet accessibility requirements. This is to ensure online public services are accessible to all users, including those with disabilities.
- 4.4.** We know that the majority of our website is accessible but will put this and our other digital channels through an assessment to ensure we adhere to the new standards, so this does not pose a threat to our work.

5. What does our new three-year communications strategy look like?

- 5.1.** The new 2020-2023 communications strategy will build on the work we have done so far and mirror the objectives in the new corporate strategy.

5.2. As a small public body, we will use our well-established relationships with stakeholder groups and professional bodies and build partnerships with other organisations to help us to deliver some elements of the new communications and organisational strategy. This will include:

- providing more links to information from partner organisations on our website and in our social media to reach more patients
- working collaboratively with other organisations to ensure that professionals, including primary care staff, have the right information at the right time to give patients and others
- using partner publications to help get our messages across to patients, their partners and professional stakeholders
- taking part in relevant events run by partner organisations

5.3. We will continue to make good use of our digital and social media channels to increase engagement with our patient and professional stakeholders.

We will:

- use our content strategy to understand what terms fertility patients are searching for
- continue to improve our rankings on search engines for the key words and questions identified in the content strategy by incorporating them into the titles, subheadings and meta data of our web content
- make changes to our website based on the user testing that was carried out in 2019.
- use our social media channels to drive people to the web content we know people are searching for
- repurpose existing rich media and create animated videos.
- consider new social media channels such as a LinkedIn group to provide a digital space for professionals to build industry relationships, share insights, ask questions, and learn from peers.
- use other forms of communication such as blogs to drive people to our website and social media channels
- continue to strategically align our social media to our press and media work to increase audience reach.

5.4. We will continue our approach to media management of speaking out proactively and boldly about topics that matter to us. We will work with the media and our partners to create media opportunities to do this and establish us as a credible source of information for fertility patients.

5.5. We know that we achieve our best successes when we involve the sector and the professional bodies working within and around it, so this is an integral part of the new communications strategy. We will:

- continue to develop our stakeholder engagement strategy so we have regular dialogue with professional and sector bodies, both face to face and via other channels
- run more face to face events aimed at particular sector professionals and on key topics.
- improve our clinic communications as clinic staff are an audience in themselves, as well as providing a channel to help us get messages across to patients.

- 5.6.** The patient voice is important to help shape our activities across the HFEA. We will develop new ways of including patient feedback into our work by developing communications to help to do this. This will include:
- investigating the introduction of a patient forum to get views from patients on a range of topics and input into our work
 - using our social media channels to get feedback from patients
- 5.7.** We will use our communications channels to make sure patients receive the right information at the right time. We will do this by:
- working to create new information flows to support and engage with GPs, practice nurses and patients by in partnership with organisations such as the Royal Colleges to develop or link to materials for primary care professionals to help them access key learning to help them guide patients
 - reviewing our website information to make sure it's meeting the needs of the organisation and patients
- 5.8.** We have done a lot to improve our communications with clinic staff and we will continue to build on this as part of this strategy. We will:
- continue to develop our clinic focus newsletter to make sure it reaches the right people in the clinic and meets their information needs
 - continue to hold the annual leadership event for clinic PRs
 - hold regular workshops on specific topics for all types of clinic staff to share learning
 - look at the information held on the Clinic Portal and get feedback from clinic staff to determine if this meets their needs as an information source and provide more content for clinic staff.
 - work with the compliance team to learn more about the information needs of clinic staff and how we can address these to ensure a two-way communication flow.

6. How will we know how we've done?

- 6.1.** We will use intelligence including analytics to determine if our communications activities contribute towards enhancing the reputation of the HFEA by us being at the centre of debates around fertility treatment and part of any discussions taking place.
- 6.2.** To be an effective part of the business, communications needs to demonstrate how it contributes to its effectiveness, that's where evaluation comes in.
- 6.3.** We will provide analytics on the following areas of communications activities:
- monthly HFEA performance report: Volume of media enquiries; social media activity; website activity
 - internal Digital Communications Board report: A detailed monthly report including performance data Twitter, Facebook and the website, including user numbers, average time spent on a page, popular pages and more
 - communications evaluation: We will provide a monthly communications evaluation for Authority and the Corporate Management Group which will include a analysis such as volume of media mentions, press highlights, audience reach, nature and volume of media enquiries;

digital performance data; events activity; clinic communication activity and performance and social media analytics.

7. Key questions

7.1. Authority members are asked to review the approach outlined in the communications strategy for the next three years and consider the following:

- Is the communications strategy satisfactorily aligned with the new corporate strategy?
- Do you agree we have identified the right opportunities for our communications?
- Do we have the right channels and methods in place to maximise the opportunities listed in this paper?
- Do you agree with the approach to our communications over the next three years as described in the strategy?
- Does the approach to our communications help to address the weaknesses identified?
- Are the evaluation methods outlined in this paper sufficient for Authority members to seek reassurance on the effectiveness of our communication activities?

Annex 1

HFEA communications strategy 2020-2023

1. Introduction

- 1.1.** This strategy builds on the achievements in the previous communications strategy and outlines our communications for the next three years in line with our corporate strategy.
- 1.2.** It is closely aligned to support the delivery of the HFEA 2020-2023 corporate strategy. It supports our strategic objectives by:
- focusing on ways to improve access to information at the earliest stage of the treatment journey
 - providing communications via a range of channels and methods so people can access the right information at the right time for them
 - providing information and links to information for partners so they can be more involved in care and treatment choices
 - developing information flows through partnership working so there is improved access to information at the earliest stage
 - using our communication channels to publish more information about the evidence-base for treatment add-ons
 - collaborating with other bodies to improve the accessibility and positioning of accurate and timely information about fertility.
- 1.3.** Our position as the fertility regulator provides both constraints and opportunities for our communications. We aim to be a provider of information to patients, but we are not a campaign group and our work must reach lots of different audiences.
- 1.4.** As the regulator we need to maintain a level of separation from providing specific medical advice and remember we are not a provider of fertility services. However, we can regularly be an advocate, and intermediary between patients and complex information and between the media and the public. This is what our communications strategy aims to do.
- 1.5.** This communications strategy details the channels and methods we will use to communicate our work to reach our stakeholders in a timely and effective manner.
- 1.6.** We will maximise the opportunities detailed in the communications strategy to increase our reach amongst our stakeholders.

2. Our strategy and channels

- 2.1.** This new communications strategy builds on the good work that took place in the 2017-2020 strategy and uses the tools and channels that we have put in place. It addresses the needs of our main audiences:
- Patients, partners donors, donor-conceived people and parents of donor-conceived people
 - clinic staff
 - professional stakeholders
 - our staff
- 2.2.** We have developed our channels and communications methods to increase our engagement with stakeholders. They are:
- our website
 - the knowledge base of the Clinic Portal
 - a strong social media presence using Twitter and Facebook
 - using more rich media including infographics
 - a new staff intranet
 - taking a more proactive approach to the media by making better use of our data and creating hooks based on bolder messaging
 - establishing new relationships with key media contacts resulting in being one of the go-to contacts for fertility related stories
 - running more multi-platform communications campaigns around key topics including treatment add-ons.

3. Our audiences

- 3.1.** This strategy covers the audiences listed in section 2. We will use specific channels to reach each of the audiences that are detailed below.

Patients, partners, donors, donor-conceived people and parents of donor-conceived people

- 3.2.** Patients, partners, donors, donor-conceived people and parents of donor-conceived people are the focus of this strategy. We will use our communications to engage with more patients and get their views on aspects of our working including treatment add-ons.
- 3.3.** We will also focus on the partners of patients by providing information specifically for them to support them in their role as part of a fertility journey.
- 3.4.** We will develop new ways of getting information to these groups of people, in a timely way and work to get this information to them as early as possible in their treatment journey.
- 3.5.** We will develop ways to increase the patient voice in our work with new ways to engage patients.

- 3.6.** We will use our communications channels to engage with more patients and get their views on aspects of our work including treatment add-ons.
- 3.7.** We will continue to seek views from patients on several aspects of our work by:
- user testing our patient information and website content
 - getting feedback on our web pages. Out of 89 pages with patient reviews 80 have been rated with 3 stars or above which indicates patients find them helpful or very helpful.
 - getting patient feedback on their clinic experience via CaFC
 - engaging with patients via our social media channels
 - engaging with patients at events such as the fertility show
- 3.8.** We will continue to provide patient information both in digital and occasionally print form to increase our engagement with patients at events.
- 3.9.** We know there are new companies who are providing patient information on all types of fertility treatment to help patients make choices. Whilst we don't necessarily need to work with them, it's important for us to be aware of what they provide and see if there are any opportunities to link to our information to further our reach. We will also need to consider the benefits and drawbacks of how they use and display our data, as well as the clinic comparison services they offer. This makes our communications activities more challenging as there is potential competition for CaFC.

Professionals including clinic staff

- 3.10.** A key audience for us are professionals, this includes clinic staff and other professionals in the health sector with an interest in fertility.
- 3.11.** Clinic staff are a captive audience for us. We don't have to fight to get their attention and we don't have to attract them via marketing. Clinic staff are an audience in themselves and are also an information channel to help us get our messages out to patients.
- 3.12.** We have done a lot to improve our communications with clinic staff and we will continue to build on this as part of this strategy. We will:
- continue to develop our clinic focus newsletter to make sure it reaches the right people in the clinic and meets their information needs
 - continue to hold the annual event for clinic PRs to ensure we have regular face to face engagement
 - hold regular workshops on specific topics for all types of clinic staff to share learning
 - look at the information held on the Clinic Portal and get feedback from clinic staff to determine if this meets their needs as an information source and provide more content for clinic staff.
 - work with the compliance team to learn more about the information needs of clinic staff and how we can address these to ensure a two-way communication flow.

Our staff

- 3.13.** Staff are our most important resource so that's why it's important that we communicate with them in a timely and relevant way, allowing for feedback wherever possible.

- 3.14.** In 2018 we launched a new intranet site which gives staff a lot of information about working at the HFEA all in one place. It allows staff to make their own work-related and social posts and give feedback on different topics.
- 3.15.** We will continue to work closely with the HR team to develop new and innovative ways to communicate with staff, both via digital channels and face to face with the all staff meetings, away days, lunch and learn sessions and SMT surgeries.

4. Digital and social media channels

Website

- 4.1.** Our website is our main communication channel to patients, partners, donors, donor-conceived people and parents of donor-conceived people. In the last communications strategy, we have made a lot of progress in raising awareness of our website and driving people to it for information but, as we know patients are changing all the time, so we need to continually raise awareness of our role and the information we can provide.
- 4.2.** Analytics (see annex 3) show us that the website is performing well and being well used, but we want to continually make improvements which is why we have developed a new content strategy.
- 4.3.** We want to get patients to turn to us first and access our information at the earliest stage. To do this, we have developed a content strategy that aims to identify what content our users want and meet those needs to bolster our reputation and become the go-to source for information on fertility treatments from the earliest stage of the treatment journey.

Analytics

- 4.4.** If we want to become the go-to source of information from the earliest possible stage, we need to know what information our audiences are looking for. To do this we will use Search Engine Optimisation (SEO), Google keyword planner and Google trends.
- 4.5.** Google keyword planner allows us to identify the most popular search terms and the competition for ranking highly against them.
- 4.6.** Whilst we rank highly for the majority of key words (annex 4) our focus is to continue to improve our ranking for these key words to ensure our information is found easily by the highest number of people.
- 4.7.** Google trends allows us to identify search terms that are becoming increasingly popular and what people are searching for in relation to a particular topic. Examination of the analytics in Google trends showed us the key words that people who search for IVF most commonly also search for. This indicates the need to concentrate our efforts on certain key words in our content.
- 4.8.** Knowing what content is shared online, and by whom, gives us valuable insight into what content our users like and who they are influenced by.
- 4.9.** Using blogs to establish HFEA experts and increase our digital presence
- 4.10.** We plan to start a blog which will be published on our website. This is because:
- blogging creates new content for search engines to index, helping to improve where we appear for online searches for fertility-related information

- we can use a blog to create more content containing the key words we know people are searching for, driving more traffic to our website
- it will support our aim to raise our profile as we can use it to speak out on issues we know to be of interest to the public, but do not necessarily warrant a media release
- providing valuable, relevant expert information will support our objective of becoming the go-to source for information on fertility treatment
- it creates an opportunity for others to share the link to our blog, generating social media content and driving more traffic to our website.

Social media

- 4.11.** We will continue to use social media to drive people to the web content we know people are searching for. A key part of our new corporate strategy is to reach patients at the right time, including reaching patients at the very early stages of their fertility treatment journey. The media plays a key part in reaching this objective as it gives us the opportunity to reach a mass audience. We will also do this by working collaboratively with partners such as the royal colleges to help get our messages across to patients.
- 4.12.** Over the last two years, we have invested in social media because we want to be connected and responsive. We want to be part of the conversation about fertility treatments and we have already gone a long way towards this.
- 4.13.** We know that we have limitations on our use of social media. There are many social media channels available and we can't use all of them.
- 4.14.** We engage with social media influencers on Instagram to increase our reach rather than us running our own account. We have already done this to publicise our fertility trends report by providing some influencers with access to our infographics and messages so they could use these for their own channels. We don't have enough visual content for Instagram, and we can see from other accounts such as the CQC and NICE that you can put a lot into the content for very little return.
- 4.15.** We are aware of forums, but we don't have the resource to monitor them, and as the regulator it would also be inappropriate for us to insert ourselves into a 'safe space' where patients are sharing their personal experiences. Instead we will use our channels to make sure we are aware of the issues being discussed.
- 4.16.** We know that our approach to social media is working based on regular analysis of our digital platform performance (Annex 3). We will build on this success by:
- timely and relevant tweets and Facebook posts
 - repurposing existing rich media and creating animated videos – this type of content has the most engagement
 - using the questions from Answerthepublic tool to populate our tweet bank, framing social media posts around the questions we know people are searching for and directing them to relevant pages on our website
 - increasing use of strategic press and social media campaigns
 - making more use of infographics

- promoting our Facebook page via other channels so more people are aware of it and choose to follow us to increase the engagement
- making more use of 'paid for' social media campaigns as these are cost effective and take a small amount of resource
- continuing to work with social media influencers to help get our messages out via their social media channels including Instagram; they already have established followers and sharing our content with them allows us to reach the right people rather than us trying to populate our own Instagram account.

Investigating new social media opportunities

- We will investigate developing a LinkedIn group to increase our engagement with professional stakeholders that might otherwise be hard to reach. This includes clinic staff, as well as other health professionals who have an interest in fertility.
- Whilst our social media platforms are good supplementary tools for communicating some messages, they are difficult to aim at the relevant professionals. They are also public facing channels and are not always appropriate for delivering messages aimed at clinic staff or professional audiences. Contrary to public pages, LinkedIn groups are established for professional audiences.
- As part of our work with clinics and professionals, teams across the organisations have piloted the use of podcasts to provide different elements of learning for clinics. These have proved very popular as they are an effective and convenient method of providing information to key audiences. We should continue to produce these, ensuring they are of high quality and should be included in projects, such as the treatment add-ons and to supplement our face to face work with clinics to further the reach of our message in an easily accessible way.

5. Using the media to shape public discussion on fertility treatment

- 5.1.** We are an internationally renowned regulator who is well respected. We are known for consulting widely with the public and stakeholders on important issues and regulating well.
- 5.2.** Being the regulator does shape and constrain some of our communications. Whilst we don't want to be part of every debate about fertility treatment, we do want to speak proactively and boldly about topics that matter to us. In order to do this, it's imperative that we as an organisation have a number of topics that we can confidently speak on to provide media with strong hooks for stories that increase awareness of our work and highlight relevant issues.
- 5.3.** This approach to media management brings us some challenges. We have been bolder with our messages, which could open us up for some criticism, so we must be able to defend our stance.
- 5.4.** We want to put ourselves in a position where we are on the 'front foot' with controversial issues and cases and are the go-to source for comments on the fertility sector. We have adopted a proactive strategy and speak out more about fertility-associated issues. We have set an agenda on key topics we want to talk about and know are of interest to the media, and we'll continue to monitor the news agenda to spot emerging trends for positive media opportunities.
- 5.5.** Our new approach to media management during the last year has enabled us to become the go-to source for information whilst raising our profile. To do this, we have changed our approach to media management by:

- being proactive
- speaking on key issues that are newsworthy and of interest to the public
- being on the ‘front foot’ of controversial issues and cases
- adopting new ways to communicate our data and reports via the media
- building relationships with journalists so they consistently come to us for comment
- training more media spokespeople so we are prepared to give interviews and comment on different topics
- making better use of our data to generate media opportunities
- exploring more proactive media opportunities by approaching journalists about the subjects we want to talk about.

5.6. Utilising media to increase our reach and shape public discussion

A key part of our new corporate strategy is to reach patients at the right time, including reaching patients at the very early stages of their fertility treatment journey. The media plays a key part in reaching this objective as it gives us the opportunity to reach a mass audience.

We know that people only start to look into fertility treatment once they are presented with a fertility issue, however reaching people with our messaging before they are accessing fertility treatment is equally important to ensure they know where to turn to for credible information if they might need it.

By continuing to focus our efforts on working with the media to communicate our messages across the most accessed and popular outlets, we can raise our profile and provide the general public, not just fertility patients, with useful information, while it also allows us to shape public discussion on fertility related topics more widely.

5.7. Speaking out in the media on key issues

We identified a number of key issues to speak on and agreed how we'll work with influencers and influential media outlets to maximise the impact of our activities. We will continually revisit these topics over the course of this strategy to ensure we are speaking out on the most relevant topics. Aligning our media to our digital communications activity

5.8. Most of our media mentions are in online publications which enables us to reach a larger audience, compared to the traditional print publications. The rise in online coverage also significantly contributes to our digital content, as we can repurpose relevant articles and mentions across our digital channels.

5.9. Being more proactive with our media approach and aligning across our communications channels has resulted in coordinated campaigns and media wins. Examples can be found in Annex 2.

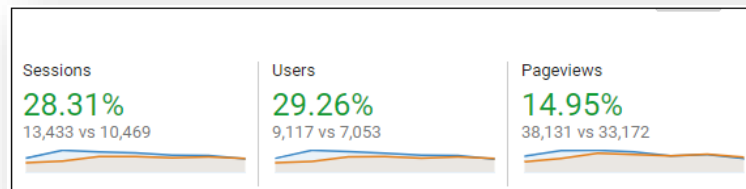
5.10. We know that positive stories in the media about us have a positive effect on our digital engagement.

5.11. We worked in conjunction with BBC radio during fertility awareness week which resulted in widespread coverage. Our work with the BBC around Fertility Week resulted in close to 70 media mentions. Discussions on both Radio 5 Live and Radio 2 used HFEA data and information on egg freezing, donation, male infertility and more to headline their discussions for Fertility Week. A special BBC Fertility webpage featured highlights from the coverage throughout the week.

5.12. A headline story generated through partnership working with the BBC as part of Fertility Week focussed on donation ‘[Sperm donors should waive anonymity, fertility regulator says](#)’

Other stories we were featured in during Fertility Week included:

- BBC News: [Frozen eggs storage 10-year limit 'should be changed'](#)
- Sally Cheshire was interviewed on the 10- year storage limit for gametes on the BBC Two’s Victoria Derbyshire programme as well as Sky news radio, with the interview being repeated throughout the news bulletins across several radio stations. The tweet we put out on this topic was our most popular tweet for the month, while our engagement on our website improved dramatically compared to the same period the previous year.



5.13. We know that of the top 20 of our most shared content the highest engagement came from five main media sources. This shows us that we should concentrate our media efforts on these titles to maximise our reach, rather than the broadsheets. The sources are:

- 45% from the BBC
- 20% The Sun
- 15% Daily Mail
- 5% Mirror
- 5% Independent

6. Working collaboratively to further our reach

- 6.1.** As a small public body, we recognise the importance and value of working collaboratively with organisations and professional bodies with whom we have shared interests.
- 6.2.** We will continue to do more of this as part of this new strategy to get our messages across to range of audiences and extend our impact.
- 6.3.** We already have good relationships with some external stakeholders, including patient and professional partners, however we aim to make them more productive and develop new relationships outside the sector to help us influence public policy and further strengthen our reputation.
- 6.4.** We know from the patient survey that GPs and other primary care professionals can be a key to reaching people before they start treatment.
- 6.5.** We will work with partners to include links to their information on our website and vice versa. This will improve the accessibility and posting of accurate and timely information about fertility issues and treatments.

-
- 6.6.** We will strengthen our relationships with the royal colleges such as the RCGP and the RCOG. We will work with them to create new information flows to support and engage with primary care professional including GPs and practice nurses.
 - 6.7.** We will continue to run our patient and professional stakeholder groups as these are a good way of engaging with these groups. In addition, we will run some themed groups on specific topics such as treatment add-ons and other areas where we need greater input from stakeholders.
 - 6.8.** We will continue to work with partners and participate in their events including the PET conference, BFS conference and study week and look to take part in other relevant sector events.
-

7. Public and professional events

- 7.1.** We've been attending the commercial fertility shows for the past three years. These give us potential access to over 3000 patients in a weekend which is valuable for qualitative engagement. They help us to understand patients' concerns to help us develop our information. It also improves our reputation with patients as being helpful and available to them.
 - 7.2.** However, our attendance at the fertility show is under review due to the commercial nature of the show and the increasing number of overseas clinics who exhibit and provide talks.
 - 7.1.** Feedback from the 2019 HFEA annual conference indicates that the workshops are the most popular parts of the conference. Therefore for 2020 we should hold a series of focussed workshops rather than one conference. The workshops will each be aimed at different types of clinic staff.
 - 7.2.** In 2020 we will hold our first researcher engagement day.
 - 7.3.** We will continue to speak at patient and professional events.
-

8. Developing new methods to include the patient voice in our work

- 8.1.** While we already regularly engage with the key patient groups in the sector through our AFPO stakeholder meetings, this group does not provide direct patient feedback, but rather represents patient's interest on specific key issues i.e., endometriosis, multiple births, emotional support, donor conception and others.
- 8.2.** Currently, patient engagement mainly takes place through our digital channels and some social media channels, but is sometimes too sporadic to interpret or use in our ongoing work.
- 8.3.** We propose to introduce a patient engagement forum to enable us to speak directly with patients, their partners, donors and donor-conceived people. The aim of the forum is to get views from patients on certain topics and for us to use those views to help shape our work and the information we produce. It will also provide an opportunity for us to source case studies and testimonials of patient's experience to inform potential new work.
- 8.4.** The patient forum will give us a formal set up for user testing our web content and other patient information. We have an informal group of user testers and recruit user testers through patient groups and social media, but this will formalise our approach and provide a diverse pool of people

with different experiences of fertility treatment. The patient forum aligns with the key objectives in our strategy by:

- providing insight into patient behaviour, choices and needs relating to treatment and donation
- giving us the opportunity to include the patient voice into our work and information
- helping us to engage with hard to reach and small sections of fertility communities (e.g., surrogates, ethnic minority or LGBTQ+ patients)
- maximising the effectiveness of our information and resources.

8.5. Following a scoping exercise, we are now looking to establish a ‘virtual’ patient engagement group, to allow patients from across the UK and different communities to participate. As an online group provides flexibility, it means that communicating with the group can be decided based on the type of work that is required.

8.6. We aim to use the output from the forum to feed into the work of teams across the HFEA.

9. Campaigns

9.1. Since the last communications strategy, we have run a small number of campaigns. We have limited communications resources in terms of staff and budget so we have to be selective as to what we will run campaigns on and the extent of the campaigns. That’s why most of the campaigns we have run have been through social media. These have included the:

- ‘only you’ campaign to encourage patients to feedback on their experience at a clinic
- campaign around the 40th anniversary of IVF
- campaign to raise awareness of treatment add-ons and our information in particular
- campaign to promote our fertility trends report.

9.2. We will run campaigns on topics identified over the course of the new strategy.

10. How we’ll know how we’ve done

10.1. To be an effective part of the business, communications needs to demonstrate how it contributes to its effectiveness, that’s where evaluation comes in.

10.2. Monthly analytics and evaluation

We provide analytics on key communications KPI’s in the monthly performance report, while we also produce a more comprehensive monthly communications evaluation looking at the following areas:

- volume and nature of media enquiries
- volume of media mentions and reach
- social media activity
- website activity

10.3. Digital Comms Board

Each month we produce a detailed digital media report for the Digital Communications Board. This board is made up of representatives of all departments. We use this to monitor and improve our website based

on the data trends and this is then reported to the monthly CMG meetings. The digital communications report covers:

- Twitter and Facebook activity including impressions and engagements
- website activity including impressions, engagement, reach click throughs, user trends and more
- how our website performs against the key word search in our content strategy
- improvements and changes to our digital channels.

10.4. User feedback testing

We carry out qualitative analysis on our website and patient information using real user testers. This feedback is incorporated into these channels and influences our strategy.

10.5. We will introduce new performance measures as part of the new strategy so Authority members can evaluate how we are making the most of the opportunities available to us.

Annex 2

Examples of media and social media analysis

1. IVF 40th anniversary – July 2018

To celebrate Louise's landmark birthday, we issued 40 IVF facts on social media throughout July. These were complemented by:

- the development of infographics to visualise the facts
- a dedicated 40-year anniversary microsite, hosting all of our celebratory activities
- a repackaged annual conference video with an interview with Louise Brown
- a celebratory podcast with interviews with Sally and inspector Janet Kirkland-MacHattie.

Thanks to the strength of this campaign, our #IVFis40 hashtag was used extensively by other groups, individuals and organisations to help spread the message.

1.1. What was the impact of our activities?

Twitter

Our twitter campaign was successful in reaching a wider audience and making us part of the wider conversation about fertility and the 40th anniversary.

Our hashtag

#IVFis40 saw a huge amount of pick up on the day of Louise Brown's birthday, as hundreds of accounts used it in their tweets to wish her a happy birthday and celebrate the important milestone.

Posts: 609

Users: 386

Reach: 2.3 million

The (relatively) small number of posts compared to the huge reach shows that it was mainly influential accounts that used this hashtag. They included The Science museum, The Lancet, Louise Brown herself, Royal College of Obs and Gynae, ITV news and ESHRE.

Lots of other prestigious organisations also tweeted about the event, such as the Nobel group.

On the day of her birthday, the keyword Louise Brown was trending on twitter in the UK. As a result of our campaign unsurprisingly, we were the most frequent user of the hashtag.

Our posts

Our 40 facts campaign on twitter saw a huge amount of pick up.

Tweets: 50

New followers: 96

Impressions: 90.5K

Retweets: 378

Likes: 544

By far the most popular content was the new infographics. Of the five best performing tweets, three were infographics. The top tweet was the IVF history timeline infographic, which saw 43 retweets, 56 likes and nearly 7,000 impressions.

The worst performing content was the tweets that tried to tie the IVFis40 campaign to the NHS70 campaign. Posts that referenced the Science Museum were also not as popular.

1.2. Facebook

On Facebook we posted all the infographics from the IVFis40 campaign, as well as the video and podcast. Though we didn't see any exceptional reach (mostly because we didn't use paid-for promotion) we did see a bit of a boost to the numbers of people who follow and like our page.

Posts: 12

Reach: 3.5K

Engagements: 491

New followers: 27 (30% increase)

New likes: 27 (24.5% increase)

The top performing post was, like Twitter, the timeline infographic with a reach of 961 and 132 engagements, however the microscope infographic visualising the most common reasons for IVF was close behind with a reach of 850 and 107 engagements.

The podcast, the attempt to link IVFis40 to the NHS70 campaign, and Sally's speech at the Science Museum were less popular posts.

1.3. Podcast

The podcast has received more than 600 downloads and this will keep increasing as The Fertility Podcast will continue to promote it and it will stay, and be searchable, on their archive.

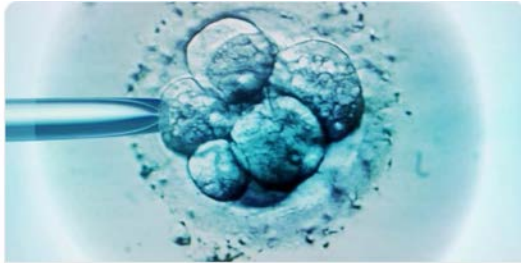
2. Treatment add-ons – 15 January 2019

To create a joined-up communications approach, we published a press release about the treatment add-ons consensus statement on 15 January, to coincide with a pre-recorded interview of HFEA Chair Sally Cheshire at BBC's The One Show. Our key messages focussed on the consensus statement, as well as the update to the traffic light rating system on fertility treatment add-ons on our website.

To maximise media mentions and reach, we focussed our efforts on target radio outlets, specifically BBC's General News Service, which provides news stories to local BBC Radio stations across the UK. As a result, more than half of all coverage achieved was across radio broadcast, including BBC Scotland, BBC Radio 2, BBC Radio 4, Sky News Radio, BBC Radio 5 Live and several other local BBC Radio stations. In total, our story on treatment add-ons received more than 150 media mentions in just one week, reaching more than 2.8 million people.

Aligning the press coverage to our social media and digital output proved successful:

- Website sessions were up 15% during this week from the previous week (18,247 sessions from 15 to 22 January vs 15,762 sessions from 7 to 14 January)
- Pageviews on the [Treatment add-ons page](#) were up 458% from the previous week (2,255 views from 15 to 22 January vs 404 views from 7 to 14 January)
- The Telegraph's story on treatment add-ons was our most popular tweet



Popular IVF add-ons fail to help women get pregnant, fertill...
 Popular IVF "add-on" treatments fail to help women conceive and in some cases harm their chances of having a baby, the fertility ...
 telegraph.co.uk

3. Older women and fertility treatment- 21 April 2019

Following conversations with the Health Editor at the Daily Telegraph, we successfully arranged an exclusive interview with Sally Cheshire to speak about IVF and older women. Our messages focussed on the risk of exploitation of older fertility patients by clinics, especially foreign clinics. As a result, the story was widely covered across national and international news outlets resulting in more than 560 media mentions. Sally was interviewed by several news outlets, including: ITV News, BBC News Channel, BBC World News, Channel 5 News, BBC Radio 5 Live, BBC Radio 4 You & Yours and LBC Radio.

The BBC's follow up story from the Telegraph interview '[Older women exploited by IVF clinics, says fertility watchdog](#)' was the 23rd most shared IVF content in the UK over the past year, with 3.5k Facebook engagements and 253 Twitter shares. With engagements from other sources, the total engagements were 3.7k.



Older women 'exploited' by IVF clinics
 Clinics are using "selective success rates" to target older women, the fertility watchdog warns.
 BBC News / 22 Apr 2019



Older women being exploited by IVF clinics - when just two a year will achieve success after the age of 44
 Older women are being exploited by IVF clinics "trading on hope" - despite the fact just two a year will achieve success after the age of 44, the fertility watchdog has warned.
 The Telegraph / 21 Apr

Engagement on our website saw a significant increase, on the back of the story:

- Website sessions were up 28% during this week from the previous week (17,956 sessions from 21 to 28 April vs 14,590 sessions from 13 to 20 April)
- The [Treatment add-ons page](#) saw a spike, with pageviews up 157% percent from the previous week (922 views from 21 to 28 April vs 358 views from 13 to 20 April)

- The [Women over 38](#) saw a spike, with pageviews up 93% percent from the previous week (519 views from 21 to 28 April vs 269 views from 13 to 20 April)
- The [Explore all treatments](#) and [IVF](#) pages also saw a spike, with pageviews up over 50% each

4. BAME fertility patients – July 2019

An exclusive story with Sky News looked at the uptake of fertility treatment in BAME communities. We recommended case studies and worked closely with Sky on the headline and angle of the story. Authority Member Yacoub Khalaf was interviewed on the issue and discussed stigma around fertility treatment as well as access to services. A joint-up approach with our digital channels, resulted in an increased audience reach.

Top Tweet earned 4,488 impressions

"We recognise that there is still a stigma attached to infertility in general, but it's important people know it's a recognised medical condition like any other", said our Chair Sally Cheshire
twitter.com/SkyNews/status...

🔄 10 ❤️ 24

Our tweet on the Sky story was the top tweet on our Twitter feed in July.

Annex 3

Digital Communications analytics 2017 – 2020

We monitor the performance of our digital communication channels at the monthly digital communications board meeting and report some of these figures in the monthly performance report. A three-year sample analysis can be found in the tables below.

Twitter Analytics	Dec 2017	Dec 2018	Dec 2019	% Change
Total impressions	46.2K	48K	65.5K	42%
Followers	4,113	4,955	5,920	44%
Post likes	175	73	72	-84%
Tweets sent	26	48	33	27%

Facebook analytics	Dec 2017	Dec 2018	Dec 2019	% Change
Posts	5	3	11	120%
Page likes	23	174	338	1370%
Followers	64	198	404	531%
Post reach	120	606	3.3k	2650%

Website analytics	Dec 2017	Dec 2018	Dec 2019	% Change
Users	22,410	24,085	29,943	34%
Sessions	31,271	38,478	47,586	52%
Pageviews	113,548	117,954	142,561	26%

Portal analytics	Dec 2017	Dec 2018	Dec 2019	% Change
Users	658	775	1247	90%
Sessions	1,707	1,961	2,624	54%
Pageviews	9,426	9,594	9,733	3%

Definitions

- Sessions:** A session is a visit to the website.
- Users:** This metric shows you how many people visited the website.
- Pageviews:** How many pages were viewed through all sessions in the specified month.
- Impressions:** The total number of times activity related to the account is seen by people in the specified month.
- Followers:** The total number of people following our page at the end of the specified month.
- Post reach:** The number of people who saw any of our posts at least once during the specified month. This metric is estimated.
- Page likes:** The total number of people who like our page at the end of the specified month.
- Post likes:** Number of likes received on HFEA posts during the specified month. Some likes may have been on posts from the previous month
- % Change:** Measures the change in activity overtime, calculated comparing the Dec 2017 data with the Dec 2019 data

5. Annex 4

Google key words and how we rank

Key word	Competition	Current ranking on Google
IVF	Medium	2
How much is IVF*	Medium	16.5
Artificial insemination	Low	6
Infertility treatment	Medium	8.5
IUI	Low	2
Fertility clinic near me	Medium	9.5
IVF process	Medium	15
How does IVF work	Low	3.5
How much does IVF cost	Medium	16.5
What is IVF	Medium	3
ICSI IVF	Medium	1
Embryo transfer	Low	4.5
Sperm bank	Medium	8.5
Sperm donor	Medium	3.5
IVF NHS	Low	25
Freezing eggs	Medium	1
IVF success rate	Medium	2
Fertility treatment add ons	Low	1



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Multiple births

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Introduction

- Fertility trends 2017
 - Multiple birth rate target of 10% met across the sector
- Further questions
 - How do clinics compare to the average and each other?
 - How has this variation changed over time?
 - Where can the sector improve?
 - Aim of this discussion is to focus on what the research and regulatory questions are for the next 1-3 years

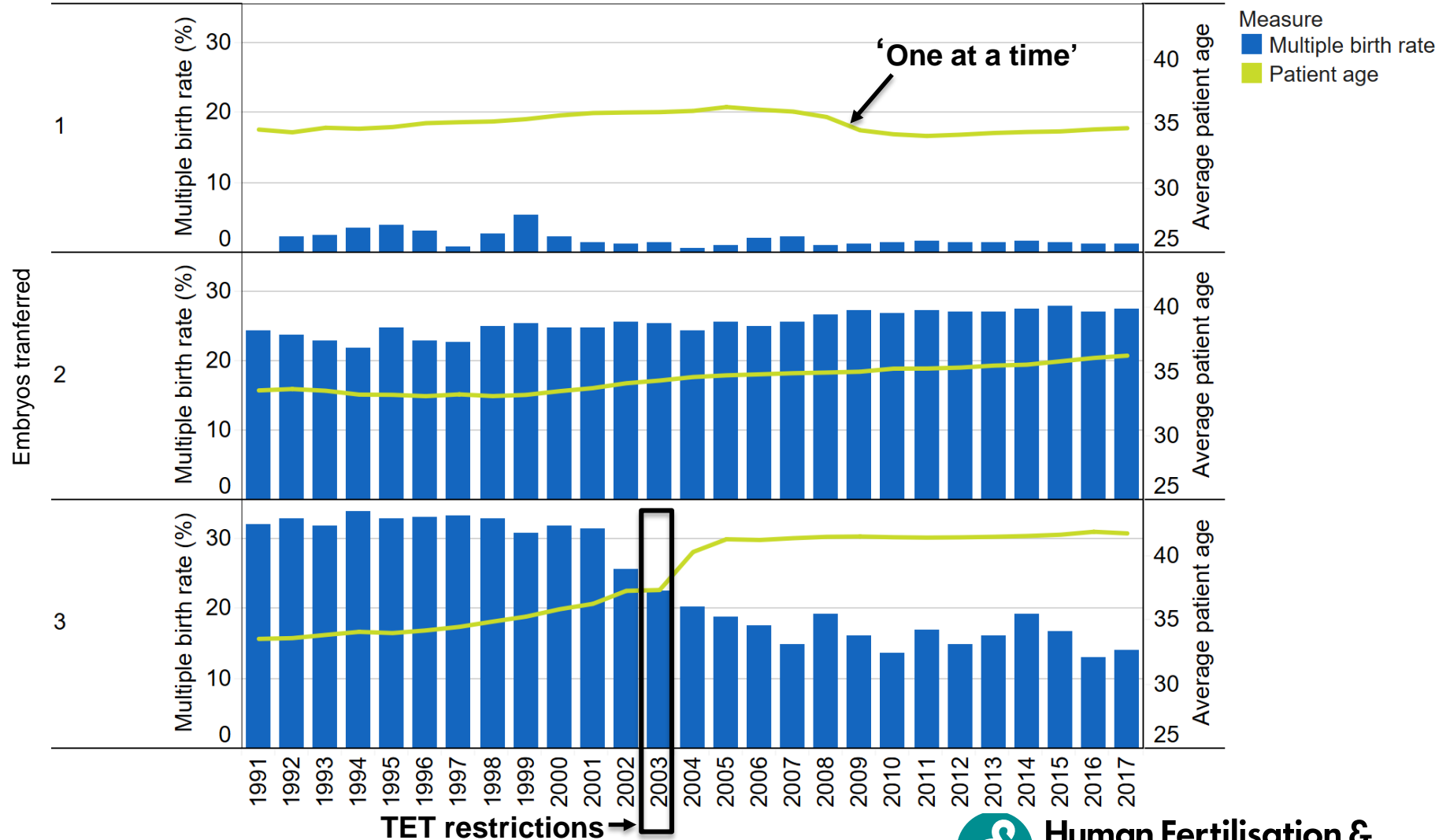
SETs have been increasing in use

Proportion of single, double and triple embryo transfers, 1991-2017



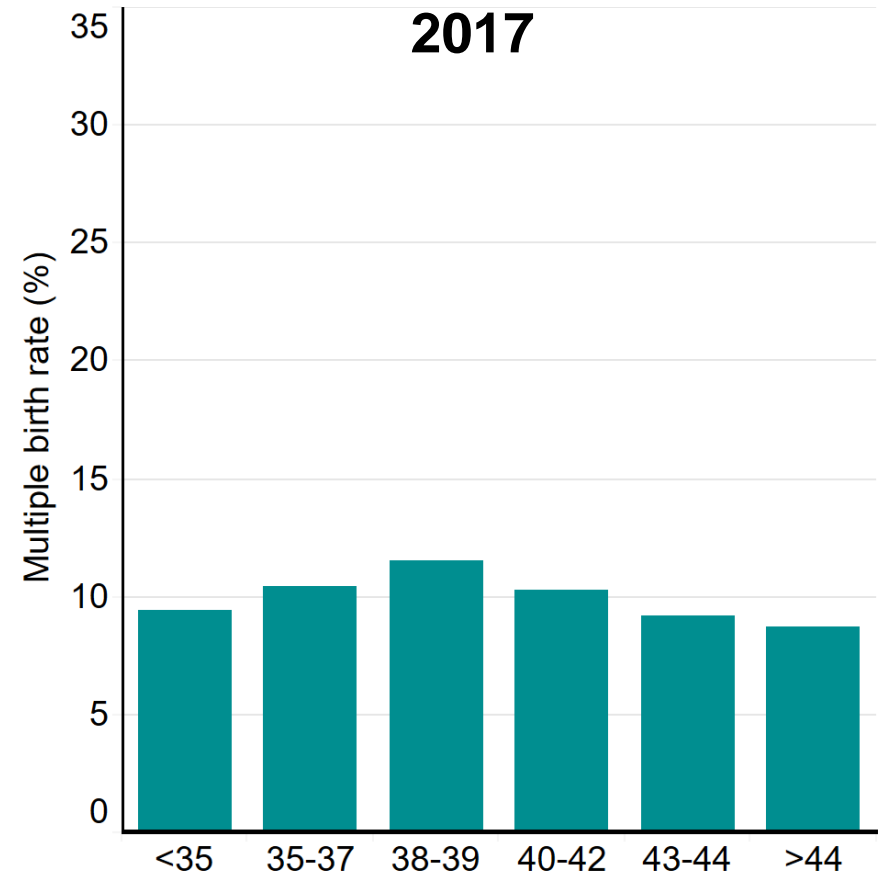
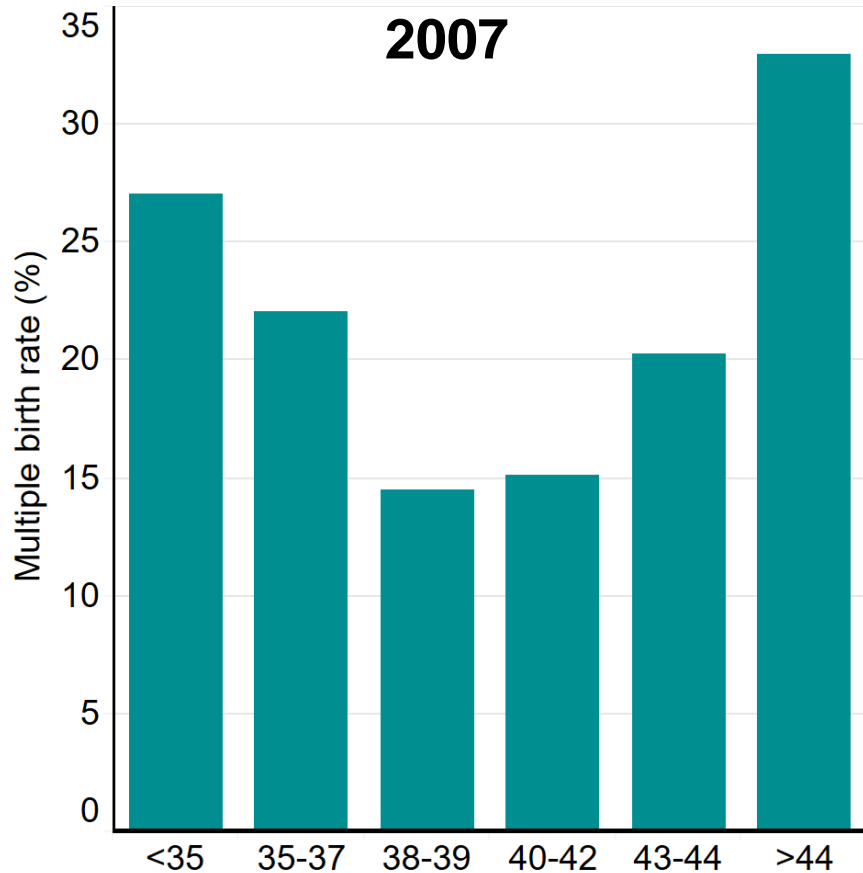
Multiple birth rate is highest for DET

MBR by number of embryos transferred, 1991-2017



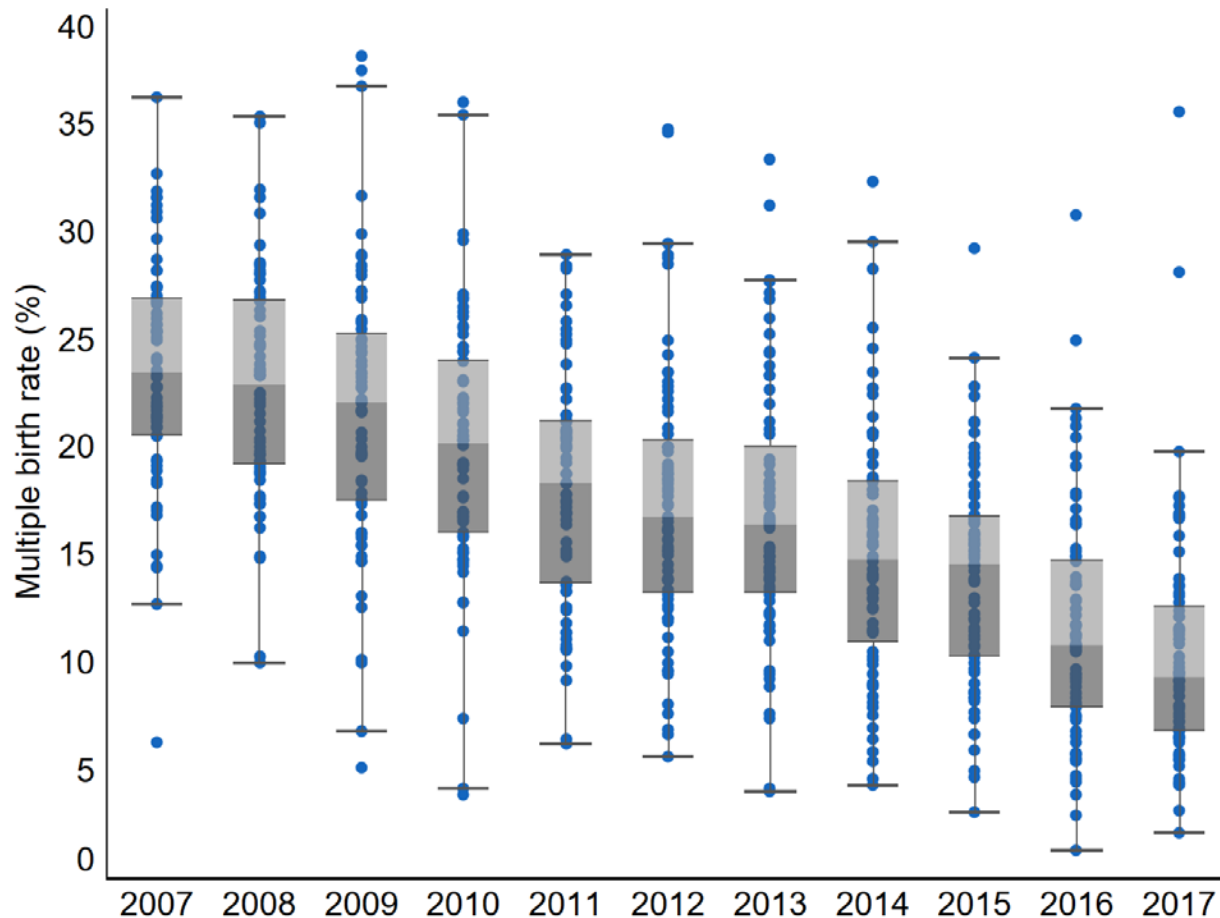
Multiple births lower for all ages

Multiple birth rate by age groups, 2007 and 2017



Multiple births decreasing across sector but some outliers remain high

Multiple birth rates by clinics, 2007-2017



Half of clinics have a multiple birth rate between 5 and 10%

Count of clinics by multiple birth rate ranges, 2017

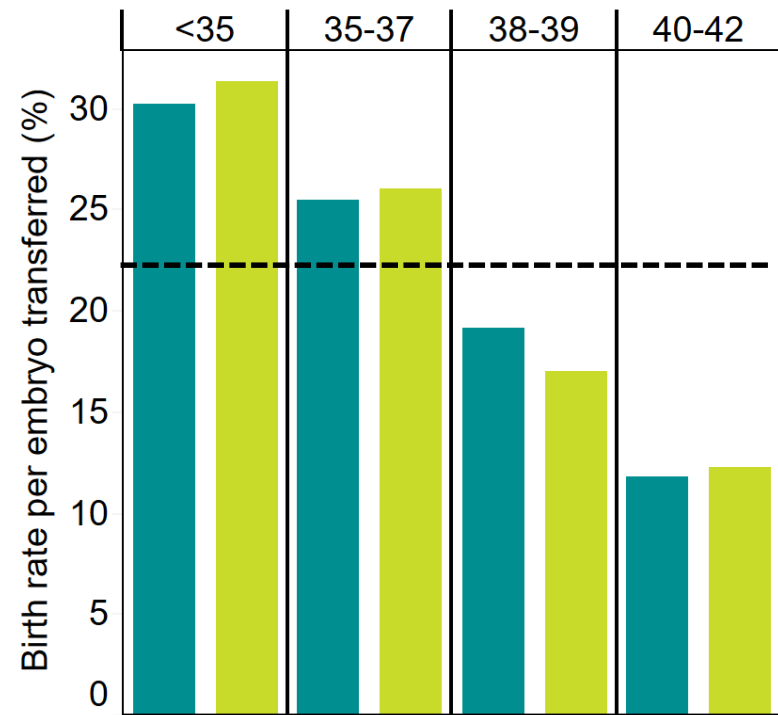
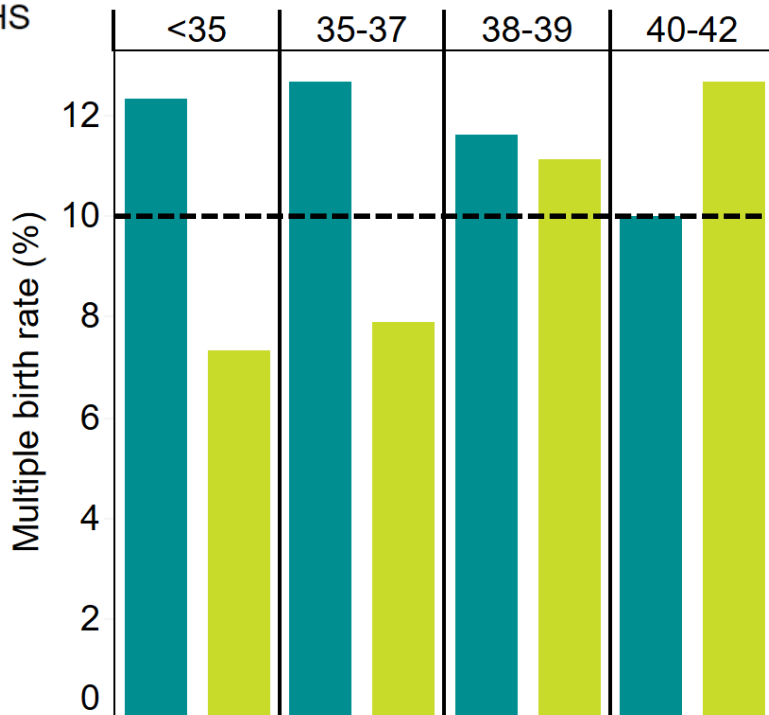
Multiple birth rate	Clinic count
<5%	6
5-9%	36
10-14%	18
15-19%	10
≥20%	2
All clinics >150 cycles	72

Note: clinics with fewer than 150 cycles have been excluded to reduce extreme values. There were only 4 non-compliances related to multiple births in 2017/18 and clinics listed here as “above target” may be consistent with the national average.

Multiple births higher for younger patients with privately funded cycles

Multiple births and birth rates by age and funding, 2017

Funding --- Average
■ Private
■ NHS



Key questions

Should the multiple birth rate target be reconsidered during the next strategy 2020-23?

- What information would we need to agree which target might be appropriate / achievable?
- What would be the appropriate timeframe to discuss this?

What more could be done with clinics to achieve the current target?

- Should we publish clinic-level data?
- How could we do more to understand and share best practice?
- Should restrictions be placed on multiple embryo transfers dependent on patient age or number of previous IVF cycles?



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Birth rates

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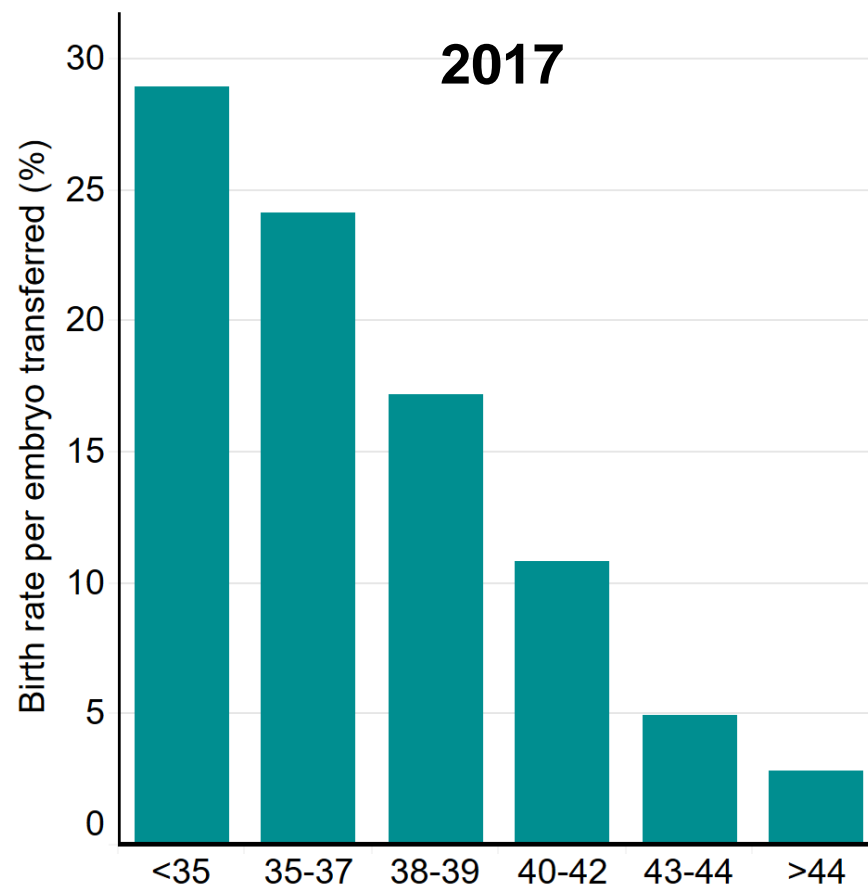
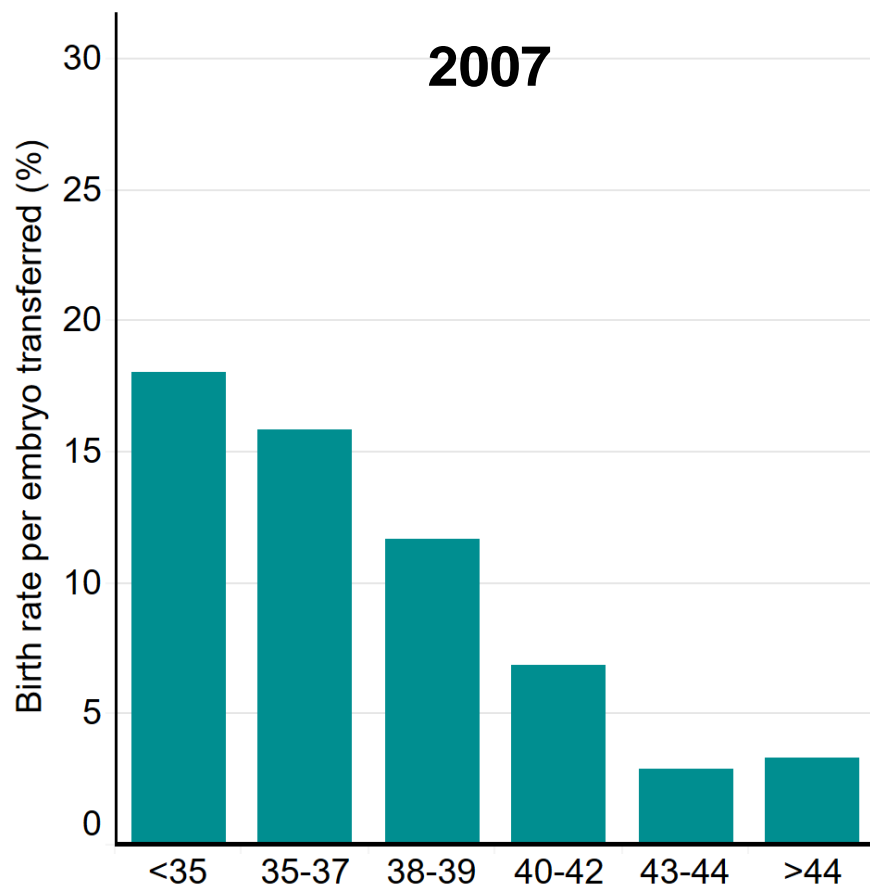


Introduction

- Fertility trends 2017
 - Highest birth rates per embryo transferred on record at 22% on average
- Further questions
 - Has the reduction in multiple births had an adverse effect on birth rates?
 - How do clinics compare to the average and each other?
 - How has this variation changed over time?
 - Where can the sector improve?

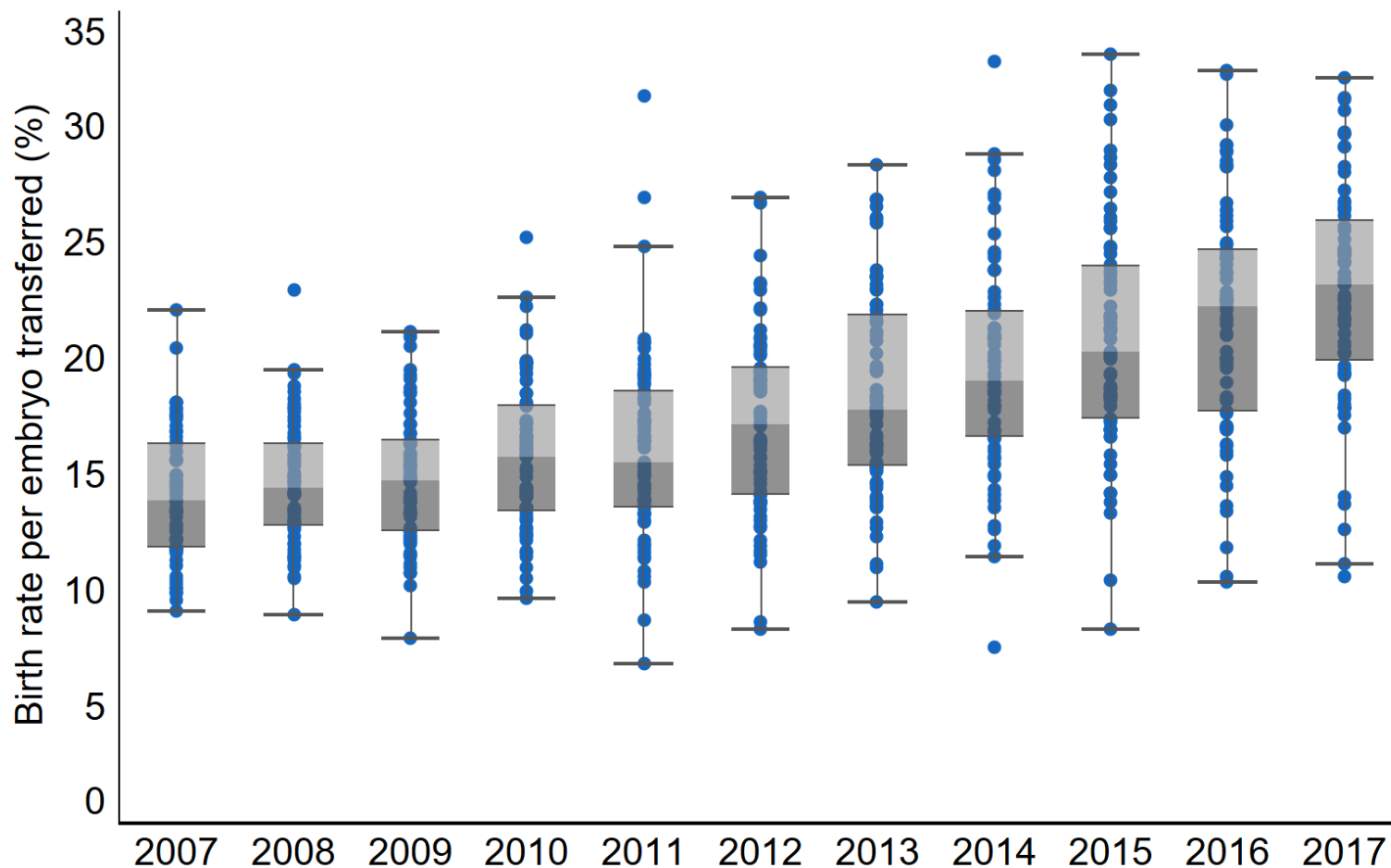
Birth rates have risen for most ages

Birth rates PET using own eggs by age groups, 2007 and 2017



Higher birth rates, wider variation

Birth rates by clinics using patients own eggs, 2007-2017



Just under half of clinics have a birth rate between 20% and 25% PET

Count of clinics by birth rates per embryo transfer ranges, 2017

Births per embryo transferred	Clinic count
≥30%	6
25-29%	17
20-24%	32
15-19%	12
10-14%	5
All clinics >150 cycles	72

Note: clinics with fewer than 150 cycles have been excluded to reduce extreme values. This table is for statistical illustration only and clinics listed are not compared to the national average. PET = live births per embryo transferred

Scotland has the lowest MBR and highest live birth rate PET

Comparison of IVF by UK nation using patients eggs, 2017

Nation	No. of cycles	% NHS funded	Average age	Average no. of ET	MBR (%)	Live births PET (%)
England	49,914	40	35.1	1.4	10.4	21.6
Scotland	3,897	64	35.0	1.2	6.5	27.0
Wales	1,928	50	34.3	1.3	7.3	20.9
Northern Ireland	1,518	46	34.4	1.4	9.3	20.0
UK	57,324	42	35.1	1.4	10.0	21.9

Differences in clinic performance

Examples of clinic differences in live births PET and MBR using patients own eggs, 2017

	Average age	Average previous cycles	Average no. of ET	Live births PET (%)	MBR (%)
Clinic A	35	1.4	1.1	29	3
Clinic B	34	1.1	1.6	18	19
UK	35	1.4	1.4	22	10

Key questions

- What are some clinics doing to achieve high birth rates while maintaining low multiple births?
- What is a successful clinic?
- What other factors should be considered when looking at success rates?
 - How can we compare clinics with small numbers of cycles?
 - How can we examine patient mix / treatments offered in centres and determine if this has an effect on birth rates
- Should clinic level data be included in our next Fertility Trends statistical release?



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Any questions?

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