

Authority meeting - agenda

16 November 2016

Venue: Etc Venues Victoria, 1 Drummond Gate, London SW1V 2QW

Agenda item	Time
1. Welcome, apologies and declaration of interests	12:45pm
2. Minutes of 14 September 2016 HFEA (16/11/16) 811 For decision	12:50pm
3. Chair's report (verbal)	12:55pm
4. Chief Executive's report (verbal)	1:05pm
5. Committee chairs' updates (verbal)	1:15pm
6. Strategic performance report HFEA (16/11/16) 812 For information	1:20pm
7. Information for Quality programme: update HFEA (16/11/16) 813 For information	1:30pm
8. Choose a fertility clinic HFEA (16/11/16) 814 For decision	1:50pm
9. Break	3.00pm
10. Annual review of SCAAC work Presentation For information	3.05pm
11. Draft business plan 2017/18 HFEA (16/11/16) 815 For decision	3:35pm
12. Strategic risk register HFEA (16/11/16) 816 For information	3:50pm
13. Any other business	4:10pm

Minutes of Authority meeting 14 September 2016

Strategic delivery:

Setting standards

Increasing and
informing choice

Demonstrating efficiency
economy and value

Details:

Meeting Authority

Agenda item 2

Paper number HFEA (16/11/2016) 811

Meeting date 16 November 2016

Author Charlotte Keen, Information Access and Policy Manager

Output:

For information or
decision? For decision

Recommendation Members are asked to confirm the minutes as a true and accurate record of the meeting

Resource implications

Implementation date

Communication(s)

Organisational risk

Low

Medium

High

Annexes

Minutes of the Authority meeting on 14 September 2016 held at ETC Venues, Victoria, 1 Drummond Gate, London SW1V 2QW

Members present	Sally Cheshire (Chair) Professor David Archard Rebekah Dundas Dr Andy Greenfield Yacoub Khalaf Margaret Gilmore	Anita Bharucha Ruth Wilde Dr Anne Lampe Anthony Rutherford Kate Brian
Apologies	Bishop Lee Rayfield	
Observers/Presenters	Ted Webb (Department of Health) Jeremy Mean (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Catherine Drennan Paula Robinson	Sharon Fensome-Rimmer Sara Parlett Andrew Leonard Paula Nolan Charlotte Keen

Members

There were 11 members at the meeting, 7 lay members and 4 professional members

1. Welcome, apologies and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the fifth meeting of 2016. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations.
- 1.2. Apologies were received from Bishop Lee Rayfield.
- 1.3. Declarations of interest were made by:
 - Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
 - Yacoub Khalaf (Person Responsible at a licensed centre)
 - Anthony Rutherford (Consultant in Reproductive Medicine and Gynaecological Surgery at a licensed centre)
 - Ruth Wilde (Senior Fertility Counsellor at a licensed centre).

2. Minutes of Authority meeting held on 6 July 2016

- 2.1. Members agreed the minutes of the meeting held on 6 July subject to minor amendments, for signature by the Chair.

3. Chair's report

- 3.1. The Chair welcomed Jeremy Mean from the Department of Health as the HFEA's new sponsor, since Ted Webb, the HFEA's sponsor for the past 14 years, was retiring. The Chair expressed her thanks to Ted on behalf of members, and HFEA colleagues, for all his support over the years.
- 3.2. The Chair also thanked Sue Gallone, the Director of Finance and Resources for both the HFEA and the HTA, as Sue was also retiring. Although Sue was unable to attend the Authority meeting, the Chair expressed her thanks to Sue for all her hard work which had been much appreciated and wished her well for the future.
- 3.3. Finally, the Chair thanked Professor David Archard, who was leaving and who was also the HFEA's longest serving member. David had been instrumental in advising the Authority on all matters to do with ethics and law and had played a major part in how the HFEA handled preimplantation genetic diagnosis (PGD), as well as working on mitochondrial donation and developing the Statutory Approvals Committee (SAC) from its infancy. Through his expert Chairing of SAC, the Chair felt that David had made a huge difference to the Authority and both she and the Chief Executive expressed their thanks to David for his valuable input during his time as an Authority member.
- 3.4. The Chair provided members with a summary of events that she had attended with organisations in the IVF sector and the wider health and care system since the last Authority meeting.
- 3.5. On 12 July, the Chair chaired the Remuneration Committee, more detail of which would be covered under item five on the agenda.
- 3.6. On 20 July, the Chair attended the Department of Health's arm's length bodies (ALBs) chairs and non-executive directors (NEDs) summer conference.
- 3.7. Finally, the Chair advised members of the public that the HFEA would mark its 25th anniversary at an event taking place on 15 September. The HFEA was the first statutory regulator of IVF and human embryo research in the world and it was testimony to all those involved that it had stood the test of time so well and was considered to be the standard against which regulation in the field was judged. The event would provide a chance to celebrate those achievements in more details with past colleagues and some of the HFEA's most important stakeholders.

4. Chief Executive's report

- 4.1. The Chief Executive advised members that on 12 July he had also attended the HFEA Remuneration Committee and provided recommendations on the Senior Managers' performance pay award.
- 4.2. On 21 July, the Chief Executive attended a meeting of the Health and Social Care Leadership Scheme which brought together the Department of Health and all of the Chief Executives of the health sector's ALBs to identify senior talent within the system. Members were aware that both the Director of Compliance and Information and the Director of Strategy and Corporate Affairs had been selected onto the programme.
- 4.3. On 28 July, the Chief Executive advised members that he was part of an interview panel for the shared Director of Finance and Resources for the HFEA and HTA, following the retirement of Sue

Gallone. The Chief Executive was pleased to inform members that Richard Sydee had been appointed and he would join the HFEA and HTA on 1 November.

- 4.4.** On 8 September, the Chief Executive attended a National Information Board (NIB) Leadership meeting. The NIB was an initiative led by the Department of Health involving all of the health sector's ALBs to make significant changes to the way in which information was used within the health and care system. The HFEA's role was limited given its specialist remit although it was appropriate that it was involved.
- 4.5.** Press coverage: the Chief Executive advised members that there had been relatively few news stories in which the HFEA had been quoted or cited directly since the last Authority meeting. However, there had been a number of stories on assisted reproduction featuring facts and figures from the HFEA's Register, details of which had been circulated to members.
- 4.6.** It was anticipated that, with the schedule of projects and events coming up in the next couple of months, media interest in the sector would resume.

5. Committee chairs' updates

- 5.1.** The Deputy Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 5 and 25 August. There had been five preimplantation genetic diagnosis (PGD) applications on 5 August, four of which were approved and one refused, together with two Special Directions applications for export, both of which were approved. At the meeting on 25 August, there had been two PGD applications, both of which were approved.
- 5.2.** The Chair of the Licence Committee reported that the committee had met on 14 July and 9 September. On 14 July, the committee considered and approved a research renewal licence application, agreed the continuance of a licence following an interim inspection and noted an unannounced inspection and an executive update. On 9 September, the minutes of which had not yet been published, the committee considered two licence renewal applications, a variation of objectives, an update on legal parenthood and a paper from the Scientific and Clinical Advances Advisory Committee (SCAAC).
- 5.3.** The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met five times since the last Authority meeting on 15 and 29 July, 12 and 24 August and 9 September. For the first four meetings, the panel had considered 12 items in total, two of which were adjourned and the rest of which were approved. There were three renewal licence applications; four interim inspection reports; four licence variations and one new licence application. At the meeting on 9 September, the minutes of which had not yet been published, the panel had considered nine items. There were three renewal licence applications; one interim inspection report; four licence variations and one new licence application.
- 5.4.** The Chair provided more details of the Remuneration Committee mentioned earlier in the meeting. The committee met on 12 July to consider proposed pay awards for staff, directors and Chief Executive, together with an appraisal of their performance. The Chair expressed her thanks to all HFEA staff for their valuable contribution to the organisation.

6. Strategic performance report

- 6.1.** The Director of Strategy and Corporate Affairs advised members that the HFEA annual conference for 2017 would be taking place on Thursday 16 March at the Inmarsat Global Conference Centre in London.
- 6.2.** The Director of Compliance and Information provided a brief summary of three issues within his Directorate which were highlighted in the Strategic Performance Report. Firstly, in June, the HFEA had a serious power outage in the building which also affected the National Institute for Clinical Excellence (NICE) and the British Council. This inevitably had an impact on the HFEA's work and the business continuity plan was invoked. As the servers were affected, this meant that staff had been unable to access the secure document storage system and subsequently this had had an effect on key performance indicators. Lessons have been learned as regards the implementation of the business continuity plan which will be useful for future eventualities.
- 6.3.** The Director of Compliance and Information also acknowledged that there had been issues around the telephony systems which inevitably had an impact on the work of the committees where video conferencing was used on a regular basis. Work was ongoing to rectify these problems.
- 6.4.** The Strategic Performance Report also highlighted delays with reports being sent back to clinics following inspection, although those delays were for valid reasons.
- 6.5.** In the absence of the Director of Finance and Resources, the Chief Executive gave an overview of financial performance. Although it was early in the financial year, looking at the June figures, two facts stood out, one of which was a significant increase in the treatment fee income against that which had been forecast. There was no obvious reason for this, and no evidence of a pattern, but the Executive were very sighted on the increase and would continue to monitor the position.
- 6.6.** The Chief Executive advised members that, on the whole, expenditure was as forecast although there had been an overspend of 35% in the legal budget. The legal budget was always difficult to predict and it was likely that the budget would right itself over time.
- 6.7.** The Chair informed members that the expert panel, who had previously met and reported on progress with mitochondrial donation techniques, had been working on a report which should be ready for publication in the near future. The Chair of the expert panel advised members that the panel had published a request for evidence and the panel was now in the process of considering that evidence and writing the report in light of that consideration. The panel had met at the end of July and would be meeting again on 16 September. The report would focus on new evidence relating to the safety and efficacy of mitochondrial donation techniques that had come to light since 2014. The Chair of the expert panel advised members that it was anticipated the report would be ready for publication by the end of the year.
- 6.8.** Following a discussion, members noted the latest strategic performance report.

7. Information for Quality: update

- 7.1.** The Director of Compliance and Information explained that the IfQ programme was a comprehensive review of the information that the HFEA held, the systems that governed the

submission of data, the uses to which it was put and the ways in which the information was published. It included:

- The redesign of the HFEA's website and Choose a Fertility Clinic (CaFC) function
- The redesign of the 'Clinic Portal' used for interacting with clinics
- A new electronic data submission system
- A revised dataset and data dictionary which would be accredited
- A revised Register of treatments, which would include the migration of historical data contained within the existing Register
- The redesign of the HFEA's main internal systems that comprised the Authority's Register and supporting IT processes.

7.2. The Director of Compliance and Information explained that this presentation was to update members on:

- Progression to public Beta for 'Release One' products and plans for a fully live HFEA website and Clinic Portal
- Progress in relation to 'Release Two' (the data submission system)
- Programme timelines and budget.

7.3. Approvals progress: the Director of Compliance and Information reminded members of the stages that government IT programmes must progress through:

- 'alpha' (build a prototype, test it with users and learn from it)
- 'beta' (scaling up, a working model)
- 'public beta' (going public with a beta version, receiving feedback and preparing to go live)
- 'live' (a tested solution ready to release and then continuously improved).

7.4. The Director of Compliance and Information reminded members that, at the July meeting of the Authority, it was noted that the website had been launched on 5 July 2016 in a private version of beta for clinics only to access. This step was taken to enable clinics to familiarise themselves with the presentation of their CaFC data on the website, and to use the Clinic Portal, for a three-week period prior to full beta public launch.

7.5. The Clinic Portal was released to public beta one week later on 12 July 2016, and further developments and improvements would continue throughout the beta phase. User feedback would also be sought, including a structured session in early September in a 'laboratory' setting where users would be able to feed back their experience directly to the HFEA's contractor. The Government Digital Service (GDS) assessment of the Clinic Portal to enable progression to 'live' was scheduled for October 2016.

7.6. It was originally planned to make the beta version of the website available to the public a few weeks after showing it to the clinics. However, the HFEA was prevented from doing so due to an injunction granted by the High Court on 14 July, following an application brought by a clinic. The injunction was subsequently lifted and the website proceeded to public beta on 12 August 2016.

7.7. The feedback from public beta would be one element of the evidence that would inform the decision on the final shape of the new website. The IfQ Advisory Group would be invited to meet

again in order to help inform the set of recommendations that would be put to members at the next meeting in November 2016.

- 7.8.** The Director of Compliance and Information advised members the Executive felt that, with the judicial review pending, it would make sense to postpone the GDS assessment until any legal disputes were resolved. The GDS 'live' assessment was therefore scheduled for late January 2017.
- 7.9.** Members noted that there were two operational issues as a consequence of this delay:
- The current HFEA website content management system was dated and no longer supported by the original supplier, which would lead to instability from time to time. This had been managed to date but this risk remained as long as it remained as the HFEA's official site
 - There had been a concentration of resources in preparing the website for beta launch. This reallocation of resources had had an effect on planning assumptions, in particular relating to development work necessary for 'Release Two' – the data submission module.
- 7.10.** Progress on 'Release Two': the Director of Compliance and Information advised members that substantial work had been completed on all the necessary processes and proof of concept such that development work and design work could progress at pace. However, the additional work set out above meant that the end of October 2016 release expectations for EDI users (those clinics submitting directly to the HFEA) was unlikely to be met. A revised plan was now being developed.
- 7.11.** The Director of Compliance and Information advised that the data migration and cleansing work was a little behind schedule, also as a result of diversion of some resources. Data cleansing work remained primarily focussed on dealing with 'severity one' issues, with all issues expected to be resolved in September. If necessary, the data migration of the existing, cleansed database to a new structure could still occur by October 2016.
- 7.12.** Arrangements to provide assurance services for the data migration was now in place and an expert in data migration had been commissioned to provide a review of all the steps the HFEA had taken, and would take, prior to transfer.
- 7.13.** Whilst most clinics had been cooperative in fixing errors, there were issues with some clinics failing to deal swiftly with requests and the Executive continued to monitor progress closely.
- 7.14.** Timelines and budget implications: the Director of Compliance and Information reminded members that a revised programme plan had been finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by the Authority. On 24 May, the Senior Management Team (SMT) decided to allocate an additional £90k to the overall Programme budget to ensure that critical staff were retained on the team.
- 7.15.** The variance in September was explained by an underspend originally forecasted for the security consultant and this underspend should balance in the coming months once the work was completed and invoiced.
- 7.16.** Following a discussion, Authority members noted:
- Progress since the last Authority meeting
 - The revised timelines in relation to the website and 'Release Two' – the data submission system

- Programme timelines and budget implications.

8. Strategy 2017-20

- 8.1.** The Head of Business Planning presented this item and advised members that the Executive had prepared an early outline of the strategy which had been informed by workshops and discussions with both Authority members and staff. The Head of Business Planning emphasised that this was a draft outline strategy for discussion with stakeholders during the autumn.
- 8.2.** Members were asked for their thoughts on whether the Executive had taken the right approach in the following areas in particular:
- Setting the strategy around the different needs of patients and donors through the various stages of treatment and donation
 - Including donor conception issues in with fertility treatment and that the Lifecycle campaign should come to an end, whilst continuing to use the good work the campaign had produced
 - Data and embryo research – whether to focus on facilitating patient choice in this area or to promote research and innovation and increasing consent rates.
- 8.3.** The Head of Business Planning advised members that the centre of the new strategy would be the HFEA's ongoing vision for high quality care for everyone affected by assisted reproduction. Based on research during the current strategy, the Executive had identified stages along the patient and donor pathway, setting out their needs at each stage and considering their interaction points with clinics and the HFEA. Members noted that patients and donors were not the HFEA's only stakeholders but they should be the main focus.
- 8.4.** The Head of Business Planning provided a summary of those stages. These were set out in more detail in the draft strategy together with what the HFEA wanted to achieve for patients and what patients should be able to do at each stage:
- Researching fertility treatment or donation
 - Making contact with a clinic and starting to make initial decisions
 - Having treatment or being an active donor
 - After treatment or donation.
- 8.5.** There were three main areas of strategic focus, under which the paper identified what the Authority believed should change, how this could be accomplished (through what tactics), and with what outcomes or measures of success. The three main areas were:
- Consistent support and outcomes for patients
 - Safe, ethical, effective, proven treatment
 - Improving standards through intelligence.
- 8.6.** The Head of Business Planning emphasised that post-IfQ and at the end of the current strategy, the HFEA would have the following tools and resources available in order to help deliver the strategy, including but not exclusively:
- New information for patients and donors on treatments, options and finding a clinic

- Easy-to-understand measures of quality in clinic services
- Patient ratings system for clinics
- Simpler data submission and clinic performance system
- A new register, enabling better analysis of treatments, outcomes and trends in clinical practice.

- 8.7.** Members noted that the proposed strategy had situated its ambitions for donor conception patients and for donors within several strands relating to support throughout treatment, good experience of care and evidence-based, effective treatments. The Lifecycle campaign was originally needed to reach new audiences (such as those thinking about going abroad for treatment). However, with the HFEA's new website and tone of voice, and a willingness to reach that wider patient audience, there was much less justification for a dedicated donation campaign and the resources to support it.
- 8.8.** The Head of Business Planning advised members that, in relation to the whole area of new and emerging treatments and developing science and whether those were evidence-based yet – or at all – there was often poor, misleading or sensationalised media coverage. Unfortunately, some of the available scientific information required a lot of expert interpretation to make it accessible to people without any scientific background. Consequently, part of the strategy would be to increase patients' understanding of subjects such as emerging new treatments or genetics and genomics, and to ensure that patients are given the right treatment for them. Members noted that the HFEA already had in place a mechanism for assessing the evidence of effectiveness, with a scientific committee in place, and the intention was regularly to update all the scientific and treatment information on the HFEA website, making it as easy to understand as possible.
- 8.9.** The Head of Business Planning advised members that, as part of its role as a regulator, the HFEA could 'raise the bar' by driving up sector standards through its regulatory work, to encourage greater consistency and excellence between clinics and within clinics, and being directive and challenging when necessary and proportionate to do so. The HFEA would also sometimes need to 'push the bar', setting new standards or higher standards and expectations, where there were perhaps none before, in response to new developments or new trends in the sector.
- 8.10.** The Head of Business Planning provided members with a summary of next steps, which would include stakeholder engagement via meetings in the autumn and winter and through a continuing conversation with staff. Focus groups with patients were also planned for the winter. Members would be presented with the stakeholder feedback so far at a workshop prior to the November Authority meeting, to shape the final draft strategy ready for sign-off at the January 2017 Authority meeting. The plan was to publish the strategy in April 2017, with a launch at the annual conference in March.
- 8.11.** The main points that emerged from the discussion were that members particularly welcomed the focus on patients. Members were of the view that it was important to ensure that the HFEA's continued commitment to donors and donation was clear throughout the strategy. There could be a risk that the HFEA was perceived as no longer being committed to donation issues because there was no longer a specific separate section about donation in the strategy, especially since the Lifecycle work was also coming to an end at the same time.

- 8.12.** Members also agreed that the final published strategy document should be short, focused and concise, and include clear strategic objectives below the vision level.
- 8.13.** Members welcomed the focus on embryo research. They felt, however, that it was important to substantiate that the HFEA had the capacity and capability to deliver the resulting work.
- 8.14.** Following the discussion, members approved the early outline of the strategy, subject to the necessary revisions and amendments raised, prior to further discussion with stakeholders in the autumn.

9. Compliance activities 2015/16: a review

- 9.1.** The Chief Inspector introduced this item and advised members that the paper was the second annual report on compliance activities. The paper included:
- an overview of the type and number of non-compliances found on inspection or identified through the HFEA's risk-based assessment tool (RBAT) or other reporting mechanisms
 - a review of the actions taken in the inspection year April 2015 to end of March 2016 to promote compliance by licensed clinics and research centres with the HFE Act 1990 (as amended)
 - an assessment of the effectiveness of the regulatory methods employed by the HFEA and the extent to which they had an impact on the sector.
- 9.2.** The Senior Inspector advised members that the paper provided an analysis of non-compliances found in the course of renewal and interim inspections between 1 April 2015 and 31 March 2016, and a comparison with the 2014/15 inspection findings.
- 9.3.** The Senior Inspector provided members with an overview of how the inspection team had been successful in meeting the objective of improving the quality and safety of care through the HFEA's regulatory activities. The analysis was set out in detail in the paper and included:
- 84 inspections at clinics: 35 treatment and or storage renewal inspections, 36 treatment and or storage interim inspections and 13 additional inspections in 2015/16, an increase of 60% on the previous year
 - In addition, 18 inspections at research centres were carried out
 - 445 recommendations for corrective action at treatment centres in 2015/16 with 373 having been fully implemented as at 26 July 2016 (84%)
 - 264 recommendations to correct higher risk critical and major non-compliances with 222 of those implemented as at 26 July 2016 (84%).
- 9.4.** The Senior Inspector advised members that, in post-inspection feedback, 93% of respondents inspected in 2015/16 agreed that inspection had promoted improvement to the way their clinic carried out its work. Generally, less than 90% of respondents were happy with the preparation, delivery and reporting of their inspection. This data suggested that the inspection team were delivering the objective to improve the quality and safety of patient care as set out in the HFEA's strategy.

- 9.5.** The Senior Inspector advised members that in 2015/16 the HFEA found the sector more compliant than the previous year. This conclusion was based on inspectors finding fewer non-compliances per inspection in 2015/16 than in the previous year. Another finding was that the improvement in non-compliance was seen across virtually all areas of practice except two: medicines management and legal parenthood consent. The increase in prevalence in these areas was thought to be related to the increased regulatory focus on these areas of practice.
- 9.6.** The medicines management non-compliances comprised four critical, 28 major and nine other non-compliances. Seven had not yet reached their implementation deadlines as at 26 July. The remainder had all been corrected. In many cases the non-compliances reflected problems in medicines management documentation and practices which were contrary to professional body guidelines or relevant legislation, and thus their severity had been elevated. The four critical non-compliances involved multiple failings which had given significant and immediate cause for concern and the inspection team had ensured corrective actions to address them were swiftly implemented.
- 9.7.** The legal parenthood non-compliances comprised two critical and five major non-compliances. All had subsequently been addressed.
- 9.8.** The Senior Inspector advised members that the HFEA had been using the risk based assessment tool (RBAT) to enhance the monitoring of clinics between inspection visits since April 2011. Members noted that the risk tool measured performance in relation to the following indicators:
- Outcomes in terms of both clinical pregnancy rates and clinical multiple pregnancy rates
 - Submission of critical register information relating to treatments using donor gametes
 - Timeliness of payment of monthly HFEA invoices.
- 9.9.** Performance was analysed based on the information submitted to the HFEA by clinics. Where the trend analysis performed by RBAT suggested that there may be a dip in performance, an automated alert was sent to the Person Responsible (PR) and clinics were expected to act on those alerts to investigate any possible causal factors and take corrective action if appropriate. Inspectors and/or members of the Register Information team also carried out targeted follow-up where appropriate.
- 9.10.** The Senior Inspector provided members with an overview of the number and type of alerts issued from the risk tool, which were set out in detail in the paper.
- 9.11.** Clinics' performance in 2015/16 had worsened compared to the previous year in relation to the submission of critical treatment information, but this was mainly due to the activity being undertaken by key teams within the HFEA, relating to IfQ developments. The number of alerts relating to invoice payments had significantly decreased, suggesting the clinics' performance in meeting the enhanced performance expectations had been successful. Further, in relation to success rates and multiple birth rates, the volume of alerts had remained constant, albeit that the population of clinics receiving these alerts had changed, suggesting an improvement in performance by some.
- 9.12.** Of the ten clinics receiving the highest number of alerts last year, five of those clinics remained in the same category. This suggested either difficulties that could take time to improve, or limitations in terms of those clinics' culture of improvement. It was clear that some refocusing of performance

in relation to some clinics' multiple birth minimisation plans was necessary to move the overall sector average performance closer to the 10% target.

- 9.13.** The Senior Inspector advised members that the HFEA felt the risk tool provided useful and timely information for clinics in order to prompt them to review processes and take subsequent action where appropriate. It also helped the inspectorate to focus its activities on quality of service and prompted interaction with specific clinics when needed.
- 9.14.** The Chief Inspector summarised the findings of the report, what the HFEA wanted to happen going forward and how the HFEA was going to implement this.
- 9.15.** The findings of the report suggested that:
- There was an increase in inspection activity by 60%
 - The inspection process was effective, and promoted improvement
 - There was evidence that some clinics had not embedded lessons learned or embraced risk based thinking
 - There was some evidence of ineffective root cause analysis (RCA) and the absence of RCAs being documented
 - Alerts on success rates had remained consistent
 - The majority of clinics embraced single embryo transfer (SET).
- 9.16.** The HFEA wanted:
- The sector to continue to be safe and to provide a quality service which was compliant
 - The HFEA to adapt its inspection techniques to ensure the above
 - Clinics to embrace quality and lessons learned
 - Clinics to be more effective at RCA
 - Clinics to be more effective at internal audits
 - More clinics achieving the 10% SET figure.
- 9.17.** The HFEA would achieve this by:
- Maintaining a credible, effective and safe regulatory process by standardising and increasing the intensity and focus, and evolving the approach where necessary
 - Continuing the series of workshops that had been established to provide assistance to the sector and giving clinic staff a better understanding of RCA and human factors
 - Working with policy colleagues, partners and the sector on re-invigorating the multiple births strategy
 - Performing more frequent trend analysis in order to respond pro-actively.
- 9.18.** Following a discussion, members noted the inspection and monitoring work undertaken, and the effect of this on the performance of the sector. In terms of lessons, the Authority saw an opportunity to address inconsistency in performance between clinics, on a range of measures including multiple birth rates. This will require signalling to clinics that the Authority is ambitious to see further improvement not just on current standards but on a continuous improvement basis - that is 'raising' the bar and 'pushing' the bar. Members noted the report and the summary of actions set out in section four of the paper.

10. Adverse incidents in fertility clinics

10.1. The Chief Inspector introduced this item and provided a summary of the presentation which included:

- The HFEA's vision for decreasing incidents
- A background on incidents
- The investigation process
- Root cause analysis (RCA)
- Human error
- Human factors
- Recommendations
- What the HFEA want clinics to do
- How the HFEA envisaged achieving this.

10.2. The Clinical Governance Inspector reminded members that the HFEA now published an annual incident report, a draft of which was included in the set of papers and would be published later in September.

10.3. During 2015, there were 517 incidents reported by the sector to the HFEA, an increase of 4%, although members noted there were more treatment cycles being carried out. However, there was still room for improvement in the sector and incidents and re-occurring incidents still continued to happen.

10.4. The Chief Inspector provided members with a summary of what constituted a good investigation, which included:

- remedial action
- RCA
- corrective action
- preventative action
- monitoring.

10.5. RCA was quite a simple methodology and, in healthcare, it was essential to discover and address the root cause to improve the delivery of care and to prevent or minimise its reoccurrence. The Chief Inspector advised members that human error was often identified as the root cause. However, human error (defined as 'an act or thought that unintentionally deviated from what was correct, right or true') would itself have a root cause, and it was important that the real root cause was identified so that learning and improvement could occur.

10.6. Following a discussion, during which the Chair emphasised that it was essential there was an improvement in clinic performance next year, members agreed that:

- The sector should continue to engage with the clinical governance team within the HFEA
- The HFEA should standardise the approach to incident investigations to maintain and increase the focus on this area of performance

- The use of 'human error' as the root cause of an incident should be avoided, since this failed to get to the true root cause.
- The fertility sector needed to adopt a more scientific and methodical approach to incident/non-conformity investigating
- A group-wide approach to lessons learned from incidents should be promoted.

11. Any other business

- 11.1.** The Chair confirmed that the next meeting would be held on 16 November at ETC Venues Victoria, 1 Drummond Gate, London SW1V 2QW. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

12. Chair's signature

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

Signature

Chair

Date

Strategic performance report

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

Details:

Meeting	Authority
Agenda item	6
Paper number	HFEA (16/11/16) 812
Meeting date	16 November 2016
Author	Paula Robinson, Head of Business Planning

Output:

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

1. Introduction

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

2. Recommendation

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

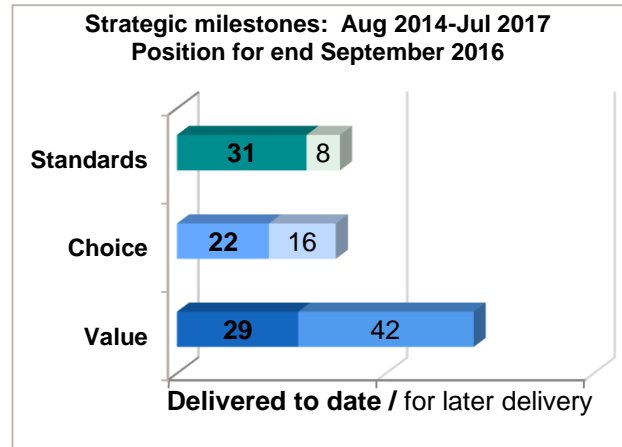
HFEA strategic performance scorecard

1. Summary section

Dashboard – September data

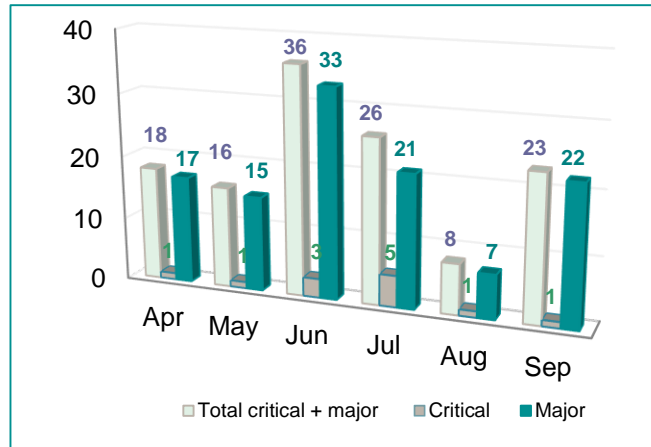
Strategic delivery totaliser

(see overleaf for more detail)



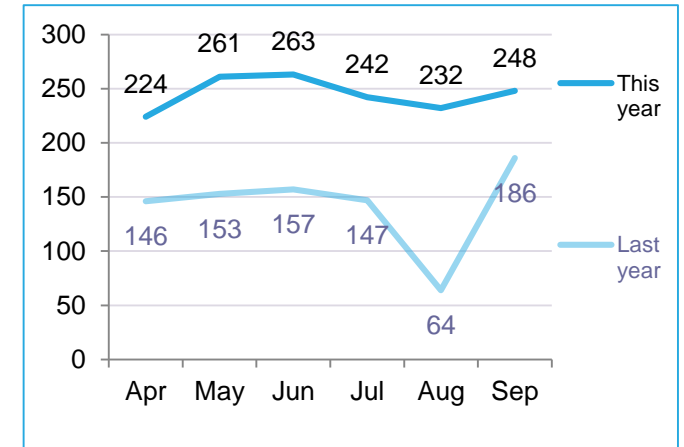
Setting standards:

critical and major recommendations on inspection



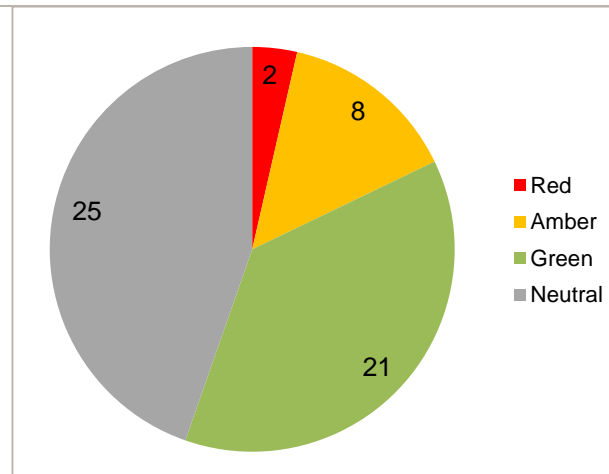
Increasing and informing choice:

public enquiries received (email)



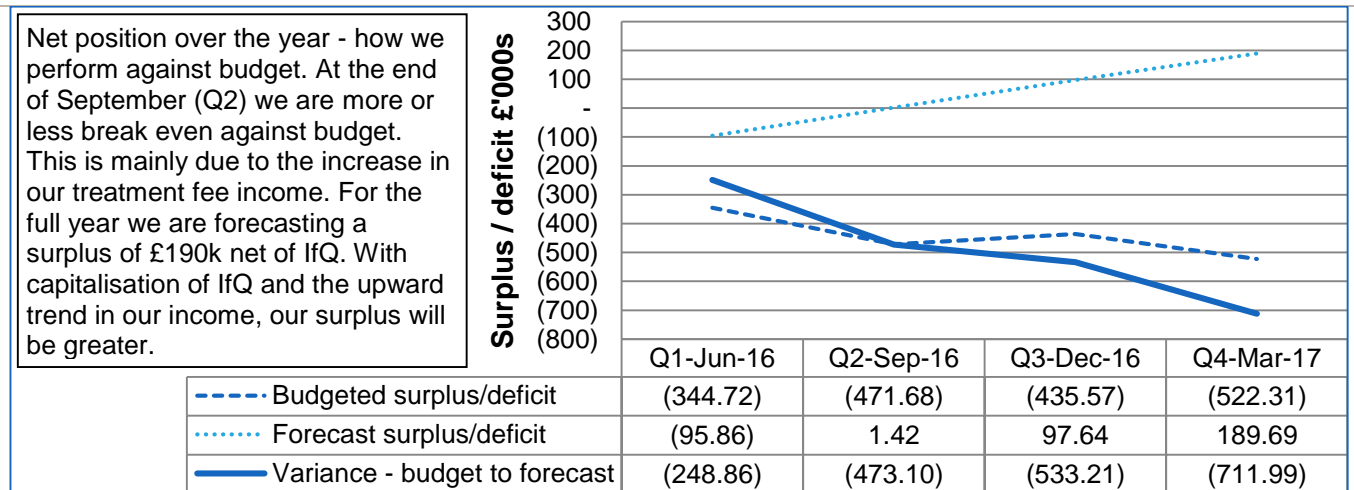
Regarding public enquiries, we intend to analyse the themes and trends, and review this at the next Corporate Management Group Performance meeting.

Overall performance - all indicators:



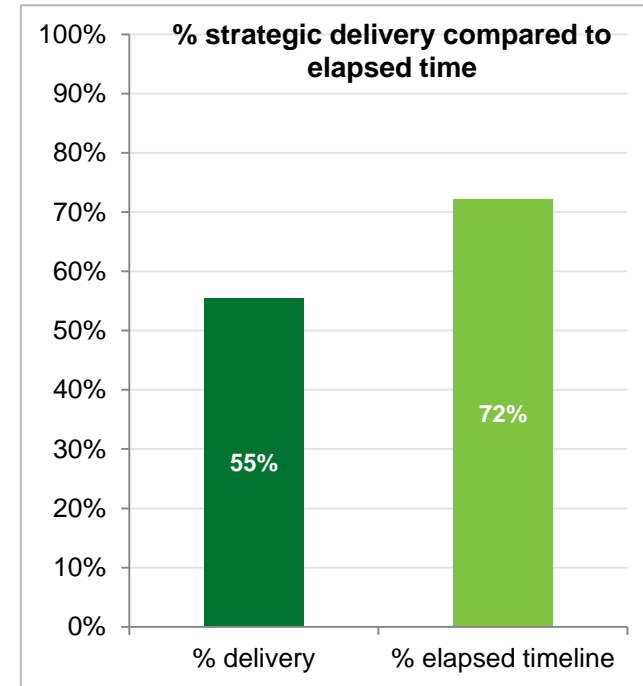
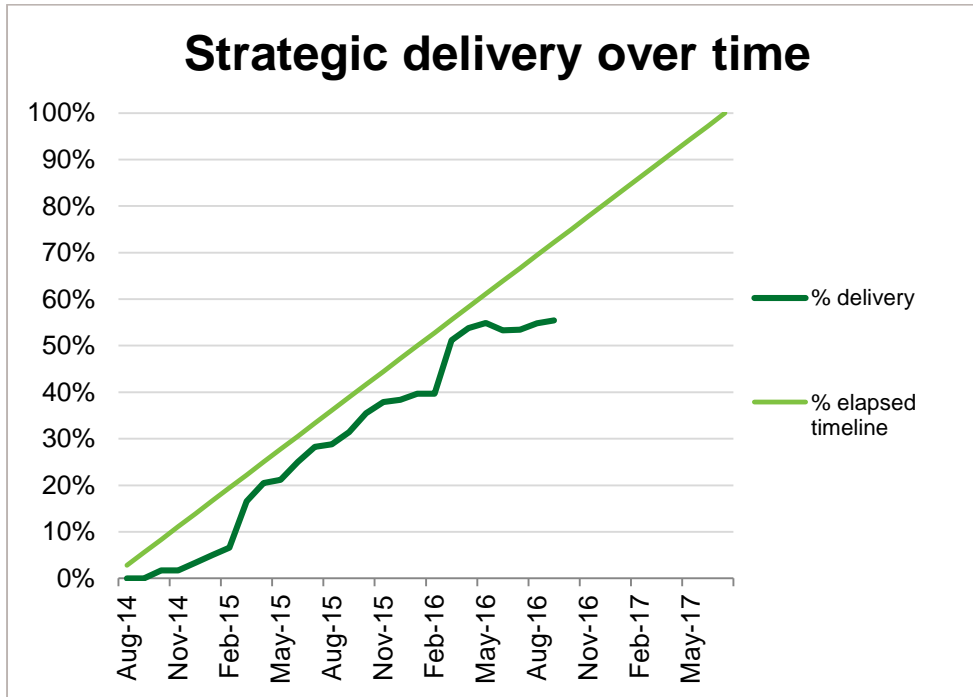
(See RAG status section for detail.)

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



Dashboard - Commentary

Strategic delivery (to end of September) – summary:



Progress on the Information for Quality Programme, IfQ, has been impeded by a number of issues, including legal challenge, supplier resource restrictions and development complexities during the beta phase of work. This means that a number of the due milestones from July to September have necessarily been deferred to later dates. A new timeline is now in place, which includes new GDS gateway approval dates for each product (the clinic portal and the website). Other milestones have been delivered on time, and the IfQ programme milestones will still be delivered within the overall strategic period, albeit later than first planned. Our staff are working extremely hard to ensure that the beta phase can be completed as soon as possible for both products, and are simultaneously commencing work in earnest on the internal systems and EDI elements of the programme, which together with a second release of the clinic portal, will comprise IfQ release 2 next spring.

Strategic delivery in July-September:

Setting standards

In July, CMG received a report back from the bi-annual meeting of the EU Competent Authorities, held in June.

In September, the annual set of Compliance reports were delivered to the Authority meeting as planned, incorporating analysis of the latest trends. The areas covered were risk tool alerts and themes, common non-compliances, and incidents.

Increasing and informing choice

A number of linked milestones have been rescheduled owing to the earlier legal action in relation to the new website. The affected milestones are:

- Delivery of key elements of the new website, including the patient feedback mechanism and the new CaFC design (rescheduled for January 2017)
- Getting the new website design ready for GDS go-live gateway review (rescheduled for late January 2017)
- Live website delivery (rescheduled for February 2017)
- Making better use of website feedback mechanisms, video content and social media integration (a post-live benefit, so this will be rescheduled for February 2017)

We were however still able to finalise our mechanisms for producing and publishing informative and accurate material when new treatment options emerge, working in collaboration with clinics and experts. This information will eventually allow patients to be better informed and better placed to deal with treatment issues and decisions. We will regularly publish information about new treatment options on the new website, once it goes live, and we have established mechanisms via SCAAC to enable this. Our existing information about available treatments has also been rewritten and expanded for the new website.

Efficiency, economy and value

There were five IfQ milestones originally due in this area for July, all of which were delayed. These are:

- Go-live GDS gateway review of release one of the clinic portal – this has been rearranged for November, following some resource loss into the website side of the programme and some technical development difficulties leading to additional problem-solving being necessary during public beta.
- Delivery of live release one of the clinic portal – this should now take place in early December, following our GDS gateway assessment in November.
- Go-live GDS gateway review of the new website and CaFC – this has been rescheduled for late January.
- Delivery of the completed new CaFC functionality – this has been deferred to February, following on from our go-live GDS review.
- Completion of data migration trial load one – this was delayed by resource diversions within the team, but was subsequently completed in September.

In August, both the clinic portal and website were able to enter the public beta phase, following a successful GDS gateway review. Two milestones that were due in September will now follow later, owing to the delays referenced above. These are the completion of trial loads and cleansing in the lead up to data migration, and delivery of key Register elements to achieve our goals for better data quality, including a successful migration to the new Register.

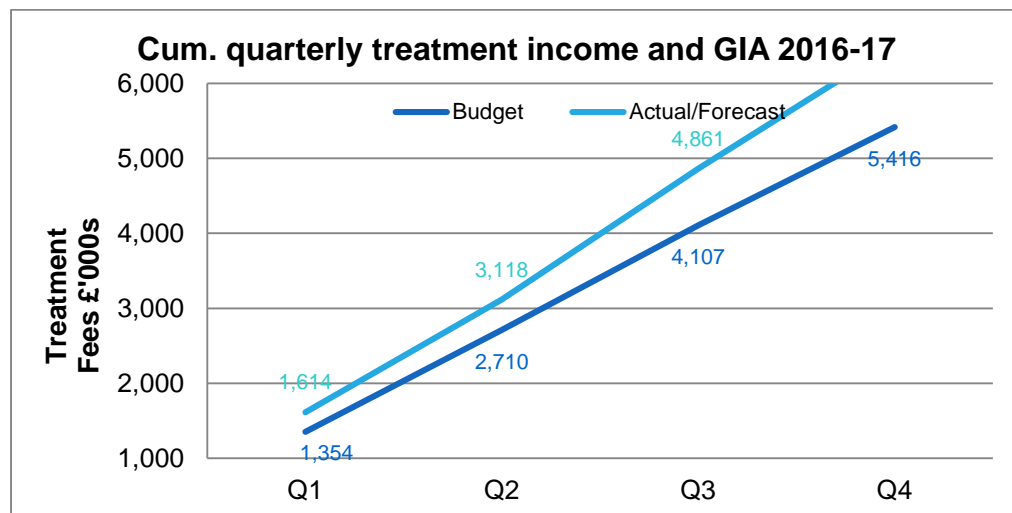
Red/amber/green status of performance indicators - September 2016

The two red key performance indicators (KPIs) shown in the 'overall status - performance indicators' pie chart on the dashboard both relate to an unavoidable delay in finalising the minutes for one particular set of Committee items.

No projects were on a red risk rating in July-September.

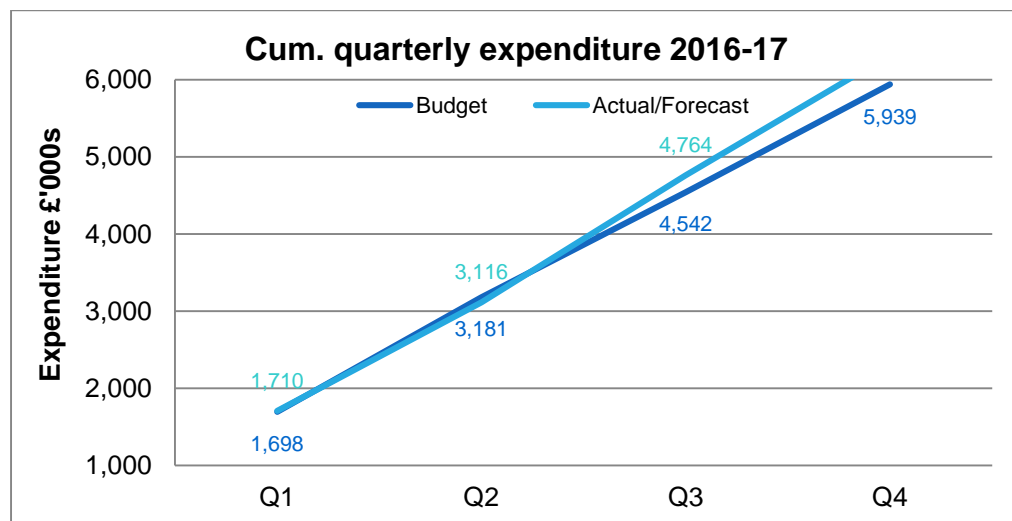
Budget status – September data

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



This graph shows our budgeted (planned) income including grant-in-aid (GIA) compared to actuals and our best forecast for the remaining 6 months (2 quarters).

As of month six (September 2016) we have exceeded our budgeted income by £409k. We continue to monitor this and review our treatment fees to ensure there are no surprises in store.



This graph is the second component that makes up the surplus/deficit. This includes costs relating to IfQ, although they are being funded from reserves and will be transferred to the balance sheet at year end.

At the end of Q2 we have conducted further review of our costs and have held meetings with Directorates to ensure we have the most up to date information with regards future business and in particular costs for IfQ which are included. There is a £400k difference between the budgeted expenditure and our forecast. This is largely due to an increase in legal costs and IfQ.

Quality and safety of care

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

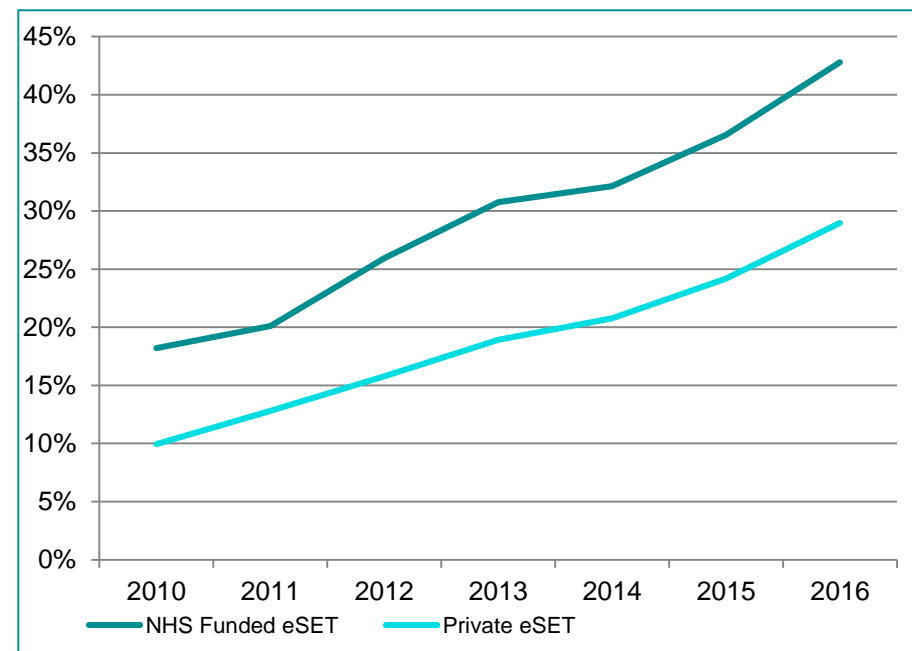
- number of risk tool alerts (and themes)
- common non-compliances (by type)
- incidents report (and themes).

The following figures and graphs were run on 21 October 2016.

ESET split by private/NHS:

Funding	Year						
	2010	2011	2012	2013	2014	2015	2016
NHS Funded:							
Recorded as eSET	4289	4903	6264	7870	8444	9748	9348
	7%	8%	10%	13%	13%	15%	17%
Not recorded as eSET	19287	19490	17870	17719	17824	16923	12497
	33%	32%	30%	29%	28%	26%	23%
Relative eSET %	18%	20%	26%	31%	32%	37%	43%
Private:							
Recorded as eSET	3422	4630	5699	6857	7737	9344	9229
	6%	8%	9%	11%	12%	14%	17%
Not recorded as eSET	31024	31547	30398	29393	29514	29313	22637
	53%	52%	50%	48%	46%	45%	42%
Relative eSET %	10%	13%	16%	19%	21%	24%	29%

Graph: eSet % trends NHS/private:



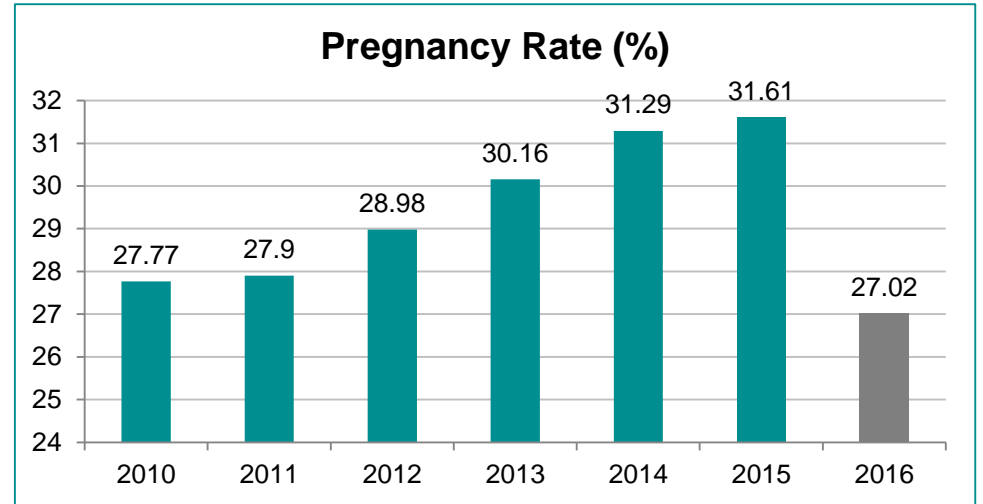
Explanatory text: Showing the total of all reported IVF treatment forms and counting those that the clinics recorded as eSET

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

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

Years	All cycles	Pregnancies	Pregnancy rate %
2010	58022	16112	27.77
2011	60571	16897	27.90
2012	60231	17455	28.98
2013	61839	18652	30.16
2014	63519	19876	31.29
2015	65328	20653	31.61
2016	53712	14515	27.02

Graph showing the pregnancy rate over recent years:


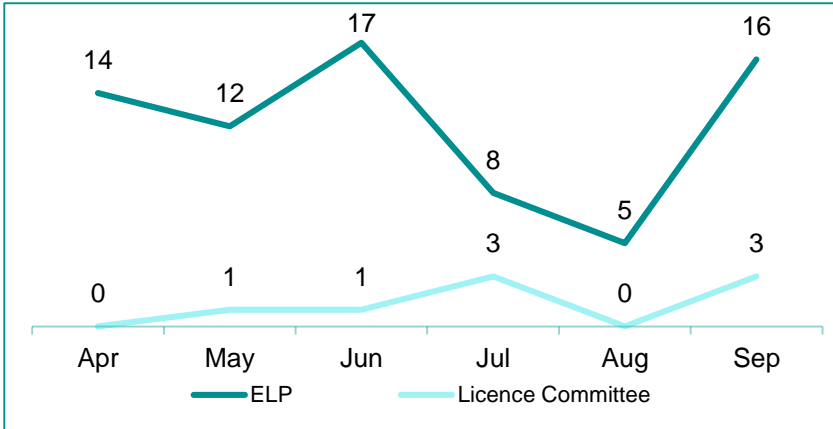

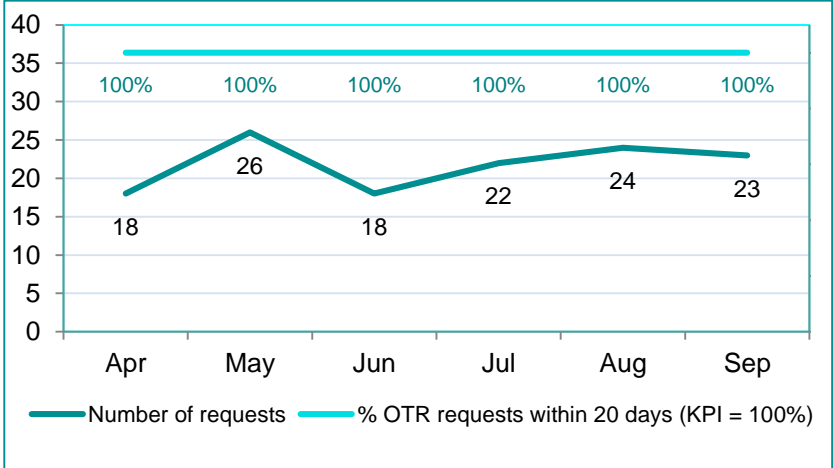


Explanatory text: Looking at all IVF treatment forms, and providing a count of pregnancies - as recorded on the early outcome form.

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

2. Indicator section

Key performance and volume indicators – September data:

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
Setting standards: improving the quality and safety of care through our regulatory activities.					
Licensing decisions made: - By ELP - By Licence Committee	16 3			No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target).
Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.					
Percentage of Opening the Register requests responded to within 20 working days	100% (23)			Maintain at 100%	KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)

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

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

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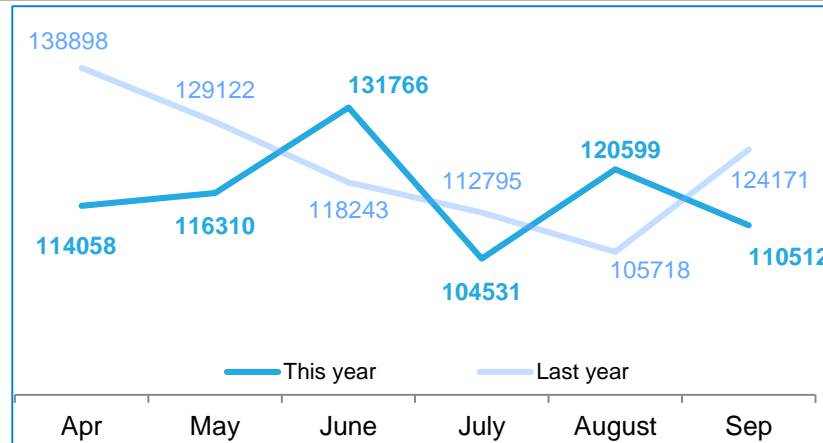
Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.

See graphs focused on quality of treatment outcomes – above.

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

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

124,171
(110,512)

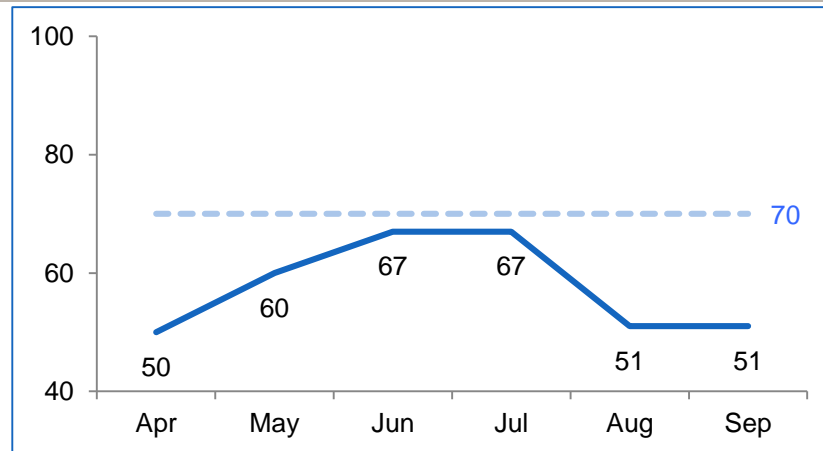


No KPI – tracked for general monitoring purposes.
 Volume indicator showing general website traffic compared to the same period in previous year. Measured on the basis of 'unique visitors'.

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

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

51 working days



KPI: Less than or equal to 70 working days.
 Maintain at 70wd or less

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes														
Monthly percentage of PGD applications processed within three months (66 working days).	100%	★	<table border="1"> <caption>Monthly percentage of PGD applications processed within three months</caption> <thead> <tr> <th>Month</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Apr</td> <td>100%</td> </tr> <tr> <td>May</td> <td>80%</td> </tr> <tr> <td>Jun</td> <td>80%</td> </tr> <tr> <td>Jul</td> <td>100%</td> </tr> <tr> <td>Aug</td> <td>67%</td> </tr> <tr> <td>Sep</td> <td>100%</td> </tr> </tbody> </table>	Month	Percentage	Apr	100%	May	80%	Jun	80%	Jul	100%	Aug	67%	Sep	100%	Maintain 100%	KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.
Month	Percentage																		
Apr	100%																		
May	80%																		
Jun	80%																		
Jul	100%																		
Aug	67%																		
Sep	100%																		
Average number of working days taken.	59	★	<table border="1"> <caption>Average number of working days taken</caption> <thead> <tr> <th>Month</th> <th>Days</th> </tr> </thead> <tbody> <tr> <td>Apr</td> <td>51</td> </tr> <tr> <td>May</td> <td>59</td> </tr> <tr> <td>Jun</td> <td>54</td> </tr> <tr> <td>Jul</td> <td>54</td> </tr> <tr> <td>Aug</td> <td>58</td> </tr> <tr> <td>Sep</td> <td>59</td> </tr> </tbody> </table>	Month	Days	Apr	51	May	59	Jun	54	Jul	54	Aug	58	Sep	59		
Month	Days																		
Apr	51																		
May	59																		
Jun	54																		
Jul	54																		
Aug	58																		
Sep	59																		
<p>Commentary: Performance dropped below the target due to two complex applications falling outside the KPI in May and June 2016. In each case this was due to the committee deferring the items in order to obtain additional legal advice on the 'significant risk' test. In August it was necessary to rearrange one of the committee dates, resulting in one item exceeding the KPI.</p>																			
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	94%	↔	<table border="1"> <caption>Annualised (rolling year) percentage of PGD applications processed within three months</caption> <thead> <tr> <th>Month</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Apr</td> <td>100%</td> </tr> <tr> <td>May</td> <td>98%</td> </tr> <tr> <td>Jun</td> <td>96%</td> </tr> <tr> <td>Jul</td> <td>96%</td> </tr> <tr> <td>Aug</td> <td>94%</td> </tr> <tr> <td>Sep</td> <td>94%</td> </tr> </tbody> </table>	Month	Percentage	Apr	100%	May	98%	Jun	96%	Jul	96%	Aug	94%	Sep	94%	Maintain 100%	KPI: As above. (Annualised score). Performance has dropped below the target due to two complex applications falling outside the KPI in May and June 2016. The annualised figure will now be impacted until 2017.
Month	Percentage																		
Apr	100%																		
May	98%																		
Jun	96%																		
Jul	96%																		
Aug	94%																		
Sep	94%																		
Average number of working days taken.	54	★	<table border="1"> <caption>Average number of working days taken</caption> <thead> <tr> <th>Month</th> <th>Days</th> </tr> </thead> <tbody> <tr> <td>Apr</td> <td>51</td> </tr> <tr> <td>May</td> <td>52</td> </tr> <tr> <td>Jun</td> <td>53</td> </tr> <tr> <td>Jul</td> <td>53</td> </tr> <tr> <td>Aug</td> <td>54</td> </tr> <tr> <td>Sep</td> <td>54</td> </tr> </tbody> </table>	Month	Days	Apr	51	May	52	Jun	53	Jul	53	Aug	54	Sep	54		
Month	Days																		
Apr	51																		
May	52																		
Jun	53																		
Jul	53																		
Aug	54																		
Sep	54																		

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
Number of requests for contributions to Parliamentary questions	Total = 0	↔		No KPI – tracked for general monitoring purposes.	Volume indicator. Last year's numbers were notably high. Many of those PQs related to the work we were then doing on mitochondria. scientific review.

Commentary: Although there have not been mitochondria related requests to report over the last few months, it is likely that interest in mitochondria will increase once more shortly, once the report of the most recent expert panel scientific review is published. The recent lull in PQs was due to the Parliamentary recess.

Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) requests and Data Protection Act (DPA) requests	4	↓		No KPI – tracked for general monitoring purposes.	Volume indicator. There does not appear to be any trend or predictability in the volume or focus of our FOI (and other) requests.
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Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes														
Staff sickness absence rate (%) per month.	2.1%	★	<table border="1"> <caption>Staff Sickness Absence Rate (%)</caption> <thead> <tr> <th>Month</th> <th>Rate (%)</th> </tr> </thead> <tbody> <tr> <td>Apr</td> <td>2.2%</td> </tr> <tr> <td>May</td> <td>1.8%</td> </tr> <tr> <td>Jun</td> <td>2.1%</td> </tr> <tr> <td>Jul</td> <td>1.9%</td> </tr> <tr> <td>Aug</td> <td>1.1%</td> </tr> <tr> <td>Sep</td> <td>0.3%</td> </tr> </tbody> </table>	Month	Rate (%)	Apr	2.2%	May	1.8%	Jun	2.1%	Jul	1.9%	Aug	1.1%	Sep	0.3%	<p>Maintain 2.5% or less</p>	<p>KPI: Absence rate of ≤ 2.5%. Public sector sickness absence rate average is eight days lost per person per year (3.0%).</p>
Month	Rate (%)																		
Apr	2.2%																		
May	1.8%																		
Jun	2.1%																		
Jul	1.9%																		
Aug	1.1%																		
Sep	0.3%																		
Cash and bank balance	£2,235k	↑	<table border="1"> <caption>Cash and Bank Balance (£k)</caption> <thead> <tr> <th>Month</th> <th>Balance (£k)</th> </tr> </thead> <tbody> <tr> <td>Apr</td> <td>£2,220</td> </tr> <tr> <td>May</td> <td>£2,108</td> </tr> <tr> <td>Jun</td> <td>£2,235</td> </tr> <tr> <td>Jul</td> <td>£1,999</td> </tr> <tr> <td>Aug</td> <td>£2,141</td> </tr> <tr> <td>Sep</td> <td>£2,363</td> </tr> </tbody> </table>	Month	Balance (£k)	Apr	£2,220	May	£2,108	Jun	£2,235	Jul	£1,999	Aug	£2,141	Sep	£2,363	<p>Reduce</p>	<p>KPI: To move closer to minimum £1,520k cash reserves (figure agreed with DH).</p>
Month	Balance (£k)																		
Apr	£2,220																		
May	£2,108																		
Jun	£2,235																		
Jul	£1,999																		
Aug	£2,141																		
Sep	£2,363																		

Commentary:

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

Management accounts:

Management accounts: September 2016:

Accounting Period Cost Centre Name Department Name	Sep-2016						
	Year to Date				Full Year		
	Actual YTD £	Budget YTD £	Variance YTD £	% Variance YTD %	Forecast £	Budget £	Variance £
Grant-in-aid	469	469	-	-	933	938	(5)
Licence Fees	2,647	2,238	410	18	5,572	4,472	1,100
Other Income	2	3	(1)	(23)	6	6	-
Total Income	3,119	2,710	409	15	6,511	5,416	1,095
Revenue Costs - Charged to Expenditure							
Salaries (excluding Authority)	1,330	1,345	15	(1)	2,653	2,679	(26)
Shared Services	42	44	2	(4)	61	81	(19)
Employer's NI Contributions	131	124	(7)	6	268	247	21
Employer's Pension Contribution	281	287	6	(2)	572	573	(1)
Authority salaries inc. NI Contributions	73	73	(0)	1	146	146	1
Temporary Staff costs	65	-	(65)		111	-	111
Other Staff Costs	119	123	8	(7)	249	265	(16)
Other Authority/Committee costs	132	151	19	(13)	293	301	(8)
Other Compliance Costs	7	15	9	(57)	20	28	(7)
Other Strategy Costs	25	45	20	(45)	133	142	(9)
Facilities Costs incl non-cash	244	266	22	(8)	483	488	(4)
IT costs Costs	57	46	(11)	23	89	93	(4)
Legal Costs	327	201	(125)	62	656	400	256
Professional Fees	35	34	(2)	5	68	67	-
Total Revenue Costs	2,867	2,754	(110)	4	5,802	5,507	294
<i>Total Surplus/(Deficit) before Capital & Project costs</i>	<i>251</i>	<i>(44)</i>	<i>519</i>	<i>1,177</i>	<i>709</i>	<i>(90)</i>	<i>801</i>
IFQ & Other Project Costs - Reserves funded	329	472	143	(30)	567	477	90
Other Capital Costs	10	25	15	(61)	100	100	-
TOTAL NET ACTIVITY	(88)	(541)	361		1,377	487	891

Indicator	Performance	RAG	Recent trend ¹	Aim ²	Notes
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Summarised management accounts – commentary September 2016

Income

At the end of Q2 (September), our treatment fee income is up on budget by 18% (£410k), a small increase from the August position. We are also forecasting a significant increase in budget. It is difficult to know how accurate our forecasting is as clinic treatment patterns may change. At present we expect income to exceed £5.5m.

Expenditure

Expenditure in Q2 is up against budget for the following reasons:

Staff costs are above budget by £15k due to contingent labour (agency staff) costs incurred to back-fill key staff working on the IfQ programme. IT costs for the year-to-date are above budget by £11k due to consumable costs which have increased as a result of both IfQ and business as usual. It is however, difficult to separate these costs.

Legal costs for the year to date are also above budget by £125k. This is because there were large bills in the month of September and accruals (for the quarter) for further work. The outcomes of cases could mean either that we receive our costs (if we win), which would positively impact on our year end position, or we may incur further costs.

IfQ and other project costs

For the year to date, IfQ is showing an underspend against budget by 30% (£142k) and is forecast to overspend by 16% (£90k) at year-end which takes into account extra budget agreed by SMT. We continue to monitor these costs in detail quarterly and liaise with the programme team to ensure all costs are accounted for.

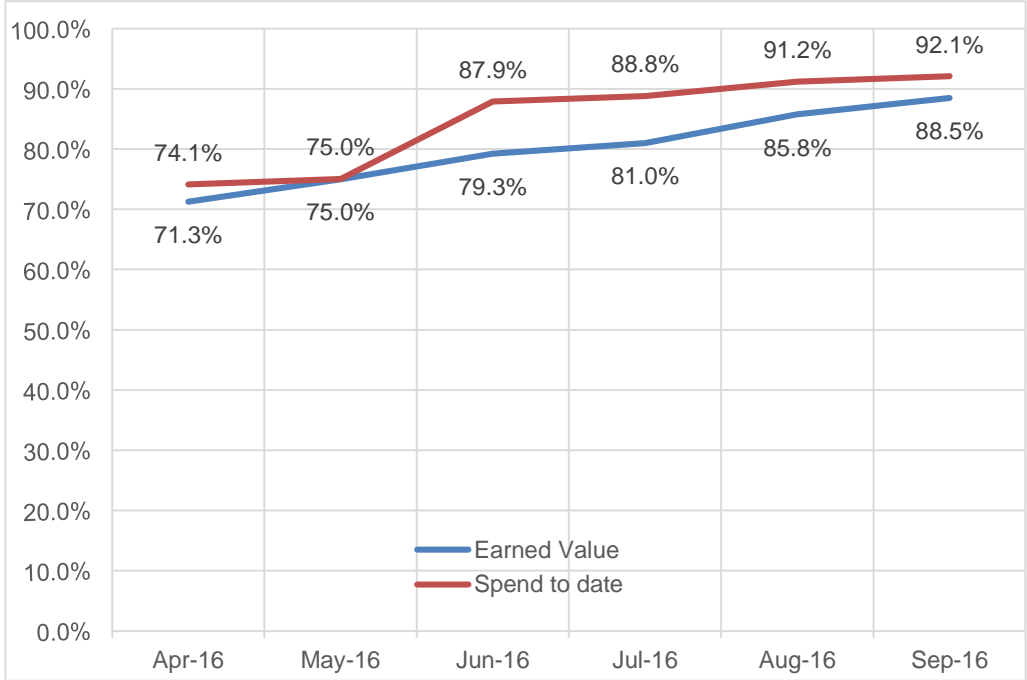
IfQ indicators: September update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
At programme set-up / major reorganisation / new tranche	MSP health check overall score achieved / maximum score as a %	Is the programme set up to deliver?	<p>July to September update:</p> <p>The MSP health check was completed with the final report circulated to the IfQ programme board. More work is to be scheduled in order to comply with the original health check assurance plan agreed by CMG, especially on the Internal Systems project side.</p>
Monthly	Timescales: we changed the burndown chart showing remaining estimate of work to a chart showing percentage of works complete.	Is there scope creep/over-run?	<p>July to September update:</p> <p>Both the website and clinic portal have entered the public beta phase. Feedback so far has been great, with bug fixing and changes being addressed and dealt with by the programme team. The work on beta remains to be finished and is delayed as explained earlier in this report.</p> <p>Significant delays have occurred across the programme affecting both the end of release one and the start of release two due to difficulties securing RR resources and resource diversions to complete planned work.</p> <p>Release two work is progressing relatively well, after an initial delay, with the first components of our API and data structure having been made available to EPRS providers on 5 October. Data migration trial load one has been completed and the external supplier to provide assurance on the Register migration has been contracted.</p> <p>The internal systems project team managed to address and overcome some serious blockages in order to progress the completion of the portal. This has also impacted on the timeline but the achieved work remains positive overall.</p> <p>The charts below provide weighted data on the work completed for both website and portal. The data includes all the features completed on each project for front end, back end design and API related work. The weighting takes into consideration the level of complexity for each feature to calculate the percentage complete. It should be noted that each is completed by the product team for that product, so there is no objective comparator between the two – for this measure.</p>

IfQ indicators: September update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:																						
			<div style="display: flex; justify-content: space-around;"> <div data-bbox="833 240 1370 730"> <p>Percent Complete - Clinic Portal R1 to Sep 2016</p> <table border="1"> <caption>Percent Complete - Clinic Portal R1 to Sep 2016</caption> <thead> <tr> <th>Total Beta Sprint</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>6</td> <td>~58%</td> </tr> <tr> <td>7</td> <td>~68%</td> </tr> <tr> <td>10</td> <td>~82%</td> </tr> <tr> <td>13</td> <td>~88%</td> </tr> <tr> <td>17</td> <td>~92%</td> </tr> </tbody> </table> </div> <div data-bbox="1384 240 1928 730"> <p>Percent Complete - Website R1 to Sep 2016</p> <table border="1"> <caption>Percent Complete - Website R1 to Sep 2016</caption> <thead> <tr> <th>Total Beta Sprint</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>10</td> <td>~62%</td> </tr> <tr> <td>13</td> <td>~70%</td> </tr> <tr> <td>17</td> <td>~75%</td> </tr> <tr> <td>19</td> <td>~82%</td> </tr> </tbody> </table> </div> </div>	Total Beta Sprint	Percent Complete	6	~58%	7	~68%	10	~82%	13	~88%	17	~92%	Total Beta Sprint	Percent Complete	10	~62%	13	~70%	17	~75%	19	~82%
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Monthly	Resource usage: The total number of days Reading Room are contracted to provide, vs the number of days consumed to date.	To monitor the rate of resource usage.	<p>July to September update:</p> <p>We have exceeded the number of days allocated for beta. Due to the nature of the capped time and resource contract with Reading Room, they are contractually required to continue building the beta product at their own cost.</p>																						

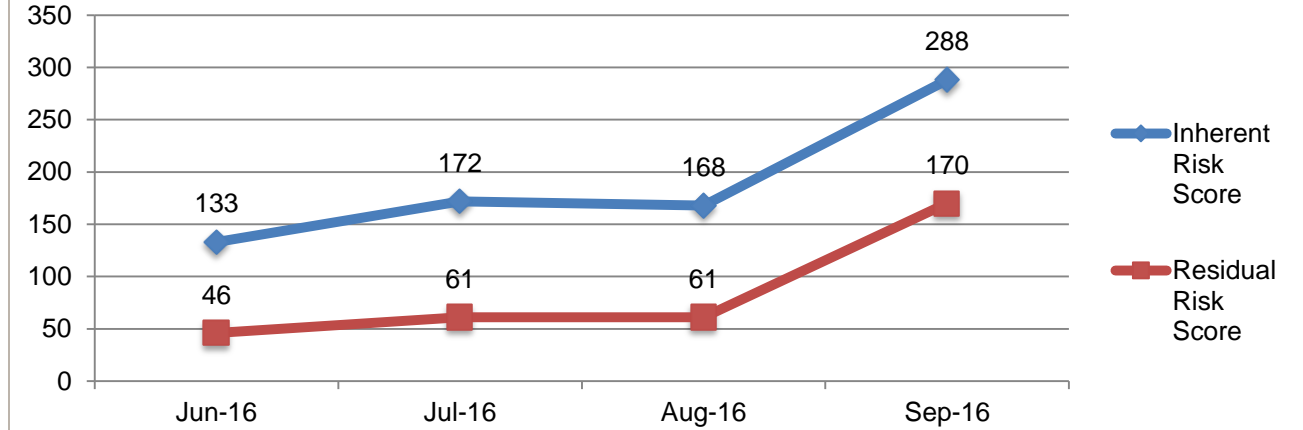
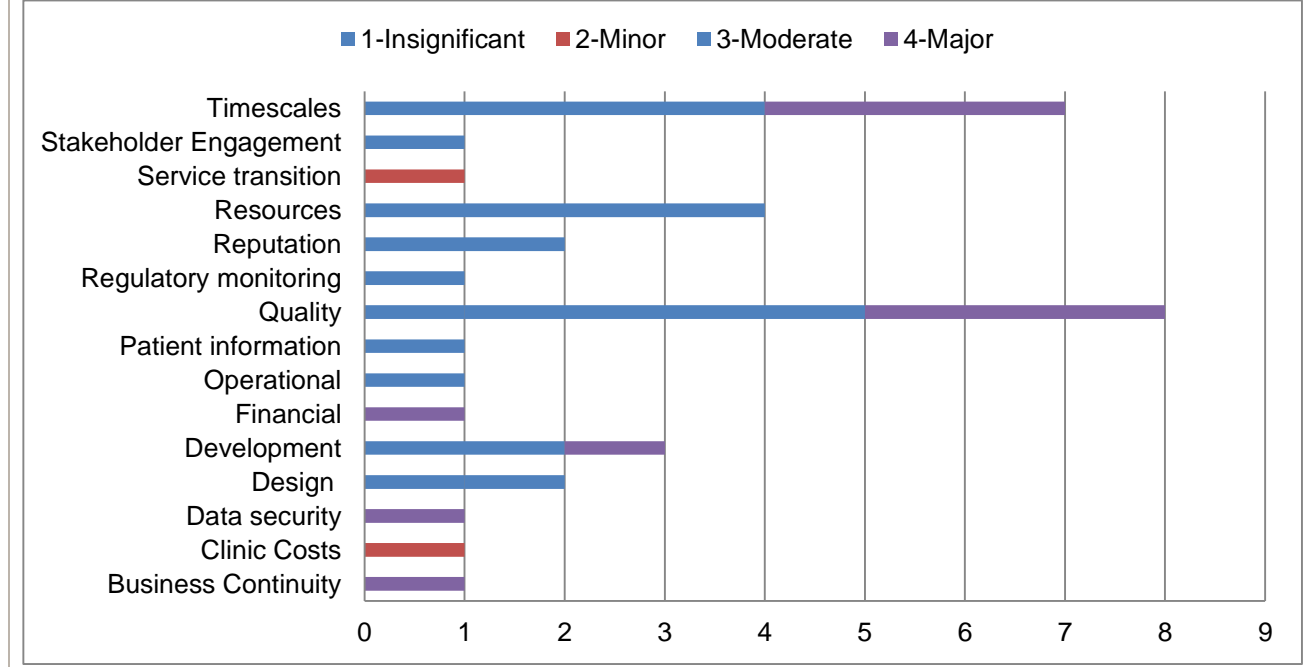
IfQ indicators: September update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:																					
Monthly	Cost: earned value (% complete * estimated spend at completion)	Is the spend in line with milestone delivery?	<p>There are four things we can attribute value to: websites and CaFC; Clinic Portal; the Register and internal systems; defined dataset, discovery, stakeholder engagement etc. 25% of the value of the 1.8M programme cost at completion has been attributed to each project.</p> <p>July to September update: The spend to date has increased slightly between August and September and is now again joining the earned value. As we reach the end of beta and complete the live phase we expect the earned value to reach its peak reflecting the work completed. Resourcing issues remain a challenge in completing all elements of beta, and this has an impact on work completion and therefore the earned value.</p>  <table border="1"> <caption>Line Chart Data: Earned Value vs Spend to date</caption> <thead> <tr> <th>Month</th> <th>Earned Value (%)</th> <th>Spend to date (%)</th> </tr> </thead> <tbody> <tr> <td>Apr-16</td> <td>71.3%</td> <td>74.1%</td> </tr> <tr> <td>May-16</td> <td>75.0%</td> <td>75.0%</td> </tr> <tr> <td>Jun-16</td> <td>79.3%</td> <td>87.9%</td> </tr> <tr> <td>Jul-16</td> <td>81.0%</td> <td>88.8%</td> </tr> <tr> <td>Aug-16</td> <td>85.8%</td> <td>91.2%</td> </tr> <tr> <td>Sep-16</td> <td>88.5%</td> <td>92.1%</td> </tr> </tbody> </table>	Month	Earned Value (%)	Spend to date (%)	Apr-16	71.3%	74.1%	May-16	75.0%	75.0%	Jun-16	79.3%	87.9%	Jul-16	81.0%	88.8%	Aug-16	85.8%	91.2%	Sep-16	88.5%	92.1%
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IfQ indicators: September update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:
Monthly	Stakeholder engagement: combined stakeholder engagement score - internal plus external stakeholder events or communications	Are we keeping stakeholders with us? Is it getting better or worse?	<p>July</p> <p>In July we launched the beta versions of the clinic portal and website to clinic staff only. This was communicated via clinic focus as we were busy preparing for the beta site to go live. Total combined score = 1</p> <p>August</p> <p>In August we launched the public beta version of the new website. We have run a social media awareness campaign alongside this to encourage people to complete the survey and provide their feedback. We contacted the members of our stakeholder groups to make them aware that the beta site was live. We didn't hold any formal stakeholder meetings but we engaged with clinic staff via clinic focus and asked them to log into the beta version of the portal. Total combined score = 3</p> <p>September</p> <p>The feedback on the beta version of the new website continued and we promoted this using our social media channels. We included articles in the September edition of clinic focus about giving feedback on the beta version of the website and what's happening with the second phase of the clinic portal. We held a workshop for clinic staff for them to give their views about how we present data on the new CaFC tool. We also sent separate communications to the EPRS providers (who supply the systems by which clinics submit data to us). Total combined score = 5</p>
Monthly	Risks: sum of risk scores (L x I)	Is overall risk getting worse or better (could identify death by a thousand cuts)?	<p>July to September update:</p> <p>The line graph below represents the overall IfQ risk score, which combines the perceived impact and likelihood of the current risks each month. The overall risk score for the IfQ programme has increased significantly following a review done by the project team. It reflects both an actual increase in risk (and issues) and the team's due diligence in updating the risk log to reflect the latest events. The increase relates primarily to the latest issues around the withholding of contractor resource, and resulting strains on internal resources, with business as usual also impacting at times on IfQ work. This is compounded by the programme timeline having to be extended, as key programme resources are leaving or about to depart the organisation.</p>

IfQ indicators: September update for beta project phase

Frequency / trigger point	Metric	Purpose	Latest status:																																																																																															
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IfQ indicators: September update for beta project phase

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

Information for Quality programme: update

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

Details:

Meeting Authority

Agenda item 7

Paper number HFEA (16/11/2016) 813

Meeting date 16 November 2016

Author Nick Jones, Director of Compliance and Information

Output:

For information or decision? For information

Recommendation The Authority is asked to note:

- Progress since the last Authority meeting, noting the launch of the HFEA website and Clinic Portal
- The delays to Release 2 – the new data submission system
- Our emerging information policy
- Programme budget.

Resource implications No additional resource implications above that already budgeted

Implementation date During 2016–17 business year

Communication(s) Regular, range of mechanisms

Organisational risk Low Medium High

Annexes: Information Policy draft: respective responsibilities

1. Background

1.1. The Information for Quality (IfQ) programme encompasses:

- The redesign of our website and Choose a Fertility Clinic (CaFC) function
- The redesign of the 'Clinic Portal' (used for interacting with clinics) and combining it with data submission functionality (Release 2) that is currently provided in our separate system (used by clinics to submit treatment data to us)
- A revised dataset and data dictionary which will be submitted for approval by the Standardisation Committee for Care Information (SCCI)
- A revised Register of treatments, which will include the migration of historical data contained within the existing Register
- The redesign of our main internal systems that comprise the Authority's Register and supporting IT processes.

1.2. Given the importance of IfQ to our strategy, we update the Authority on progress at each meeting and seek approval for direction and actions.

1.3. This paper updates Members on:

- Concluding the Programme
- Work in progress
- Release 2 – data submission development
- Our emerging information policy
- Programme budget

2. The IfQ Programme

2.1. The IfQ Programme is scheduled to conclude in March 2017. As this is the last meeting of the Authority this calendar year and given the approaching financial year-end, this paper both brings members up to date with progress and identifies the critical next steps as regards programme delivery. A fuller discussion will be presented to the next meeting of the Audit and Governance Committee in December.

2.2. As stated at previous meetings IfQ has been developed according to an 'agile' methodology required by the Government Digital Service (GDS). This methodology divides programmes into a number of stages. IfQ is currently at the 'public beta' stage, which involves going public with a beta version, receiving feedback and preparing to go live. This is followed by a final 'live' stage – a tested solution that is ready to release and then continuously improved. This latter reference, to continuous improvement, is an important feature. The IfQ Programme needs to close for funding and governance purposes, but that does not mean that there will be no further work on the various elements of the programme. On the contrary, GDS expectations assume a different way of working with a focus on meeting user needs through

‘continuous’ feedback and, where necessary, improvement. Our business planning processes – our funded programme of activity within the HFEA to meet our strategic objectives – will need to adapt accordingly.

3. Work in progress

- 3.1.** The period since the last meeting of the Authority has seen the continuation of an intense period of activity by the teams. The work has been progressed due to the substantial efforts of the many people working in the HFEA and our partners.
- 3.2. Website and choose a fertility clinic:** these two products were released to public beta in July 2016. Feedback has been positive and is discussed in detail in an accompanying paper to this meeting. However, as reported at the September meeting of the Authority we now propose that both the website and CaFC do not proceed to live until February 2017. This is in recognition of the Judicial Review, which is scheduled to take place on 19 and 20 December 2016, and the need to secure final GDS approval which is currently planned for late January 2017.
- 3.3.** For the purposes of the Programme the website and CaFC is largely concluded, and the additional design and development work that needs to take place is already included within the existing contract. Subject to assessment the product will be live in February 2017 – and the current HFEA website decommissioned.
- 3.4. Clinic Portal (Release 1):** this element of the portal will allow clinics to conduct all transactions with the HFEA (other than for treatment data submission) – applying for a new licence, PGD condition and so on; seeing their performance on a range of measures on an enhanced dashboard; being able to find regulatory requirements using an enhanced search facility; two-way communications between us and clinics, and so on. The report to the September meeting of the Authority confirmed that the portal was released in beta form on 12 July 2016, and anticipated that the GDS assessment was scheduled to take place on 28 October 2016.
- 3.5.** A consequence of the beta testing (and, to a large extent, its purpose) was the identification of issues and bugs and the resolution of these has required more time and effort than expected. As a consequence, we have decided to reschedule the GDS assessment – now 21 November 2016 – so that further and final user testing could be undertaken on 3 November 2016.
- 3.6.** For the purposes of the Programme the Clinic Portal (Release 1) is, subject to GDS assessment, largely concluded. It is expected that the Clinic Portal will be released as live in December 2016 and the current portal decommissioned.
- 3.7. Clinic Portal Release 2:** This is the component that replaces the current clinic data submission application (EDI, or, for the majority of clinics, bespoke

electronic patient record systems (EPRS)). This is a substantial undertaking requiring both extensive foundational work and a new 'front end' service that will be experienced by clinic users. Much of the foundational work is well advanced – as reported to previous meetings of the Authority. We have designed a new Register database with a new data structure, with each item defined in a data dictionary, which is in the process of being accredited by NHS Digital. We are finalising the cleansing of vital data prior to the migration of the current Register database, and that Register migration process is backed by a Register migration strategy. And we are developing a set of new expectations as regards clinics' information management arrangements once we move to the new database. More detail is provided in section 4 below.

- 3.8.** This work underpins the 'front-end' service as experienced by clinic users. At the previous meeting of the Authority it was reported that our end-October 2016 release expectations would not be met for EDI users, albeit our original expectations for clinics with EPRS of 31 March 2016 was achievable. We expect to launch EDI at the same time although there are operational benefits in not implementing the two variants at the same time. We continue to consider this.
- 3.9.** In summary, proof of concepts and business processes have been mapped – and tested with clinic users, and act as the specification to the developers who are making steady progress building the 'input questions' and screens that clinics will utilise.
- 3.10.** Challenges remain with this aspect of the Programme. While much of the foundational work has progressed well over a significant period of time it is likely that the remaining work will absorb the majority of the remaining time and resource attached to the Programme.

4. Release 2 – data submission development

As outlined in 3.7 above, there has been much progress, with more to do, on the necessary foundational work in transforming the data submission system.

Data dictionary and accreditation

- 4.1.** The data dictionary – the basis of all the information we need to collect and the definition of each field is complete, and is the basis for the components of information set out in 3.9 above.
- 4.2.** The Standardisation Committee for Care Information (part of NHS Digital) accreditation process for the 'UK ART dataset' and its implementation is on-track. It is an intensive process requiring the submission of substantial documentation considered by several committees but is a good external test of the thoroughness by which we have gone about our work.

Data 'cleansing'

- 4.3.** Over the last 12 months, the Register has been subject to a thorough overhaul, or cleansing exercise. As the data moves from the current Register structure or

database to a new more efficient database, to allow for much greater ease of interrogation and less manual intervention, it is vital that critical fields are reviewed for error, absence or duplication and resolved – as far as possible.

- 4.4.** We identified 14160 fields or records requiring intervention, and there are now fewer than 800 where additional intervention is necessary – a manageable sum.
- 4.5.** Within this sum is the work that clinics must undertake. Since April 2016 we have incrementally returned records to clinics which have problems, usually outcome forms where the treatment forms is missing. The team worked very hard to minimise the burden and sent back only 354 records to clinics. Over half of these reviews have been completed and there is steady progress on the balance.

Register data migration

- 4.6.** Due to the importance of the Register and the highly sensitive nature of the data contained within it, a well-managed and successful data migration process is central to realising many of the anticipated benefits of the IfQ Programme.
- 4.7.** Our migration strategy required a foundational ‘health check’ of the data to be conducted, which identifies data quality issues at the outset of the project. Following the health check of the data, the strategy requires five separate data migration ‘loads’ of all of the historical data in to the new Register structure.
- 4.8.** It was expected in the Summer that the migration would have been completed, in line with the timetable for introducing the new data submission system. This is predominantly a task that needs to be undertaken by skilled and experienced staff in the HFEA. The knock-on effects of delays to the website (particularly choose a fertility clinic, and the Clinic Portal) has meant the migration work has slowed.
- 4.9.** That said, trial load 1 has been successfully completed and the team is currently finalising the reconciliation and migration exceptions reports in the lead up to commencing subsequent work

Assurance of this careful progress will be provided by Programme oversight, which in turn will receive a report from an independent data management specialist, commissioned to provide reports to the Authority.

Information policy

- 4.10.** Clearly, there has been a substantial investment by the HFEA in developing a new information architecture that relies on licensed clinics to meet our information management expectations of them – such that the benefits anticipated by the investment can be realised. We have no reason to doubt that they will not. Equally we want to take the opportunity to renew our expectations of them.
- 4.11.** We will want to develop a set of principles to underpin the HFEA’s approach to information and how they support the delivery of our strategic objectives recognising the increasing role digitisation is playing in facilitating choice and

access, supporting research, improved safety and outcomes and reducing treatment delivery costs.

- 4.12.** Due to the somewhat inefficient nature of the current submission system and Register structure there has been a blurring of lines of accountability between the HFEA and clinics in relation to clinics' performance in submitting timely data, of the right quality, and dealing with errors promptly. This necessitates a careful and cautious approach by our compliance and audit teams as regards escalation of concerns. In a regulated environment this is far from ideal.
- 4.13.** The new data submission system will require less resource for both clinics and the HFEA. As such this presents a good opportunity to recalibrate and make very clear the respective responsibilities, of the HFEA and licensed clinics. A draft information policy will be presented at the January 2017 meeting of the Authority setting this out in greater depth - but our thinking on establishing clearer responsibilities is set out at annex A, for early comment.

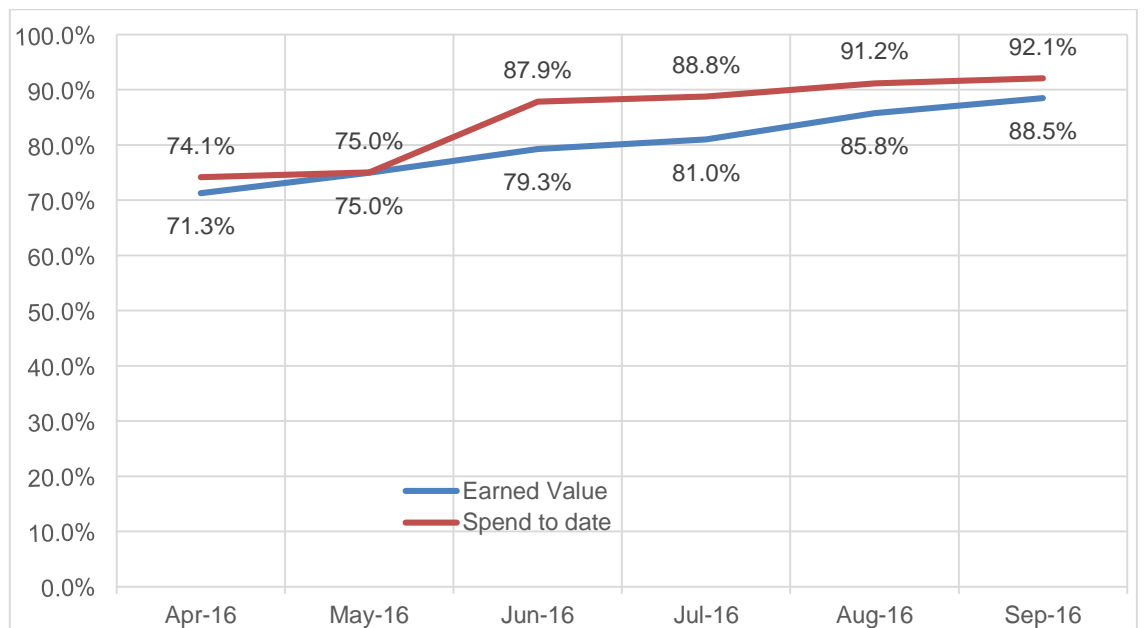
5. Programme budget

- 5.1.** As reported previously, a revised IfQ programme plan was finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by Authority. We do not expect the Programme will exceed this figure at 31 March 2017.
- 5.2.** This month variance is explained by an underspend originally forecasted for the security consultant. The underspend should balance in the upcoming months once the work is completed and invoiced.
- 5.3.** The current budget position for 2016/17 is as follows:

Total IfQ budget May 2016	Budget this FY (16/17)	Planned spend (Sep 16)	Actual to date (Sep 16)	Monthly Variance
1,227,402	£619,025	£1,111,888	£1,132,111	£20,223

- 5.4.** The spend to date has increased slightly between August and September and is now again joining the earned value. As we reach the end of beta and complete the live phase we expect the earned value to reach its peak reflecting the work completed.

Period	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16
Earned Value	70.0%	75%	79%	81%	91.2%	92.1%
Spend to date	74.1%	75%	87%	88%	85.8%	88.5%



6. Recommendation

6.1. The Authority is asked to note:

- Progress since the last Authority meeting, noting the launch of the HFEA website and Clinic Portal;
- The delays to Release 2 – the new data submission system
- Our emerging information policy
- Programme budget.

Annex A – Information Policy draft: respective responsibilities

HFEA	Licensed clinics
Register data submission	
<p>to provide clear definitions and justifications for the data to be submitted and ensure it is consistent with the Standardisation Committee for Care Information (SCCI) UK ART information standard;</p> <p>to consult sector representatives before changing data elements and carefully consider the balance of the additional benefit changes confer to users of the data collected and the impact of changes on the sector who supply it;</p> <p>subject to statutory, regulatory and provision of information requirements to consult the sector prior to setting or changing data submission timeframes;</p> <p>to minimise the administrative consequences of register data submission;</p> <p>to clearly specify the minimum technical/software requirements for register data submission;</p> <p>to respond to requests for technical and non-technical support within 48 hours where requested via official support channels;</p> <p>to promote technical interoperability and wherever appropriate adopt open standards;</p> <p>to provide suppliers of third-party data submission systems with at least 6 months' advance notice of changes they may need to make to their software to maintain compatibility with changing data submission requirements and to provide them with the information necessary to make the changes.</p>	<p>to submit register data in the form and at intervals specified by the Authority in Directions.</p>
Data quality	
<p>to promote data quality by provision of mechanisms to: reject data and require re-submission where it fails to meet the minimum quality standards; minimise input</p>	<p>to correct error identified in submissions within the period specified by the Authority in Directions.</p>

<p>error; identify error in a timely way; and ease of error correction;</p> <p>to provide transparency with respect to data held by the HFEA to the licensed centres that have submitted it along with the ability to extract and use the data submitted in a common format;</p> <p>to disclose the status/quality of the data published to licenced centres and users of register information via use of status messages; caveats; data quality metrics;</p> <p>to review and report on information performance as part of our overall inspection assessment;</p> <p>where data quality issues give rise to particular concern and/or remain unaddressed, to take corrective action in accordance with the HFEA's compliance and enforcement policy.</p>	<p>to apply the quality management requirements detailed in licence conditions to data submission processes;</p>
Data publication	
<p>The Authority publishes extracts of Register Data in the form of 'Choose a Fertility Clinic' pages on its website (http://www.hfea.gov.uk/guide/), which is updated regularly;</p> <p>to disclose to a licenced centre in advance of publication, the data to be published about it along with the basis and reasons for any processing of the date;</p> <p>to allow a reasonable time between notification of data to be published for centre review, update and feedback to the Authority to ensure the published data is accurate;</p> <p>to disclose the status/quality of the data published to users (e.g. published as clinic confirmed, unconfirmed by clinic, caveated and/or with data quality metrics).</p>	<p>to review the data to be published and to correct it/inform the HFEA of any inaccuracies within the timeframe specified in Directions;</p> <p>to confirm\verify that the data to be published is complete and accurate by the date required by the HFEA.</p>

Choose a Fertility Clinic

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

Details:

Meeting Authority

Agenda item 8

Paper number HFEA (16/11/2016) 814

Meeting date 16 November 2016

Author Juliet Tizzard, Director of Strategy and Corporate Affairs
Helen Crutcher, Policy Manager

Output:

For information or decision? For decision

Recommendation

1. That the Authority notes the feedback received during the beta period.
2. That the Authority review the options described in the paper and any recommendations and decide:

- whether to change the headline birth rate
- what headline birth rate information should be at the top of the page
- the treatment aggregation to be used for the headline birth rate
- the age aggregation for the headline rate at the top of the page
- the age aggregation to be used for statistics further down the page
- whether to change the births per egg collection time period.

Resource implications Within IfQ web development budget

Implementation date Launch of the live service, expected to be February/March 2017

Communication(s) Letter to PRs about the outcome of this meeting to be sent on 1 December

Organisational risk Low Medium High

Annexes Annex A: Beta feedback report (including annexes 1 – 5)
Annex B: User testing report (with covering addendum from the website)

development team)
Annex C: IfQ AG recommendations

1. Background

- 1.1.** A major strand of work within the Information for Quality (IfQ) programme is the redesign of the HFEA website, which incorporates the Choose a Fertility Clinic (CaFC) service. The current CaFC service is used by 15,000 patients each month to research and select a licensed clinic for their fertility treatment. Last redesigned in 2009, the current CaFC is dated, overly complex and built on old technology. The new service, currently in its 'beta' (or draft) phase, has a fresh new design with new features and a much simpler presentation of birth statistics.

Policy decisions made to date

- 1.2.** To inform the design of the new CaFC service, we ran patient focus groups and a public consultation seeking views about a range of issues relating to IfQ, including how birth statistics should be calculated and presented on a redesigned website. We presented the findings of this consultation period – alongside recommendations from the Information for Quality Advisory Group – to the Authority in January 2015. At that meeting, the Authority made the following policy decisions relating to birth statistics on CaFC:
- There should be a better balance between statistical and non-statistical information and easier comparison between clinics.
 - Non-statistical information should include patient ratings (with no free text), inspection findings and the availability of donated eggs, sperm or embryos.
 - The headline IVF birth statistic should be births per embryo transferred and should include all types of IVF treatment (IVF, ICSI, PGD, PGS, donor egg IVF, natural IVF) and both fresh and frozen transfers.
 - The second headline statistic should be the cumulative IVF birth rate (or births per egg collection), calculated as births following one egg collection and all subsequent transfers within a two-year period.

Presentational decisions made to date

- 1.3.** After the January 2015 Authority meeting, we started a period of design and development, launching an 'alpha' (or prototype) version of the new website in autumn 2015. We tested the alpha version on users, before starting development of the beta version, which we launched in August 2016.
- 1.4.** Although the IfQ Advisory Group had met for the last time in February 2015, we continued working with stakeholders during the design and development period. We formed a smaller stakeholder group which included a few members of the original advisory group, as well as members of patient and donor voluntary organisations. This group reviewed the website whilst it was being developed, giving feedback on presentational issues.
- 1.5.** The presentational decisions made during the design and development phase were:

- Birth statistics should be separated into two pages, with different levels of detail.
 - The first page (known as the clinic profile page) should present simple headline information and we know from user testing that most patients will find the level of information on this page sufficient. This page should have information at the very top, consisting of the patient rating, the inspection rating and a single IVF birth rate¹ of births per embryo transferred, showing all age groups together.
 - Further down the same clinic profile page, the IVF birth statistics should be separated into two age groups: under 38 and 38 and over. Here, the presentation should include confidence intervals (called the 'reliability range' on the beta site). These were felt to be important, given many clinics are small and the data is starting to be stratified by age at this point. Without this statistical health warning, the data for small clinics risks being misleading.
 - From this page, users should be able to click to a second page, which offers detailed statistics. Here, users should be able to search for more specific data using the following parameters: the time period (pregnancy rates for the most recent year, births rates for the year before that and three years of birth statistics); the IVF treatment type; fresh or frozen transfers and patient's own eggs or donor eggs; and the age band (separated into six). They should also be able to select either births per embryo transferred or births per cycle started as the calculation.
- 1.6.** The beta version of the new website and CaFC, launched on 12 August, incorporates all the policy and presentational decisions listed above. The aim of the beta phase has been to test the new service with users whilst it is still in draft form, so that we can make improvements before the new service goes live and the existing website is taken down.
- 1.7.** One clinic has legally challenged the new CaFC service, focussing particularly on the way that birth statistics are presented. Given that the service is in the beta phase – and therefore likely to change in response to feedback – the court hearing has been scheduled for mid-December, after feedback has been received and analysed and the Authority has made today's final decisions about how the service will look.
- 1.8.** In this paper we present the evidence gathered during the beta feedback period and make recommendations for improvements to CaFC. We will then make the improvements to the service before it goes live in early 2017.

2. The beta feedback period

- 2.1.** To gather feedback on the beta CaFC service, we ran an eight-week public consultation, with the following elements:

¹ The profile page for clinics not offering IVF shows pregnancy or birth statistics for either donor insemination or IUI.

- an online survey (see the report at annex A)
- a workshop for clinic staff (see annex 5 of the feedback report annex A)
- one-to-one user testing (report at annex B).

- 2.2.** We also sought advice from the Information for Quality Advisory Group, which we reconvened for one meeting on 26 October to make recommendations to the Authority (recommendations at annex C). The group was augmented by members of the smaller stakeholder group which gave feedback on presentational issues during the design and development stage. The meeting on 26 October was chaired by Kate Brian.
- 2.3.** In the survey, at the workshop and in user testing, we asked for views about how IVF birth statistics are presented on CaFC and whether we had made the right decisions about how the data should be aggregated or stratified. Members of the advisory group considered the feedback and made recommendations – referenced throughout this paper – about how the IVF birth statistics on CaFC could be improved.
- 2.4.** A total 1500 people visited the beta website during the feedback period, which ran from 12 August to 7 October 2016. 210 people responded to the online survey, of which roughly half were patients, donors or donor-conceived people and a quarter were professionals. 38 clinic staff attended the workshop and 12 patients took part in user testing.

3. The new beta Choose a Fertility Clinic

- 3.1.** The current CaFC service is well used by patients and other users. It attracts around 15,000 visitors per month, most of whom find it via an internet search (where it ranks first in most searches), rather than being referred by another site. Where they are referred, most come from NHS Choices.
- 3.2.** From face to face interactions with patients and from user testing, we know there is a real appetite for this service amongst patients. They value a neutral space where they can make like-for-like comparisons between services from an independent body they can trust.
- 3.3.** However, the current service is complex, multi-layered, built on old technology, and uses a headline rate that is no longer supported by the sector nor promotes best clinical practice.
- 3.4.** The new CaFC service is built on the following principles, as agreed previously by the Authority:
- That birth rates are not the only measure of quality in a clinic – patient experience and our assessment at inspection are equally important and should be seen alongside birth rates.
 - Information about each clinic should be clear and helpful – it should show any meaningful difference between clinics, but equally show where there is no meaningful difference in performance.

- CaFC should be the go-to place for birth statistics, not individual clinics' websites. Patients value enormously having a service which enables them to compare like with like, where statistics are presented clearly, transparently and in a way that they can trust.

4. The UK fertility sector

- 4.1.** Although outcome statistics are available for many other medical specialisms, there are some peculiarities in the fertility sector in the UK which provide important context when considering how IVF birth statistics should be calculated and presented.

Competition between clinics

- 4.2.** Because of the low level of IVF provision within the NHS, 60% of IVF cycles are funded by the patients themselves and nearly all clinics (including those within NHS trusts) offer services to private patients. In London, 71% of IVF cycles are self-funded. As a result, clinics compete with one another to attract customers. And given that patients rank birth rates as their most valued quality measure, how birth rates are presented matters greatly to many clinics. It affects the bottom line. That said, in Scotland, 55% of cycles are funded by the NHS, so attracting customers is not such an issue.

Clinic size variation

- 4.3.** The volume of treatments carried out varies in the 73 clinics offering IVF. Excluding one clinic which only carried out 2 cycles in 2013/4, the smallest clinic carried out 29 cycles and the largest 3800 cycles (including PGS, PGD, egg donation, fresh and frozen transfers).
- 4.4.** Whilst only around 15% of clinics are small (ie, they carry out fewer than 500 treatments each year), as soon as data is split by age and treatment, the numbers in each birth rate calculation reduce significantly even for medium-sized clinics (those carrying out 500-999 treatments). This affects the statistical reliability of the data presented and makes it necessary to add caveats and confidence intervals so that patients do not draw false conclusions from statistics based on small sample sizes. This is why we have aggregated so much of the data in the beta service.

Patient case mix variation

- 4.5.** Many factors could impact on the outcome of treatments. The data presented cannot show the success of fertility treatment broken down by patient case mix because by doing so the groupings shown would be very small. The only factor we are including is patient age at egg collection. This means the other variations between patients, such as reasons for needing treatment, previous obstetric history, previous treatment history, etc, are not included in any rates we present although the variation has the capacity to significantly affect the outcomes clinics achieve.

Geographical variation

- 4.6.** There is a large concentration of clinics, many of which are large, in London and the South East. This region contains 40% of all UK clinics treating 42% of all UK patients. The region also contains 45% of the large clinics in the UK (ie, those carrying out more than 1000 cycles per year).

Data accuracy

- 4.7.** The data in CaFC has a high level of completeness and accuracy. Clinics submit data to us very soon after the reported activity has taken place. Some validation takes place at the time of submission and some data is chased up by our staff.
- 4.8.** Clinics then have an opportunity to verify the statistics we publish on CaFC before it goes live. The statistics are refreshed every six months.

It's complicated

- 4.9.** Given this context, how birth rates are presented is a complex issue. We need to balance clarity with statistical meaningfulness. We need to help patients navigate their way through what is a largely commercial, highly competitive sector whilst remaining neutral. Given the sometimes different interests of clinics and patients, we will never please everyone and we will never get it completely right, even if we have more data at our fingertips.
- 4.10.** However, as the independent regulator of the sector across the whole of the UK, we have an important role to play, which might be summarised as follows:
- We have a legislative duty to publicise the services that we regulate and to provide advice to patients – and there is clear demand for this information.
 - We have a legislative duty to promote compliance with the legislation and our good practice guidance.
 - Through our strategy, we have committed to increase and inform choice by using our data to improve outcomes and publishing high quality meaningful information for patients.
- 4.11.** CaFC has an important role to play in achieving these aims. It can – and does – help patients make decisions about clinics and, where they have no choice of clinic, to understand more about the one they've been referred to. Besides offering information about services and clinic features, it presents accurate statistics about each clinic's pregnancy and birth rates.
- 4.12.** However, CaFC is not a predictor tool²: it cannot tell an individual patient what their chance of conception is at a particular clinic. Only a face-to-face clinical

² The Authority agreed to developing a predictor tool in future, though this has been scheduled for later development

consultation can do that. All CaFC birth statistics can do is to give a general idea of how good a clinic's IVF service is and how it compares to others.

5. Statistical reliability

- 5.1.** The most reliable statistics are calculated from national data. Each year, the UK fertility sector carries out nearly 70,000 IVF treatments. Even when stratified by treatment type and age bands, the sample sizes are large enough to be confident that any chance variation has no real impact on overall rates.
- 5.2.** Once data is presented clinic by clinic, however, statistical reliability becomes a real issue. For the larger clinics, chance variation does not have a huge effect on outcomes, but this is an issue for small clinics and even medium sized ones.
- 5.3.** The following example illustrates the point. Let's say we have two clinics with exactly the same IVF birth rate, but with very different cycle numbers:

	<i>Clinic A</i>	<i>Clinic B</i>
<i>Birth rate</i>	50%	50%
<i>Number of embryos</i>	2000	500
<i>Number of births</i>	1000	250

- 5.4.** But what happens to the birth rate when, by chance, each clinic achieves 50 fewer births?

	<i>Clinic A</i>	<i>Clinic B</i>
<i>Birth rate</i>	47.5%	40%
<i>Number of cycles</i>	2000	500
<i>Number of births</i>	950	200

- 5.5.** The birth rate for the large clinic is marginally different, whilst the birth rate for the small centre is dramatically lower. Both clinics, however, are within the national average, any difference in their performance is in fact illusory.
- 5.6.** This is why we have included confidence intervals in the CaFC data since it was first launched in 2009. Without them, the data would be misleading. In the beta CaFC, we have used the term reliability range and shown it as follows:

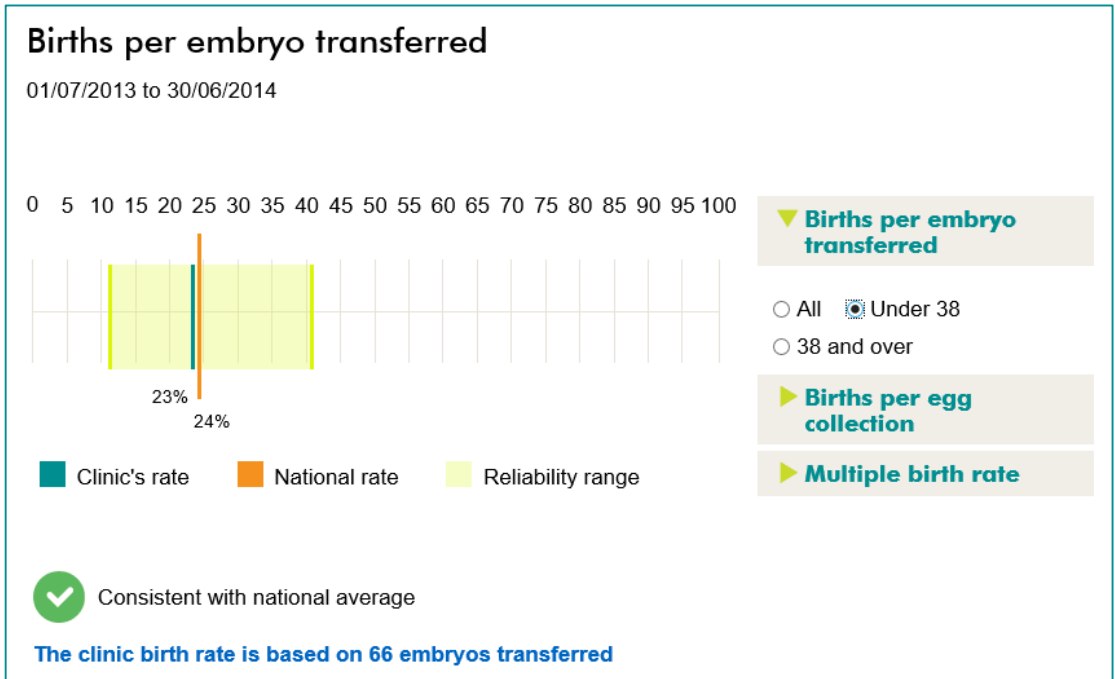


Figure 1: reliability range for a small sample

- 5.7. The clinic in figure 1 transferred only 66 embryos in this year and, although their birth rate was 23%, the reliability range is 11% to 41%.
- 5.8. For a large clinic, however, the range is much narrower. Figure 2 shows that for the large clinic, transferring 984 embryos in this year, the reliability range is only 17 and 24%. Crucially, however, the performance of both clinic is within the national average.

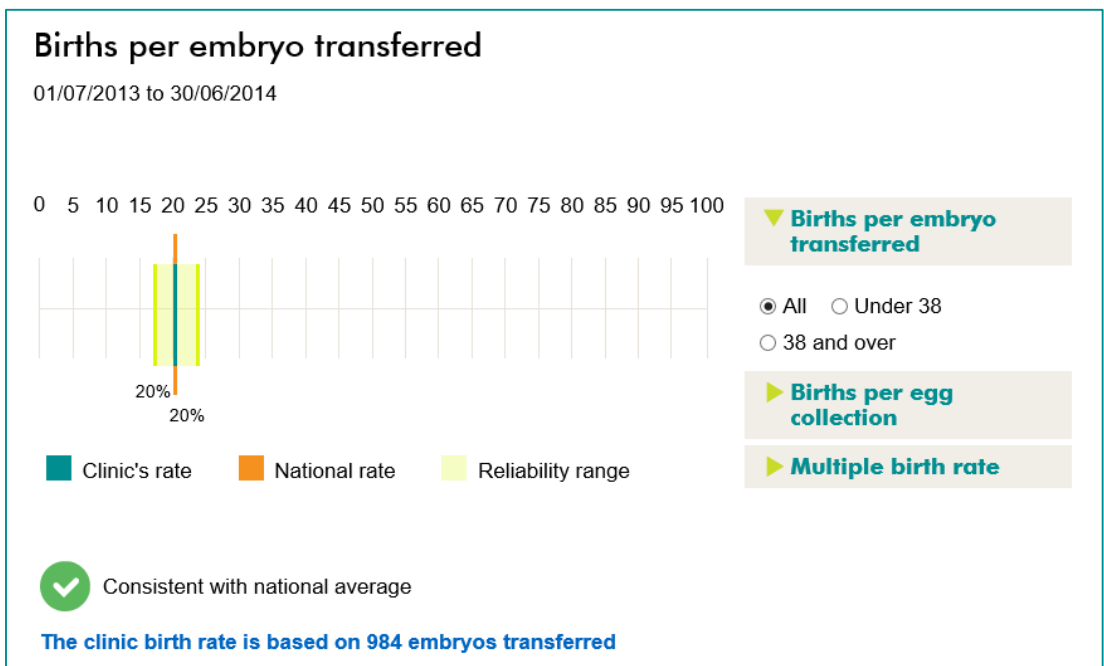


Figure 2: reliability range for a large sample

- 5.9.** Below the chart, we explain what the reliability range means:

“Reliability range

The reliability range shows how confident we are that a clinic will repeat its success rate in the future – the narrower the range, the more confident we can be. Large clinics normally have a narrower reliability range. That’s not because their data is more accurate but because their rate is less likely to be affected by small changes in the number of births in one year. Small clinics aren’t worse but their success rate is more likely to be affected by these kinds of changes.”

- 5.10.** These are difficult concepts to convey to patients. It seems counter-intuitive to be told to treat statistics with caution when they reflect events that really happened. But it can be done. In user testing, we found that patients struggled to grasp it, but most understood it when they read the explanation. The problem was that the explanation was too far away from the chart, which can be addressed in the design. We will also teach patients how to understand statistics on the CaFC landing page (<https://beta.hfea.gov.uk/choose-a-clinic/learn-about-choosing-a-clinic/>), which they have to navigate through to get to the search page. We have just commissioned a short animation for this page too, which will be ready by the time we go live.
- 5.11.** The advisory group discussed this issue and agreed that although patients find this difficult to understand, we should not abandon such an important health warning. Instead, we should seek to increase clarity and understanding through the design and wording on the page, using feedback from the user testing.

6. Births per embryo transferred

- 6.1.** In January 2015, based on advice from the Information for Quality Advisory Group, the Authority decided that the primary headline birth rate for IVF should be births per embryo transferred. Adopting this rate would mean a greater emphasis on the clinical and embryological practices of the clinic and would promote our policy on single embryo transfer as a double embryo transfer would reduce a clinic’s birth rate in this calculation. The beta CaFC service uses this birth rate measure.
- 6.2.** We did not ask in the beta feedback survey about the IVF headline measure of births per embryo transferred. However, there was an opportunity to make comments in open text on any aspect of the website and some respondents raised issues about the headline both in the responses and at the clinic workshop. A few respondents argued against births per embryo transferred (see paragraphs 3.15-3.20 in the feedback results report) claiming that it:
- acts as a disincentive to replace the number of embryos that are clinically indicated
 - is difficult for patients to understand and doesn’t give them a picture of their overall chance of success

- does not show the clinic's performance around safe ovarian stimulation practices.

6.3. In the legal challenge it has been suggested that births per embryo transferred:

- is a more complex measure than live births per cycle started and is harder for patients to understand
- relates to a smaller subset of patients who reach the embryo transfer stage
- can be confusing for patients if a multiple embryo transfer results in the birth of twins or triplets
- makes it difficult for patients to identify a successful clinic which uses double embryo transfers when clinically indicated.

6.4. However, a number of respondents took the opportunity to restate their support for births per embryo transferred as the headline IVF birth rate measure (see annexes 1 and 2 of the feedback results report). In light of comments both critical and supportive the IfQ Advisory Group was asked whether it still supported the measure.

6.5. The advisory group restated its support for the measure. At the meeting on 26 October, there was some confusion about whether the original IfQ Advisory Group recommendation to the Authority was *babies* per embryo transferred, rather than *birth events* per embryo transferred, although subsequent discussions amongst the group confirmed that the recommendation was in fact birth events per embryo transferred. This was clearly the question in the 2014 consultation and the recommendation to the Authority in January 2015.

6.6. One member of the advisory group maintains that babies per embryo transferred is the preferred measure arguing that it is a better reflection of the clinic's embryology skills. The downside of this calculation is that it does not promote single embryo transfer. They argue that this is captured by the third headline rate of proportion of multiple births. However, the advisory group as whole agrees that birth events per embryo transferred is the best measure because it reflects good embryology skills *and* promotes single embryo transfer.

6.7. Looking at the views expressed during the beta feedback period, we can see no case for changing the policy of having births (ie, birth events) per embryo transferred as the headline measure, for the following reasons:

- It promotes good clinical practice around embryo transfer, namely the transfer of one good quality embryo with the aim of producing a birth event, preferably a singleton baby.
- As such, it reinforces our policy to minimise multiple births following IVF, thereby reducing significant risks to IVF mothers and their babies.
- It is possible to explain the rate and the reasons for using it to patients, and we have useful feedback from user testing about how to do this.
- Finally, births per embryo transferred is supported by a majority of professionals in the field and by the British Fertility Society, the body representing all professions within the fertility sector.

- 6.8.** The argument that the measure makes it difficult for patients to identify a successful clinic where double embryo transfer is clinically indicated underestimates the importance of a measure which promotes single embryo transfer. Births per embryo transferred removes the disadvantage currently faced by clinics with good embryo transfer policies which are disadvantaged in the births per cycle started calculation. The move to births per embryo transferred therefore reflects a wider policy to minimise the proportion of twins following IVF and to promote the birth of a single healthy baby as the best outcome of IVF. The births per cycle started measure has not been removed from CaFC, it is still available on the detailed statistics page.

Recommendation and alternative option for the Authority: births per embryo transferred

1. Recommended option: retain births (ie, birth events) per embryo transferred as the headline IVF birth rate on CaFC.
2. Alternative option: consider using a different birth rate, such as births per cycle started or babies per embryo transferred.

7. Presenting births per embryo transferred

- 7.1.** As noted above, the beta CaFC service shows IVF birth statistics in three areas, presented differently in each one. At the highest level, in the search results (figure 3 below) and at the top of each clinic's profile page (figure 4 below), the births per embryo transferred is displayed alongside the patient and inspection ratings. The underlying calculation is all types of IVF treatment (IVF, ICSI, PGS, PGD, using the patient's own eggs and donor eggs) and patients of all ages:

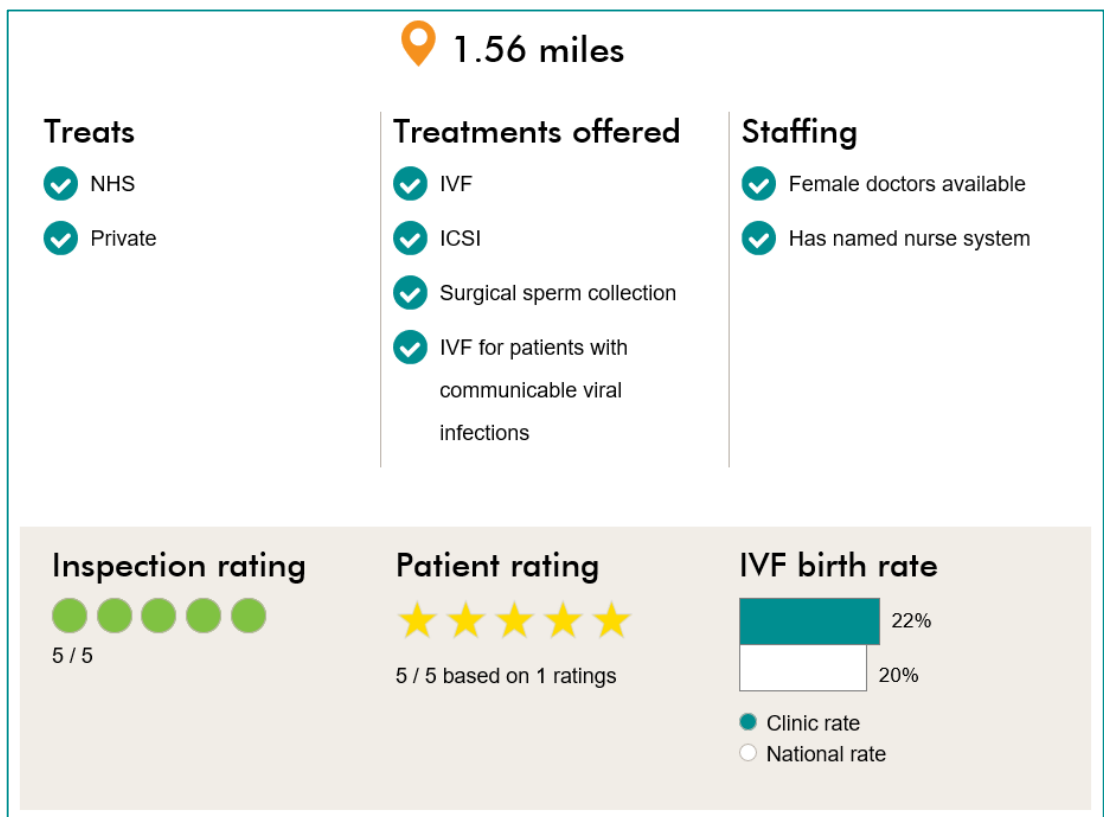


Figure 3: search results

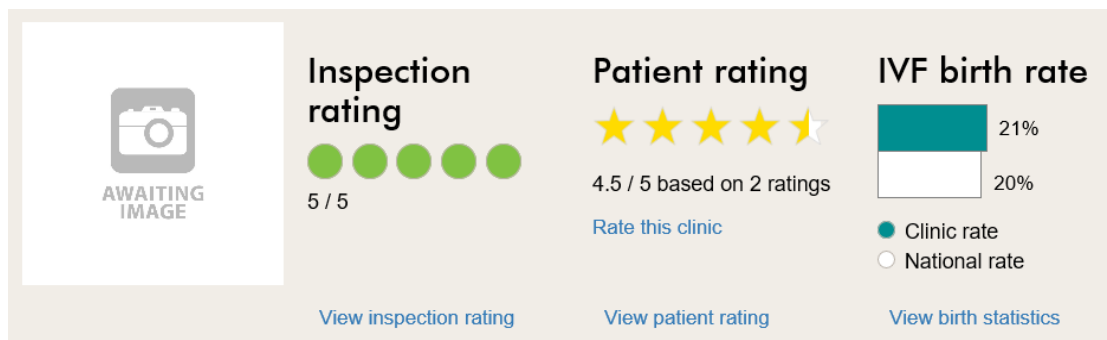


Figure 4: top of the clinic's profile page

7.2. Further down the profile page, we present births per embryo transferred alongside births per egg collection and multiple births (figure 5 below). At this point we split the statistics into two age groups: under 38 and 38 and over. We also introduce the time period covered in the calculation; the concept of a reliability range; whether or not the clinic's rate is consistent with the national average and the size of the sample (in figure 5, 984 embryos):

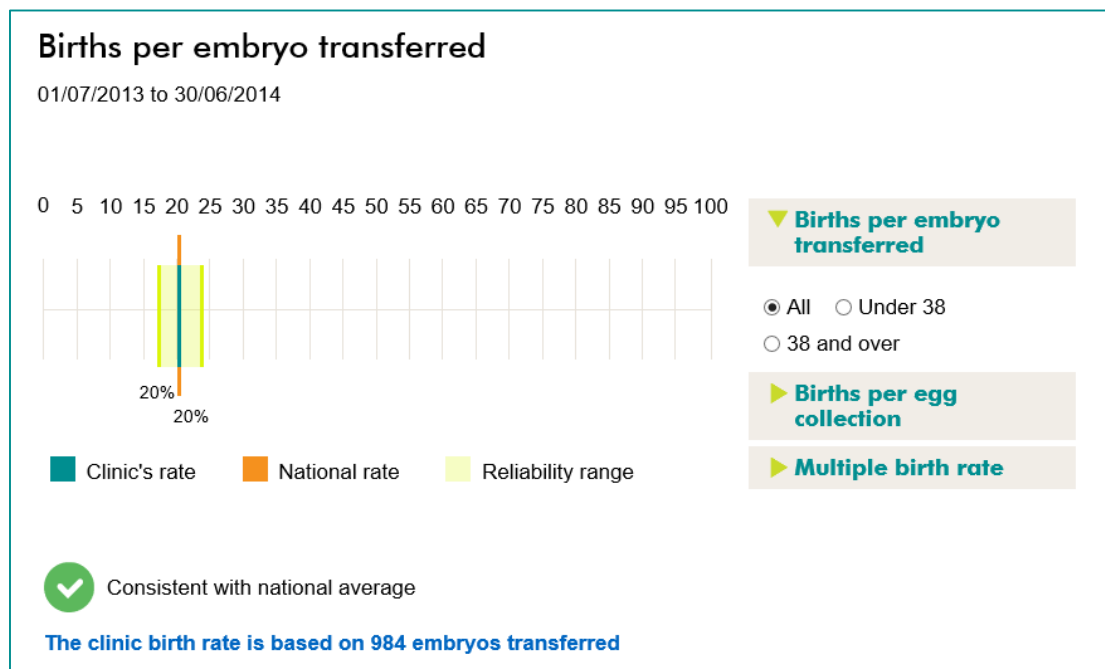


Figure 5: births per embryo transferred on the profile page

- 7.3.** From here, users can click to a separate page giving details statistics. The detailed statistics page allows users to search for statistics by treatment type, age band, embryo source and time period – and for IVF to see either births per cycle started or births per embryo transferred.

8. Headline information at the top of the page

- 8.1.** In the beta feedback period, we asked users for their views about the IVF birth statistics presented in the search results (figure 3 above) and at the top of the profile page (figure 4 above).
- 8.2.** When asked whether it was right to have a single headline measure for IVF birth rate at the top of the page, more than three quarters of respondents to the survey disagreed. Unfortunately, this question is ambiguous, since it could be interpreted as meaning one of two different things: 'is it the right *place* for the information', ie, should there be a headline statistic at the top of the page? Or 'is it the *right information* to have in that place' ie, should this or something else be at the top of the page?
- 8.3.** The comments made by survey respondents and by those attending the workshop reveal that it is most likely to have been understood to be, and answers to have been given to, the latter. Most respondents think that it is reasonable to have a single birth rate measure at the top of the page, but that this should not include patients of all ages nor all types of IVF treatment. Workshop attendees said they would be much more comfortable with a single headline measure at the top of the page *if* it were less aggregated. However, a

few respondents felt strongly that IVF outcomes are affected by too many factors for any single measure to be meaningful.

- 8.4.** The advisory group agreed that a headline measure at the top of the page is useful and allows simple comparison between clinics. However, they agreed that this should be less aggregated to make the comparison more meaningful to patients and less unfair to clinics. Whilst they agreed that the headline measure should only include women under 38 having fresh, stimulated transfers of IVF or ICSI (see below for full discussion), their recommendation was to move away from percentages in the presentation at the top of the page and to focus patients instead upon whether or not the clinic is consistent with the national average. So the top of the page might look something like this instead:

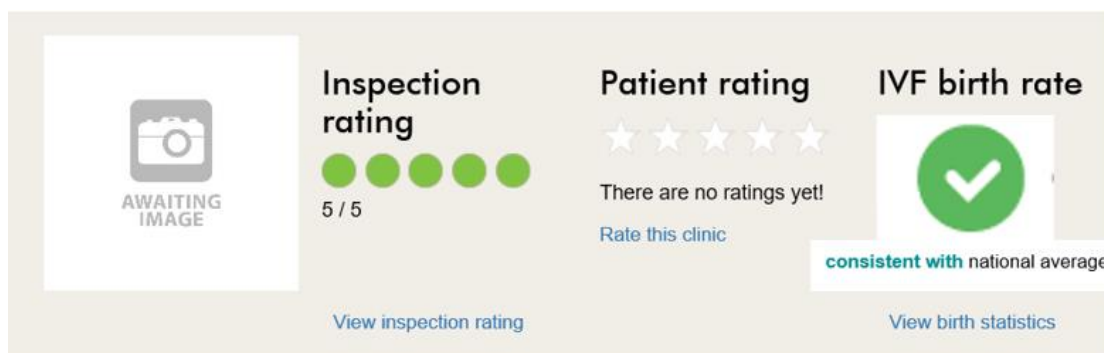


Figure 6: possible presentation of IVF birth rate

- 8.5.** The advantage of a consistency measure is that it offers a simple depiction of the birth rate, in keeping with the simplicity of the inspection rating and the patient rating alongside. For each of these quality measures, there is an opportunity to view more detail elsewhere on the page.
- 8.6.** However, the disadvantage is that it shows something which does not really differentiate between clinics, since few clinics are either above or below the national average. The ultimate question is whether it is important to differentiate between clinics at this point, or to reassure patients that the clinic is within national average, drawing their attention away from slight (and therefore illusory) differences in rates between clinics.
- 8.7.** The other option is to remove birth rate information from the top of the page altogether, relying instead on inspection and patient ratings. However, given that the non-professional respondents to the survey ranked birth rates above inspection rating and the patient rating in terms of importance to them, to remove birth rates from this section would be very unpopular with patients.

Options for the Authority: headline information at the top of the page

1. Remove birth rate information from this section altogether, or
2. present only whether or not the rate is consistent with the national average (see figure 6), or

3. present the clinic rate as a percentage, alongside the national rate (figure 4, as it is on the beta service).
-

- 8.8.** If the Authority decides on either option 2 or 3, there is a further decision about the patients and treatments which are included in this measure (see below).
-

9. What should be included in the births per embryo transferred calculation?

- 9.1.** If the Authority decides to keep the IVF birth rate in the search results and at the top of the profile page, however presented, members need to review what is included in that calculation. This decision also applies to births per embryo transferred statistics further down the profile page (figure 5 above). As mentioned above, this currently includes all types of IVF (PGS, PGD etc), patient's own and donor eggs, fresh and frozen transfers and patients of all ages.

Treatment aggregation

- 9.2.** The feedback received during the beta phase was unambiguous in its rejection of grouping all types of IVF together in the IVF birth rate calculation. The advisory group reinforced this view. There was broad agreement that the following should be included in the measure:
- IVF and ICSI
 - Cycles using the patient's own eggs
 - Fresh embryo transfers
- 9.3.** There was some debate about whether frozen embryo transfers should be included. Most felt that the outcomes of frozen embryo transfers are different enough to warrant exclusion, whilst a few felt that they were comparable enough to warrant inclusion. On balance, the advisory group recommended that frozen transfers should be excluded.
- 9.4.** There were mixed views about whether unstimulated (or 'natural') IVF should be included in the IVF birth rate calculation. One group of clinics which performs a high proportion of natural IVF cycles felt very strongly that it should be excluded on the grounds that it is effectively a different treatment offered to a different patient group (see annex 3 of the feedback report). However, there was a heated debate at the clinic workshop, where some argued for natural IVF cycles to be included on the grounds that patients should be clear that it has a much lower birth rate than that of stimulated IVF (see annex 4 of the feedback report).
- 9.5.** The advisory group had differing views about this issue, but ultimately agreed that natural IVF should not be included in the IVF birth rate. This means that for clinics offering a high proportion of natural IVF cycles, the headline rate will only represent their performance on stimulated IVF. To address this, the advisory

group recommended displaying natural IVF outcomes further down the page, rather than having to delve into the detailed statistics page.

Age aggregation

- 9.6.** The feedback received during the beta phase on age aggregation gives rise to a number of options, both for the headline rate at the top of the profile page and statistics further down the page. These are discussed in detail below but it is helpful to set out some high level considerations here:
- Patients want more specific information relating to their age group.
 - Age does affect the chance of success.
 - However, there is an open question as to whether this more tailored information should be shown by reference to the national data, rather than at clinic level. Presenting many age bands will inevitably mean small sample sizes, which in turn means the rates are relatively meaningless and reliability ranges very wide (thereby confusing patients).
- 9.7.** It was clear from the feedback that respondents to the survey and professionals attending the workshop think the headline rate at the top of the profile page should *not* represent all ages. They thought this made meaningful comparison between clinics difficult and was unfair to clinics who treat an unusually high proportion of older patients.
- 9.8.** The advisory group agreed with this feedback, though it thought that the age breakdown further down the clinic profile page – under 38 and 38 and over – was reasonable. They felt that splitting into any more age bands at this point would encourage patients to read too much into the results and would reduce the sample sizes, resulting in reduced statistical reliability.
- 9.9.** Some felt that it is important to present statistics in more age bands on the profile page, so as to present more specific information for patients and to show how much the birth rate differs according to age. At the clinic workshop, some argued that small sample sizes are only an issue for small clinics (15% of all clinics) and data presentation should not be organised around them. However, it is important to remember that we are talking about reducing the sample sizes in more than one way: removing frozen transfers (23% of transfers) and donor egg cycles from the IVF calculation and *then* stratifying by more than two age bands would significantly reduce sample sizes – and will be likely to affect medium-sized clinics too. One solution to this quandary might be to use a differential approach for large and small clinics by showing national data where the sample size in a particular category dips below a certain threshold.
- 9.10.** An alternative suggestion at the clinic workshop was to present the birth rate for the 'gold standard patient'. This might show fresh, stimulated IVF and ICSI in women under 35, using the patient's own eggs. There was a suggestion at the workshop that this should include a minimum number of eggs collected, as a proxy for ovarian reserve. One argument against using eggs collected as a proxy for ovarian reserve is that the number of eggs collected may depend on the particular stimulation patients have and how they responded to it. For

instance, the 'mild' stimulation process that some clinicians use aims to only get five eggs, so low numbers of eggs is not always correlated with what the patient could produce.

- 9.11.** There was also a suggestion that we allow users to filter information according to their own age (rather like on the detailed statistics page), though this functionality is not currently available and would have to be added later in 2017 at additional cost.
- 9.12.** After considering these options, the IfQ Advisory Group recommended using under 38 for the headline rate at the top of the profile page, since the birth rate generally declines after this age. The cohort of patients in this age group is also larger across most clinics, making comparison more meaningful. It was also felt that this would remove any unfairness that might otherwise arise for clinics treating a larger proportion of older patients as such women have on average a lower chance of success than younger age groups, regardless of where they are treated.
- 9.13.** There might be a concern that older patients, on seeing that the single headline birth is based on patients under 38, see it as an irrelevant quality measure for them. However, there is a good argument that if a clinic can successfully treat one cohort of patients (under 38) it can successfully treat other age cohorts. Therefore, a headline rate derived solely from the under 38 cohort is a good illustration of the quality of the clinic's clinical and embryological practices. It will be clear to users which age band the headline IVF rate is based upon and why we think this is a good overall measure of the clinic's performance in this area.
- 9.14.** When it came to presenting more age groups on a clinic's main page, the beta user research findings reflect the fact that patients have differing information needs – some want more information and others are happy with the higher level. This view led a minority at the clinic workshop and at the IfQ Advisory Group meeting to suggest that data could be shown divided into more age groups on the main clinic page rather than only on the detailed statistics page. The downside of this is that showing more age breakdowns may make patients feel like the data is representative of their own individual chances, which it is not. Equally, many users do not need or want this detail and so having this presented on the main clinic page may frustrate them.
- 9.15.** The IfQ Advisory Group was happy to continue to show the two age breakdown (under 38 and 38 and over) further down the clinic's main page as it is currently, alongside the data for all ages, as long as is clear that these statistics are a measure of how the clinic performs, rather than a predictor of individual patient success. The advisory group felt that more detailed age breakdown at this point of the site was inappropriate, but wanted us to continue showing this data divided into the existing six groups on the detailed statistics page.
- 9.16.** So, pulling all these considerations together, what are the options for presenting the births per embryo transferred calculation? It's clear from feedback and the recommendation of the advisory group that the calculation should not include

as many different types of treatment as it current does, though there is a more open question about unstimulated (natural) IVF.

Recommendation and options for the Authority: treatment aggregation

1. Recommendation: the IVF birth rate calculation should only include fresh, IVF and ICSI, using the patient's own eggs.
 2. Option: the IVF birth rate calculation should exclude unstimulated (natural) IVF, or
 3. Option: the IVF birth rate calculation should include unstimulated (natural) IVF.
-

- 9.17.** It is also clear that aggregating all ages is an unpopular approach. There are a number of options available for which age group to base the headline rate on instead of aggregating all ages. Equally, the statistics further down the clinic page could be presented as they are in three bands, or divided into more categories.

Recommendation and alternative options for the Authority: age aggregation for headline rate at the top of the page

1. Recommended option: present the statistics for just under 38s
 2. Alternative option 1: present the statistics for the 'gold standard' patient.
 3. Alternative option 2: present the statistics for both under 38 and 38 and over
 4. Alternative option 3: present the statistics for more age categories (some debate as to 3, 4 or 6 age bands).
-

Options for the Authority: age aggregation for statistics further down the page

1. Retain the current age banding of all ages, under 38 and 38 and over, or
 2. Present the statistics in more age categories
-

10. Births per egg collection time period

- 10.1.** A few respondents suggested that we review the time period for the births per egg collection calculation, so that we align it with the time period for births per embryo transferred.

- 10.2.** We didn't ask about this issue in beta survey, but we did discuss it briefly at the workshop. It is also mentioned in the clinician's submission at annex 1 of the beta feedback report (see page 46).
- 10.3.** The advisory group discussed the issue and recommended that we should retain the current time period of two years from the time of egg collection. They felt that their original recommendation had been made after lengthy deliberation and they could not see a compelling reason for departing from that decision.
- 10.4.** There will be advantages and disadvantages of any time period chosen. Whilst a shorter time period will make the data more recent, it will inevitably exclude some patients who may have a successful transfer after the time period has elapsed. As with all of the measures presented in CaFC, we will keep this measure under review to make sure that we strike the right balance.

Options for the Authority: births per egg collection time period

1. Recommended option: retain the two-year time period recommended by the IfQ Advisory Group.
 2. Alternative option: reduce the time period to one year to align with births per embryo transferred.
-

11. Next steps

- 11.1.** The timeline running up to the launch of the service is as follows:
- Today's decisions
 - Court hearing: mid-December (Judgment likely at some point in January 2017)
 - Verification exercise for clinics to check data: December to February 2017
 - Design improvements to CaFC: January 2017
 - Government Digital Service assessment: early February
 - Final improvements following assessment (if suggested): February
 - Launch of the live service: February/March
- 11.2.** Before the website goes live we will carry out further user testing to test any changes that are made. An in-page feedback mechanism will also be in place when the website is live so that users can tell us what they think of each page. In this way, we will continue to receive feedback throughout the life of the site and so keep everything under review.



Human
Fertilisation &
Embryology
Authority

Information for Quality
Beta website and Choose
a Fertility Clinic
Feedback findings



1. Executive Summary

1. Introduction

- 1.1.** The aim of our Information for Quality (IfQ) programme is to review the data clinics submit to us, how that data is submitted, the use to which we put that information, and how we then publish it through the website or Choose a Fertility Clinic.
- 1.2.** As part of this IfQ work, we have now developed the new version of the website up to the beta stage. This was launched for the public to view on 12 August 2016, so that they could provide us with feedback on the new design and content.

2. Background

- 2.1.** We sought feedback on the beta (draft) website and CaFC to discover how well the content was received and where it could be improved before launching the live version.
- 2.2.** The feedback consisted of three elements:
 - an online survey
 - a workshop for clinic staff
 - one on one user testing with patients and others.
- 2.3.** All respondents were self-selecting, so the responses are not representative of all stakeholder groups and interests, but they give a sense of the thoughts of a variety of individuals, clinics and some professional stakeholders. The different methods of seeking feedback were designed to accommodate different preferences.
- 2.4.** The online survey ran for eight weeks, between 12 August and 7 October 2016.
- 2.5.** The workshop with clinic staff was held on 29 September. We particularly asked for feedback on detailed questions about the presentation of clinic success data. The focal point of this session was how age and treatment types should be used as factors in presenting clinic data.
- 2.6.** The user testing was carried out by Reading Room, our design and development agency, between 10 and 14 October 2016.
- 2.7.** This report sets out the findings from each of these feedback strands and makes recommendations on possible changes we can make in response to these before the website goes live in 2017.

3. Summary of findings

3.1. Below is a summary of the questions we asked and the feedback findings.

Usability ratings

3.2. We asked how people rated different aspects of the design and content of the beta site.

- The respondents' ratings of aspects of the beta site are overwhelmingly positive but do reflect that the website is a work in progress with room for development.
- There is particular space for improvement in the range of information and how easy it is to find.

Finding information

3.3. We wanted to get a sense for how we might need to support the website if people couldn't find what they needed. This is called our 'assisted digital support'

- Individuals will take a wide range of approaches when they cannot find what they want and they need a variety of support.
- This 'assisted digital' measure will be a useful baseline for future website development.

CaFC search

3.4. We wanted to hear how easy this was to use.

- It is clear that the CaFC search is not yet easy enough to use.
- One clear reason seems to be that the search is more complicated to get to in the first place than the current website. We may want to consider how to address this.
- Patients seem to be looking for other facilities in the search tool than are currently available, such as clinic comparison by success rates.

Headline information

3.5. We present some headline summary information at the top of clinic pages and in search results. We wanted to hear what users thought of this.

- Responses suggest that many people including clinicians, agree that the concept of having headline information is helpful, particularly to compare across clinics.
- The results suggest that many people do not think the way we calculate the headline IVF birth statistic for the beta site is right as it is not meaningful with so many factors aggregated. In the clinic workshop this was the consensus.
- To make the birth rate statistic more meaningful we could consider adjusting this for other factors.
- We should continue to make the limitations of statistics and particular measures clear to users.

Importance of headline figures

3.6. We asked people to rate the three measures we have chosen as the headline figures to see which they thought was the most important.

- Most respondents believe that a birth statistic is the most important headline figure.

- Though it is clear that birth statistics information is very important, respondents agree that other figures should also be highlighted.

Age breakdowns in the headline figure

3.7. The headline figure in the beta CaFC site shows all ages grouped together. We wanted to hear whether people thought this was right.

- Most believe that all ages should not be aggregated for the headline figure.
- The clinic workshop highlighted three main alternative approaches we could consider:
 - Presenting the success rate for one, more comparable age bracket
 - Presenting the success rate for a 'gold standard' patient (eg, patients meeting the same categories for age, fertility etc. based on no. eggs collected)
 - Presenting a number of headline figures for different age brackets

Understandability of clinic birth statistics

3.8. We wanted to know if people could understand the statistics that we provide for each clinic.

- The majority of users found the birth statistics understandable, though a significant minority found understanding them hard.
- Explanations available with the statistics seem to be widely appreciated and we could consider providing more of these to improve user understanding.
- We could consider making it clearer to users exactly what the measures can indicate to them.
- Because the graphs are non-standard, we may want to consider whether users need more guidance to familiarise themselves with the new presentation.

Reliability range

3.9. We show a reliability range so that users can see how confident we are that a clinic will reproduce its past performance. We wanted to know whether people understood this.

- The current format of the reliability range is not generally understood by those it is intended to inform.
- We may need to further consider the purpose and presentation of this range.
- The meaning of the range may need to be explained more clearly.
- Going further to highlight the number of cycles that data is based on may provide a clearer indication of the reliability of the data.
- We may also wish to consider providing information on CaFC statistical methodology for a more expert audience.

Division of data at 38

3.10. We provide data split into two age categories, under 38 and 38 and above. We wanted to hear whether people agreed with dividing the data like this.

- The two age breakdown at 38 was not a popular way of presenting high level birth statistics, some felt that this could mislead patients.

- An option to consider could be providing high-level statistics covering more age categories and doing away with the two group split further down the clinic page. Another could be providing more of a breakdown at the second level where we currently show just the two ages.

Grouping treatment types in the success rate headline figure

3.11. In the beta CaFC we group all IVF treatment types in the headline figure. We wanted to hear if people thought that this was right.

- Most people disagreed with grouping all treatment types together.
- There was general agreement for grouping standard fresh IVF and ICSI and excluding other treatment types.
- However, there was more debate around how to deal with natural cycle and frozen transfers. We may want to consider these issues further.
- Different treatment types should be clearly displayed in the detailed statistics.
- We should provide national data for each treatment type as this would make it clearer to patients what the average success rate was before they get into the detail for individual clinics.

Balance of detail between main page and detailed statistics

3.12. We wanted to know if people thought the balance of detail was correct.

- The survey responses provide little clear reasoning for the respondents' dislike of the balance between the detailed statistics and the main page.
- Clinic workshop attendees felt that many users may not access the more detailed statistics page. This raises the question of how much information should be provided on the main clinic page - perhaps the main clinic page is not providing enough information for users in its current format.

Overall opinions - Likelihood to recommend

3.13. We asked people to tell us how likely it was that they would recommend the site to others and also to provide us any other comments and suggestions for the service.

- We now have a baseline figure for how likely people are to recommend the site. They are somewhat likely to recommend it. Ongoing measurement of this will be helpful for improving and developing the website once it goes live.
- Positive feedback is helpful, but the particular constructive critical comments provided can be reviewed as we consider what changes we may wish to make before the new site goes live and assist in improving the service.

2. Who responded?

1. Feedback participants

Survey respondents

1.1. During the eight weeks it was open we received 210 responses to the beta survey.

1.2. The table below breaks the survey respondents down by respondent type – not all who started the survey answered each question.

Type of respondent	Percentage	Number
currently seeking fertility treatment	11.5%	23
currently seeking treatment for reasons other than infertility (eg, to freeze eggs or sperm or have embryo testing)	7.0%	14
currently having fertility treatment	7.0%	14
previously had fertility treatment for reasons other than infertility (e.g. froze eggs or sperm)	5.5%	11
previously had successful fertility treatment	7.5%	15
previously had unsuccessful fertility treatment	9.5%	19
donor conceived person	14.5%	29
a parent of a donor conceived person	7.5%	15
has donated or plans to donate sperm, eggs or embryos	0.5%	1
a fertility doctor	6.0%	12
a fertility counsellor	2.0%	4
another member of clinic staff	15.5%	31
other	6.0%	12
Did not disclose	-	10
Total		210

1.3. Separated into three broad groups we can see that patient groups made up 48 per cent of responses, 22.5 per cent were donor groups and 23.5 per cent were clinic groups.

- 1.4.** A further 17 responses, not listed here, were responses to notify us of errors, since the survey had this dual function over the period of the detailed beta survey.
- 1.5.** Of the twelve people who described themselves as 'other', we can see that four were specific types of clinic staff or medical professional and the others were patients, donors, members of the public or other professionals related to the IVF field (ie, an academic and an ex-HFEA staff member). These included a digital lead in health and a statistician currently researching IVF outcome measures. For the purpose of analysis, these people have been considered under the 'other' group that they selected.
- 1.6.** Additionally, we had written responses on behalf of the British Fertility Association and two clinicians. These are included in the annexes to this paper.

Workshop attendees

- 1.7.** The workshop for clinic staff was held on 29 September 2016. 38 clinic staff attended the workshop. A summary of discussions and points raised has been included in this report at relevant points and the write up of the workshop is included in full at annex 5.
- 1.8.** The attendees of the workshop represented around twenty different fertility clinics and many different types of clinic staff, including persons responsible, embryologists, nurses, clinic and medical directors and admin and office managers. Because this workshop was London based, inevitably the majority of attendees were from London and often larger clinics. The majority also represented private clinics, less than twenty per cent of those attending came from NHS centres.

User testers

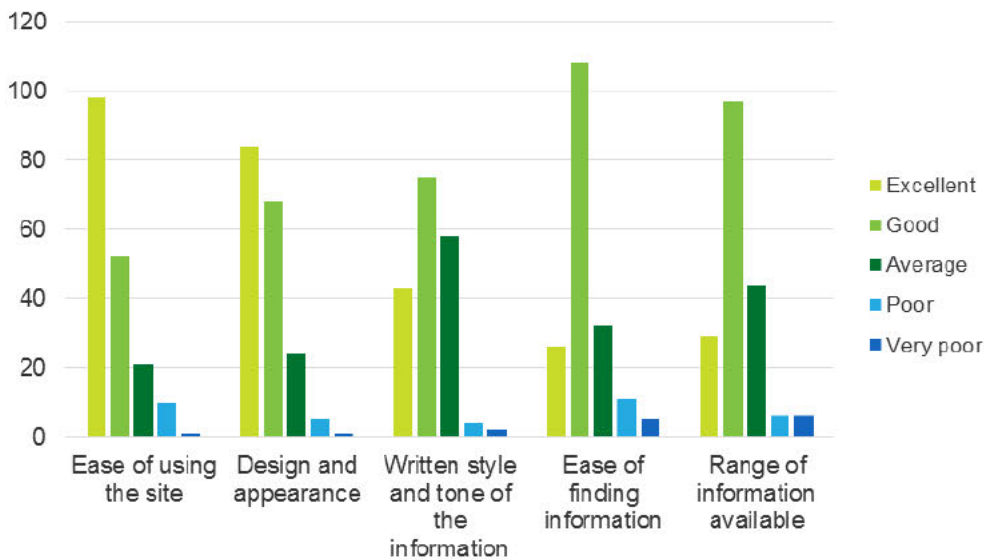
- 1.9.** The user testers came from a variety of different groups. 12 people participated and gave their feedback on the beta service. These people covered a variety of different situations including:
- women undergoing treatment
 - partner undergoing treatment
 - partner in a same sex couple
 - partner in a heterosexual couple
 - women who have donated eggs (egg sharing)
 - single women who have undergone treatment
 - a GP (being interviewed as a fertility patient rather than as a doctor)
- 1.10.** Further user testing of the beta service will be ongoing. A report on these initial findings has been completed by Reading Room, this will be provided to the Authority in full, but a sense of the feedback is noted at the relevant points of this report.

3. Using the website

1. User ratings

1.1. We asked users to rate different aspects of the beta website against a five-point range, from excellent to very poor. The graph below shows the number of people selecting each rating.

Overall, how would you rate our beta website in the following areas?

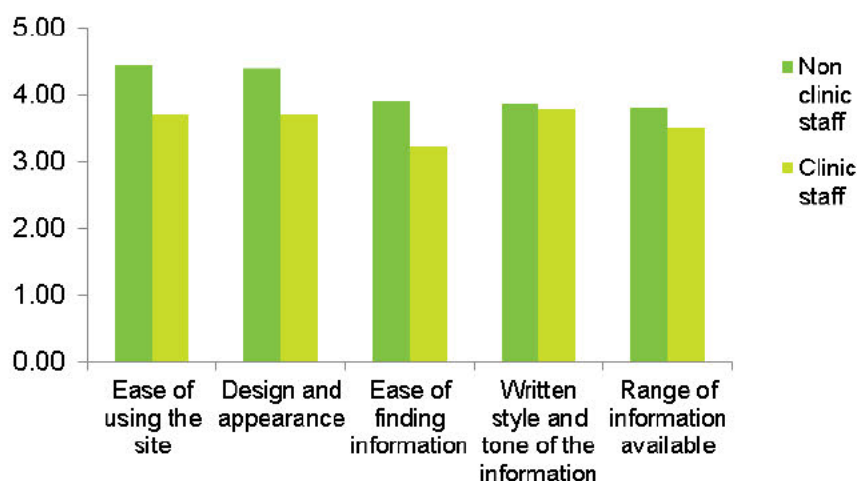


182 respondents. 28 skipped this question

1.2. We can see that a clear majority found the site excellent or good in each area.

1.3. If the answers are given a rating on a five-point scale, where excellent equals five and very poor equals one, we can compare the average rating of clinic staff responses to the average answer by non-clinic staff (excluding 'others' and 'undisclosed'), as in the graph below.

Graph plotting average clinic versus non-clinic ratings ('others' and 'undisclosed' not included)



137 non-clinic responses, 37 clinic responses. 15 skipped this question

- 1.4.** The graph suggests that clinic staff may have given slightly lower ratings on average than other groups.
- 1.5.** This finding is somewhat limited as there was a much smaller group of clinic staff, so the outliers will have had more of an impact on the average rating.

Positive responses

- 1.6.** The general positive feedback is clear when looking at the clinic and non-clinic average ratings, which ranged between 3.22 and 4.45, which represents the average to excellent range. Most respondents found the site easy to use and liked the new design and appearance.
- 1.7.** There was no option to provide comments alongside this rating question, so we have no reasons for these ratings.

Areas for improvement

- 1.8.** A significant minority of respondents felt that the written style and tone of the website was 'average' or worse. This may be due to respondents not liking the more personable tone of voice or it could be that the tone is not personable enough.
- 1.9.** In user testing we found that content was seen as welcoming and well written, with the conversational tone coming across very well with patients. It may be that 'average' ratings from the survey responses mainly reflect no strong preference either way, rather than demonstrating a pressing need to change anything about the tone and style.
- 1.10.** 'Ease of finding information' and 'the range of information available' scored the lowest. Since this was in response to the beta site and there was not yet a full range of information uploaded, this may explain why people had difficulties finding information and felt the range could have been better.

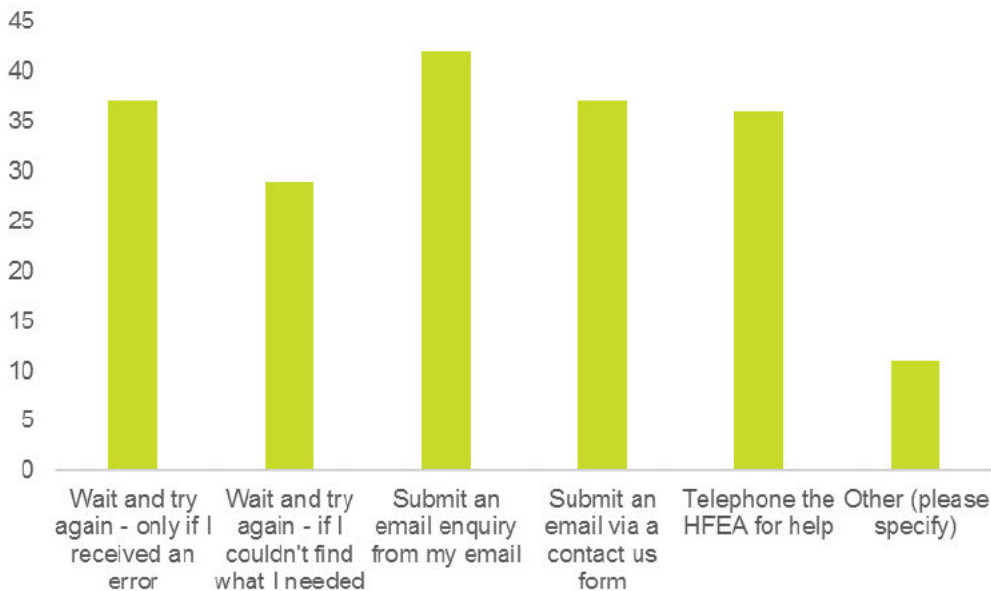
Summary

- The respondents' ratings of aspects of the beta site are overwhelmingly positive but do reflect that the website is a work in progress with room for development.
- There is particular space for improvement in the range of information and how easy it is to find.

2. Finding information

- 2.1.** We asked participants what they would do if they were unable to find the information they wanted, so that we could see what the next line of enquiry would be.
- 2.2.** When building a digital service, you must provide help for people who need to use the service but don't have the skills or access to do so on their own. This is called 'assisted digital support'. We wanted to know which methods of assisted digital support people might use, in case this meant we needed to better support particular methods (ie, provide more telephone support).
- 2.3.** We did not have a baseline measure for assisted digital before this beta feedback.

If this were the live service (not the beta one) and you were unable to find the information you needed, what might your next step be? (please select all that apply)



173 respondents. 37 skipped this question

- 2.4.** The answers to this question demonstrate that people would take a range of different actions if they were unable to find information. There is no clear preferred next step, though email contact was a common choice.
- 2.5.** The 11 people who selected 'other' mainly indicated that they would look for the information elsewhere, through a search engine or often directly with a clinic.

2.6. Although the answers demonstrate a broad range of approaches, regularly monitoring the support methods that users need and use in support of the website will be an ongoing concern for our communications team. This will enable us to make sure that the website, and the support around it, provides for the needs of all users.

Summary

- Individuals will take a wide range of approaches when they cannot find what they want and they need a variety of support.
- This 'assisted digital' measure will be a useful baseline for future website development.

4. Using Choose a Fertility Clinic and headline information

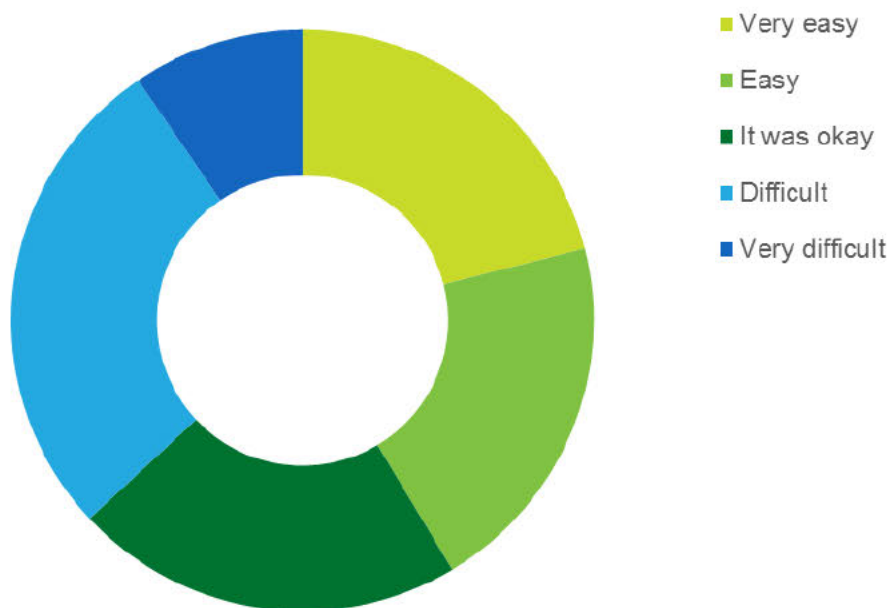
1. Introduction

- 1.1.** Of those who answered the survey, 170 people, about 80 per cent, also indicated that they had used Choose a Fertility Clinic (CaFC). We asked people a number of detailed questions about the way we had chosen to present statistics in CaFC. Between 157 and 166 people answered these detailed questions.
- 1.2.** The first section of questions was about general usability of CaFC and the high level headline information at the top of clinic pages and in search results.

2. Ease of search

- 2.1.** The search function on CaFC allows users to search by postcode or clinic name. We asked people to tell us how easy it was to use this function.

When you used the search to find a clinic, how was it to use?



157 respondents. 53 skipped this question or did not use the search

2.2. Over 60 per cent of those who had used the search found it to be okay or better. Nonetheless, this means a significant number (58 respondents) reported that they found the search difficult or very difficult to use. If the clinic groups are excluded and only donor and patient groups are measured, the result is around five percentage points lower, with over 40 per cent finding it difficult or very difficult.

2.3. Since only 18 respondents gave comments and most of these came from clinic staff, the reasons that non-clinic users found the search less user friendly are not clear from the survey.

Positive responses

2.4. Of the comments, a number stated they found the search function clear and did not have any difficulties finding clinics using the postcode search:

‘The layout is good and the tool is very simple to use. The information delivered about each clinic is clear and displayed well.’ **another member of clinic staff.**

‘gave the postcode and several options were immediately available, very clear.’ **a fertility counsellor.**

Areas for improvement

2.5. The main criticism in the comments was not about the search itself, but that it was difficult to get to the first page of the CaFC search because you must first scroll through other information and then click through to CaFC at the bottom of this information:

‘very difficult to find in the first place’ **another member of clinic staff.**

‘When you select ‘Choose a Fertility Clinic’ from the main menu you have to scroll right to the bottom of the page to find the button to start your search so its [sic] not immediately obvious; although it could just be that I am used to it being right at the top of the page on your current site though.’ **another member of clinic staff.**

‘...The user has to scroll down to the bottom of the page to click on the link, which is allows you to access the list of the clinics, which is too long to navigate’ **another member of clinic staff.**

2.6. However, others saw the benefit of the information users need to scroll through:

‘I think people tend to expect the link to be at the top of the page but the information you have to go past to get to the link is good’ **a nurse.**

2.7. It is worth noting that the design of the beta CaFC intentionally provided background information before the CaFC search page, so that those accessing the tool were properly informed before using it. There is also a link directly to the search page as a sub-menu item at the top of the page, though this may not be obvious to users, as noted by one user when asked for recommendations for improvements:

‘Navigation to "choose a Fertility Clinic" should move to the top of the page rather than the bottom’ **another member of clinic staff.**

Clinic comparisons

2.8. One potential patient wanted to be able to compare clinics and search based on factors other than proximity or name, a point which was also made at the workshop:

'Want to reorder clinics by success rates' someone currently seeking fertility treatment.

2.9. This position was supported by suggestions for improvements given by patients and others at other points in the survey:

'To have a summary comparison page, comparing all uk [sic] clinics' **someone currently having fertility treatment.**

'To look for success rates information for clinics across the uk[sic]. This information [sic] was not available as the information is only available if you search for one clinic at a time.' **someone currently having fertility treatment.**

'Should create a page where patients can store the various pregnancy rates of different centres on the same page so that they can easily compare the different centres.' **a fertility doctor.**

'It doesn't seem possible to evaluate ALL the licensed centres. ... What if a prospective [sic] patient wanted to "Choose a Fertility Clinic" from the all the licensed centres [sic], based solely on inspector and patient ratings, and results?' **another member of clinic staff.**

User testing

2.10. The user testing showed that users had a number of issues with the search function, many of which were the same as those highlighted in the survey. These included:

- Finding the CaFC search at the outset was not easy – some found the link too hard to get to
- Some users missed links to detailed pages from the search results
- The treatments list on the search listing is not exhaustive, and some users pointed out omissions
- Some users didn't understand certain parts of search pages eg, how the ratings are calculated

2.11. The user testing report shows that there are a number of improvements that can be made to CaFC search in order to make it more useable. A key consideration will be how different information is shown to patients to make them aware of what things mean and how to get to other more detailed information.

Summary

- It is clear that the CaFC search is not yet easy enough to use.
- One clear reason seems to be that the search is more complicated to get to in the first place than the current website. We may want to consider how to address this.
- Patients seem to be looking for other facilities in the search tool than are currently available, such as clinic comparison by success rates.

3. **Headline information**

3.1. Individual clinic pages show three headline figures, which we think gives an overview of the clinic's performance in different key areas. These figures are:

- IVF birth rate (per embryo transferred), including all IVF treatments (which is currently includes ICSI, IVF, PGD/PGS and egg donation treatments; for IUI only clinics we show their IUI pregnancy rate)
- inspection rating (based on length of licence)
- patient rating (based on a survey).

3.2. We asked respondents whether they agreed that this headline information should be provided at the top of the clinic page, in the most prominent position.

Do you think it's right to have this headline information at the top of the page?



163 respondents. 47 skipped this question

3.3. The majority, more than three quarters of respondents, did not agree.

3.4. In hindsight, this question is ambiguous, since it could be interpreted as meaning one of two different things. On the one hand it could be read as 'is it the right *place* for the information', ie, should it be at the top of the page? Or it could be 'is it the *right information* to have in that place' ie, should this or something else be at the top of the page? We can call the first the concept of having headline information and the second the execution of that principle.

3.5. The text responses to the question give a better indication of the issues people had with the headline information. There were a number of responses agreeing with the *concept* of having some form of headline information:

'I think all this essential information is available clearly and quickly and is easy to understand.' **a nurse with a specialist interest in fertility and maternity services and women's health.**

'Really helpful to see top information up front' **a service manager.**

'These are the things patients want to know about a fertility clinic' **another member of clinic staff.**

3.6. These responses may suggest that the principle of having headline data was not the problem for people; there appears to be agreement that these are areas that are very important for patients. But in the execution of the headlines there seems to be a problem; this could explain the largely negative response. A potential patient who agreed with the headline figures expressed the nub of the issue directly:

'Useful to compare across clinics – although is dangerous as top line statistics don't always tell the full story – e.g. age / health conditions of patients.' **someone currently seeking fertility treatment.**

3.7. A statistician expressed similar concerns:

'In terms of clarity, transparency and ease of interpretation for patients, this strikes me as a considerable step backwards compared to the existing Choose a Fertility Clinic site. [...] by obfuscating the characteristics of patients/treatments that go into this overall figure, the headline statistic actually becomes more difficult to interpret. Clearly, as this very website points out on the preceding Choose a Clinic information page, overall figures may be very misleading due to the differences in characteristics of patients treated at each centre. It therefore seems bizarre that HFEA would make a change that actually exacerbates this problem.' **a statistician currently researching IVF outcome measures.**

3.8. Some respondents proposed changes which also suggest that the problem was mainly with the way in which the success figure was calculated, rather than the principle of a headline measure:

'However, I do think that the birth or success rates need to be split in to age groups as on[sic] over all figure can give patients a false understanding on their chances.' **an admin manager of fertility clinic.**

'The birth rate is confusing. It lumps too many factors together. I appreciate simplicity is required but there is the potential for being very misleading depending upon the characteristics of each clinic. Combining data from different treatments / ages can lead to misleading data.' **a fertility doctor.**

3.9. This is also the thrust of the argument from a clinic director who wrote to us criticising the concept of a single success headline figure that was not broken into different age groups (annex 1):

'HFEA should stop publishing a single headline figure per clinic. The continued transparency of clinic data reporting is essential. Clinic outcomes are not simple and dependent on a number of clinical, demographic, funding and financial factors. The HFEA has to accept and indeed promote that data publication and success rates is a complex matter. The duty of the HFEA is to educate both patients and the wider public of this and outline why a single figure is inappropriate.' **a clinic director.**

3.10. Similarly, adding a breakdown for age to the headline and so avoiding having a single headline figure entirely was a suggestion made in a number of comments to improve this headline rate, this is discussed in more detail at section 5 of this chapter.

3.11. There were no comments explicitly disagreeing with the other two headline figures.

Workshop responses

- 3.12.** In the clinic workshop, clinic staff broadly agreed that having some form of headline figures at the top of the page was helpful and that more than anything, patients wanted high-level indicators of the quality of a clinic. Many saw the benefits of providing information other than just success rates, since that isn't the only measure of a clinic.
- 3.13.** There was a minority of attendees who felt that the concept of having any headline success rate at the top of the page was inappropriate. They suggested that stating whether a clinic was in line with the national average or not might be fairer to clinics and clearer for patients. A smaller group still said no to a single success headline.
- 3.14.** The majority view was that they would support having a single headline figure provided it enabled meaningful and fair comparison between clinics. There was clear agreement that grouping by all ages and treatment types to show a single success figure was inappropriate. These two issues are discussed directly later in this report.

Other issues with the headline birth statistic

- 3.15.** In January 2015, following earlier consultation, the Authority agreed the policy of 'births per embryo transferred' as the primary IVF birth statistic. For this reason, the question of which measure we use was not asked again as part of this survey. Nonetheless, this was an issue that some wished to give their views on. These are noted below.
- 3.16.** A very small minority in the clinic workshop disagreed with using 'live births per embryo transferred' although the majority agreed with this measure. The main concern referenced was that it acted as a disincentive to replace the number of embryos that were clinically indicated.
- 3.17.** In response to the survey, a couple of respondents stated a preference towards births per egg collection as a headline figure, rather than the second level figure, as it is on the beta site.
- 3.18.** A detailed response to the survey by a statistician also raised concerns about live births per embryo transferred as a headline measure. The preference of this respondent was to present data by cycle started:
- 'presenting results that exclude patients who did not reach the transfer stage does [not] provide any indication of the chance of success to patients considering whether or not they should start IVF treatment. Success rates reported 'per transfer', 'per egg collection' or per 'embryo transferred' are likely to be higher than rates reported 'per cycle started', which includes patients who drop out in the earlier stages of treatment [...] results must be reported 'per cycle started' so as not to hide this fact from patients' **a statistician currently researching IVF outcome measures.**
- 3.19.** 'Births per embryo transferred' supports our policy to minimise the incidence of multiple births following IVF. The British Fertility Society repeated their support for this measure in their submission to us (annex 2). A detailed discussion of the benefit of this figure is also included in the submission from a clinic director (annex 1).
- 3.20.** In 2015, the Authority also agreed to make clear to users what the information is able to tell them. This includes explaining the reasons why we present certain measures. Some explanations have been provided for the measures, but it may be worth further considering these to address the concerns raised and clearly show the limitations of each measure.

Summary

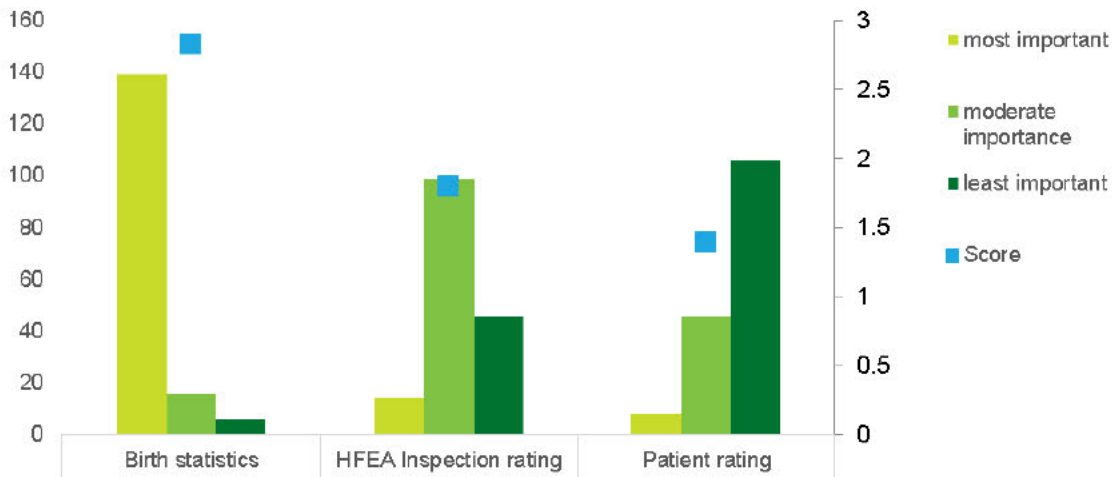
- Responses suggest that many people including clinicians, agree that the concept of having headline information is helpful, particularly to compare across clinics.
- The results suggest that many people do not think the way we calculate the headline IVF birth statistic for the beta site is right as it is not meaningful with so many factors aggregated. In the clinic workshop this was the consensus.
- To make the birth rate statistic more meaningful we could consider adjusting this for other factors.
- We should continue to make the limitations of statistics and particular measures clear to users.

4. Importance of headline measures

4.1. Although, as we have seen, respondents did not agree with the way we currently present the headline information, when asked to rank the headline figures there was broad consensus around what was more important. This can be seen in the graph below.

Please rank these headline measures in order of importance to you, with one being the most important and three being the least important.¹

Graph shows the number of people and the blue markers show the overall score of each measure



161 respondents. 49 skipped this question

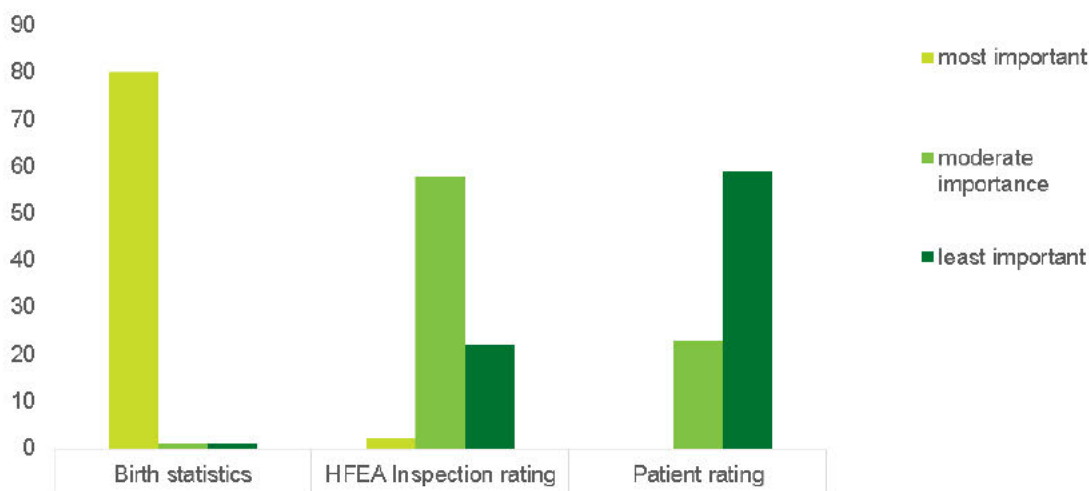
4.2. The score of each measure, calculated by weighting the ratings, shows that the most important headline was birth statistics. Over 85 per cent of those responding thought that figure was the most important of the three. Inspection rating was rated the second most important by over 60

¹ The wording of this question was clarified slightly on 25/08/16 at 13:40 pm from 'Please rank these headline measures in order of importance to you.' to 'Please rank these headline measures in order of importance to you, with one being the most important and three being the least important.' In order to provide more clarity for respondents.

per cent of responders, followed by patient rating, which about 65 per cent of people thought was the least important of the three ratings.

4.3. The responses from past, present and potential patients were more polarised than those of all responses grouped together, as can be seen in the graph below.

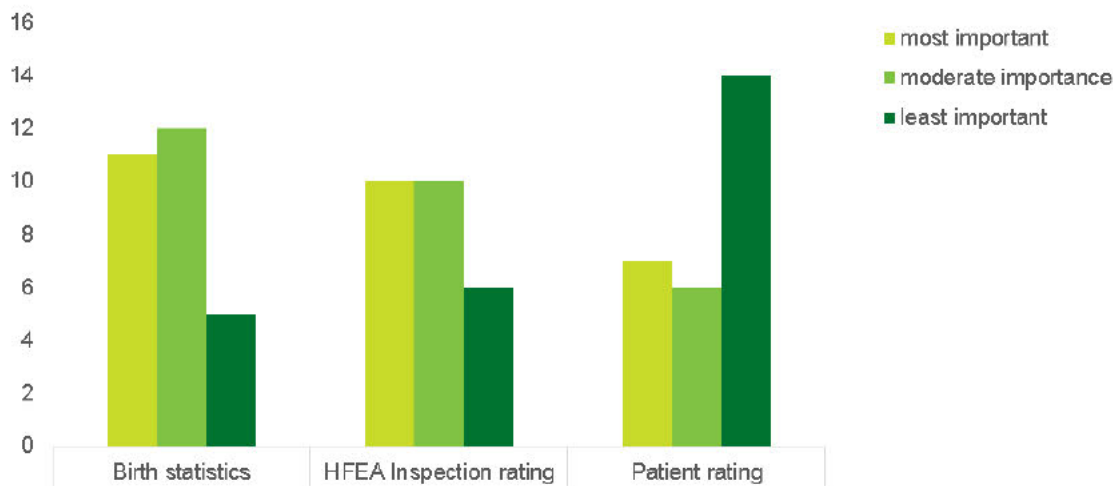
Responses for past present and potential patients (excluding all clinic professionals, donor groups, 'others' and 'undisclosed'.)



82 respondents. 14 skipped this question

4.4. Clinic staff responses were more balanced between the different measures, although the same trend emerges, as shown in the graph below.

Responses for all clinic staff groups (excluding all patients, potential patients, donors, donor families, 'undisclosed' and 'others'.)



28 respondents. 19 skipped this question

- 4.5.** This general consensus on the importance of the headline figures may support the finding that issues perceived with the birth statistic headline may have been a key motivator for those who disagreed with the headline figures.
- 4.6.** Although it is clear that for most the perceived importance of the measures was not equal, there is also evidence in other comments provided about CaFC that some strongly agree with presenting all three different headline figures, as they show distinct aspects of clinic effectiveness.

‘Excellent to see patient feedback and really liked the advice given on choosing a clinic’
another member of clinic staff.

‘I think the consistent message to take into account all aspects of the clinic services and not just the data is excellent.’ **a nurse with a specialist interest in fertility and maternity services and women’s health.**

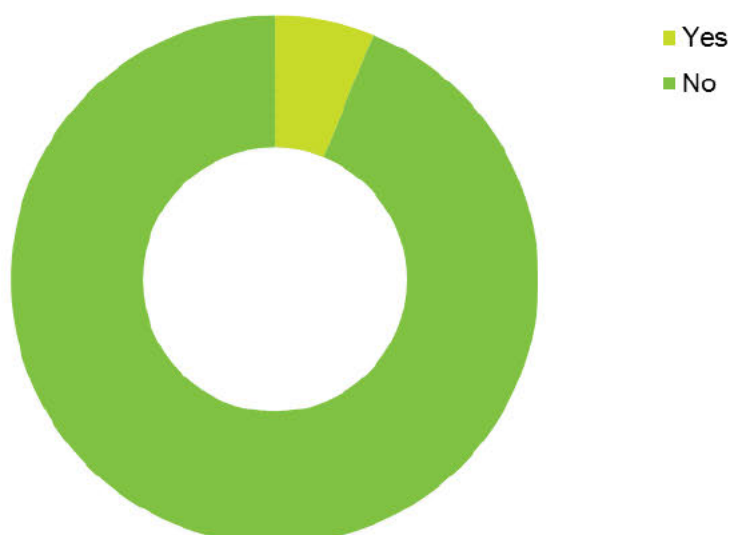
Summary

- Most respondents believe that a birth statistic is the most important headline figure.
- Though it is clear that birth statistics information is very important, respondents agree that other figures should also be highlighted.

5. Grouping all ages

- 5.1.** In the beta version of Choose a Fertility Clinic, the headline success figure currently consists of all ages grouped together. One motivation for doing this was to provide a bigger sample size which could offer more meaningful information to patients.
- 5.2.** We asked people whether they thought doing this was right and requested reasons for their responses.

Is it right to group all ages together?



164 respondents. 46 skipped this question

5.3. Responses were overwhelmingly against grouping all ages together for the headline figure.

5.4. There were 26 comments explaining reasons for different replies. These responses fell into four broad themes:

- it is OK to do this or no strong view
- age is a key success factor so should be reflected in the headline
- it wouldn't be as meaningful to patients to group all ages
- it would be unfair to clinics to group all ages.

5.5. Most of the text responses came from clinic staff with only six coming from other respondent groups. The arguments are summarised below.

Grouping all ages is OK/ no strong view

5.6. Although it is clear from the overall responses, that this was a minority view, a few people did tell us that they thought it was reasonable for the headline figure to be for all ages, though only as long as detailed figures were available elsewhere by age:

'This is good for headlines, but would also be good to be able to filter search results by "people like me" **a service manager.**

'It is fine for an overall figure, as long as there is a breakdown of ages at a different section' **another member of clinic staff.**

'this will give an idea of the overall success of the clinics. As long as these figures are easily available by ages somewhere easily accessible.' **another member of clinic staff.**

'no strong view. makes it easy to compare but need to be clear whether IVF or IUI is being looked at.' **another member of clinic staff.**

5.7. In the beta CaFC users could see that these different age options are available elsewhere where clinic statistics are presented and age is not aggregated.

Age as a key success factor

- 5.8.** Those who highlighted that age was really important and shouldn't be excluded as a factor in presenting the headline birth rate, focussed on the significant impact of age on success rates:

'Different ages have completely different statistics' **another member of clinic staff.**

'because success rates differ dramatically between different age groups eg 35 vs 39 yrs old' **another member of clinic staff.**

'Success rates depend so heavily on the patient's age that grouping them all together gives a misleading or inaccurate idea of a patient's chance of success. I think it would be more useful for patients if success rates were still broken down into age groups.' **another member of clinic staff.**

Meaningfulness to patients

- 5.9.** A related view expressed in a number of responses was that when looking for clinics, patients want to be able to see figures that might reflect their own chances. They asserted that grouping all ages would not do this and could mislead patients.

'From our experience, patients very often request age and treatment specific statistics and therefore a headline figure may be of limited use for patients. [...]' **another member of clinic staff.**

'I think this should be split up into smaller age brackets to give women a true understanding of the average chances of a live birth based on their age. I think this displays the clinics in a better light because it adds clarity and the patient may be able to better understand the figures.' **a trainee embryologist.**

'No, the headline needs to be split by age as it is more meaningful for patients who want to know results specific to their age range and once again centres treating a higher age range are not misrepresented.' **another member of clinic staff.**

Fairness to clinics

- 5.10.** The final argument of those who disagreed with grouping all ages in the headline figure was that it is unfair to clinics, as different clinics have different mixes of patients. Clinics who treat a higher proportion of patients over 38 could be disadvantaged as their success rate would naturally be lower due to their patient mix.

'Some clinics only deal with over 40's this will impact on their business' **another member of clinic staff.**

'In relative small unit with relative low number of cycles, the grouping of older patients with younger ones may distort the true success rates of the unit and its quality.' **a fertility doctor.**

- 5.11.** It is worth noting here that the issue of ages affecting clinic statistics may be more likely to affect clinics treating private patients, since within the NHS women over a certain age may not be considered for treatment.

Workshop feedback

- 5.12.** At the clinic workshop, all of the arguments above were touched on in discussion. Clinic staff agreed that the current headline figure, grouping all ages is oversimplified. They suggested a number of different options for adjusting the headline success rate for age by either:
- Presenting the success rate for one, more comparable age bracket, such as under 35 year olds
 - Presenting the success rate for a 'gold standard' patient (eg, patients meeting the same categories for age, fertility etc. based on no. eggs collected)
 - Presenting a number of headline figures for different age brackets to be more meaningful to patients - perhaps either showing all 6 age brackets or alternatively 3 categories.
- 5.13.** Attendees noted that each of these approaches will have pros and cons but they felt that they would lead to a fairer comparison which was more meaningful for patients.
- 5.14.** One additional issue discussed was the impact of using a smaller sample for the success figure and the fact that this could make rates for smaller clinics less meaningful. Some attendees noted that it would not be appropriate to let the impact on small clinics sway the whole presentation of CaFC especially because most clinics would undertake enough treatments to allow for age breakdowns. An option suggested to address this was an explanatory note to be presented for small centres with less than 50 treatments in a given age group.

Summary

- Most believe that all ages should not be aggregated for the headline figure.
- The clinic workshop highlighted three main alternative approaches we could consider:
 - Presenting the success rate for one, more comparable age bracket
 - Presenting the success rate for a 'gold standard' patient (eg, patients meeting the same categories for age, fertility etc. based on no. eggs collected)
 - Presenting a number of headline figures for different age brackets

5. Using Choose a Fertility Clinic: birth rates

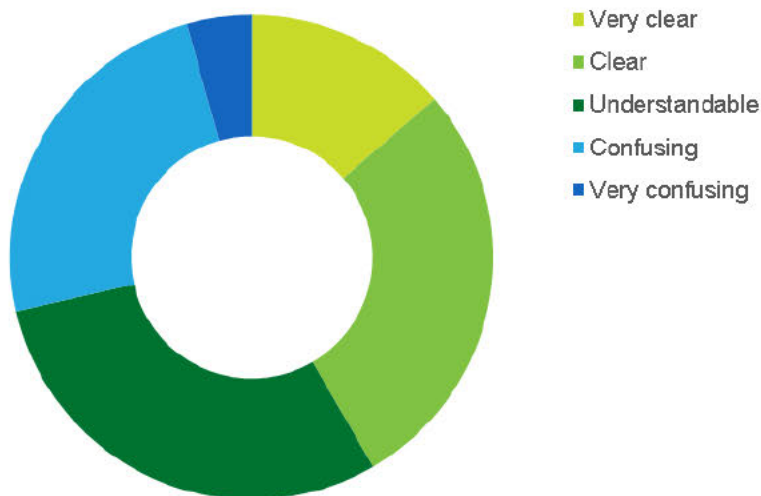
1. Introduction

- 1.1. After asking questions about the high level, headline data, we asked more detailed questions on what people thought about the clinic pages themselves and particularly about the presentation of clinic birth statistic data.
- 1.2. The data used in beta CaFC site is largely the same as the current CaFC dataset but the site presents clinic data in significantly different ways to the current site.
- 1.3. In the beta site we present the headline data, which is then supplemented further down the clinic page with data divided into two age brackets. There is then a separate detailed statistics page where the user can specify the age, treatment type, source of eggs and time period they would like to see.

2. Understandability of birth statistic presentation

- 2.1. We wanted to hear how easy users found the beta presentation of birth statistics to understand, so we asked a general question about this.

Generally speaking, how understandable was the presentation of the clinic’s birth statistics?



161 respondents. 49 skipped this question

- 2.2.** It is clear that the majority of people gave positive answers and found the statistics ‘understandable’, ‘clear’ or ‘very clear’. However, 30 per cent of respondents found the clinic birth statistics to be ‘confusing’ or ‘very confusing’.
- 2.3.** Clinic staff responses were slightly more likely to be critical than the overall responses, though a greater proportion also found the statistics very clear.
- 2.4.** For past, present and potential patients, the level of understanding was generally a little lower again, with more than 40 per cent either finding the statistics ‘confusing’ or ‘very confusing’.
- 2.5.** Although the patient group results were slightly lower, the difference between them and the overall responses or clinic ones is not significant. This may demonstrate that there is not a barrier to understanding that is particular to patients. The same barriers may affect everyone.
- 2.6.** These responses suggest that improvements are needed to these pages to make them more understandable. The text responses to this question give some indications of suggestions that might help in doing this, however, it is notable that very few past, present or potential patients, donors or donor conceived families chose to provide additional explanations for their answers.
- 2.7.** The two comments from these groups give a small indication of what might help them understand:
- ‘Explanatory text is useful’* **someone currently seeking fertility treatment.**
- ‘Reliability range?’* **someone currently having fertility treatment.**
- 2.8.** These comments suggest that being very transparent about what is being displayed and providing clear explanations may increase user understanding. The reliability range is examined in detail in the next section.
- 2.9.** When answering this question, clinic staff gave a range of comments, both positive and negative. These are summarised below.
- Positive responses**
- 2.10.** Many responses praised how clear the presentation was. People generally liked the demonstration of the national average, as well as the explanations of various components. The new graph style also received a positive mention:
- ‘I think it is extremely helpful to have the national average so clearly presented. I like the consistent reminder that small variations in the statistics are not significant.’* **a nurse with a specialist interest in fertility and maternity services and women’s health.**
- ‘Showing the clinic rates and national average as a graph is much clearer and easier to understand at a glance than all of the tables which the data is currently presented in.’* **another member of clinic staff.**
- ‘Each element is explained and defined well.’* **a trainee embryologist who is also considering oocyte freezing.**
- 2.11.** These comments suggest that putting the clinic statistics in the context of the national average and their significance has helped increase understanding.

Areas for improvement

- 2.12.** However, others did not feel the site went far enough to make the information understandable. This particularly centred around the type of graphs used which some did not think were simple enough:

'This way of presenting data is good for people who are statistics savvy, but may not be for everyone Tom, Dick & Jerry' **a fertility doctor.**

'It is not easy to understand immediately, especially for patients not used to looking at graphs etc as this is not a standard graph like a bar graph' **another member of clinic staff.**

'Didn't understand Concept of lines first time I looked at it' **another member of clinic staff.**

- 2.13.** Two other respondents, reporting concerns with CaFC under a different question noted similar thoughts about explaining terms and clarity of information, and gave some ideas for how this could be made clearer:

'The statistics pages about each clinic are great - really helpful visualisations, but there are a lot of terms in there presented without explanation or glossarisation [sic].

Would be helpful if I was trying to choose a clinic to have hyperlinks or tooltips which explain each technical term for me like ""Proportion of all embryos transfers that were blastocysts"" - no idea if this is good or bad!

*As this is for the public too, personally you might be better saying ""Treatments resulting in the birth of one baby"" or ""Treatments resulting in the birth of two or more babies (twins or triplets)"" rather than ""singleton births"" and ""multiple births"". It would make it more accessible to the general user' **a service manager.***

'Need to explain more about the meaning of each type of success rates. For instance, pregnancy rate per embryo transferred would indicate a) the quality of the laboratory service and therefore exclude units that transfer high number of embryos in order to artificially elevating their pregnancy rate, b) the adherence of the unit to eSET policy and reduction in risks of IVF.

Also need to clear to patients that the cumulative pregnancy rates per egg collection relate to treatments that were carried out 4 years ago and therefore do not reflect current success rates, but give idea of how good the unit is with respect to both fresh cycles and frozen cycles.' **a fertility doctor.**

User testing

- 2.14.** The user testing with patients showed that most users did not instantly understand the graphs used to present statistics. Most users missed the explanatory text associated with the graphs. There were also features of the graphs and statistics that some users were particularly unclear about such as the 'national rate' and 'reliability range'.
- 2.15.** It is clear that elements of the presentation need to be clearer to help users to understand features of the statistics and to make them more meaningful.

Summary

- The majority of users found the birth statistics understandable, though a significant minority found understanding them hard.
- Explanations available with the statistics seem to be widely appreciated and we could consider providing more of these to improve user understanding.
- We could consider making it clearer to users exactly what the measures can indicate to them.
- Because the graphs are non-standard, we may want to consider whether users need more guidance to familiarise themselves with the new presentation.

3. The reliability range

- 3.1.** The reliability range has been designed to show how confident we are that a clinic will repeat its success rate in the future – the narrower the range, the more confident we can be.
- 3.2.** Large clinics normally have a narrower reliability range because their rate is less likely to be affected by small changes in the number of births in one year. Small clinics aren't worse but their success rate is more likely to be affected by these kinds of changes.
- 3.3.** On the current CaFC site we describe this as the 'predicted chance'. We believe that providing this range is important, since it highlights the impact of small sample sizes, however we know from user testing the current site that patients find the concept of 'predicted chance' confusing.
- 3.4.** We asked respondents about whether the range made sense to them.

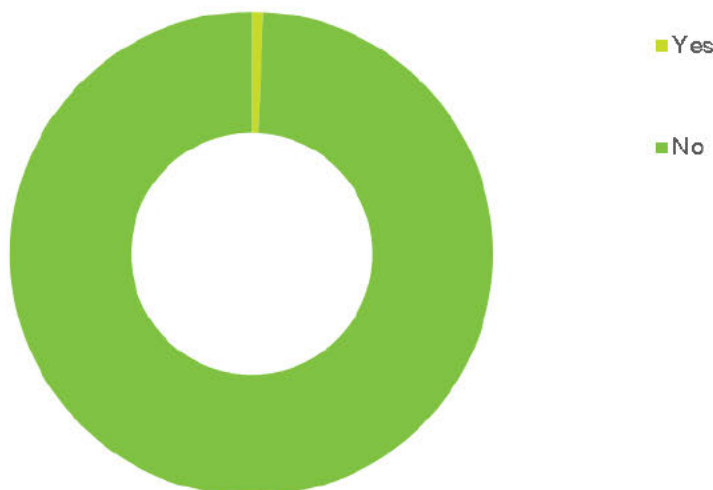
We show something called a reliability range for each rate. Did that make sense to you?



161 respondents. 49 skipped this question

- 3.5.** A significant majority, more than 85 per cent, could not understand the reliability range. More telling still is the result when the answers of clinic staff, fertility doctors, fertility counsellors and 'others' are removed, as in the graph below.

Responses of patient and donor groups (excluding fertility doctors, fertility counsellors, other clinic staff 'others' and 'undisclosed'.)



126 respondents. 15 skipped this question

- 3.6.** Only one person from any of the patient or donor groups understood the reliability range. A lack of understanding of the reliability range among patients and the public is something that the clinicians themselves predicted when they told us:

'It makes sense to us professionals but it might be a bit more difficult to understand for the public' **another member of clinic staff.**

'I do [know] what this data is but the explanation needs to [be] clearer or[sic] patients and general public' **another member of clinic staff.**

- 3.7.** Some suggestions for how to make the information clearer were provided by respondents. One suggestion was adding an indication of the number of cycles to the headline figure. This is actually available however, which suggests that it may not be prominent enough:

'...I think it may be useful to give an idea of the average number of cycles per clinic in the relevant areas so that patient's [sic] can consider the reliability range with actual figures.' **Another member of clinic staff**

'No data [on] how many cycles have been completed I [sic] total, therefore its [sic] not very clear.' **Another member of clinic staff**

- 3.8.** Of the other respondents, a statistician expressed other technical concerns. One of these was around the intention of the reliability range and how it should be presented:

'It is unclear what [the reliability range] actually is; it may be a confidence interval or a prediction interval (the text indicates that the range can be used as a guide to how the clinic will perform in the future – this is reasonable if the range is calculated as the latter but not if it is calculated as the former).' **a statistician currently researching IVF outcome measures.**

- 3.9.** It is clear that this respondent felt the intention of the range could be better explained, although the explanation is designed for a less expert audience, so may not touch on the statistical detail that this expert wanted. The same statistician was also concerned that the correct interval should be used to effectively present the HFEA confidence in the assessment of a clinic's performance.

Summary

- The current format of the reliability range is not generally understood by those it is intended to inform.
- We may need to further consider the purpose and presentation of this range.
- The meaning of the range may need to be explained more clearly.
- Going further to highlight the number of cycles that data is based on may provide a clearer indication of the reliability of the data.
- We may also wish to consider providing information on CaFC statistical methodology for a more expert audience.

4. Division of data by under 38 and 38 and above

- 4.1.** Underneath the headline success rate we split the data into two broad age categories. This was done to give patients more relevant information whilst keeping the presentation simple.
- 4.2.** We chose age 38 as the cut off because the success rate is significantly lower after this age. Data split by six age categories can be found on the detailed statistics page.

Do you think we have got the right balance of age detail between this page and the detailed statistics page?



159 respondents. 51 skipped this question

4.3. Over 85 per cent of respondents disagreed with the balance of detail between the detailed statistics page and the first level of detail where data is broken down into two age groups, with 38 as the dividing point for the two.

4.4. However, comments from the survey do not present a coherent reason for this. Some comments actually supported this age cut off and the balance between the high level and detail:

‘Yes, agreed 38 as the cut off because the rate is significantly lower after this age’ **another member of clinic staff.**

‘Yes, the main page is basic and gives a brief outline. The detailed statistics page is still clear and the layout is appropriate. A significant amount of information is listed here and I think it is user friendly.’ **another member of clinic staff.**

‘I feel there is adequate information given’ **a fertility counsellor.**

‘Probably but need to make it clearer that patients can drill down further for more detail.’ **another member of clinic staff.**

4.5. Some comments suggested various alternative ages to use as a cut off:

‘should be below 36 and above’ **another member of clinic staff.**

‘The cut off should be below 35, 35 - 39 and 40 or above.’ **a fertility doctor.**

‘may be better for patients to link with the NICE age cut off guidance so that NHS funding might make more sense’ **another member of clinic staff.**

4.6. Meanwhile, some gave other suggestions indicating that more detail was desired, although it is not clear if this was because they wanted more at an earlier stage (before the detailed statistics) instead of the two groups:

‘Good to show in detail’ another member of clinic staff.

‘Other factors such as low amh not considered which are very key to someone looking into an IVF cycle.’ **someone currently having fertility treatment.**

4.7. This final comment about AMH is not applicable to this discussion however, since we do not collect information on patient AMH levels.

4.8. The detailed response from the clinic director (annex 1) outlines stronger arguments against using this two age breakdown, stating that this could be overly reassuring for those who are at the upper limit of the lower category and could be misleadingly positive for those in the older category where individual chances of pregnancy vary greatly. In brief:

‘Published data for outcomes by the current 6-tier age bands (adopted by the HFEA for more than a decade) make it abundantly clear how outcome drastically changes from band to band even within the <38 or >38 group and as such the simplification to 2 simple bands is therefore misleading’ **a clinic director.**

Workshop feedback

4.9. The discussion on this topic at the clinic workshop was more illuminating about the reasons some didn’t like the two groups with the dividing age of 38.

- 4.10.** Though some could see why 38 was chosen as the cut off, some clinic staff felt that this was a fairly arbitrary figure and some asked whether it had been informed by user testing. Some people noted that patient prognoses could be highly variable in the above 38 category, so this grouping wouldn't be very helpful.
- 4.11.** Others raised concerns that the over 38 figure could give false reassurance to older patients who could think their chance of success was higher than it really was.
- 4.12.** There was discussion of other age division options, overall, some felt that the more detailed groupings were better and that two sub-categories should not be used at all, since they would always be too broad, especially when it came to the chances of those in the higher age category.

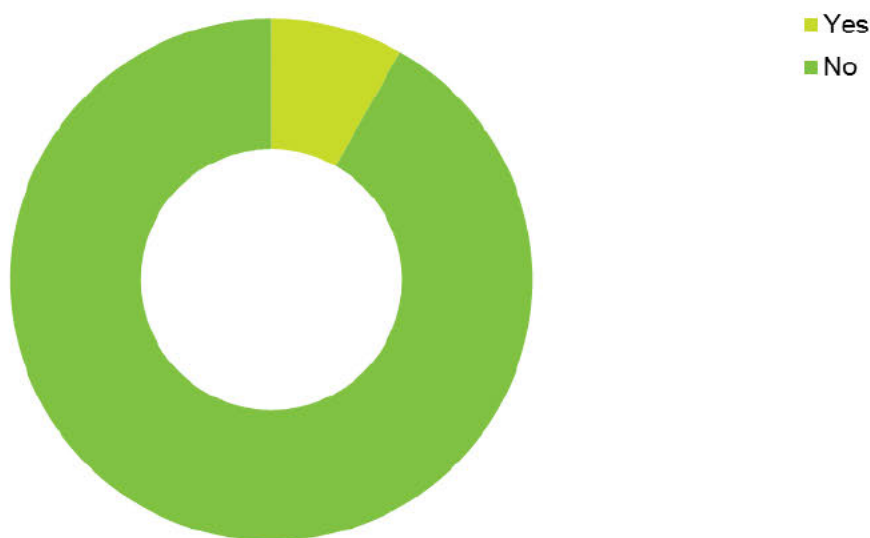
Summary

- The two age breakdown at 38 was not a popular way of presenting high level birth statistics, some felt that this could mislead patients.
- An option to consider could be providing high-level statistics covering more age categories and doing away with the two group split further down the clinic page. Another could be providing more of a breakdown at the second level where we currently show just the two ages.

5. Division of data by treatment type

- 5.1.** For the headline figure on the beta site, all IVF treatment types (IVF/ICSI/egg donation/PGS/PGD/fresh/frozen and natural cycle) have been grouped because the figure is showing the success rate once you have an embryo (births per embryo transferred).
- 5.2.** We asked people if they agreed that was right.

Because we use births per embryo transferred as one of our three headline measures, we don't think it's relevant to separate the different treatment types. That's because, once you have an embryo ready for transfer, how it was created is less important. So, we have included IVF, ICSI, PGS and PGD. Do you think it's right to group treatment types together in this way?



159

respondents. 51 skipped this question

- 5.3.** Over 90 per cent of those who responded disagreed with having a headline figure including all IVF treatment types.
- 5.4.** Some in the minority who agreed with the proposal commented and stated that they agreed that it didn't matter how the embryo was created:
- 'The chance of an embryo implanting is not hugely affected by how it was created - I think?' **a nurse.**
- 'Agree with your reasoning' another member of clinic staff.
- 'I agree that it is not relevant to separate the different treatment types' **a nurse.**
- 5.5.** Among the responses of the majority there were several particular treatment types that many people thought should not be included in the headline figure. These suggestions for exclusion were PGD, PGS, natural cycle, and egg donation.
- 'Egg Donation, Natural IVF and PGS/PGD has to be kept separate' **a clinic admin manager.**
- 'We think that the most helpful way to present the data would be as follows:
IVF/ICSI fresh and frozen transfers within a two-year period

Egg donation, PGS, PGD, surrogacy and natural cycles should be presented separately, as they may be artificially high or low which could skew the data and be misleading for patients' **another member of clinic staff**.

5.6. The possible reasons given for excluding each technique are summarised below where these were provided in responses:

PGS/PGD

5.7. Those who thought PGD and PGS should be excluded said:

- these patients usually don't have a fertility problem.
- centres performing a higher proportion of these treatments will have better statistics.
- conversely, some felt that embryos from PGS and PGD are associated with lower success rates.
- clinicians have genetic information about PGS and PGD embryos and not for IVF/ICSI embryos. It is possible that PGS/PGD embryos could be more likely to result in a live birth due to the known genetic stability.

Natural cycle IVF

5.8. The arguments for excluding natural cycle IVF were:

- The complexity of the natural cycle issue is highlighted in the submission by the BFS (annex 2) which stated it is 'a little vexed' by this issue. It highlights that the term 'natural cycle' is unclear since different amounts of medication are provided to patients. In essence it suggests that the natural group should not be included:

'Whilst it is difficult to argue against implantation rate in a defined group including the natural group [in] this may hide a multitude of sins.'
- one person felt that centres performing a higher number of these cycles will be negatively represented.
- A detailed response was provided by a clinic addressing the issue of natural cycle IVF in detail, (annex 3). This submission argues that natural IVF and conventional IVF are:

'two fundamentally different treatment methods and are offered to different patient populations.'
- Consequently, the authors believe natural cycles should not be included with standard IVF in the same headline statistic but should be shown separately.

5.9. The arguments against excluding natural cycle IVF were:

- Conversely, the clinic director's response (annex 1) expresses a view that both natural and standard IVF should be grouped together in the headline success rate:

'every egg collection performed should be included in the denominator when results are expressed as LB_EC. This is true whether the cycle was unstimulated or stimulated or with batching embryos.'
- The respondent agrees with the view that the HFEA should highlight the different success rates for natural and stimulated cycles in the detailed statistics.

Other factors raised

- 5.10.** Freeze-all cycles were seen by one commentator as not being properly presented to patients with this headline metric:

‘What about freeze all embryo cycles done to achieve 1 pregnancy. Patients should be able to evaluate the data based on how much money they will need spend to achieve the pregnancy, therefore this data doesn't help with the money side.’ **another member of clinic staff.**

- 5.11.** Some other commenters were not keen to amalgamate IVF and ICSI success rates:

‘It is still useful to present figures on percentage [sic] of ICSI as some units do unnecessary ICSI’ **a fertility doctor.**

‘People want to know what is the difference in success rates between IVF/ICSI or if they are having a specific treatment they want to know what are their chances using that intervention’ **another member of clinic staff.**

- 5.12.** We should note that the data for IVF and ICSI success figures are available separately on the detailed statistics page so that they could be compared at that point.

Workshop feedback

- 5.13.** The clinic workshop discussed a number of issues with grouping all treatment types and as noted earlier, clinic staff universally disagreed with combining different treatments in the headline figure. The attendees reached the following conclusions:
- 5.14.** The headline figure would be more meaningful if it included only fresh stimulated IVF/ICSI cycles with the patient's own eggs.
- 5.15.** Because these treatments are fundamentally different, it should exclude:
- Egg recipients
 - Frozen (though there was debate around this issue and some felt the first frozen transfer should be included for freeze-all cycles and some were more relaxed on this)
 - Surrogacy
 - PGD/PGS
- 5.16.** They also discussed natural cycle IVF and strong and differing views were expressed about how this information should be presented. The overall feeling was that we should consider excluding natural cycle IVF from the headline figure since this is a different treatment type. Some suggested that to include it would mean not comparing like with like. Although a minority of clinicians disagreed with this and thought it should continue to be included in the headline.
- 5.17.** The majority in the workshop felt natural cycle results should be presented separately and clearly in the detailed statistics to facilitate informed patient choice.
- 5.18.** They also recommended that we should make national success data available for different treatment types before patients see the clinic statistics.
- 5.19.** This last point was also previously recommended by the Authority in January 2015.

Summary

- Most people disagreed with grouping all treatment types together.
- There was general agreement for grouping standard fresh IVF and ICSI and excluding other treatment types.
- However, there was more debate around how to deal with natural cycle and frozen transfers. We may want to consider these issues further.
- Different treatment types should be clearly displayed in the detailed statistics.
- We should provide national data for each treatment type as this would make it clearer to patients what the average success rate was before they get into the detail for individual clinics.

6. Detailed statistics – is the balance right?

- 6.1. The first clinic page includes high-level statistics, but the majority of the available statistics are included on the detailed statistics page for each clinic.
- 6.2. We asked whether the first and detailed clinic statistic pages had the correct balance of information.

If you had a look at the detailed statistics page, do you think overall we’ve got the right balance of information about statistics between the first clinic page and the detailed statistics page?



157 respondents. 53 skipped this question

- 6.3. Of those who responded, over 85 per cent disagreed with the balance between the statistics available on the first clinic page and the detailed statistics page.

- 6.4.** Unfortunately, the comments do not give a coherent overview of why people did not think the balance was right, since we only received nine. Many of these comments were actually positive, noting the information was clear and helpful to patients and that it went into sufficient detail. Some also just noted the person had no additional comment.
- 6.5.** One person gave a particular pointer that they wanted live birth per embryo transferred on the first page, although had not realised that this is actually already there. This suggests some users may not be able to find information in the beta presentation.
- 6.6.** Other comments on the detailed statistics pages and on CaFC as a whole reiterated that some people were most concerned that different treatment types should be separately presented, perhaps on the main clinic page rather than just on the detailed page:

‘Different treatments should be separated’ **another member of clinic staff.**

‘[patients should be able to see data] for cycles where no ET have been performed’
another member of clinic staff.

Workshop responses

- 6.7.** The workshop attendees thought that the detail available was valuable, particularly for displaying the success rates for different treatments, but some people felt that many users of CaFC may never access this detailed level of information.
- 6.8.** In such cases the headline and first page information is particularly important. They therefore recommended that the detail should be as accessible as possible to encourage its use and the higher level data to be as meaningful as possible for users.

User testing

- 6.9.** The user testing showed that some users were happy with the level of detail provided and others felt that they didn’t need it.
- 6.10.** Although the detailed statistics were too much for some people, others thought it was very good, with one even commenting that this was the only data that really mattered as it meant she could access data for people in a much more similar situation to her own.

Summary

- The survey responses provide little clear reasoning for the respondents’ dislike of the balance between the detailed statistics and the main page.
- Clinic workshop attendees felt that many users may not access the more detailed statistics page. This raises the question of how much information should be provided on the main clinic page - perhaps the main clinic page is not providing enough information for users in its current format.

7. Overall opinions - Likelihood to recommend

7.1. We asked those responding to the survey to give us an idea of their overall opinion of the site by providing a score for how likely it was for them to recommend it to others. The results are displayed in the table below:

Would you recommend this site to a friend, relative or colleague requiring similar information?

Not at all likely	1	2	3	4	Neither 5	6	7	8	9	Extremely likely 10
4	2	6	3	15	26	42	32	26	8	10

174 responded, 36 skipped this question

7.2. On the 11-point scale (including 'not at all likely') the weighted average rating was 6.14.

7.3. The likelihood of recommending did vary very slightly for different groups and average ratings of different groups is summarised in the table below:

Average recommendation ratings for different groups

Group:	All patient groups	All responses	All clinic groups	Donor groups
Average rating	5.97	6.14	6.16	6.18
Number of responses this is based upon	88	174	32	45

7.4. It is clear that opinions on the website are broadly similar for all users and the average rating has limited significance since it is based on only a few responses in each category.

7.5. These figures are not especially valuable for analysis in isolation, but they will form a baseline against which the website could be measured in the future.

7.6. Other general feedback comments are summarised below.

Patient views

7.7. As one clinic staff member added, the patient view of improvements to the service are very important:

'It is really for the patient and their understanding and information need, therefore the most important feedback would be from the patients themselves.' **admin manger of fertility clinic.**

7.8. Unfortunately, again, there were not many patient comments regarding recommendations on the site. Those that there were did not necessarily give feedback on what could be done better, as in:

'I found this site hard to understand' someone who previously had successful fertility treatment.

7.9. Meanwhile, some gave very particular comments which we can consider about the content and presentation of the site:

'I note you have no advice for single men. While this may be a small demographic, this seems an obvious oversight.' **someone who previously had successful fertility treatment.**

'the original site has links to enable downloading the forms to sign, and this was the greatest help to us from the whole site.' **someone currently having fertility treatment.**

'The colours you combine and use when text is written inside box (like the orange box) in the section where you speak about same sex couples and options are a bit annoying for the eye.' **someone who previously had successful fertility treatment.**

User testing

7.10. The user testing was another source of qualitative information and showed that:

- The website experience is very well aligned with user expectations and needs, and participants were unanimous that it is a huge improvement on the current version.
- CaFC was highly praised, although there are still usability improvements that can be made to the search, search results and clinic detail pages.

Clinic staff views

7.11. Clinic staff acknowledged there was work to do and gave specific comments for improvements on additional features than those discussed already in this paper, particularly on content issues:

- two counsellors noted that counsellor details were not available under the staff heading on clinic pages
- one person thought the term 'research' a clinic should be more carefully used since patients will be spoken to about scientific research later
- one person felt we should provide more up to date figures
- someone expressed dislike of having to scroll lots.

7.12. Positive responses covered a number of aspects:

- clarity and quality of information
- ease of navigation
- helpful presentation – particularly graphics and flow charts
- user friendliness
- providing the right points for choosing a clinic
- an improvement on the current site.

Summary

- We now have a baseline figure for how likely people are to recommend the site. They are somewhat likely to recommend it. Ongoing measurement of this will be helpful for improving and developing the website once it goes live

- Positive feedback is helpful, but the particular constructive critical comments provided can be reviewed as we consider what changes we may wish to make before the new site goes live and assist in improving the service.

Annex 1

Submission from a clinic director in response to the HFEA beta website survey.

Received via email on 28 September 2016

Dear Sirs,

The objective of fertility treatment is to achieve a healthy live birth event preferably a singleton full term birth. This is universally considered by all professional and advisory bodies as the optimal outcome of all forms of fertility treatment. On occasion, clinicians transfer more than one embryo because they are not sure which of them has the best chance to implant. When clinics are judged only on the basis of the fresh cycle, the pressure to transfer more than one has often been irresistible. The thinking has historically been “After all, buying two lottery tickets will improve your odds rather than only one”. The price for that is a risk of multiple birth around 30% with all its associated complications for mother and child.

The use of “Live Birth per embryo transferred” (LB_Emb) is not new as the HFEA has been reporting this since 2010 when the latest format of data publication was launched. The only difference is that it was published in a table that comes second to the table reporting live birth per cycle. The new publication will give priority to this measurement.

The human embryo is the final product of all IVF laboratories. It is the competence and quality of these embryos that what will determine the pregnancy and live birth rate. LB_Emb could therefore be seen as the measure that assesses the quality of what we produce to achieve what we want (a live birth event). So whether this event is singleton or twin it will be counted as one. The denominator, however, will be the number of embryos transferred.

The LB_Emb provides a headline rate that corrects for under reported cycles started, differences in embryo transfer policy and has a commendable public health advantage of encouraging the transfer of the lowest number of embryos that would be effective in achieving a pregnancy, thus reducing multiple pregnancy rate. The move to this measure should, therefore be celebrated by all.

Using this measure (LB_Emb), Abdalla et al 2010, found that the apparent significantly higher live birth rate per fresh cycle in the USA (37.6% with multiple rate of 36% of which 4.4% were triplets) compared to the UK (29.6% of which 30% multiple and 0.2% were triplets) was almost solely explained by the embryo transfer policy (See Table below). There was a significantly higher number of embryos transferred in the USA (an average of 2.4 compared to 1.9 in the UK). The LB_Emb however, was very similar (18.1% and 17.6% respectively).

Table II Comparison between cycles performed in USA* and UK† (2005) for women under the age of 35 years (Abdalla, 2009)

	USA	UK
Cycles Started	41 302	13 947
Live birth	15 406	4131
Live birth per cycle (%)	37.3	29.6
Multiple rate (%)	36	30
Triplets or more (%)	4.4	0.2
Cycles reaching embryo transfer	35 497	12 135
Average number of embryos transferred	2.4	1.93
Total number of embryos transferred	85 193	23 413
LB_Emb (%)	18.1	17.6
Emb_LB	5.5	5.7

*CDC, 2005.

†<http://www.hfea.gov.uk>.

Indeed, in the same paper, the apparent differences between clinic within the UK disappeared using this measure. (see graph below)

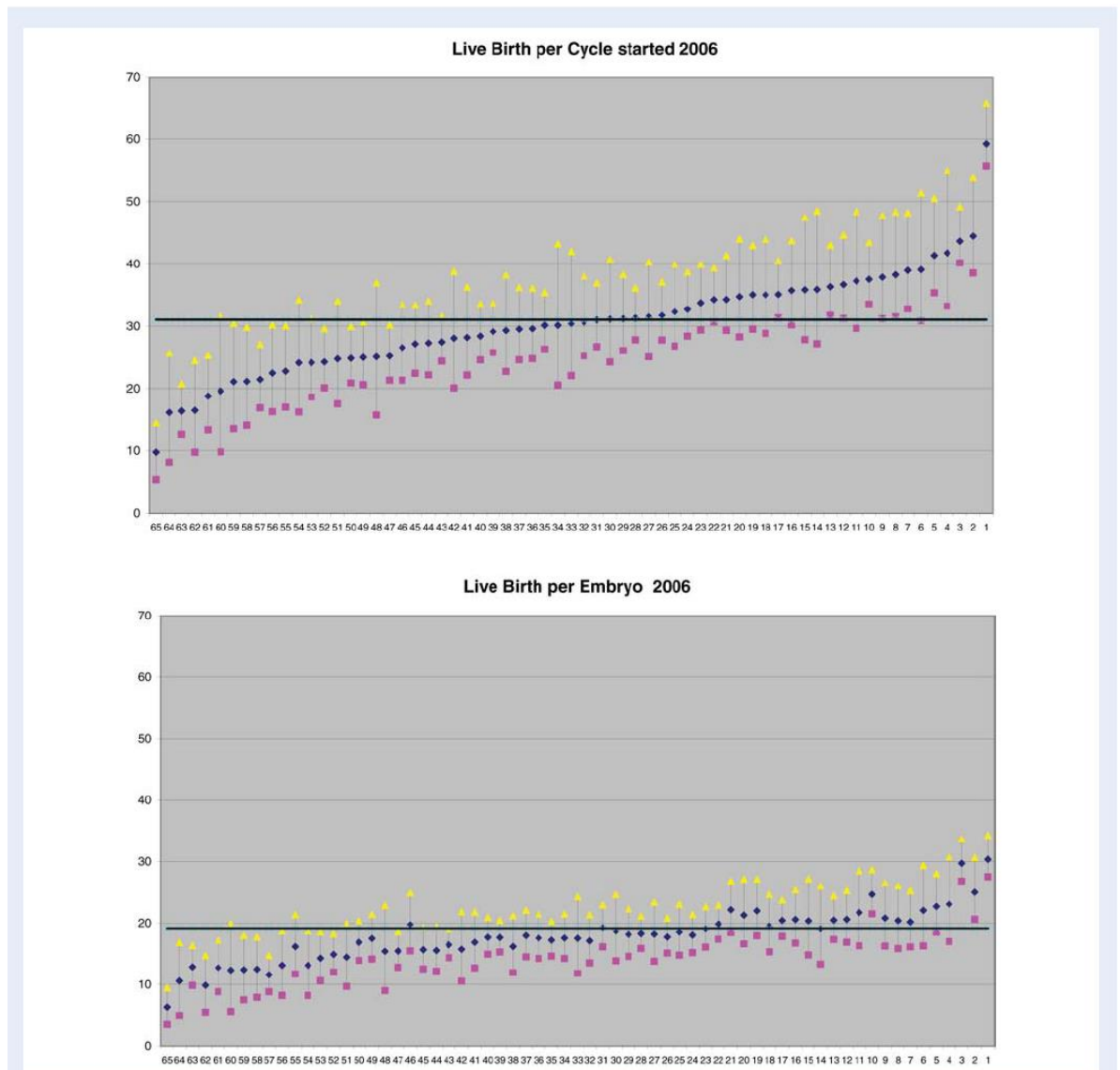


Figure 2 (A) Ranking of clinics based on live birth per cycle started for women under 35 years of age as taken from The Human Fertilisation and Embryology Authority's find a clinic (<http://www.hfea.gov.uk/>) with confidence interval calculated for 2006 data. (B) Results for live birth rate per embryo (with corresponding confidence interval) for the same patient group appearing in the same order of that seen in (A). Solid line represents national average.

As early as 2004, Thurin et al in a randomized multicenter trial in the *New England Journal of Medicine* demonstrated that the transfer of 2 fresh embryos had a significantly higher LBR (43%) compared to an elective fresh single embryo transfer (30%). However, when a single frozen embryo was transferred into those that did not get pregnant in the eSET group the LBR became 39% which is no longer significant. The multiple birth rate in the double transfer group was significantly higher (33% vs 1% in the single transfer group). Kalu et al in 2008 (*BJOG*. 2008 Aug;115(9):1143-50) showed that the LBR following elective single blastocyst transfer and additional frozen transfer in those that did not achieve a LBR in the fresh cycle was equivalent at 68% compared to those with double blastocyst transfer of 69%. The multiple birth rate however was 5% and 46% respectively.

Given the above data, if we are comparing two clinics; Clinic A transfers the best two embryos in the fresh cycle and Clinic B transfers one and freeze's the other. In looking

at the fresh results (as is the case with the current data reporting) Clinic A will look significantly better than clinic B, but with a multiple birth rate of 30 - 50% dependent on age and embryo quality. When Clinic B transfers the other embryo a month or two later it may achieve similar results but with negligible multiple birth rate. The introduction of Live birth per collection (LB_EC) as an additional frontline measure negates this effect as clearly in this example there is no difference in the quality of either clinic. The difference in success rate is totally dependent on the embryo transfer policy of either clinic and the way the data is reported. (We have a problem with the time span for the data used – see later)

The use of LB-Emb and LB_EC will play some role in minimising the effect of embryo transfer policies and the under reporting of started cycles and will certainly improve the safety and health of babies born following IVF through the reduction in multiple birth rate. However, for such changes to truly benefit both patient and clinic, the published information must provide clarity to all and avoid any potential to mislead.

It is important, however, to understand that the use of these measures or any other will never be sufficient to prevent clinics from playing the system. The other way is how to treat patients with reduced ovarian reserve.

Treating mainly patients with good ovarian reserve

For the same age group, a patient with good ovarian reserve is bound to do better than her counter part of similar age who has a reduced ovarian reserve. The former will produce a good number of eggs / embryos to choose from and the latter will produce a much smaller number of eggs or embryos so that the one transferred may probably be the only embryo available. It is well documented that the chances of pregnancy in the former will be higher.

Therefore, clinics who primarily treat patients with high ovarian reserve will have higher LB_Emb even with a similar number of embryos transferred by virtue of more embryos to select from. Clinics who treat patients with reduced reserve should accept this. However, the data for patients should be transparent; for example, the average number of eggs collected (a reflection of ovarian reserve) per patient of different age groups ought to be published. The HFEA should be able to provide national results for success rate per eggs collected e.g. group the data 1 egg, 2-3 eggs, 4 – 6 eggs, 7 -10 egg, 10 - 15eggs and so on. The use of the national data is very informative and can and should guide treatment.

Diverting patients with low reserve to other modalities not reported in the headline figure

a) Natural cycle IVF

- Advising patients with reduced ovarian reserve to undergo natural cycle IVF when the results of those cycles are not published in the headline figure is another method of driving patients with low reserve outside published headline data. It is because of this the inclusion of unstimulated cycle in the outcome is paramount – This however must also be included in the results per egg collection procedure. Obviously, some patients elect to use unstimulated cycles but we believe that they must be made aware exactly of the significant difference in the outcome even if the ovarian reserve is low. In London alone in 2014 data there were 750 natural cycles reported mainly

from 3 clinics. The total live birth from them was 26 making the success rate per cycle of only 5%. This is significantly less successful than the overall outcome for stimulated cycles not merely 'it can be less successful' as you mention in the information you provide. (Please see Appendix II)

b) Batching eggs or embryos

- In this situation, patients are advised to undergo 2-3 cycles of stimulation where eggs are collected and frozen, to all be thawed and inseminated later and all and the best embryo is transferred. The problem here is that the patients pay for 3 egg collections which with current methods of publishing are not included in the stats of the clinic.

c) `Advising egg donation

- This of course can be appropriate advice, particularly if low reserve is coupled with advanced female age.

PROBLEMS WITH THE WAY THE HFEA PROPOSES TO PUBLISH DATA

As our licensing authority and independent regulator, your strategy statement sets out your duty to *increase and inform choice* by “ensuring patients have access to high quality meaningful information”. The unmistakable drive to reduce a clinic’s output to a **single headline figure** is anathema to this philosophy. This approach to data publication ignores the complexities of the treatments we perform and the plethora of factors that affect outcome and can skew data.

The desire to publish a single headline figure that encompasses all ages, all types treatments, on the front page of any clinic belies a desire to provide the definitive ANSWER when everybody knows that there isn’t one. Such a single figure is against the advice of all statisticians, who have in the past recommended to the HFEA the use of a range with no central point.

This approach will inevitably mislead patients, inaccurately assess clinics and go further towards creating a “league table” approach to data interpretation; a consequence that the HFEA have long denied was their goal. In its quest to simplify and achieve a simple headline figure, the HFEA rendered valueless the new approaches it has adopted. This is particularly pertinent when you take into account academic research that highlights ***that over 85-90% of people delve no further than the first page/level of an internet search.*** Therefore, a single “headline” piece of data on the first page, may be the only data at which a patient glance.

We will outline our concerns in more detail below.

Age bands

“All age groups” is a meaningless data point as highlighted by the HFEA many years ago and has never been used by any body as different clinics are likely to treat differing patient populations and the average age of the population treated can be significantly different.

When the HFEA first published data regarding clinic outcomes in 1995, success rate was expressed as adjusted live birth per cycle. This was based on an unpublished

statistical model developed by HFEA statisticians, taking into account factors such as age, embryo freezing, number of previous attempts, cause and duration of infertility and number of embryos transferred. This approach was soon abandoned and data was published crudely for ages below and above 38. This in turn was criticized and thus HFEA changed to adopting the internationally recognized and widely used data range to represent assisted conception outcomes (≤ 34 , 35-37, 38-39 40-42 etc.). This is because age is the most important factor in determining the success rate for IVF regardless of the denominator used.

Furthermore, to then also revert to the simplification of only using <38 and ≥ 38 age bands beggar's belief. Published data for outcomes by the current 6-tier age bands (adopted by the HFEA for more than a decade) make it abundantly clear how outcome drastically changes from band to band even within the <38 or >38 group and as such the simplification to 2 simple bands is therefore misleading; (See appendix 1)

- A 37 year old may will be given an artificially higher expectation of livebirth success by virtue of her inclusion in a <38 group that includes all ages below this mark.
- Those above 38 are an even more heterogeneous group and success rate will be substantially different dependent on age distribution for patients above that age.
 - o Those well above the 38 year cut off may be given misleadingly high expectations
 - o Those just above the 38 year cut off may be given misleadingly low expectations

Time Span for Live Birth per Collection (LB EC)

We really do not understand why should the results for LB_EC be five years earlier. It is understandable to have an extra year, after all, once a patient has a live birth she is not included in the analysis. So, if the last egg collection was at the end of June, say 2013, then the last potential transfer from frozen embryos should be 2014. The data therefore should refer to cycles performed between 2012 – 2013 and not as currently published (2011-2012) So, one extra year is more than enough for the absolute majority of patients who have frozen embryos and did not get pregnant from the fresh transfer to come back and use them (Your statisticians should be able to confirm this). Waiting for a full two years is not understandable and really makes the published data very old.

It should only include data from patients undergoing fresh egg collection for the purpose of IVF or ICSI using their own eggs including natural cycle and PGS and the subsequent frozen transfers for extra year from those treatment types.

Mixing all of this with egg freezing, donated eggs and so on makes the data difficult to verify and understand and subject to changes between different clinics so we may not be comparing like with like.

Misleading Headline Figure (ALL IVF),

As we mentioned before, livebirth per egg collection should be one year earlier than that being published for LB_Emb from fresh cycles.

It should only include data from patients undergoing fresh egg collection for the purpose of IVF or ICSI using their own eggs including natural cycle and PGS and the subsequent frozen transfers for extra year from those treatment types. Mixing all of this with egg freezing, donated eggs and so on makes the data difficult to verify and understand and subject to changes between different clinics so we may not be comparing like with like. The results from egg freezing, from egg donation, should be published separately for each clinic as well as nationally.

The collective use of all sorts of treatment such as fresh, frozen transfer, egg freezing and egg donation into one single headline figure (ALL IVF), demonstrates a total misunderstanding of the difference between these modalities and the effect they can have on the apparent success of a clinic.

1. It is one thing to look cumulatively at live birth from fresh and subsequent frozen cycles as is the case with LB_EG. It is another thing to include all frozen and fresh cycles performed in the same period, whether a pregnancy already resulted or not is simply wrong. This may make a clinic that carry on transferring single frozen embryos repeatedly looks worse than one that mainly use fresh.
2. A clinic with a high proportion of egg donation cycles may appear to have a higher success rate than a clinic with no donation program. The results from egg donation, should be published separately for each clinic as well as nationally.
3. The inclusion of cycles where eggs are frozen within the LB_EC is hard to understand. They should either be included in both birth per embryo transferred and per collection or not at all. We believe that egg freezing cycles should be treated as a separate entity alone and not included in either due to a lack of data on outcomes that may distort success in those clinics with a high number of such cycles. The results from egg freezing, like that from egg donation, should be published separately for each clinic as well as nationally.

Natural or Unstimulated Cycles

We welcome the inclusion of unstimulated cycle in the figures for LB_Emb as it is long overdue. However, there should be consistency here whatever the denominator is. It is very important that every egg collection performed should be included in the denominator when results are expressed as LB_EC. This is true whether the cycle was unstimulated or stimulated or with batching embryos. These are all cycles of treatment that the patients undergo and pay for; either directly or through the NHS.

Therefore, the HFEA should publish data for stimulated and unstimulated cycles together whatever the denominator as well separately highlighting the success rate from natural cycles both nationally and at the level of each clinic. This is important since many such cycles are performed with the belief that the outcome of that treatment will be similar to the overall success rate of that clinic.

Furthermore, given the debate regarding unstimulated cycles we advise that the HFEA publish national results outlining success rate related to the number of eggs collected. This is paramount as it will help a lot of patients with reduced reserve to understand what can and can't be achieved. (See Appendix III – Lister Fertility clinic data related to number of eggs)

Choose or Find a Fertility Clinic

The information for quality group twice voted that the title of the new data publication would be “Find a Fertility Clinic”. Yet this was ignored by the executive and I am not sure whether this discrepancy was put to the authority or whether the authority supported the executive’s view.

“Choose a Fertility Clinic” directs the reader to believe that the information provided by the HFEA (especially results) is of a definitive nature. So, we, the “Authority”, will help you (the patient) to choose between the clinics. As oppose to, we the “Authority” providing you with information about different clinics and allowing you to decide where to go.

Past publications by the authority used the title ‘Guide to Fertility clinics’. Although, this all appears to be semantics and all these publications are ultimately used as a league table, the emphasis in the name implies how the HFEA thinks of its publication.

Other technical comments about website and data presentation .

1. Going to the detailed stats section, the system asks 4 question, which is fine. The defaults in the choices is really is not what it should be.
 - a. You ask first, about the time period, the default, however is the oldest period in this case, 2011/2012. There is nothing wrong in involving previous years but the default should be the latest data publication i.e. 2013-2014 in the current published data. If the observer wants to look for earlier year or all combined as you provide them well and good. This is not difficult to programme the default choice should be latest years with live birth, followed by the most recent data for pregnancies. Other choices including combined data can follow that. This, we believe, would reflect the most recent activity in any clinic and will not be confusing in make the choices (as is the case with current publication).
 - b. Moving on to the type of treatment, normally we believe that should be combined IVF / ICSI. Other choices can follow so the observer can look at IVF alone or ICSI alone or egg donation alone it becomes easier (as is the case with current publication). Unfortunately, the default choice is what is called “all IVF”. This can be the last choice if at all, as it encompasses all sorts of treatments including frozen transfers, fresh transfers, egg donation and in this case they are not even related to the cycles so whether a patient became pregnant or not. We believe it is an inappropriate choice but if you insist on keeping it , it ought not be the default.
 - c. Age the defaults to 35 – 37 we believe going chronologically is more appropriate with under 35 is the first choice. You should also have all ages as the last choice (as is the case with current publication)
 - d. Finally, the choices in whether what type of embryos, eggs, fresh or frozen, again, it should really default on the most common which is fresh embryo, patient’s eggs followed by Frozen embryos patients eggs then

followed similarly with donor eggs (as is the case with current publication).

2. There is inconsistency in the way the data is presented. In the front page LB_Emb is displayed first. In detailed analysis page, the default choice is live birth per cycle. We believe that LB_Emb should have the same priority in detailed stats section
3. You provide single live birth per cycle and multiple live births per cycle. We would have thought that the multiple live births should be referred to the total number of births rather than the percentage of those from the cycle as it starts.
4. In the tap that address the proportion of Blastocyst to embryos transfer please add (%)
5. Finally, it is impossible to go back from the detailed stats to the front page

Summary

Publishing LB_Emb is not new. It has been published by the HFEA for the last 6 years at least. The only difference that the HFEA gave it priority over LB per cycle started.

I propose that the HFEA publish the front page exactly as before but putting LB_Emb in the top table followed by LB_EC, both of them broken down into the standard age bands in the same page format as it is published now. The HFEA can also add the star system etc.

Every egg collection procedure – whether stimulated or unstimulated - MUST be counted when data is published, whether that related to LB_EC or the current standard of per cycle started. Although there should be the ability to tease out data per clinic for stimulated or unstimulated cycles, overall results for any clinic, whatever the denominator, should include stimulated and unstimulated cycle and whether the eggs used were fresh or batched.

HFEA should stop publishing a single headline figure per clinic. The continued transparency of clinic data reporting is essential. Clinic outcomes are not simple and dependent on a number of clinical, demographic, funding and financial factors. The HFEA has to accept and indeed promote that data publication and success rates is a complex matter. The duty of the HFEA is to educate both patients and the wider public of this and outline why a single figure is inappropriate.

Annex I

Inaccurate assessment of clinic quality

Changing to the age bands suggested may inaccurately portray the quality of clinic, which we can demonstrate using a worked example.

Age Distribution Of Treated Patients ≥38 and effect on LB/embryo:

The data below confirm that nationally 34.3% of cycles are performed in women ≥ 38 and shows the decline in outcome as age group increases.

HFEA website data

<u>Age group</u>	<u>Proportion of Transfer cycles : National Average</u>	<u>LB / Embryo transferred</u>
18-34	43.9%	26.9%
35-37	21.7%	21.9%
38-39	14.6%	14.9%
40-42	13.4%	8.3%
43-44	4.0%	3.0%
45+	2.3%	0.9%

If we therefore compare the outcomes of 3 clinics.

CLINIC A (“HFEA National Average Clinic”):

- National average for age distribution
- National Average for LB/embryo transferred in all current age bands
- Transfers 1.75 embryos in all women ≥ 38 (National HFEA data)
- **Headline combined ≥ 38 LB/Embryo: 10.0%**

<u>Age group</u>	<u>Distribution of cycles (National Average)</u>	<u>Number of Transfer Cycles</u>	<u>Embryos transferred</u>	<u>Livebirths</u>	<u>LB/Embryo (National Average)</u>
38-39	14.6%	146	256	38.1	14.9%
40-42	13.4%	134	235	19.5	8.3%
43-44	4.0%	40	70	2.1	3.0%

45+	2.3%	23	40	0.4	0.9%
Combined		343	601	60.1	<u>10.0%</u>

CLINIC B :

- Minimal cycles in older age groups
- Highest proportion of ≥38 group in the current 38-39 band than any clinic
- Headline combined **≥38 LB/Embryo: 14.0%**

<u>Age group</u>	<u>Distribution of cycles</u>	<u>Number of Transfer Cycles</u>	<u>Embryos transferred</u>	<u>Livebirths</u>	<u>LB/Embryo (Lower than Clinic C)</u>
38-39	12.1%	125	192	29	15.1%
40-42	2.2%	23	37	3	8.1%
43-44	0%	0	0	N/A	N/A
45+	0%	0	0	N/A	N/A
Combined		148	229	32	<u>14.0%</u>

CLINIC C:

- Less selective policy with even distribution in all age groups
- Headline combined **≥38 LB/Embryo: 11.1%**

<u>Age group</u>	<u>Distribution of cycles</u>	<u>Number of Transfer Cycles</u>	<u>Embryos transferred</u>	<u>Livebirths</u>	<u>LB/Embryo (Higher than Average)</u>

38-39	16.0%	328	477	99	20.8%
40-42	22.2%	455	726	74	10.2%
43-44	9.8%	200	307	6	2.0%
45+	3.4%	69	93	0	0%
Combined		1052	1603	179	<u>11.1%</u>

The data above clearly demonstrate that the proportion of patients treated in each age band above 38 can significantly influence the outcome of a single headline figure of ≥ 38 .

The clinic with the lowest LB_Emb outcome in all age groups appears to have the highest success rate using a combined figure for all ages ≥ 38 by virtue of their patient group, either as a consequence of perhaps clinic selection criteria, demographics or funding differences. Similarly, the clinic with the highest LB_Emb in all age bands appears to have the lowest success.

- National Average clinic: LB/embryo ≥ 38 10.0%
- Clinic B: **Poorer outcomes** in all bands LB/embryo ≥ 38 **14.0%**
- Clinic C: **Higher outcomes** in all bands LB/embryo ≥ 38 **11.1%**

Similarly distorted outcomes can be shown for LB_EC when comparing such clinics.

Such differences in clinic demographics are not uncommon and could mislead a significant proportion of patients as well as unfairly impact on clinics.

Annex II

Stimulated and Unstimulated Cycles

The following example highlights the importance of inclusion of unstimulated cycles in both LB_Emb and LB_EC. Often, in such cycles, there may be no embryos to transfer due to no oocytes being collected or failed fertilization or cleavage.

Worked Example: This is HFEA data 2014 for 3 London-based clinics (one of them receives all its eggs from a sister clinic nearby). This clearly outlines the effect of including all cycles on outcome, but in particular LB_EC (using cycle as a surrogate for collection).

Clinic A

	Stimulated	Natural	All
--	------------	---------	-----

	Cycles			Cycles			Cycles		
	Cycles	Embryos	Livebirths	Cycles	Embryos	Livebirths	Cycles	Embryos	Livebirths
	313	510	81	379	353	26	692	863	107
LB/Embryo	15.9%			7.4%			<u>12.4%</u>		
LB/Cycle	25.9%			6.9%			<u>15.5%</u>		
	<i>Current Headline Data Reported</i>			<i>Currently not included in Headline Data</i>			<u>Correct Data analysis</u>		

Clinic B

	Stimulated			Natural			All		
	Cycles			Cycles			Cycles		
	Cycles	Embryos	Livebirths	Cycles	Embryos	Livebirths	Cycles	Embryos	Livebirths
	558	856	238	164	88	7	722	944	245
LB/Embryo	27.8 %			7.9%			<u>25.9%</u>		
LB/Cycle	42.6 %			4 %			<u>33.9%</u>		
	<i>Current Headline Data Reported</i>			<i>Currently not included in Headline Data</i>			<u>Correct Data analysis</u>		

Clinic C

	Stimulated			Natural			All		
	Cycles			Cycles			Cycles		
	Cycles	Embryos	Livebirths	Cycles	Embryos	Livebirths	Cycles	Embryos	Livebirths
	546	1136	141	198	204	4	744	1999	145
LB/Embryo	12.4%			2 %			<u>7.2%</u>		

LB/Cycle	25.8 %	2 %	<u>19.5%</u>
	<i>Current Headline Data Reported</i>	<i>Currently not included in Headline Data</i>	<u>Correct Data analysis</u>

Annex III

Li[v]e birth per cycle (Lister Fertility Clinic 2011 -2014) related to number of eggs collected

	1 egg	2 eggs	3 eggs	4-6 eggs
< 38	(7/66)	(16/113)	(33/151)	152/500
	8%	14%	22%	30%
38 - 44	6/197	16/291	40/309	135/812
	3%	6%	13%	17%

Annex 2

Submission from the British Fertility Society in response to the HFEA beta website survey.

Received via email on 7 October 2016

We support the idea of a headline figure presented for each clinic, but are concerned that that figure should as closely as possible represent a figure that gives a fair indication of that clinic's performance.

In order to achieve this, we suggest including in the headline figure only patients and treatments that fall within set, agreed criteria.

We suggest that those criteria must include:

- (i) Age: female partner e.g. <38 years old

- (ii) Treatment type: include all ICSI/IVF with own eggs, ejaculated semen, no egg or sperm donation cycles, no PGD or PGS cycles

We support the intention to present figures on outcome per embryo

We are a little vexed about the issue of “natural cycles” as different clinics use the term in different ways and some also do give medication. Whilst on the one hand with a truly natural cycle there is never the option of transferring more than one embryo, so one cannot compare with stimulated cycles. Yet, on the other hand, including natural cycle treatment in the headline is the “intention to treat” figure and hence cancellation rates. Whilst it is difficult to argue against implantation rate in a defined group including the natural group this may hide a multitude of sins. Perhaps secondary highlights should be multiple pregnancy rate, cycle cancellation rate (including where no ET performed) and OHSS rate.

Annex 3

Submission from a clinic in response to the HFEA beta website survey.

Received via email on 7 October 2016

6 October 2016

For the attention of: Mr. Peter Thompson and Mr. Nick Jones

Natural and Stimulated cycles should not be combined in headline success rates

This short submission is to explain why we at Create Fertility believe that Natural cycle IVF should be regarded as a separate treatment methodology compared to stimulated IVF and consequently that success rates from these two methodologies should not be combined in a single headline figure. It should be read in conjunction with our previous submissions and correspondence with the HFEA in this regard.

Context

IVF is performed with oocytes collected in natural and stimulated cycles. Different approaches to ovarian stimulation are employed in IVF. Following the concerns regarding multiple births and Ovarian Hyperstimulation Syndrome, there has been a revival of physiological approaches to IVF in order to reduce health risks to mother and baby and to make treatments cheaper and women-centered. Natural cycle and Mild IVF have been increasingly used in selected patient populations to optimise health outcomes and reduce the burden of treatment.

In order to establish consistency in the terminology and protocols used, the International Society for Mild Approaches in Assisted Reproduction published a consensus paper in Human Reproduction (1). Subsequently, a glossary was published jointly by ICMART and WHO in Fertility and Sterility (2). The scientific publications have clearly recognised that stimulated IVF and natural IVF are two different entities with different aims, methodologies and outcomes that are applied to different patient groups. Hence, the scientific literature does not combine results of natural and stimulated IVF cycles in a single group.

The principles and definitions of Conventional stimulation, Mild stimulation and Natural IVF approaches could be found in publications mentioned above (1 & 2). Although different in concept from conventional IVF, Create are content to have our mild IVF data included with the conventional IVF data in the Headline Success Rate because they are both classified under stimulated IVF.

Our Scientific team at CREATE consists of Prof Campbell, Prof Frydman, Prof Nargund, Prof Chian and several experienced consultants and embryologists. Many members of our team have developed protocols to make natural and physiological approaches to IVF successful and our commitment to giving women the choice to have a baby with their own eggs and to reduce costs and health risks of IVF treatments are well known. Nearly 60% of our patients have natural IVF and we are extremely concerned about the proposal to combine success rates of natural and stimulated IVF under one headline figure. We cannot see any valid scientific reason to change the existing model wherein they are separated. We are grateful for the opportunity to explain our position as to why natural and stimulated IVF cycles should not be combined under one headline figure.

Rationale behind Natural Cycle IVF

Natural cycle IVF was originally applied to women who did not wish to have stimulating drugs or were advised to avoid such drugs because they had an oestrogen dependent cancer or were at high risk of such a cancer. However it became apparent in the early 2000's that it was also a more effective method of treating older women over 40 years of age and younger woman with low ovarian reserve who were only capable of maturing one or two oocytes and in whom the use of stimulation was ineffective or counterproductive. Traditionally such women would be offered egg donation or at best a stimulated cycle which, if it did not result in at least 3 mature follicles, would be cancelled before egg collection took place.

Natural cycle offered hope to such women because although it was accepted that their eggs were biologically less efficient than those of women with normal ovarian reserve, there was evidence that the natural approach and the natural selection of the oocyte increased their chance of conception (albeit significantly lower than with women with normal ovarian reserve). In our practice, women undergoing Natural Cycle IVF were usually advised to undergo up to 3 cycles to optimise their chances of having a baby.

Low Ovarian Reserve

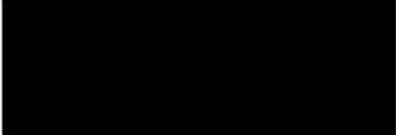
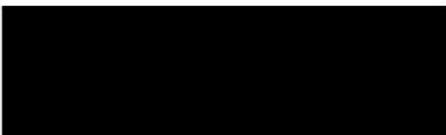
There are currently two accepted tests of a woman's ovarian reserve i.e. Antimullerian Hormone (AMH) and Antral Follicle Count (AFC). AMH is secreted from small antral follicles in the ovary and is measured in the woman's blood. Levels below 3 pmol/ml. are accepted as indicating low ovarian reserve i.e. low number of oocytes and low percentage of biologically efficient oocytes (3). An AFC below 4 (i.e. combining the count from both ovaries) also indicates a low ovarian reserve of oocytes. As explained above, conventional stimulation is not appropriate for such ovaries that are not able to respond in the conventional way (i.e. falling into the "poor responder") category and high doses of gonadotrophins might render biologically inefficient oocytes even less efficient. That is why a natural and physiological approach is required to give such women a chance to conceive a child with their own eggs. It has been proven to be more successful than high dose stimulation in such women giving them an opportunity to have a baby with their own eggs (4).


Why the results of Natural and Stimulated IVF Cycles should not be combined in Headline Success Rate tables

In summary, Natural and Stimulated cycles are two fundamentally different treatment methods and are offered to different patient populations. Women who receive Natural Cycle IVF have low success rates compared with stimulated IVF because they have biologically less efficient oocytes and embryos. Natural cycle offers them some hope but to combine success rates between Stimulated and Natural cycle IVF is unfair, illogical, unscientific and misleading. Such publication would go against the principles of fair, clear and transparent public information.



We also make the following observations:

- Women with very low AMH are offered Natural cycle IVF
 - Women with low AMH have a choice, either to have Natural IVF to have a baby with their own oocytes or to use donor oocytes. The success rates are evidently different but the success rate with a woman's own eggs is not negligible and many women would at least like to feel they have tried to conceive with their own genetic oocytes.
 - Women who are offered natural IVF because of low AMH and AFC do not benefit from stimulated IVF (as indicated by previous repeated failures and cancellations with stimulated cycles and as evidenced by scientific publications). Our aim is to promote patient choice and cost-effective options for these women with their own oocytes
 - Oocytes from women with low AMH behave like oocytes from older women who have lower success rates per embryo transferred because of lower quality oocytes. AMH is a reliable biomarker of oocyte quality (5). The mean implantation rate is lower in younger women under 35 years with AMH levels less than 1 ng/ml suggesting lower biological efficiency per embryo related to lower quality oocytes.
 - The studies have also shown that there is an association between oocyte pool and aneuploidy (6). It confirms that women with low AMH and AFC who undergo natural cycle IVF have less biologically efficient oocytes and embryos.
 - Furthermore, studies have also indicated that AMH levels in the follicular fluid of pre-ovulatory follicle are a predictor for oocyte fertilization and embryo quality (7). The oocyte regulates granulosa cell AMH expression. This is another physiological explanation for lower quality embryos in women with low AMH who undergo natural IVF.
 - Natural IVF cycles require a 7-day a week service and special expertise (such as advanced ultrasound, Doppler and 3D) in assessing the maturity and quality of follicles and to monitor closely in order to avoid spontaneous ovulation and to time the egg collection. Clinics with no experience or expertise in Natural Cycles IVF can attract patients because of their overall headline rate. This will mislead couples seeking Natural Cycle IVF who will be attracted by a headline success rate inappropriate to their needs.
- 
- 



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Annex 4

Further submission from a clinic director in response to the HFEA beta website survey. (additional to annex 2)

Received via email on 14 October 2016

15-10-2016

Dear Juliet

Further to my previous letter regarding data publications and following the meeting on the 29th September, I am writing to summarise what I believe the HFEA should do to improve the publication of IVF data in such a way that helps the patients and the rest of the stakeholders.

If you must have a single headline figure, then this must be age dependent and therefore, the results should be published according to all the agreed upon 6 age groups (less than 35, 35-37, 38-39, 40-42, 43-44, 45+) data. Nevertheless, as this data is optimised to mobile applications and that it will be very difficult for any patient to keep browsing into data of different age groups that are not of interest to them, I propose that once the patient press the button for choose a fertility clinic, after reading the information that you are providing, she is asked one question;

What is your age? Or enter your age

Once the patient enters her age, the system automatically assigns her to the appropriate age group out of the standard six. Thereafter, the headline figures for that age group is what the patient sees (exactly the same way you are providing currently for all ages), whether this is live birth per embryo or per egg collection procedure. This way you have a headline figure but specific for the observer.

I do propose, however, that once the patient is assigned to age group, the system should provide the patient with the National average detailed results for (IVF/ICSI combined including stimulated and unstimulated cycles) for that age group published as

- Life birth per embryo (LB_Emb).
- Life birth per EC (LB_EC)

Detailed info should also be provided after the above for

- IVF alone
- ICSI alone
- Natural cycle alone
- Frozen Embryo Transfer cycles alone

Going to the national data can be made obligatory before going to separate clinics (preferable). Alternatively, it can be available by choice; two buttons beside each other “Go to National Data” and “Go to a Fertility Clinic”.

Principles I believe agreed upon in the meeting:

All IVF is totally meaningless and should be abandoned (replaced by default of IVF/ICSI) at all levels of choices i.e. from headline data and when you go to “have a closer look”

In LB_Emb the denominator includes all IVF/ICSI cycles using own eggs fresh (and in case of all frozen, then the first transfer of the frozen thawed embryos is included). Cycles included regardless of method of stimulation; including unstimulated cycles). Excluded from this are egg donation, frozen transfers and PGD/S cycles.

In LB_EC the denominator includes same as the above types of patients from the moment they go to egg collection (so whether egg collection successful or not). Frozen transfers are included till the woman has a live birth or the embryos are exhausted in one more extra year. Excluded here egg donation or PGD cycles (the results are published separately). You go back only one year extra than in the case of LB_Emb (not 2 years as it is currently proposed - data looks very old).

As long as natural cycle IVF data are not included in the headline figures, there is always the potential for using it for patients with reduced reserve with significantly reduced chances of success so as to hide their poor outcome from the headline figures. Alternatively, it is sold to patients as the treatment that depends on quality rather than quantity, therefore convincing patients who prefer not to take medications that this is an alternative and equivalent route for success. I can assure you that none of the clinics that use a high number of natural cycles, highlight the poor outcome of the natural cycle on their websites.

I would, therefore, like to refer you to a most recent publication (Sunkara et al 2016)*, this paper studies the outcome from natural unstimulated cycles and compares it, to stimulated cycles for all treatments performed in the UK between 1991 and 2011 (HFEA data). The overall live birth rates were 4.7% per cycle following unstimulated fresh IVF versus 22.5% following stimulated fresh IVF. They estimated that to achieve one live birth across all ages you need to perform 21 natural cycles as opposed to 4.5 stimulated cycles. In other words, stimulated IVF cycles are 5 times more successful than a natural cycle. For all these reasons it is paramount that the HFEA publishes the

National figures for natural cycles and includes them in the overall stats for each clinic.

In all cases providing detailed analysis utilising national data is perhaps substantially more important than individual clinic success. That is why; patients are advised to refer to national results. National data is more robust and given the numbers used is more accurate. Finally given the increasing number of patients with reduced ovarian reserve, I suggest publishing national data related to number of eggs collected. This will help these patients understand their potential success (for example if they produce 1, 2, 3, 4 or more eggs) and what method of treatment to adopt.

I hope that the above helps in optimising data presentation and helps patients en rout to an important step in their lives. Please do not hesitate to contact me if you need to discuss any further details.

██████████

**Sesh Kamal Sunkara, Antonio LaMarca, Nikolaos P. Polyzos, Paul T. Seed, and Yakoub Khalaf. (2016) Live birth and perinatal outcomes following stimulated and unstimulated IVF: analysis of over two decades of a nationwide data Human Reproduction, Vol.31, No.10 pp. 2261–2267*

Advanced Access publication on September 2, 2016 doi:10.1093/humrep/dew184

Summary of plenary sessions and table discussions

Age stratification

There was broad consensus in the room that a headline success rate figure was important as patients really want this, though aggregating all ages was flawed and could be misleading for patients. Age has a huge impact on outcome and needs to be reflected.

Though some felt a success rate for comparison should not be included as a headline figure (and instead an indication of whether the clinic was above, below or in line with the national average), the majority agreed with having a headline figure, since patients want this and they accepted that the Authority wishes this to be births per embryo transferred. A small minority felt there are flaws with this particular measure and that other figures, for instance, 'births per cycle started' were better.

Attendees understood that grouping all ages was intended to create bigger sample sizes but noted that most clinics would undertake enough treatments to allow for age breakdowns. An explanatory note could be included to account for small centres with less than 50 treatments in a given age group.

Many groups suggested alternative approaches in presenting the headline. A number noted that showing the rate for a 'gold standard' patient would be a better approach but there were questions on how to identify the best comparator or what patient mix the gold standard would be. In lieu of this, a younger patient group would be a better comparison.

Some did feel that choosing to present a single headline figure was in itself misleading for patients. They felt that the concept of a single headline figure was too simplistic, suggesting either showing all 6 age brackets or alternatively 3 broad categories.

Discussing the age breakdown (into under 38 and 38 and over) further down the clinic profile page, some attendees felt this was fairly arbitrary and could be counterproductive in terms of clarity for patients about their chances of success. Some felt this could be unnecessary if more age breakdowns could be provided in the headline.

Conclusions for the HFEA to consider:

1. Present some indication of birth rate alongside the other headlines – but make sure this is meaningful.
2. The current headline figure, grouping all ages is too oversimplified. Adjust success rate for age in the headline by either:
 - a. Presenting the success rate for one, more comparable age bracket such as under 35 year olds
 - b. Presenting the success rate for a 'gold standard' patient (eg, patients meeting the same categories for age, fertility etc. based on no. eggs collected)
 - c. Presenting a number of top-line figures for different age brackets to be more meaningful to patients

Any of these approaches will have pros and cons, but they would lead to a fairer comparison which was more meaningful for patients.

3. Detailed statistics should continue to be available, with an understanding that some patients may not access this and will only see the headline rate. Two broad age bands were not thought to be a helpful sub figure by some and potentially a little arbitrary; the more detailed groupings were better.
4. Consider showing the average age of patients the clinic treats to give patients an indication of the usual mix for that clinic.

Treatment types

There was agreement around the room that grouping the range of treatment types together was a problematic approach and some changes were needed to present a more meaningful headline figure.

There was detailed discussion of the benefit of including frozen embryo cycles in the overall headline success rate. Freezing currently occurs for a wide range of reasons, both clinical and patient preference, so to include these treatments could be misleading. This could be misleading and so the majority felt it could be better not to include this. Equally there are different factors such as length of freeze and type of freeze methodology ie, vitrification, which are important but are not reflected in a single 'frozen' category. Some thought an option could be to include the results from the first embryo transfer for a freeze all cycle, but this was not a universal view. Others were more relaxed about including frozen cycles and were happy for these to be included with fresh.

They also discussed natural cycle IVF and strong and differing views were expressed about how this information should be presented. The overall feeling was that we should consider excluding natural cycle IVF from the headline figure since this is a different treatment type. In natural cycle IVF only one egg may be produced which is very different from most standard IVF. Some suggested that to include it would mean not comparing like with like. Some raised that the term 'natural cycle' could be used for a spectrum of different treatments – the term was not universally consistently applied. Although a minority of clinicians disagreed with this and thought it should continue to be included in the headline.

The clear feeling from the workshop was that natural cycle results should be presented separately and clearly in the detailed statistics to facilitate informed patient choice.

Participants generally agreed that donor egg recipients are a different patient group and since the eggs come from healthy, fertile donors the inclusion of these treatments is misleading in the overall success figures. It could mean clinics encourage more patients to use donor eggs to improve success rates. The same is true for surrogacy which is likely to be undertaken for different reasons than standard IVF/ICSI.

Clinicians were worried that including PGD/PGS in the figures this might encourage the practice of referring all patients to have PGS, even when it isn't needed. Also, those having these treatments might be doing so for entirely different reasons, so one would not be comparing like with like.

Conclusions for HFEA consideration:

1. The HFEA headline figure would be more meaningful if it included:

- a. Only fresh stimulated IVF/ICSI cycles with the patient's own eggs
 - b. Because these treatments are fundamentally different, it should *exclude*:
 - i. Egg recipients
 - ii. Frozen (though some felt the first frozen transfer should be included for freeze-all cycles and some were more relaxed on this)
 - iii. Surrogacy
 - iv. PGD/PGS
2. HFEA should consider excluding Natural Cycle IVF from the headline figure and presenting this separately and clearly in the detailed statistics to facilitate informed patient choice.
 3. HFEA should publish national success data for different treatment types before patients get to the clinic statistics.

HFEA recommendations to the Website and CaFC

Public beta usability review – initial findings - addendum

Summary:

The report attached comprehensively focuses on the last round of user testing (November 2016) and provides a good view of the specific moment in time in which testing took place. However, as a result of this it needs to further capture the broader context for why the direction has been taken on various features. The development team have requested revisions to be made to the report to meet this need as well as provide greater clarity and fairness for the findings in our usability testing.

The Authority is asked to note this addendum when reviewing the report.

Areas to be revised cover the following points:

- As the service is in a beta state we have tested it 'as is'. This means that some elements of functionality were not in the preferred state of presentation. The report recommends certain changes be made that the development team are already aware of and will be made as part of the continued development of the website. By also looking at the 'as is' state it does not take into account previous testing comments which will have influenced the current iteration.
- The testing method applied aimed to provide as realistic a setting as could be gained from an observed hour long test. The method presented an emotionally engaging experience that resonates with the participant moving the testing away from a potentially artificial task based exercise.
- As the report deals with a small sample set (specifically for the purpose of qualitative feedback) the report will replace percentage measures to actual participant numbers.
- A short bullet point will be applied to each section to introduce the positive aspects of the site so the team understands what is working well. The report itself focuses on areas for improvement but the positive aspects will help set the broader picture of how close to meeting user needs the site is.
- Referencing the existing HFEA service – we acknowledge that the new website is an improvement on the existing one given the foundation level of understanding of its flaws. To this end we do not want to compare it with the old site as a measure of quality. The old website is of its time and thus is fully expected to not be as good as the new one.
- There is generalisation applied to various points throughout the report. We are asking for references to user testers to be stated in majority/minority or specific numbers. This will avoid ambiguity in weighing up the decision to act on recommendations or areas of concern raised in the report.
- An overview paragraph will set out the development team's approach to the redesign of the website. This will context set the instances of 'long' scrolling pages etc.

- Assumptions are made from the user testers actions. We want to reflect more accurately on what has come directly from them. These should be quoted or more accurately noted. Additionally, where an individual commented on something that has been presented it will be stated. The comment will be viewed in the broader context of suitability for the majority of users.
- More clarity will be provided around points of frustration to better explain whether the fault lay in content, layout, usability or design. Issues known by the team (for example the page stepping process currently applied to the detailed statistics section of CaFC) will be acknowledged.
- More generally, the report will be adjusted to cite specific areas of the site that a comment was targeted at. For example, the presentation of CaFC tackled a different set of user needs to the information pages. This will help set the priority of development work needed.
- Comments that needed to be pushed for will be made clearer. For the most part the testing aimed to get the views as they were from the participants; where necessary the team would probe with more exploratory, open questions.
- There is a strong focus on rationalists and as a result some of the suggestions for conformists and 'intuitive/dependant' thinkers will be elaborated upon for balance.
- The pre testing questionnaire will be packaged as an appendix. The charts displayed provide an aggregated score applied by the user testing team to determine the cognitive behavioural fit.

HFEA
Public beta usability review

Point of Contact for Questions

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Website and CaFC
Public beta usability review – initial findings

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1 EXECUTIVE SUMMARY

Reading Room conducted a review of the Public Beta website with a representative sample of 12 potential site users.

The purpose of the review was to examine whether the user experience is meeting expectations and needs and identify improvements that can be made.

Tests were conducted on site at Reading Room and on Skype. The HFEA product owner and other staff observed the sessions.

- The website experience is very well aligned with user expectations and needs, and **participants were unanimous that it is a huge improvement to the current version.**
- The Choose a Fertility Clinic service is the USP for the site and was highly praised, although there are still usability improvements that can be made to the search, search results and clinic detail pages.
- Content was seen as welcoming and well written, with the conversational tone coming across very well. However, in some places the site was seen as lacking emotional engagement.
- We studied how well the site meets the needs of the three cognitive decision making types who had been identified in the discovery research. Currently it is working well for 'rational/critical' types but there are improvements that could be made to the experience to better meet the needs of 'conformists' and 'intuitive/dependents'.
- Changes to information architecture and content introduced at Public Beta stage, especially around the Choose a Fertility Clinic and Treatments sections have had a negative impact on findability of key content since the previous round of testing and should be reviewed.
- There were concerns over the presentation of Patient Feedback, and the process for gathering it, and doubts about how reliable this data will be.
- There are a number of site wide design issues to address to improve the experience.
- More could be done to link-up content around informative / educational journeys.

This report focusses on issues – once we have had an opportunity to discuss findings with the HFEA project team members we will be in a position to make recommendations.

The HFEA should then review and decide which recommendations to take forward, adding any changes to the backlog for the Website and CaFC where they can be prioritised alongside other work.

2 METHOD

2.1 Public beta prototype

The project is at Public Beta stage, a working prototype of the final system. The public beta prototype is built onto the full Umbraco environment, and hosted in Azure. The only difference between the environments and those that will be used for the final system is bandwidth, since the hosting was using a free test area, speed of page load is compromised, but it is otherwise a similar experience.

The prototype had been loaded with a substantial amount of content by HFEA, including the full Choose a Fertility Clinic dataset.

2.2 1-to-1 usability testing

To test the usability of the Website and Choose a Fertility Clinic service we followed an industry standard technique known as 'think aloud testing' whereby a small sample of potential users of the site are asked to use the site. The tests are facilitated one-to-one sessions with a usability expert who observes their behaviour and asks them to explain as they go what they are doing and what they are thinking.

For the beta tests we focussed on self-driven journeys, starting with a short interview in which people were asked about situations in the past where they had needed advice or guidance on fertility treatment, and then asked them to show us what they would have done with the HFEA website if they had access to it at the time. This gives deep insight into their user experience and any issues that are preventing them from achieving their objectives.

Half the tests were conducted face to face, with the remainder being conducted over Skype. All sessions were recorded.

2.3 Recruitment of users

The 12 participants included 11 women and one man undergoing treatment. They represented a range of our target audiences, including:

- women undergoing treatment
- partner in a same sex couple
- partner in a heterosexual couple
- women who have donated eggs (egg sharing)
- single women who have undergone treatment
- a GP (who was being interviewed as a fertility patient herself rather than as a doctor)

Participants were paid a small financial incentive for taking part.

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The sample had an over-representation of people who had been through treatment already, as opposed to those seeking treatment. This may introduce bias due to people looking at the site 'in hindsight', with much greater knowledge of fertility treatment than they would have had at the start of their treatment journey.

There was also an over-representation of people who had used donor eggs or sperm, due to the recruitment channel adopted by the HFEA. It is not thought that this will have had much influence on their views or information needs with the exception of an interest in the practical and legal issue around use of donated gametes.

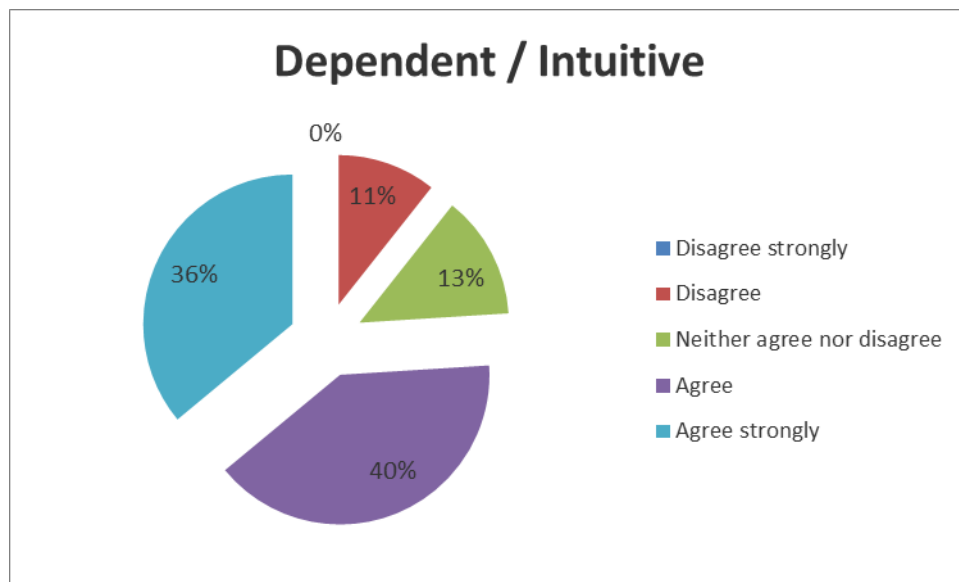
3 THREE DECISION MAKING STYLES

A pre-session questionnaire was designed in order to assess the individual differences in the ways people prefer to process information and make decisions (rational, dependent/intuitive, and conformist). This approach enabled us to explore how well the HFEA website meets the needs of the varied audiences and helped us understand how we can increase the level of engagement of the different decision-making styles with the new version of the website. The decision-making style, as a measure, was formed by averaging responses to 15 separate questions and in total all 12 people who were recruited to participate in the 1-to-1 usability sessions completed the questionnaire.

Based on earlier research we have identified three decision styles; a rational style; a dependent/intuitive style; and a conformist style. However, it is worth mentioning that the decision-making styles are independent but not mutually exclusive and that some people seem to use a combination of decision-making styles when making important decisions. Out of the 12 people who participated in the testing we have identified two patterns: some people exhibit a mix of decision-making styles while for others only one of the aforementioned styles dominates.

3.1 Dependent / intuitive

Most respondents (**76%**) revealed that they tend to rely on hunches and feelings whilst they are making a decision and that they value the advice of people in similar situations to them (e.g. “When I make a decision about the right clinic for me, it is more important for me that the decision feels right”, “When I make decisions about which clinic(s) to consider, I tend to rely on my intuition and my inner feelings & reactions after talking to the clinic”, “It’s important to me that I talk to women who have undergone similar treatment before I make any decisions”). Only 11% of respondents indicated that they are not dependent/intuitive, as can be seen in the graph below.



Respondents who were identified as dependent / intuitive were generally happy with the look and feel of the new version of the website. Font style and colour choices were well received and the absence of baby images was very much appreciated. Tone of voice and language were also praised as were the personal stories in the emotional support page. The idea of including videos alongside the written text was welcomed by most participants.

One notable example was a woman who had successful treatment in the past and when she was prompted to read a personal story, commented:

“The more that you feel that you are not on your own the easier it becomes.”

However, participants were unable to connect with the patients’ stories that are scattered through the audience and treatment pages due to lack of images, names, and links to expanded stories. Additionally, a desire to find information about emotional support and post treatment counselling was expressed by some participants. There were also some concerns that there was no content aimed at men (or at least, they didn’t see themselves in any of the categories offered) and single women sometimes objected to the term ‘single’.

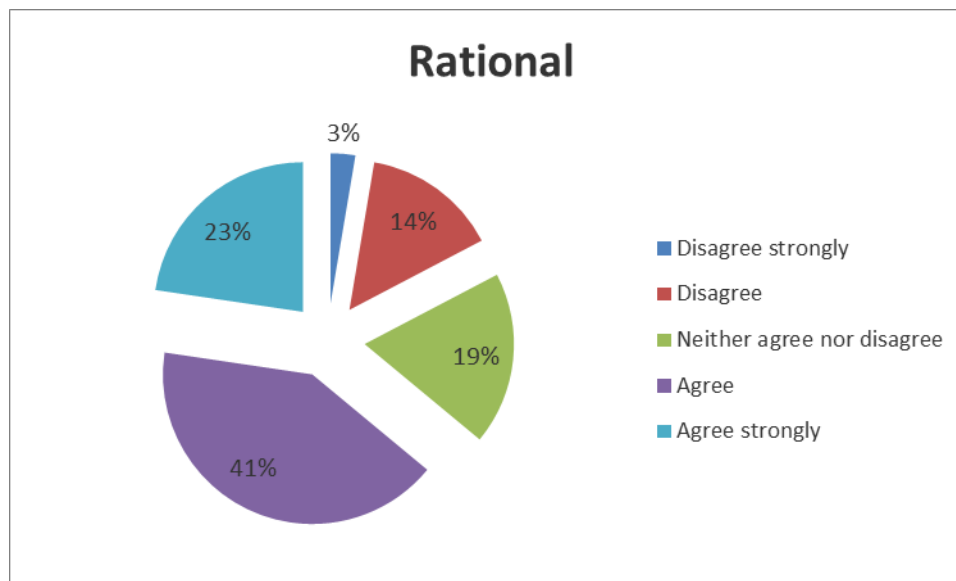
Patient ratings were considered as a very important factor in their decision-making process, for example one participant commented:

“There is nothing more useful in this world than the experience of people who actually were patients in a clinic.”

However, some participants struggled to relate to the star ratings alone and expected to see free-text comments and reviews. There were also some people who felt that it wasn’t clear if the patients’ rating comes from the clinic or HFEA. Finally, it is worth mentioning that for people who have the tendency to trust their gut feelings and the advice of people they can relate to, statistics and success rates still matter to them as long as they are presented in a clear and uncomplicated way so that they can understand and appreciate them.

3.2 Rationale / Critical

The rational / critical style, which refers to the tendency to make decisions using rationality, seems to apply to the majority of the participants, since 64% either agreed or strongly agreed with questions aiming to identify the rational decision-making style (e.g. “My decisions about the clinic I use requires a lot of careful thought”, “I will make any decisions about the right clinic in a logical and systematic way”, “When making a decision about which clinic to use, I initially consider all clinics in my area that I feel can help me, and research each of them in turn before narrowing down the number”). Only 17% of them disagreed or strongly disagreed with the relevant statements, although it is worth mentioning that 19% remain indecisive, as can be seen in the graph below.



In general, respondents who were identified as rational decision-making styles admitted that the new version of the website was a significant improvement on the current HFEA website. Rational decision makers use analysis, facts and a step-by-step process to come to a decision and the structure and content of the beta website resonated with them. The key facts in the treatment pages as well as the more detailed information about clinics drew people’s attention and received a warm approval. In general, the language and tone of voice appeal to participants, commenting that: “tone of voice feels appropriate”, “language is good and uncomplicated”, “very straightforward language and easy to understand”. It is worth noting, though, that a lack of clarity and explanation over language was noticed and criticised by some respondents. More specifically, a need for more precise language around birth rates (live or all), success rates (for which treatment, which age), and inspection rating was expressed and led some to question the value of the data. Particularly regarding the inspection rating some respondents weren’t aware

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that the HFEA gives clinics a rating and didn't know where this data had come from, and there were also a few misinterpretations of some questions, e.g. "How do our inspectors rate **the** clinic?" caused confusion as to whether the question refers to a specific clinic or implies more generic information with some respondents stating that "How do our inspectors rate **this** clinic?" would be clearer.

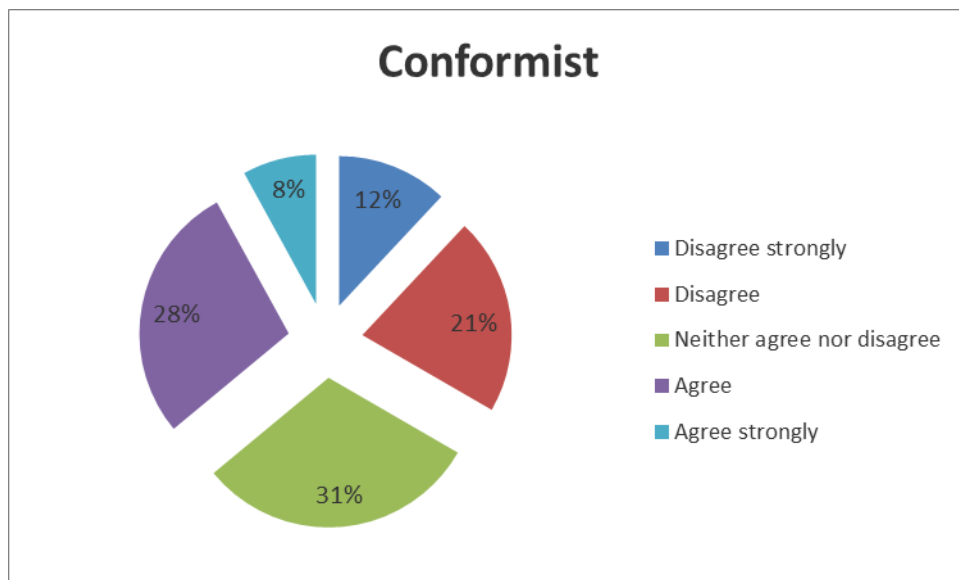
There is a large amount of information presented to users while searching for a fertility clinic, the main purpose of which was to help them make a more informed decision by breaking down the searching process. The downside is that there is now so much content in advance of finding the call to action that inadvertently results to overloading people with too much information. Most of the respondents were unable to process the amount of information presented to them and they were ending up feeling lost or frustrated and some even giving up.

Rational decision makers seemed really happy with the detailed statistics and more importantly with the fact that they would be able to access data for people in a much more similar situation to their own. There was even one respondent who commented: "this is the only data that really matters" and another one who revealed "statistics for me is the most influential thing". However, the process that needs to be followed in order to review the detailed statistics, splitting the form over 4 pages, frustrated respondents with one giving up entirely. Furthermore, even for people with a reasonable understanding of basic statistical ideas, a confusion around the graphs was evident and whilst most people correctly interpreted the clinic birth rate vs the national rate, there was little understanding of 'reliability' despite an explanation being on the page itself.

Finally, it became apparent that for people who are making decisions using rationality, the patients' rating plays a less important role in their decision making process, as one of the respondents clearly explained: "I will definitely take patients' ratings into consideration but for me it's the actual statistics and success rates that are most important". In addition to that, people appeared more suspicious of the authenticity and value of the ratings, expected more clarity on how the ratings are to be policed and how the HFEA intends to establish whether ratings are from patients, and some even questioned whether they would trust the ratings without this knowledge.

3.3 Conformist

Interestingly, only 36% of respondents indicated that they are conformists and that they rely purely on the opinions of healthcare professionals and medical experts whilst they are making a decision (e.g. "My choice of clinic is influenced by the recommendations of my GP", "I spend time reading the thoughts and opinions of experts before making any decisions about treatment and/or clinic", "It's important that I am given guidance by professionals about which clinic I should use"). An almost equal number of respondents (33%) disagreed or strongly disagreed with the questions aiming to identify the conformist decision-making style. Also, 31% didn't express a clear view and preferred to remain neutral, as can be seen in the graph below.



Although the data suggests that respondents tend to rely less on the opinions and recommendations of professionals and medical experts when they are making decisions for a treatment and/or clinic, this by no means infers that they don't value the impartial, valid and accurate information that comes from an expert or an independent source. One notable example was a donor conception parent who commented: "Legitimacy is the most important thing for people, anything endorsed by HFEA would be reassuring for me". Similarly, another woman who had successful treatment revealed that: "just the fact that the information comes from HFEA makes it safe". Based on these comments and given that there was no content specifically aimed at conformists within the treatment pages (for example, HFEA endorsement for treatment pages or explanation of the role of HFEA at this level), we recommend to add HFEA endorsements that would establish the authority of the content. As one participant stated: "I wouldn't question the authenticity of HFEA".

4 HOME PAGE

The home page was well received – seen as providing a good statement as to who the HFEA are, and was a welcoming route in.

Users liked the vibrancy of the colours used and the bold, large text.

Since the last version we tested, the “I am seeking treatment for” and “Treatment search” boxes had been switched round. This appeared to work better for users.

Few users took the time to review content below the green box, although this may be because of the nature of testing and the scenarios we asked them to explore, which didn’t call for them to find anything specifically on the home page.

The screenshot shows the HFEA website home page. At the top, there is a navigation bar with links for Home, Contacts, I am..., Treatments, Donation, Choose a clinic, and About us. A search bar is also present. Below the navigation is a green banner with the text "Welcome to the HFEA" and a sub-header: "We provide free, clear and impartial information to all affected by assisted reproduction. We are the UK Government's independent regulator overseeing fertility treatment and research." A search bar for treatment is located below the banner, with a dropdown menu for "I am seeking information for...". Below the search bar are six buttons with arrows: "I want to research a clinic", "I want to know about egg freezing", "I want to find out about my donor", "I want to find out about treatments", "I want to understand funding", and "I want to donate my sperm or eggs".

The "Latest information" section features several news items:

- HFEA Business plan:** Find out about our plans for 2016/17.
- News:** New HFEA report indicates more needs to be done to reduce incidents in fertility clinics. 7 October 2016.
- News:** Celebrating 25 years of overseeing fertility treatment. 25 Regulating fertility treatment for 25 years.
- News:** Egg freezing figures available for the first time in Fertility Trends report 2014.
- Publication:** View our step-by-step guide to fertility treatment.
- News:** Sally Cheshire is reappointed as HFEA Chair until 2020.
- Event:** Next Authority meeting takes place 16 November.

The "More about us" section includes:

- How we make decisions:** Our committees make a lot of important decisions on behalf of our Board.
- What we do:** We license and monitor fertility clinics and research centres in the UK.
- Work for us:** Our staff make a difference to the lives of thousands of people every year.
- A bit of history:** The first IVF baby was born in 1978 and we were formed in 1991.

The footer contains social media links for Twitter and Facebook, and a "Fertility Focus" section with links for Work for us, For new clinics, Get information, and Clinic Portal. Below these are links for Jobs, Corporate partners, Patient resources, Press releases, Fertility information, Research data, and Complaints.

Recommendations

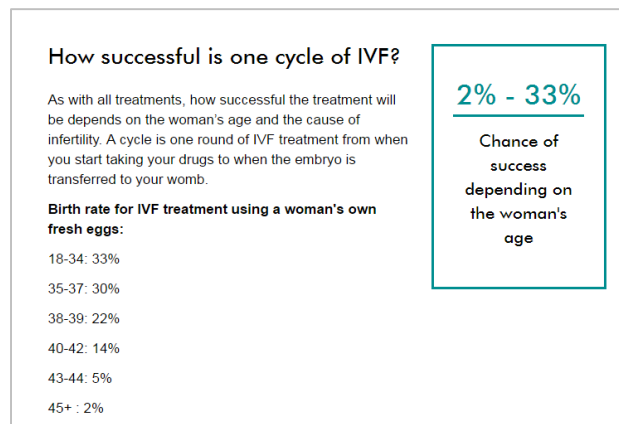
We have no specific recommendations for changes to the homepage, which appears to be performing well. However, please refer to later recommendations on providing a cue to indicate long scrolling pages, and closing up unneeded whitespace – in Section 7.

5 AUDIENCE AND TREATMENT PAGES

5.1 Audience journeys, connection with navigation options and expectations of context

- People who start their journey by accessing one of the audience pages such as Women over 38, or Single Women are then expecting that this will set the context for the rest of their journey, and are surprised at seeing general information on treatment types.

To explain this observation in more detail – we saw people who started by selecting an audience landing page as their route in who then seemed to expect it to set the context for their usage of the site, as if these were routes into dedicated site areas for this type of user. For example, one participant who had chosen “Women over 38” as her starting point then was confused when she had navigated to a page about IVF treatment, because the site switched back to talking about the treatment in general and not about her specific needs as a woman over 38.



We may need to do more to emphasise that the landing pages are just a starting point, they are not dedicated audience specific sub-sections of the website.

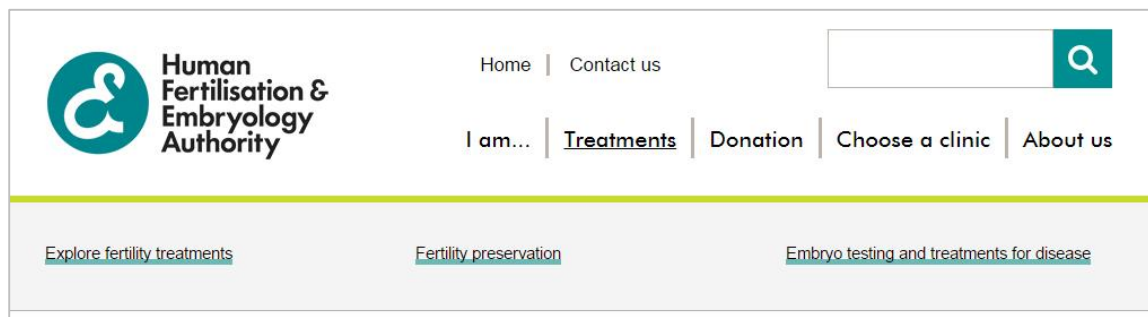
Recommendations

Description	Type
On the audience pages we recommend changing link texts to indicate that these are linking out of section – for example under treatments, the link for IVF currently just says “Find out more”. This could be changed to the version shown on the right, which indicates that the target is in a different section.	Content

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<p>In vitro fertilisation (IVF)</p> <p>IVF is suitable for people with a wide range of fertility issues and is the one of the most commonly used and successful treatments available for many people.</p> <p>Find out more</p>	<p>In vitro fertilisation (IVF)</p> <p>IVF is suitable for people with a wide range of fertility issues and is the one of the most commonly used and successful treatments available for many people.</p> <p>Read about IVF in the Treatments section</p>	
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- The IA of the Treatments section includes a layer that groups treatments as “Explore fertility treatment”, “Fertility preservation” and “embryo testing and treatments for disease”, with actual treatments such as IVF, ICSI and IUI moving down a level. This appeared to lead to more people going through audience landing pages as they relate to the terms more, and haven’t seen the treatment options that they were seeking.



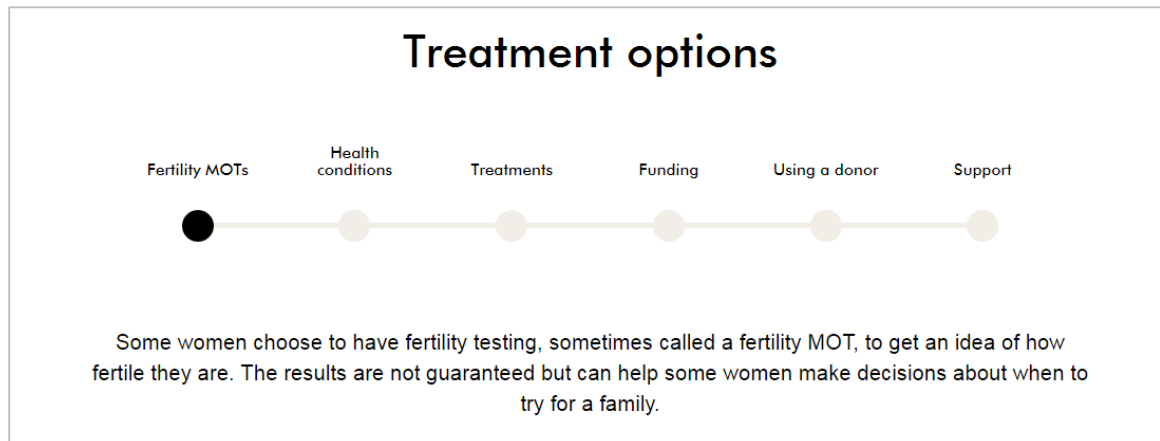
The reasoning here is that people have in their mind what they want to find, and that relates to treatment types and clinics (the two main use cases for the site), but the Treatments navigation doesn’t feature familiar terms, and this appeared to lead to most users ignoring it and instead selecting one of the audience landing pages, which they could relate to more closely.

Recommendations

Description	Type
<p>We could add the three high profile treatments, IVF, IUI and ICSI, as navigation options in the Treatments menu, running as a second row beneath the current options and providing short-cuts that take the user directly to the relevant treatment page.</p> <p>However, we recommend that action on this recommendation is deferred until after launch once analytics on live site usage are available.</p>	Content

5.2 Treatment journey feature

- Within the Audience pages the “Treatment journey” content is seen as navigation and its purpose misunderstood.



The treatment journey feature was misunderstood, with several users assuming it to be a next level of navigation, and expecting all the content below this feature to change based on their selection, not just the paragraph of text below.

One woman also commented that the depiction of a linear journey was interesting, but not necessarily reflective of the order in which some women need to consider the various stages.

In addition, the treatment journey feature is wrapping on some smaller screen dimensions and looks messy.

Recommendations

Description	Type
Review the design of the Treatment options page component. Recommend that the feature is placed inside a surrounding or background box or border to indicate that it is separate from the rest of the page.	Design
The wrapping issue might be able to be sorted out by sticking to content guidelines about the maximum number of content items in this feature. However, if the HFEA genuinely needs space to include more options then the design will need to be adjusted to accommodate this.	Content / design

5.3 Emotive user stories

- People are not connecting with the patients’ stories that are scattered through these sections due to lack of images, no names, and no links to expanded stories

The site contains many quotations and a fair number of user stories. People didn’t relate to these closely which is likely to be caused by the lack of imagery, lack of named sources and lack of expanded stories to click through to.

“ Donating to someone who wants a family is, quite simply, an extraordinary act of kindness”

Without a name or a face to attach to, it is not immediately clear who the quotes are from: the HFEA, a patient, a doctor? This led to people not associating themselves with the people the quote is from.

Recommendations

Description	Type
The quotation component appears to be being used for both pull-quotes from an article and for quotes from a patient story. The designs for these two elements need to be distinctly different. Early designs for patient stories included imagery of the people involved, names and links to detailed stories. These should be revisited as they will resonate with users much more.	design

5.4 Q&A styling

- The Q&A style is liked but implementation is clunky – especially the “open” and “close” controls, and the impact of long side boxes linked to a Q&A area that create lots of white space

In general people responded very positively to the question and answer style and the tone of voice being used. However, some didn’t understand the ‘open’ and ‘close’ controls. This is likely to be caused as the user needs to click on a separate control rather than the text of the question itself, which would be more intuitive. It is made worse when the presence of a side bar feature forces the length of the content area to expand (as shown below), and in this case the “close” control is some distance away from the actual content it relates to, and the other side of a dividing line which some will see as a mental ‘stop’ signal.

What are fertility drugs?

Fertility drugs can be used by some women who have been trying to get pregnant but have been unable to do so naturally. They are the main treatment for women who have fertility issues related to polycystic ovary syndrome and men and women who have fertility issues related to hormone imbalances.

Key facts:

Medication could be the first course of treatment for women with polycystic ovary syndrome

Women with no or irregular periods may also be treated with fertility drugs

Supplements may help with some sperm problems although current evidence is poor

These drugs should only be taken under the care of a specialist

– CLOSE

Description	Type
Change the design of the Q&A block so that the user clicks on the actual text of the question to open the content feature. Also, review the styling of the 'close' link to be more closely associated with the text of the Q&A content.	Design
The whitespace issue with "Key Facts" shown above is best treated as a content issue. Editors needs to write content to achieve balance in length between the central column and the content blocks used on the right.	Content

5.5 Precision of language

- There is a need for more precise language around birth and success rates

Some users were annoyed by the lack of precision when quoting statistics. For example, on the treatment page for ICSI the following statistic is shown.

How successful is one cycle of ICSI*?

ICSI itself is very successful at helping the sperm and the egg to fertilise – fertilisation happens in around 90% of cases. However, as in IVF there are still many other factors affecting a successful pregnancy, including the age of the woman and whether she has any fertility difficulties herself. Success rates for ICSI tend to be very similar to IVF so we don't include separate stats.

[Find out more about IVF success rates](#)

90%

Fertilisation will happen in around 90% of cases with ICSI

One woman questioned whether this was for women of all ages, or only for younger women. Also on the IVF treatment page the statistics refer to the “birth rate” and one woman questioned whether this was referring to live births, or all births (i.e. including still birth).

Recommendations

Description	Type
Review content, especially where statistics are stated that could be misinterpreted to remove any ambiguity.	Content

5.6 Treatment abroad

- The content on treatment abroad was seen as scaremongering

Some participants who had been for treatment abroad thought that the content on this topic was painting a negative picture and did not relate to their actual experience. Whilst they agreed that there are factors that potential patients need to consider, they also pointed out that they believed that they had received a high standard of care, in some cases better than their experience of UK clinics. They did not think that it was right for the HFEA to appear to be wanting to put women off this option.

Recommendations

Description	Type
Review content for tone and balance	Content

5.7 Audience categories

- Some participants questioned the audience categories, struggling to see themselves in the options available.

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In particular, there was no content aimed at men (or at least, the male participant didn't see himself in any of the categories offered), Single women sometimes objected to the term "single" and some donor conceived parents questioned being put into a joint category with donor conceived children.

Recommendations

Description	Type
Add an audience category and content page for "Men" (exact name tbc)	Content
Consider separating out Donor conceived children and Parents of donor conceived children into two separate categories.	Content
N.B. We do not recommend having more than 12 audience categories at the very most, as the navigation will become visually difficult to process.	


5.8 A lack of content aimed at 'Conformists'

- There was no content specifically aimed at conformists within the Treatment pages
Conformists are likely to respond well to content that they see as coming from an authority on a particular topic. The HFEA is one of the leading authorities on fertility treatment. Opportunities to communicate this authority to first time visitors are being missed. We think this is especially true on the key treatment pages for IVF, ICSI and IUI, which are known to be some of the most popular landing pages on the website.

An HFEA endorsement on these pages explaining the role of HFEA could help to establish the authority of the content.

Recommendations

Description	Type
Create a styled spotlight for inclusion on the Treatment pages that informs people this is official guidance from the government regulator. This could be placed at the top left of all Treatment pages	Design / content

 <p>Fertility treatment information provided by HFEA, the official regulator for fertility treatment in the UK.</p>	
<p>This needs design review – it is just a mock-up for illustrative purposes</p>	

5.9 Content aimed at Donors

- There is some confusion over the information architecture for donors, donor-conceived people, parents of donor conceived people + people seeking treatment with a donor

This round of testing involved several women who had used donor sperm or eggs, and some who had donated eggs as part of their own treatment. There was some confusion over the arrangement of content on the site aimed at the various circumstances.

- Some patients questioned the “Donation” section grouping which encompasses content aimed at people looking to become a donor, people seeking treatment with donor gametes and donor-conceived children and their parents.
- One patient questioned the audience category “A parent of / or a donor-conceived child” suggesting that they believed these should be separate groups.

Although it is possible to construct an argument for splitting out all these groups into their own section it should be highlighted that donor gametes are used in only 6% of all treatment, and so giving this audience an entire section of the website is already offering them high prominence given their numbers. It may be better to look at this as an issue of better sub-division and labelling of content within the relevant sections.

Recommendations

Description	Type
<p>On the Donation section landing page – use content headings to clearly sub-divide the page into information for different audience groups, as is done on the audience landing page targeting Parents of / Child born through donor conception.</p>	<p>Content</p>

6 CHOOSE A FERTILITY CLINIC

6.1 Supporting content around CaFC search

- Some users are getting lost or frustrated trying to find the actual search form, and some giving up completely

The HFEA took a decision that it doesn't want to provide direct access to the CaFC search from the homepage (as is done on the current live site) and rather it would like people to only access it after first having considered what it is they should be looking for in a clinic. A lot of content has been added to explain to users the various factors they may wish to take into account and to explain where the data comes from and how to read it.

We saw at Private Beta stage that the users responded well to this content and were still able to find the search form, however since then the content in this section has expanded, and based on our observations it appears to have gone too far, with some users struggling to find the search form and some giving up entirely.

It should be pointed out that users did feel there was a lot of useful content here, and things that they really should know about – it's just that there is so much of it between them and their actual goal that they are getting lost.

- Too many similar titled pages in the CaFC section caused confusion, including people ending up on circular journeys.

Part of the issue above is caused by having several pages with similar titles and content that appears to cross-over. We observed several users appearing to get lost on circular journeys taking them back to the page they started on, and others ending up going off on a tangent and leaving the Choose a Clinic section.

- “Choose a clinic” (from the main navigation and “Learn how to choose a clinic” (from the second level navigation) appear to be identical.
- “Choose a fertility clinic” (from the second level of navigation) is ambiguous given that the whole section of the IA is called “Choose a clinic” – many saw this as the same thing.
- “What to look for in a clinic” sounds very similar to “Learn how to choose a clinic” but these are different pages – this link also appears twice in the current page content, once at the top and once in a blue box

How to choose a clinic

If you're paying for treatment yourself you'll want to make sure you're choosing the right clinic, but with so many to choose from deciding which one best meets your needs can feel a bit overwhelming.

It may be tempting to rely solely on success rates but the reality is that most clinics are broadly all as good as each other – small differences in rates are usually down to the different types of patients treated.

Finding out how other patients and our inspectors rate the clinic, the clinic's opening hours and location and whether they have a female doctor could all be equally important factors to consider.

[Find out more about what to look for in a clinic](#)

Data we publish

We collect data from fertility treatments and publish much of it on our website including individual clinic data.

If you want to find out how success rates for different treatments are you can read our annual report.

If you're looking for clinic data you can view: how our inspectors rate clinics; how our inspectors rate birth rates; donor insemination rates; partner pregnancy rates; multiple pregnancies; and rates using donated eggs, sperm or embryos.

[How we manage your data](#)

These link to the same page but the titles and link labels are different

Things to consider

What to look for in a clinic

Struggling to choose a clinic? Let us help with our tips on what to look for in a great clinic.

[Find out more](#)

Your wellbeing

Every licensed clinic is required by law to give you the chance to receive counselling. Find out more about how to look after your wellbeing and find support groups.

[Find out more](#)

Problematic clinic

Thankfully, patients can have a problem. However, a mistake can change your life.

Content labelling within pages can also be misleading, for example in the 'What to look for in a clinic' page we observed users reading the "Start the process" content and following the link to "learn about the different treatments and add-ons", but expecting this to be the first step of a step by step process towards finding a clinic. In fact, it takes them out of the section and into the Treatments area of the site.

Starting the process

If you've been trying to have a family for some time, there's sometimes a temptation to get on with treatment as soon as possible.

However it's really worth taking some time to understand your diagnosis, [learn about the different treatments and add-ons](#) and research the right clinic.

The more informed you are, the easier it will be to make key decisions throughout your treatment and the more in control you'll feel at every stage of the process.

This is a complicated field, but with a little preparation and research you'll be able to start your fertility journey in the best possible way: being as prepared as you can be for what's round the corner.

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Also on this page there are links to “Search for a clinic”, “Searching for a clinic” and “Choose a clinic”. These all take the user to the search form, having three different labels caused confusion with people wondering if they are the same page.

- The main CTA button for CaFC doesn’t draw the users’ attention and was missed by some even if they were on the correct page, and on the right area of the page.

The placement and styling of the main CTA for CaFC didn’t help users to find the search form.

Apart from appearing right at the bottom of a very long page (5 pages of scrolling on an average laptop screen), the placement and styling caused some users to miss it entirely. This could be because the label “Choose a Fertility Clinic” is too similar to the label of the section as a whole, or could be because of the poor colour contrast on the CTA button (white on lime green), or because the content box it is contained in looks remarkably similar to the other coloured content boxes on the page. Either way, it was not apparent to some users, even those who were looking at the right area of the page.

Ready?

Use our Choose a Fertility Clinic service to find the clinic that’s right for you. If you’re an NHS patient, use it to research the clinic you’ll be having treatment at.

Choose a Fertility Clinic is the only tool that publishes comparable information about all fertility clinics in the UK. That’s because we collect data from clinics about all the treatments they carry out. And we inspect each clinic at least every two years to check their standards.

The statistics we publish on the beta service are calculated from real data which has previously been provided and checked by the clinics themselves. Some of the statistics on the beta service are different from those on the current Choose a Fertility Clinic service. This includes a new births per egg collection rate which links fresh and frozen transfers, and the use of age at the time of egg collection rather than at transfer for donor or frozen treatments. Before the beta service goes live we will ask all clinics to check their statistics for the new site.

Please remember that this is a beta service, so it’s not the final version. We’d love you to try it out and give your feedback, but if you are selecting a clinic, you should use the existing [Choose a Fertility Clinic service](#).

Choose a Fertility Clinic

Recommendations

Description	Type
Review page titles in this section to remove cross over and ambiguity.	Content
Reduce the number of and/or length of content items on the main Choose a Fertility Clinic page.	Content
Avoid using terms like “start the process” unless referring to an actual online process.	Content
Consistently refer to the Choose a Fertility Clinic search with the same link title ... e.g. “Choose a Fertility Clinic” (if that is to be the chosen name).	Content
Review styling of the final CTA on the Choose a Clinic page. Suggested style is centred, full width and using large type and high contrast for the call to action button.	Design / Content

6.2 CaFC search form

The CaFC search form had been rearranged since the Private Beta to draw attention to the ability to specify a distance from a postcode. The new arrangement worked a lot better.

Recommendations

Description	Type
Shorten “Please enter your location (Optional)” removing the word “(optional)” – although GDS do encourage labelling of optional form fields, this isn’t really a form in the true sense, and this is probably superfluous. The functionality to show all clinics should be made more explicit if that was the intention.	Design / Content (RR)

6.3 CaFC results listing

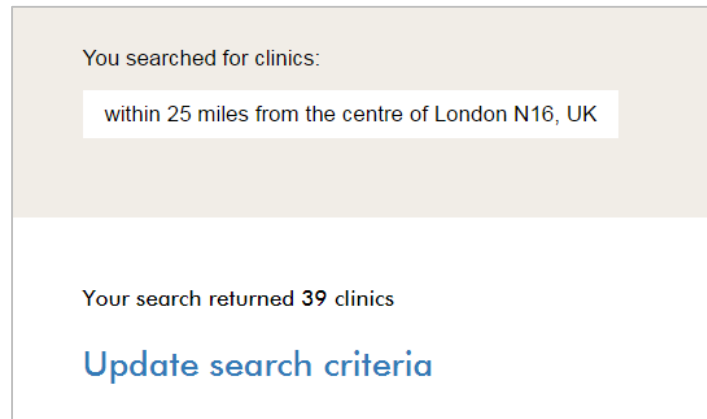
- Cannot update search criteria from the results page, users needed to go back a page.

From the Search results page we asked some users how they would update their criteria, and we observed people looking for a way to do this on the page, and then generally hitting the browser back button.

In the page content the link to “Update search criteria” is visually separated from the statement of the criteria used, which may have led to people missing it. Although it should also be questioned

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why they cannot simply update the criteria from this page, given that there are only two (a postcode and a distance).

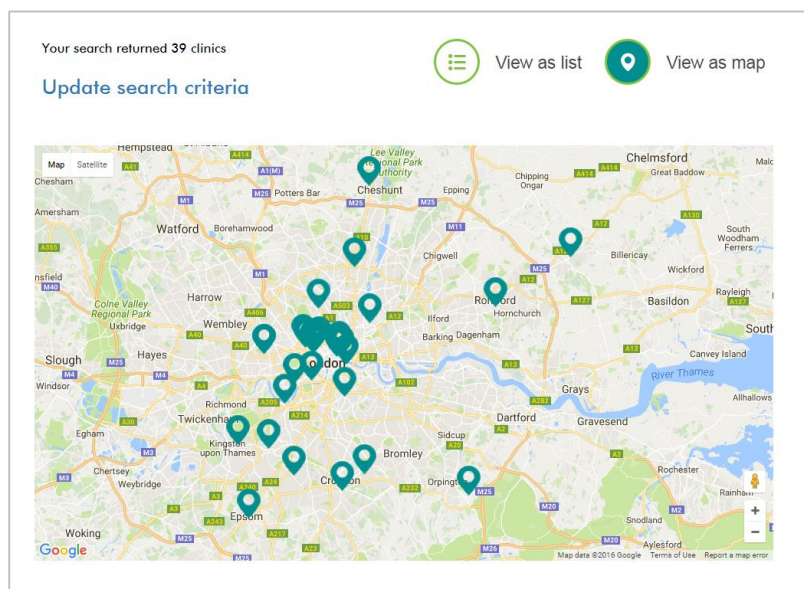


Recommendations

Description	Type
Place controls to update the location and distance criteria directly onto the search results page, and then remove the “update search criteria” link which will no longer be needed.	Design / Functionality

- The “view as map” option was missed entirely

Nobody used the “view as map” feature on the listing page, despite some users suggesting that the exact location of a clinic is important to them. This could be because they are only interested in the exact location after first deciding if this is a clinic that interests them, or could be because they were missing the ‘view as map’ control.



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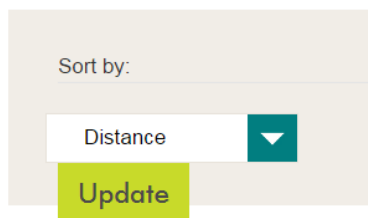
Although it did not come up in testing, the accessibility of the map function should also be reviewed.

Recommendations

Description	Type
Move the “view as list” “view on map” controls to sit directly above the search results list. N.B. Connected to recommendation to remove sort control below.	Design / Functionality
Review functionality of map to add a side bar with a basic list, working in a similar way to the main Google Maps service. N.B. This did not come up in testing.	Design / Functionality

- Sorting options were misunderstood, and seen as superfluous by some

Some of the users who tried interacting with the sort control didn’t understand the sort options offered – “distance”, “A-Z” or “Z-A”. Some thought that the “Z-A” option this was unnecessary, and others thought the whole control was unnecessary.



Recommendations

Description	Type
Based on lack of interest / understanding of this feature – recommend it is removed (commented out).	Design
ALTERNATIVE If the feature is to be kept it should be on the same horizontal line as the “view as list” and “view on map” controls.	Design

If all the three recommendations above are all implemented the search results page might look something like the wireframe illustration shown below.

Your search results

Location

Enter your postcode or region

N16 7AQ

Distance from postcode

Select a distance from your location that you would be willing to travel

Within 25 miles



Search

Your search returned 39 clinics



View as list



View as map



Homerton Fertility Centre

Treatment with storage

- Some users missed links to detailed pages

There is no indication that the clinic name is clickable unless you hover over it, and the style reuses the H1 style. Some users did not actually think there were detailed pages about each clinic until prompted.

Treatment options

H2 tag – not clickable

Intrauterine insemination (IUI)

IUI or artificial insemination is commonly used by people who are using donated sperm in their treatment, including single women and female

In vitro fertilisation (IVF)

IVF is suitable for people with a wide range of fertility issues and is the one of the most common, used and successful treatments



Barts Health Centre for Reproductive Medicine

Treatment with Storage

Clinic name – uses same style, not clickable

3.3 miles

Treats

✓ NHS

Treatments offered

✓ IVF

Staffing

✓ Female doctors available

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Recommendations

Description	Type
Review design of hyperlinks in the search results – either adding a consistent style to the hyperlinks such as the underline used elsewhere on the site or a button to “view clinic details”.	Design
ALTERNATIVE RECOMMENDATION Make the entire rectangular area for each clinic clickable rather than just the title, and use a visual affordance such as brightening/dimming to indicate that the results can be clicked	Design

- The treatments list on the search listing is not exhaustive, and some users pointed out omissions such as donor insemination.

The image below shows the display of treatments for the Homerton Fertility Centre. On the results page, only three of the four treatments were shown (see inset). One user who had been to a clinic that she was reviewing highlighted a similar omission. This confused them to a point where they were saying “I’m sure they offer donor insemination, so this isn’t right”

Homerton Fertility Centre
Treatment with Storage
1.53 miles

Treatments offered

- ✓ IVF
- ✓ ICSI
- ✓ IVF for patients with communicable viral infections

Staffing

- ✓ Female doctor
- ✓ Has name

Treatments

- IVF
- ICSI
- Insemination
- IVF for patients with communicable viral infections

Recommendations

Description	Type
If treatments are to be listed on the results page they must be the full set offered by that clinic, not a subset. This may mean changing the style of this area as some clinics will have long lists of treatments and the current bulleted list style may not be appropriate given the content area limitations. Given that the two surrounding content areas (“Treats” and	Design

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“Staffing”) use the same style, it may be necessary to include those in the review as well.

- Inspection rating sometimes is not understood as being a rating from HFEA by some users (some weren't aware that HFEA gives clinics a rating and didn't know where this data had come from).

Not everyone who participated was aware that HFEA gives ratings to clinics. Some were also questioning on the results page, where this inspection rating has come from.



Recommendations

Description	Type
Change the Inspection rating feature so that the text below the green circles reads “HFEA gave this clinic a rating of X / 5”	Functionality / Content (RR)

- Assumption from some people that patients rating comes from the clinic not HFEA

One user questioned the “Patient rating” statistics on the results page – and her assumption was that this was a rating provided by the clinic, not by patients.

Recommendations

Description	Type
No action required – focus on communication on the detail page instead	–

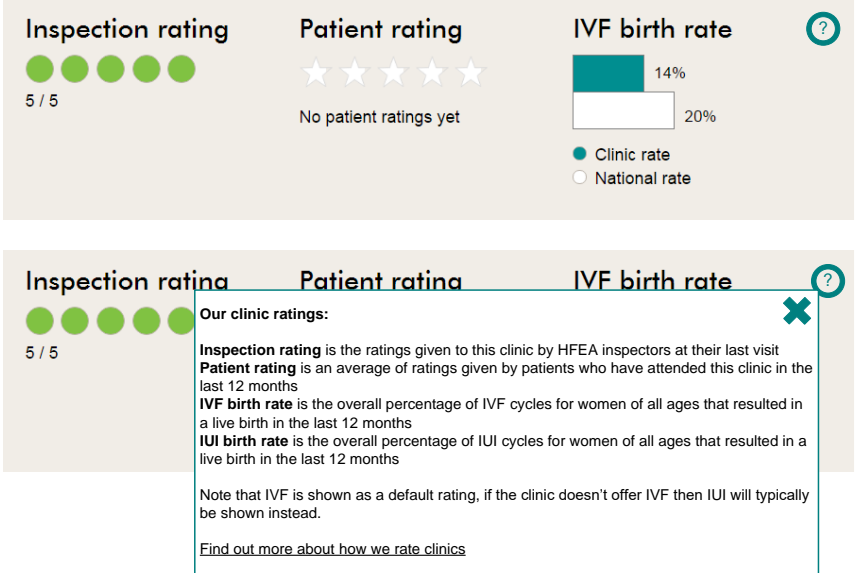
- Some users wanted an explanation and a bit more precision over the statistics.

One user was specifically wanting to know if the IVF birth rate referred to “live births”. Others wanted to understand what HFEA means by the “national rate” and how they arrive at this statistic, for example – whether it includes all cases or just a certain age range, and if it includes

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patients of a particular type – such as single women and same sex couples who may not have a fertility problem.

Recommendations

Description	Type
<p>Include a help icon as part of the ratings bar which can be used to reveal information on how clinics are rated.</p> <p>A mockup of how this might look is below:</p> 	<p>Design / functionality</p>

- There were some cases where for a clinic the IUI rate is reported on the results page, but it wasn't clear to users why some clinics show IVF and some IUI

The data shown on the results page is based on a simple choice, if the clinic offers IVF then this is shown, if it doesn't then IUI is shown. The exception being clinics that have recently begun treatment in which case no data is shown at all.

Users were confused by these discrepancies, including one who was frustrated that the clinics were showing different treatments and pointed out that they weren't "comparing like for like", and another who had received IVF treatment at a particular clinic but their data wasn't showing, presumably because it was a new service, but there was nothing on screen to explain this, just a blank space. She commented that "I know they offer it, because I've been a patient there".

Recommendations

Description	Type
<p>See recommendation above concerning adding a help icon to the ratings box.</p>	<p>-</p>

6.4 Clinic detail pages

It should be pointed out that in general users responded very well to the clinic detail pages and saw them as a huge improvement on the current site. That is not to say there isn't room for improvement.

- Some key details may need more prominence as users were searching around for them—particularly Clinic web address, Clinic street address and Opening hours



These details are in the Clinic Details accordion at the bottom of the page. Some users felt that they needed more prominence as they thought this was important information.

Recommendations

Description	Type
Replace the text hyperlink for the clinic's web-address with a CTA button labelled "Visit clinic website"	Functionality / Design
Change the ordering of items in Clinic details to show address, contact and opening hours first, followed by the map and image, followed by the remaining details.	Functionality / Design

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Clinic details ⬆

<p>Address</p> <p>Homerton University Hospital NHS Trust Homerton Row London E9 6SR</p>	<p>Contact</p> <p>P: 020 8510 7660 F: 020 8510 7637 E: fertility.unit@homerton.nhs.uk</p> <p style="background-color: #90EE90; padding: 2px; text-align: center;">Visit clinic website</p> <p>Licence holder Miss Tracey Fletcher</p> <p>Person responsible Mr Anil Gudi</p>	<p>Opening hours</p> <p>Monday to Friday: contact the clinic Saturday: contact the clinic Sunday: contact the clinic</p>
		 <p style="font-weight: bold; font-size: 1.2em;">AWAITING IMAGE</p>
<p>Eligibility</p> <p>BMI limit Patients from abroad Treats NHS patients Treats private patients Upper age limit of patients treated Upper male age limit</p>	<p>Treatments</p> <p>IVF ICSI Insemination IVF for patients with communicable viral infections</p>	<p>Donor services</p> <p>Known donor programme</p>
<p>Counselling and support</p> <p>Compulsory counselling for donors Counselling services at clinic Dedicated counsellor Number of counselling sessions included</p>	<p>Staffing</p> <p>Female doctor available</p>	<p>Facilities</p> <p>Wheelchair access Parking</p>

6.5 Clinic detail pages: Stats

- The explanatory texts around the graph were ignored by most users, they aren't visually associating them as an explanation of the graph

Many users struggled to correctly interpret the graph for statistics. In particular, there was confusion over the term “national rate”, with some wondering how this is calculated, and also over the “reliability range”. The explanatory text for both of these is visually disassociated from the graph due to the number of things that are being said on one page. Above the graph, the full explanatory text for all three charts is shown although only one is visible on screen. Whereas with the reliability range, on a standard laptop screen, if the graph is in the middle of the page the explanation of reliability is off the bottom of the screen.

What are the clinic's statistics?

We collect data about the treatments clinics carry out. See this clinic's latest statistics below.

What is the clinic's IVF birth rate?

Find out this clinic's IVF/ICSI rates for births per embryo transferred, births per egg collection and multiple births.

Births per embryo transferred
We present births per embryo transferred (rather than births per cycle) because fertility professionals say it's the best measure of a clinic's success and it allows you to make a fair comparison between clinics. Remember, it can't tell you your individual chance of success (only your doctor can do that), but it does give a fair overall view of their performance.

Births per egg collection
This rate shows the chance of success from all the fresh embryo transfers within two years of one egg collection. Births per embryo gives you an indication of success rates for individual transfers, births per egg collection gives an overall picture of success rates for a full course of treatment (which can include one fresh and a number of frozen transfers).

Multiple birth rates
For some people, having twins may seem like a wonderful thing, but multiple pregnancies are much less safe for both mother and babies. That's why we've set a target for all clinics to have a multiple birth rate of 10% or lower – see how well they're performing below.

Births per embryo transferred
01/07/2013 to 30/06/2014

14% 20%

■ Clinic's rate ■ National rate ■ Reliability range

● All ● Under 38 ● 38 and over

► Births per embryo transferred
► Births per egg collection
► Multiple birth rate

Consistent with national average

The clinic birth rate is based on 1754 embryos

National rate
It may be tempting to obsess over success rates, but the most important thing to focus on is whether the clinic's results are consistent with the national average. Try not to read anything into differences of few percentage points, as these are often down to chance rather than being a reflection of a clinic's abilities.

Reliability range
The reliability range shows how confident we are that a clinic will repeat its success rate in the future – the narrower the range, the more confident we can be. Large clinics normally have a narrower reliability range. That's not because their data is more accurate but because their rate is less likely to be affected by small changes in the number of births in one year. Small clinics aren't worse but their success rate is more likely to be affected by these kinds of changes.

[View detailed statistics](#)

Recommendations

Description	Type
Move the explanatory text for each graph inside the dynamic screen area, so that only the explanatory text for the current active graph is shown.	Functionality / Design
Use in-line help icons to reveal the explanation of "national rate" and "reliability range" instead of this text being visible all the time.	Functionality / Design

- The graphs themselves were not well understood – whilst most, but not all, people correctly interpreted the clinic birth rate vs the national rate, there was little understanding of 'reliability' despite an explanation being on the page itself.

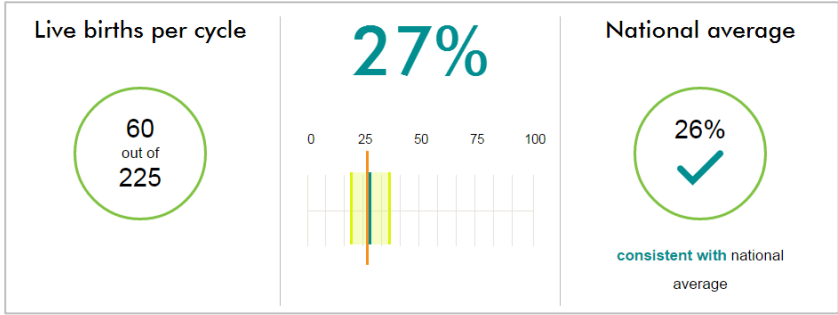
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Not everyone understood what HFEA means by the National Rate. It is notable that the explanatory text that appears simply advises people on not reading too much into statistics, it does not actually say what the National Rate represents or how it is calculated. Some wanted to know if there were age brackets used in the calculation, for example. Others wondered if it included types of patient like same sex couples, who do not have a fertility problem.

In terms of the chart itself one user questioned why the national rate line is longer than the clinic's performance line, and if this signified anything. Two users questioned why the scale of the chart isn't labelled and didn't know what the numbers mean.

Reliability was more problematic, with the majority of users not understanding correctly what this was indicating. On some screens the reliability bar was not seen by the user due to low contrast with the background, they only saw the end strips. Some users were observed clicking or hovering over the text 'reliability range' and expecting a pop up hint of some type.

Recommendations

Description	Type
Review the explanation of "national rate" which does not actually state how this is currently calculated.	Content
<p>Change the styling of the graph to be closer to that styling used on the "detailed statistics" page (example shown below). Specifically introducing bigger fonts for a statement of the clinic rate, and a clearer indication of the national average, and whether this clinic is consistent with it.</p> 	Design

- Some users thought this information was too detailed and wanted something that was more high level.

It should be noted that the mathematics behind confidence intervals are difficult to explain, and some participants still didn't understand fully even when it was explained to them by the facilitator. Some did comment that this was too much detail for them, they would be happy with a simple percentage.

Recommendations

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Description	Type
See recommendation above regarding introduction of large font for the headline stat from the clinic.	Design

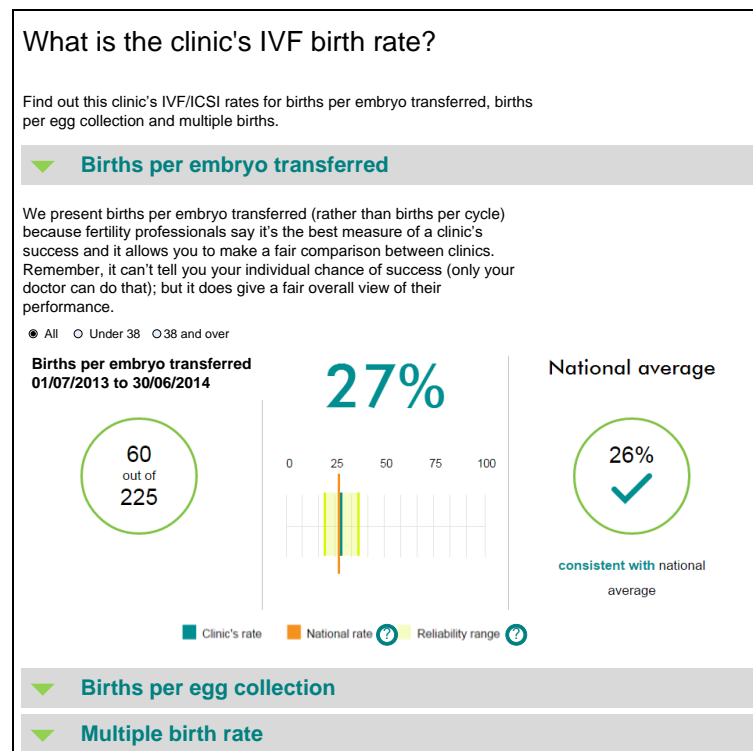
- The graph controls were missed by some

Not everyone initially saw the graph controls to the right – although most did figure them out eventually. Some used the “view detailed statistics” button before noticing the control.

Recommendations

Description	Type
Integrate the graph controls into the central column rather than to the right.	Design

If all the recommendations on graphing are followed the page might look something like the mock-up below, although design input is clearly required:



6.6 Clinic detail pages: Detailed stats pages

- Splitting the form over 4 pages frustrated people, with one giving up entirely

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Many users were frustrated with the interface to access detailed statistics, which is split over four pages, made more cumbersome as the control is off the bottom of the page on a standard laptop screen dimension, meaning users have to scroll to reach it.

Recommendations

Description	Type
Create a single, dynamic form page instead of four separate pages, using the four separate pages as a fall back only for people who don't have JavaScript.	Functionality / Design

- Some users were very happy with the level of detail, others didn't need it

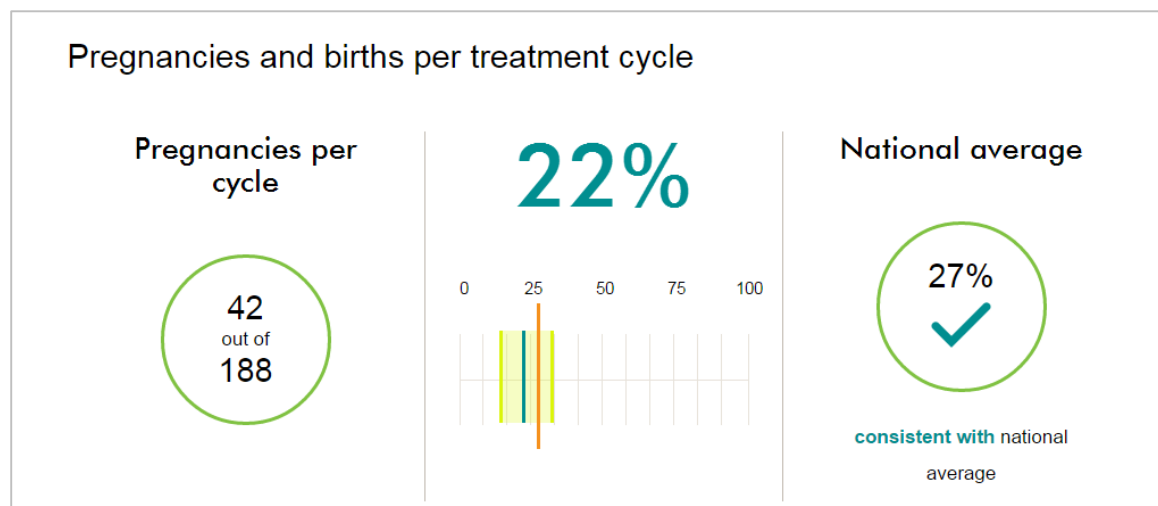
Although the detailed statistics were too much for some people, others thought it was very good, with one even commenting that this was the only data that really mattered as it meant she could access data for people in a much more similar situation to her own.

Recommendations

Description	Type
No action required	-

- The colour coding on graphs and page features was not explained

On the detailed graphs for pregnancies and births some commented that the colour coding on the graphs isn't explained (it is the same as on the main clinic detail pages, but not explained here).



Recommendations

Description	Type
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Add a key to the colours used, as appears on the main clinic details page	Design
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- The display of high level percentages and the “Consistent with average” badges was seen as better than that on the main Clinic details page.

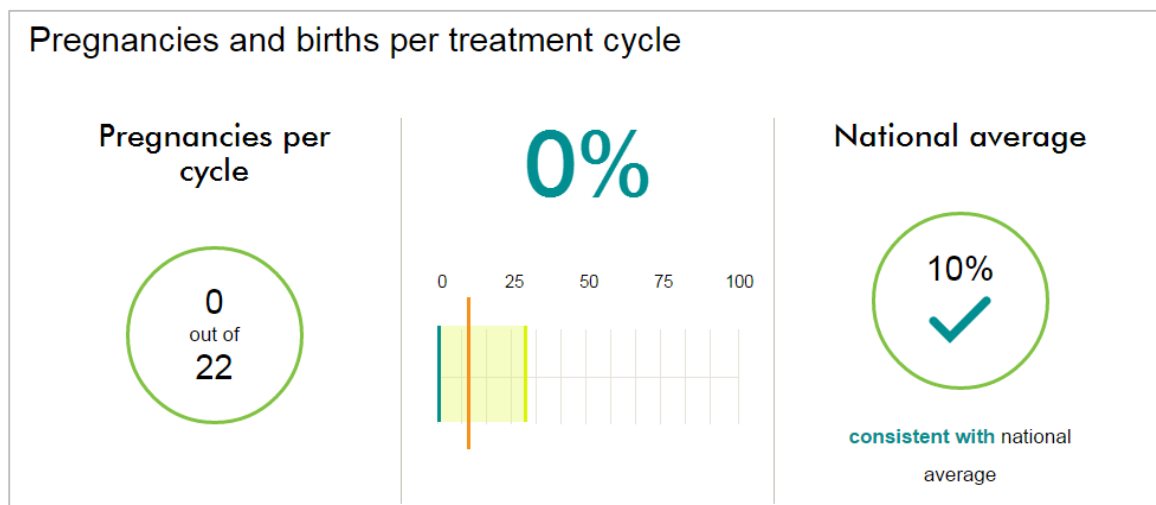
Some users commented that they preferred this presentation of data to the main clinic detail pages, in particular they liked the big clear statistics in large type.

Recommendations

Description	Type
No action required	

- One user questioned what stats of 0% meant

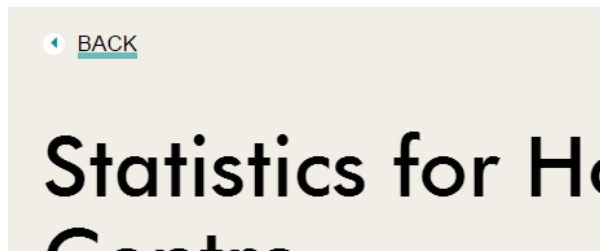
One participant spotted that some of the graphs show a statistic of 0% and questioned whether this meant the clinic had no successes, the HFEA has no data, or the clinic doesn't actually offer that treatment option. Note that this can be interpreted in the example below by looking at the number of pregnancies per cycle, in this example the clinic has performed the operation 22 times with no successes, it is possible that if the user had longer on the task they would have worked this out.



Recommendations

Description	Type
No action required	-

- The link back to the clinic details page was not clear,



We asked people how they would get back to the clinic page, and saw that most users used the browser back button instead of the “back” link. This may be because it is the only page on which a back button appears and it was simply missed. The issue is complicated by the nature of the interface to reach the detailed stats page, meaning the user needs to press their back button four times.

Recommendations

Description	Type
Changing to a single page form to access the detailed statistics section will resolve the issue with having to click multiple times to get back to the clinic details page, after which the back button is superfluous and should be removed.	Functionality / design

6.7 Clinic detail pages: Patient ratings

- People wanted clarity on how the ratings are to be policed, and how HFEA intends to establish whether reviews are from patients

Whilst patient ratings were a popular feature, some questioned whether they would trust the ratings without having knowledge of how HFEA intends to police the reviews. They were expecting that the reviews would be from patients only. The situation may not have been helped as several clinics appear to have added a perfect rating for themselves already.

Recommendations

Description	Type
HFEA should add content that explains how it intends to police ratings to ensure they genuinely come from patients. This should be linked to from the Clinic Details page.	Content

- As with previous rounds of research - people expected to see free-text comments

Throughout the project end users have consistently said they would prefer to see written reviews and comments rather than just star ratings. Some users struggled to relate to the star ratings on their own without having any context for who was giving ratings and the circumstances of their case.

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Recommendations

Description	Type
Given that HFEA has decided not to publish free-text reviews, it should instead state why it does not, and go on to explain that comments left as part of the rating process will be made available to HFEA inspectors. This should be communicated on the Clinic details page and on the Rating form.	Content

- One user questioned why of the 4 ratings, four provide only an average, whereas the fifth shows how many people voted each rating.

The screenshot shows a rating form with five questions and their corresponding star ratings and vote counts:

- Question 1: "How likely are you to recommend this clinic to friends and family if they needed similar care or treatment?" - 5 stars, "Based on 1 ratings".
- Question 2: "To what extent did you feel you were treated with privacy and dignity?" - 5 stars, "Based on 1 ratings".
- Question 3: "To what extent did you feel you understood everything that was happening throughout your treatment?" - 4 stars (1 greyed out), "Based on 1 ratings".
- Question 4: "Was the level of empathy and understanding shown towards you by the clinic team?" - 5 stars, "Based on 1 ratings".
- Question 5: "Did you pay what you expected?" - A bar chart showing 1 vote for "It was about right" and 0 votes for "It was much cheaper", "It was slightly cheaper", "It was more expensive", and "It was way above the estimate".

The rating system used shows four ratings as an overall average and one split out into separate numbers of votes for each grade. One user questioned why the extra detail wasn't available for every rating. This may be because they are expecting to be able to drill down into the ratings based on experience of using similar systems on sites like TripAdvisor and Google Maps.

Recommendations

Description	Type
The four-star ratings that show only an average should support drill down to reveal how many people gave each rating. This could be delayed until more data has been gathered, as it would be rather superfluous before then.	Functionality / design

7 GENERAL COMMENTS

7.1 Navigation

- Implementation of main navigation could be improved – some users struggled

The hover interaction used on the main navigation is very sensitive, especially when trying to traverse the mouse from right to left. It is easy to accidentally trigger a neighbouring section of the navigation when making sweeping mouse movements.



This was most apparent on the Choose a clinic menu, where the menu options appear at the opposite end of the screen to the user's mouse, making this problem more apparent. Several users became frustrated with the navigation.

Recommendations

Description	Type
Right align options in the mega drop-down menu on desktop view to reduce the issue with having to make large mouse movements to reach items at the other side of the screen.	Design

7.2 HFEA role in complaints

- Some didn't know that HFEA can get involved in complaints against clinics. Some people see failure of fertility treatment as personal rather than anything to do with the clinic, and also don't know how to complain.

As an observation some participants were surprised to hear that HFEA can get involved in complaints against clinics. This may need to be brought out more.

Recommendations

Description	Type
Add information about HFEA's role in complaints handling to the About Us landing page.	Content

7.3 Technical / design glitches

- Some technical issues were seen with users on older version of IE

Two users were testing on IE9. We saw some graphical glitches, especially within CaFC search and clinic detail pages.

Recommendations

Description	Type
Review and resolve design glitches in IE 9	Design / Functionality

7.4 Antivirus software conflict

- Some issues were seen when viewing the site with particular anti-virus plug-ins, especially Norton

Users with Norton AV were having pop up alerts on most pages that they had to continually dismiss.

Recommendations

Description	Type
Review and resolve clashes with common AV software	Functionality

7.5 Whitespace

- Some templates have strange amounts of whitespace, in extreme cases leading to people erroneously believing they were at the bottom of a page

On some pages the gaps between content seem to be notably wider. Some users erroneously believed they were at the bottom of the page, for example, on the Choose a Fertility Clinic page.

This issue is extenuated for users of Internet Explorer, where the browser scroll bar is hidden automatically when the user isn't moving their viewing window, so there is no visual cue that there is more content further down the page.

Recommendations

Description	Type
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Review all page templates and determine if proportion of whitespace between / within content components is appropriate, especially when viewed on 'standard' sized screen resolutions.	Design
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7.6 Length of pages

- There is a concern that some pages have become too long.

Whilst people did scroll, many didn't go all the way to the bottom or had stopped reading the detail lower down long pages. There is no prompt to tell them to keep scrolling on some pages.

Recommendations

Description	Type
Add a visible indicator that there is more content below the current viewing window, with a click action that the user can press to scroll down by the height of one screen.	Functionality / design

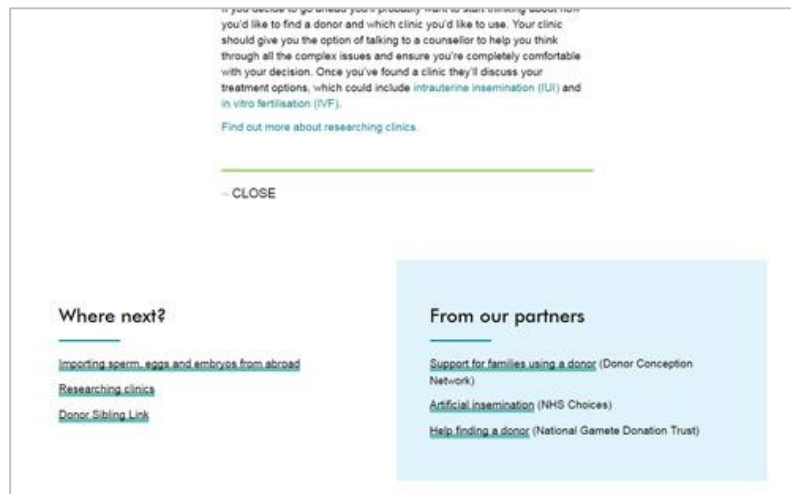
8 ENCOURAGING EXPLORATION AND LEARNING JOURNEYS

Note – this content is repeated from the report from the Private Beta stage. The observations and the recommendations have not changed.

- We want to take users on a journey where they learn through using the site. Some areas of the site do a good job of educating the user, others less so
- There are many instances of things users wanted to click on to find out more, that don't currently go anywhere – HFEA should consider expanding content in these areas



- Onward journeys through “where next” features at the bottom of the page were not noticed by many, they need to be seen as part of the page flow rather than a bolt on



- CaFC pages are not currently linking back to main site content to explain terms and concepts and educate site visitors

Treats	Treatments
BMI limit	IVF
Patients from abroad	ICSI
Treats NHS patients	Insemination
Treats private patients	Surgical sperm collection
Upper age limit of patients treated	Fertility preservation
Upper male age limit	In vitro maturation
	IVF for patients with communicable viral infections

Recommendations

Description	Type
Fact box/spotlights should link through to more information on that topic OR be positioned next to a content section where they are pulling data out from that content block.	Design & Content
"Where next?" content blocks should be part of the main page column layout – to make them appear to be part of the article not the footer.	Design
CaFC pages should be linking back into content on treatments to help people to learn what they are looking at. (also discussed in the Clinic Details recommendations)	Design

IfQ Advisory Group beta CaFC recommendations

Headline IVF birth rate – births per embryo transferred

- The AG has not changed its recommendation that birth events per embryo transferred is the best measure because it reflects good embryology skills and promotes single embryo transfer.

Headline IVF birth rate – grouping all ages

- The HFEA should only present whether a clinic is consistent, above or below the national average in search results and at the top of a clinic page (as the headline birth measure) because this is the most important message for patients.
- The basis for this calculation should be the under 38 group of patients.

Headline IVF birth rate – grouping treatments

- Natural cycles, donor egg and cycles including embryo testing should be excluded from the calculation of the headline IVF birth rate.
- The HFEA should consider presenting the natural IVF birth rates for clinics that do this treatment further down the clinic page next to DI, IVF and IUI.
- The HFEA should use only fresh IVF and ICSI cycles with the patient's own eggs for the headline calculation.
- The HFEA should make it even clearer to patients that the headline figure and all clinic statistics will indicate to them the quality of a clinic but will not be a personal predictor.

Births per egg collection (cumulative rate)

- The HFEA should continue to calculate the cumulative rate, 'births per egg collection' on a two-year period.

Detailed statistics – age breakdown at 38 and getting the right balance

- The HFEA should continue to use the two age bands (under 38, 38 and over) on the clinic profile page along with data for all ages.
- Other more detailed age bands (the 6 currently used) should still be available on the detailed statistics pages.

Reliability range and small sample sizes

- The reliability range is a useful piece of information when presenting clinic statistics and the HFEA should ensure that this is made more understandable to users.
- The HFEA should set a sensible minimum data level for data presentation so that data is not identifying when there are small sample sizes

Draft business plan 2017/18

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

Details:

Meeting	Authority
Agenda item	11
Paper number	HFEA (16/11/16) 815
Meeting date	16 November 2016
Author	Paula Robinson, Head of Business Planning

Output:

For information or decision?	For decision
Recommendation	The Authority is asked to approve the draft business plan at its current stage of development, and to note that a draft will be submitted to the Department of Health according to their timetable.
Resource implications	In budget.
Implementation date	Throughout 2017/18 business year.
Communication(s)	Publication on HFEA website and Intranet.
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex A: Draft business plan for 2017/18 – activities section

1. Background

- 1.1.** The Authority has been developing its new strategy for some months now, and this work is progressing well.
- 1.2.** Our business plans are designed to help us deliver our overall strategy, year by year. This business plan will deliver the first phase of our new three year strategy, which is still in development and will be published next April, to synchronise with the business year.
- 1.3.** As a reminder, the business planning cycle consists of the following main steps:
- | | | |
|-------------|---|--|
| August | – | Early thinking by CMG (done) |
| October | – | First draft of 2017/18 business plan produced (done) |
| November | – | Draft approved by Authority (this meeting) |
| December | – | Draft submitted to Department of Health (DH) |
| January | – | DH comments received |
| February | – | DH checkpoint meetings and budget discussions |
| March | – | Finalisation of budget with Authority and DH |
| April / May | – | Formal DH approval and publication on website. |

2. Early draft

- 2.1.** Since our new strategy is not yet final, it may prove necessary, over the next few months, to reprioritise activities in this draft business plan. The Authority will agree the strategy in January, and the business plan will be reviewed following that meeting to ensure it reflects the strategy.
- 2.2.** Some sections of the business plan are always written later in the business year for practical reasons. Therefore, at this stage only the activities section is included in the annex. The sections that will be produced later include:
- What we did in 2016/17
 - Measuring our performance in 2016/17
 - Financial picture.

3. Recommendation

- 3.1.** The Authority is asked to approve the draft at Annex A for submission to the Department of Health in December (or when requested).
- 3.2.** The Authority is asked to note the steps involved in the continuing development of the business plan. If major changes are made to the current version prior to submission to DH, the new version will be circulated to members for comment.

- 3.3.** The Authority is also asked to note that we will later add to the business plan a specific action plan to address recommendations in our Triennial Review report, which we expect to be published shortly.
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Annex A: Draft business plan 2017/18 – activities section

Activities	Methods and channels	Benefits and outcomes	Timescale
Consistent support and outcomes for patients and donors			
Strategic objective 1: increase consistency in treatment standards, outcomes, value for money, and support for donors and patients			
<p>Ensure that all clinics are well regulated and provide a high quality, consistent service.</p> <p>Outcomes in this area of work will support the Department of Health's shared delivery plan (SDP) – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities, with an increased emphasis on consistent standards across the sector, and between inspections. We will be clearer about what good performance looks like and will use our skills and our data to help clinics to be more compliant, more of the time.</p>	<p>All clinics and research establishments in the sector are appropriately inspected and monitored against the requirements of the Act and published performance indicators, and issued with licences for up to four years.</p> <p>Continued programme of unannounced inspections. Assurance of consistent standards and safety for the public and other stakeholders.</p> <p>Positive overall impact on quality of care, outcomes, safety, support, and information clinics provide to the HFEA and publish (eg, on their websites). Patients know that all clinics are safe and appropriately licensed.</p> <p>Reduction in the number of critical, major and other non-compliances.</p> <p>Reduction in the number of clinic incidents, owing to learning from own and others' mistakes.</p>	<p>Throughout year</p>
	<p>Implementation of any recommendations for the inspection regime resulting from the HFEA's triennial review (reporting in November 2016).</p>	<p>Identification of further quality improvements that we could make.</p>	<p>September 2017</p>
	<p>Ensuring governance tools underpinning licensing and other decisions are in place and effective.</p>	<p>Efficient and effective decision-making is maintained. Decisions are evidenced and consistent.</p>	<p>Throughout year</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
	<p>Completing an options appraisal, started in 2016/17, for the future handling of representations and appeals processes.</p>	<p>To ensure that the HFEA's processes balance sound governance with cost effectiveness.</p>	<p>Date tbc</p>
	<p>Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.</p>	<p>Growing area of work dealt with effectively and efficiently, with applications processed according to performance indicator timelines.</p> <p>Public confidence assured in the regulation of mitochondrial donation.</p> <p>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.</p>	<p>Throughout year</p>
<p>Identifying and implementing ways of improving the quality and safety of care.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Continuing our relentless focus on quality and safety of care in inspection activities – in particular through focusing on shortcomings in the taking and recording of consents, medicines management, data submission, multiple birth rates, and information published on clinics' websites.</p>	<p>Improved compliance and a positive impact on the quality of care, outcomes and safety of patients.</p> <p>Clinics have reduced vulnerability to expensive adverse legal and reputational risks, and greater awareness of these risks.</p> <p>Tracking of non-compliances, and the responsiveness of clinics in completing actions arising from inspection recommendations, in order to measure our impact (through our internal strategic performance monitoring mechanisms).</p> <p>Clinics' understanding of, and adherence to, correct consent procedures (including those associated with legal parenthood) and their understanding of the importance of getting this right, is improved.</p> <p>Patients and donors have a better experience of being asked for consent, and feel fully informed.</p> <p>If an issue subsequently arises (such as the death of someone with gametes in storage), the correct consents are more likely to be in place and are legally clear and robust.</p>	<p>Throughout year</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to evaluate areas of regulatory concern and identifying performance levers.	Improved levels of compliance. Inspection recommendations and advice or alerts targeting relevant issues, for maximum impact on quality of care, outcomes, and the safety of patients in clinics.	Throughout year
	Continued strong focus on learning from incidents, adverse events and complaints from patients, in dialogue with the sector. This will include a focus on incidents and clinics' learning culture during inspections, and publication of our annual review of clinical incidents.	Publication of report on clinical incidents 2016. Sector provided with useful information about learning points from incidents and adverse events. Learning gained, to inform future inspections. Patients' negative experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse event. Collaborative relationship established with the recently established NHS Improvement so as to consider wider lessons learned that may have relevance.	November 2017 Throughout year
	Improved Register data quality, as a result of work done under the Information for Quality (IfQ) programme.	More 'right first time' data submission from clinics into the Register. Better service quality for Opening the Register (OTR) applicants. Fewer data submission and data accuracy related non-compliances found on inspection and audit.	March 2018

Activities	Methods and channels	Benefits and outcomes	Timescale
	Working with commercial groups of clinics so as to improve quality, consistency and compliance on a group-wide basis, when relevant.	<p>A clinic group's central Quality Management System (QMS) can be used to best effect across the whole group.</p> <p>A benefit in one clinic is shared to others in the group without needing to wait for the next inspection date - for the ultimate benefit of patients.</p> <p>A more efficient, effective and quality-driven way of working for the clinics involved and the HFEA.</p>	March 2018
	Collaborating with professional stakeholders (including the British Fertility Society, the BFS) to put patients in touch with better information and services when they first realise they may have a fertility issue.	<p>More informative signposting on our website, for those who are seeking preliminary information about fertility issues and options.</p> <p>Empowering patients, so they feel more equipped and are able to ask the right questions, regardless of the level of knowledge of their own particular GP about fertility issues and available treatments.</p>	March 2018
<p>Using our data to improve the chances of successful treatment</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	<p>With the aim of increasing birth rates, while avoiding adverse outcomes, we will work with our professional stakeholders to define success rates and what affects them. Analysing our outcome data, we will identify areas where there is scope to improve outcomes, and publish our findings.</p> <p>Continuing to publish the annual Fertility Trends report, and to focus on success rates through inspection reports and risk tool alerts.</p>	<p>Agreed definition of success rates, published on our website.</p> <p>More information published so that clinics can compare themselves more easily based on different factors such as patient age.</p> <p>Fertility treatment in 2016 report published.</p> <p>Patients' chance of a live birth is maximised.</p> <p>Patients understand the risks of a multiple birth and the advantages of single embryo transfer.</p> <p>The debate about success is reconfigured according to a new, shared, understanding of it, and a set of substantiated success factors.</p>	<p>March 2018 and further work in 2018/19</p> <p>March 2018</p>
Improving value for money, for both patients and NHS commissioners.	Exploring how we can make use of externally generated benchmarking information to assist NHS commissioners in securing fairly prices and effective fertility services for patients.	Patients know the price of a treatment at a given clinic at the start of treatment, and pay what they expect to pay.	March 2018

Activities	Methods and channels	Benefits and outcomes	Timescale
<p>Outcomes in this area of work will support the Department of Health's SDP – objective 9: Improving services through the use of digital technology, information and transparency.</p>	<p>Eliciting more feedback from patients as to whether they paid what they expected to pay for fertility services.</p>	<p>Patients question costs, and particular additional costs, more often.</p> <p>Less variation in the price of treatment.</p> <p>The NHS pays a consistent and fair price for IVF.</p>	
<p>Improving the support patients and donors receive from clinics.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Improving the emotional experience of care in clinics, by defining and promoting best practice to clinics, and focusing on support at inspection.</p> <p>Ensuring that best practice is applied to donors and donor conceived people as well as to patients.</p>	<p>When patients or donors first walk into a clinic, they know what they should expect.</p> <p>People realise they should seek an assessment and diagnosis before commencing treatment.</p> <p>A consistently positive experience of care including properly taken consents and wrap-around support at all stages.</p> <p>Regardless of treatment outcome, but especially if it was unsuccessful, patients know they should expect care and support from the clinic beyond their final treatment.</p> <p>More information on our website for prospective patients, and specific signposting for patients who have experienced unsuccessful treatment.</p> <p>Clinics more aware of their responsibilities to patients beyond the immediate treatment setting.</p>	<p>March 2018</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
<p>Evaluating the provision and take-up to date of the counselling support pilot for donor-conceived people wishing to access information held on the HFEA Register.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Evaluation of the second full year of the three year pilot of counselling support services for applicants to the Register¹.</p>	<p>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, throughout the pilot period.</p> <p>Mediation services are in place for when donors and donor-conceived people meet.</p> <p>Basic mediation training and systems in place for dealing with identity release to donors and donor-conceived people.</p> <p>OTR applicants feel more supported and will be prepared to deal with the information they receive from us.</p> <p>Second annual evaluation of the pilot provided to the Authority.</p>	<p>Piloting continues through to June 2018.</p> <p>September 2017</p>
<p>Implementing new EU requirements relating to the import and coding of donor eggs and sperm.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	<p>Completion of projects initiated in 2014/15 to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells.</p>	<p>Improved clarity for clinics, patients and donors.</p> <p>Improved internal clarity and updated procedures for our decision-making committees.</p> <p>Compliance with the new EU directives.</p> <p>Robust processes in place to ensure the quality, safety and traceability of imported gametes and embryos.</p>	<p>October 2017</p>

¹ Explanatory note: While those conceived following the law change in 2005 are not yet old enough to access identifying information about their donor, those conceived before this law change (but after 1 August 1991), with a donor that was originally anonymous but who has since removed their anonymity ie, re-registered as identifiable, are in many cases aged 18 or above, and therefore old enough to access identifying information.

Activities	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 2: use our data to improve access to donation and treatment			
<p>Improving access to treatment, and information about access to treatment.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 7: Enabling people and communities to make decisions about their own health and care.</p>	<p>Providing advice for patients about access to treatment, through various channels, including information for those considering going abroad for treatment on how they might access services in the UK.</p>	<p>People understand the possibilities and the hurdles, and can weigh up the options open to them (measured through patient surveys).</p>	<p>March 2018</p>
<p>Improving access to donation, support for patients and donors and information about access to donated gametes.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 7: Enabling people and communities to make decisions about their own health and care.</p>	<p>Providing advice for patients about access to donated gametes, and encouraging better donation support for donors and patients, including those considering using unlicensed donor sperm services.</p> <p>Working with clinics, sperm banks and voluntary organisations to improve the availability of donor sperm.</p>	<p>People understand the process and the hurdles, and are prepared for donation and treatment (measured through patient/donor surveys).</p> <p>Donors and patients are better supported by clinics.</p> <p>An increase in UK-based sperm donation.</p>	<p>March 2018</p> <p>March 2018</p>

Safe, ethical, effective, proven treatment

Strategic objective 3: publish clear information for patients about the efficacy and safety of treatments and treatment add-ons, while supporting innovation

<p>Make use of our new website and other channels to increase patients' insight into the science and evidence base of new and existing treatments, including treatment add ons.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care; and objective 9: improving services through the use of digital technology, information and transparency.</p>	<p>Inclusion of up to date scientific content in our website so as to provide and maintain our expanded range of information about current and future treatment options and treatment add ons, and the scientific evidence base for these.</p> <p>Responding to new scientific developments and associated reporting, correcting myths and misunderstandings where necessary.</p>	<p>Patients and others turn first to the HFEA for up to date, clear unbiased information. Prospective patients have clear information on which to base decisions about treatment or add ons.</p> <p>Patients feel safe, knowing they can expect certain standards in clinics, and are more aware of the potential risks of new/different treatments or add ons as well as the possible benefits.</p>	<p>Throughout year</p>
	<p>Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.</p>	<p>The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year.</p> <p>The horizon scanning panel meets once per year.</p> <p>Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments.</p> <p>Future work planning is facilitated by early identification of upcoming issues.</p>	<p>Throughout year</p> <p>June/July 2017</p> <p>Throughout year</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
Strategic objective 4: support and promote data and embryo research			
<p>Improving the overall quality of data and embryo research, by improving both the rate and accuracy of reporting of patient consents.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 6: supporting research, innovation and growth.</p>	<p>Promoting and explaining research findings and research that is in progress (both embryo research and data research).</p> <p>Encouraging more patients to allow their data to be used in research, and to donate unused embryos for research.</p> <p>Ensuring that clinics explain research consent adequately and record consent properly, and report consents accurately to the HFEA.</p>	<p>Patients know they can take part in research, and how it might benefit future patients.</p> <p>Patients can easily donate embryos to research and research centres can gain access to donated embryos for their projects.</p> <p>Higher rate of consent to research from patients.</p> <p>Improvement in consent-taking and reporting by clinics.</p>	March 2018
	<p>Information provision for researchers requesting access to Register data.</p>	<p>Information for researchers is provided within 90 calendar days of approval.</p> <p>Register information is used to best effect, to promote understanding and facilitate good research, and ultimately patient benefit.</p>	Throughout year

Improving standards through intelligence

Strategic objective 5: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve our information for patients.			
<p>Driving quality improvements in treatment standards and outcomes by using our data and regulatory intelligence.</p> <p>Outcomes in this area of work will support the Department of Health's shared delivery plan (SDP) – objective</p>	<p>An information strategy setting out how we will analyse, publish and use our data.</p> <p>A re-shaped organisation equipped with enough analytical capability and capacity to extract more value from the data we hold.</p>	<p>An information strategy setting out our plans.</p> <p>Donors, parents and donor-conceived people understand where their information is stored, the responsibilities of the clinic and the HFEA, and their access rights.</p> <p>Patients have confidence in their clinic as a life-long information guardian with excellent data submission practices.</p>	March 2018

Activities	Methods and channels	Benefits and outcomes	Timescale
2: creating the safest, highest quality healthcare services.		Better outcomes from NHS cycles.	
<p>Maintaining our role as the UK's competent authority for ART in the European Union.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	Participation in competent authority events and implementation of associated EU decisions.	<p>We attend and participate in two meetings per year.</p> <p>Up-to-date intelligence gained about European perspective, helping to inform UK approach to patient safety and care.</p> <p>Free movement of gametes and embryos enabled within the UK and standards upheld in the UK that are consistent with the rest of the EU.</p>	<p>June and December, annually.</p> <p>Throughout year</p>
<p>Maintaining the Register of Treatments and Outcomes and supporting clinics in reporting the data.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 2: creating the safest, highest quality healthcare services.</p>	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.	<p>High quality data available to develop patient information and respond to information requests.</p> <p>Risk-based regulation and evidence-based policy-making are better supported.</p>	Throughout year
<p>Publishing and supplying the information we hold, for the benefit of stakeholders.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care; and objective 9: improving services through the use of digital technology, information and transparency.</p>	<p>Regularly updating Choose a Fertility Clinic (CaFC) information to assist patient choice.</p> <p>Continued publication of inspection reports on CaFC.</p> <p>Following the implementation of the revised CaFC, continuing to develop and improve the presentation of clinic comparison information and user experience scores, guided by patient feedback.</p>	<p>Six monthly verification and publication schedule in place, maintaining provision of up-to-date and accurate information.</p> <p>Inspection reports continue to be published via CaFC, providing useful insights for patients.</p> <p>Published outcome data is more useful and easier to understand and sets up positive incentives for improvements.</p> <p>Acquisition of ongoing feedback enables us to evaluate the effectiveness and usability of the new presentation, and to plan future improvements.</p>	<p>Throughout year</p> <p>Throughout year</p> <p>Throughout year</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
	Continuing to facilitate timely access to information from the Register for those who are entitled to it.	Opening the Register requests continue to be met in a sensitive manner and within required time limits (20 working days, excluding time for counselling).	Throughout year
	Facilitating access to information under various regimes and fulfilling Government requests.	Legal and Parliamentary requirements continue to be met within time limits.	Throughout year
	To continue to publish statistical and other reports.	<p>'Fertility treatment in 2016' report covering 2015–2016.</p> <ul style="list-style-type: none"> - Provides patients, clinic staff and others with up-to-date, high quality information about a range of topics. - Provides important information to those affected by donor conception, to patients seeking treatment and to us, to help us to enhance the quality of care that patients and donors receive in clinics, through our regulatory work. - Report carries 'official statistics' status. <p>Report on incidents and alerts.</p> <ul style="list-style-type: none"> - Contributes to a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. - Promotes transparency and maximises opportunities for learning from incidents to improve quality of care for patients. - Provides the sector with the most up-to-date information. 	<p>March 2018</p> <p>November 2017</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
<p>Gaining insight into the patient experience in clinics and promoting good practice based on feedback.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care.</p>	<p>Collecting more patient feedback through new routes, including our website and social media.</p> <p>Analysing and using this intelligence to inform our activities and our messaging to clinics, sharing the information with professional stakeholders.</p>	<p>Improvement in the quality of services and patient/donor support as a result of patient ratings and other feedback.</p> <p>Quantifiable increase in the amount and frequency of patient feedback available to the HFEA and our professional stakeholders.</p> <p>Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach.</p>	<p>March 2018</p>
<p>Responding effectively to specific enquiries from individuals.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 7: enabling people and communities to make decisions about own health and care.</p>	<p>Continuing to respond to the many individual patient and public enquiries we receive each year.</p>	<p>Individual patients and members of the public are able to ask specific, sometimes complex, questions and receive a tailored and meaningful response.</p> <p>We remain responsive, and continue to be able to handle the range of one-off enquiries raised by individuals, providing a considered and informed response within a reasonable timescale.</p> <p>We are able to identify any trends and common themes in the enquiries we receive, informing the development of additional information which could be placed (for example) on our website.</p>	<p>Throughout year</p>
<p>Making more targeted and responsive regulatory interventions, in the interests of quality and consistency, based on our data.</p> <p>Outcomes in this area of work will support the Department of Health's shared delivery plan (SDP) – objective</p>	<p>Applying the intelligence available to us from inspections, the sector, patient feedback, and analysis of our data to make more targeted and responsive interventions.</p>	<p>Ability to make earlier and more responsive regulatory interventions, without the need to wait for the next inspection point.</p> <p>Regulatory performance is more consistent across the inspection cycle.</p>	<p>March 2018</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
2: creating the safest, highest quality healthcare services.			
<p>Ensuring the HFEA is a good value organisation and makes best use of its limited resources.</p> <p>Outcomes in this area of work will support the Department of Health's SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance.</p>	<p>Working more smartly with our limited resources, capitalising on recent improvements in our information systems.</p> <p>This will entail re-shaping our capability and capacity profile, so as to make best use of our new website and Register.</p>	<p>Resources are deployed in the interests of high quality care for everyone affected by assisted reproduction.</p> <p>Achieving measurable 'added value' and internal efficiency.</p> <p>Benefits of Information for Quality Programme realised.</p>	Throughout year
	<p>Maintaining our staff capacity and skills, in line with our people strategy.</p>	<p>We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties.</p> <p>Continuing to develop our staff to ensure they have the skills they need, through Civil Service Learning and other means.</p>	Throughout year
	<p>Ensuring internally provided support services run smoothly and are efficient.</p>	<p>Our infrastructure is effective and supports the delivery of the strategic vision.</p> <p>Central systems, processes and tools are efficiently run, giving good value and service.</p>	Throughout year
	<p>Responding to the HFEA's triennial review report, as required, when it is published.</p>	<p>Ensuring the organisation is soundly run, providing best possible value, and compliant with Government targets.</p>	Publication expected in November 2016
<p>Ensuring the HFEA is easy to deal with and offers a professional service.</p> <p>Outcomes in this area of work will support the Department of Health's</p>	<p>Full release of the HFEA's improved Register function and processes (the completed EDI, data submission and verification system, the Clinic Portal, and the data dictionary).</p>	<p>Reduced transactional costs for clinics and increased satisfaction.</p> <p>'Right first time' data quality and reduction in unnecessary effort by clinics submitting the data.</p>	October 2017

Activities	Methods and channels	Benefits and outcomes	Timescale
<p>SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance.</p>	<p>Continuation of the engagement arrangements with clinics on fees charged, established in 2014/15.</p>	<p>Accountability and transparency in respect of the fees we charge clinics.</p> <p>Fees Group continues to be run effectively, and annual review of fees takes place.</p>	<p>Throughout year</p>
<p>Responding as appropriate to new government rules on transparency, innovation and better regulation (the Enterprise Bill, the ‘growth duty’ and the Regulators’ Code).</p> <p>Outcomes in this area of work will support the Department of Health’s SDP – objective 3: maintaining and improving performance against core standards while achieving financial balance, and objective 6: supporting research, innovation and growth.</p>	<p>Complying with new better regulation requirements that may emerge from the current consultation exercise by:</p> <p>Consulting on an innovation plan in Spring 2016.</p> <p>Reporting in our Annual Report on the growth duty and compliance with the Regulators’ Code .</p> <p>Complying with the Business Impact Target by identifying and reporting any ‘in-scope activity’ (a new ongoing duty).</p> <p>Note: Regarding the proposal to establish a Small Business Appeals Champion in every body, it was proposed by BIS in their February 2016 consultation that the HFEA should not be in scope for this requirement. Subject to the outcomes of that consultation no activity is expected in this area.</p>	<p>The HFEA responds in a manner consistent with its legal status, and proportionately within our small resource envelope, carefully recognising our duties.</p> <p>Innovation plan consultation completed and responses considered.</p> <p>Annual Report publication including additional required information.</p> <p>Compliance with the Business Impact Target for any activities that may be in scope.</p>	<p>Throughout year</p> <p>June 2016</p> <p>July 2016</p> <p>Throughout year</p>
<p>Ensuring the HFEA is an effective collaborator and partner in the interests of the efficiency of the wider Department of Health group of ALBs and other health organisations.</p> <p>Outcomes in this area of work will support the Department of Health’s SDP – objective 4: improving</p>	<p>Continued participation in the collaborative ‘one stop shop’ for life sciences to provide regulatory advice to those working in the life sciences industry.</p>	<p>Continued constructive joint working between the HFEA, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Authority (MHRA).</p> <p>Businesses and other organisations in the life sciences industry enabled to quickly and easily navigate the different regulators and allow them to access the right advice more quickly.</p>	<p>Throughout year</p>

Activities	Methods and channels	Benefits and outcomes	Timescale
efficiency and productivity of the health and care system.			
	<p>Sharing services and infrastructure with other organisations as practicable:</p> <p>Maximising benefit of finance resources shared with HTA.</p> <p>Continuing with service level agreements (SLAs) with relevant other organisations for certain HR services and using Civil Service Learning as a key learning and development provider.</p> <p>Continuing to receive support services from the landlord of our office premises, via an SLA.</p>	<p>We continue to operate in as efficient a way as possible, extracting maximum value from shared support arrangements and seeking other opportunities.</p>	Throughout year
	<p>Collaborative and partnership working with other ALBs and health regulators UK wide, such as the CQC, MHRA, UKAS, HRA, GMC, NIB and the home nations, maintaining the close positive working relationships that have been developed over the past several years (particularly in response to the McCracken report, reviewing the HFEA and the HTA, which was published in 2013).</p>	<p>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 (as was done previously with the CQC, removing overlap in relation to the regulation of medicines management and surgical procedures in clinics).</p> <p>Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators.</p>	Throughout year
Maintaining our previously established collaborative information management relationships.	Maintaining our good working relationships with relevant other bodies, such as the Government Digital Service (GDS) the Health and Social Care information Centre (HSCIC)	<p>We contribute to the objectives of the wider health system, with respect to information management.</p> <p>Learning from best practice and sharing expertise, so that we can make use of each other's strengths and</p>	Throughout year

Activities	Methods and channels	Benefits and outcomes	Timescale
<p>Outcomes in this area of work will support the Department of Health's SDP – objective 4: improving efficiency and productivity of the health and care system.</p>	<p>and being an active member of the National Information Board (NIB).</p>	<p>knowledge in data management, systems integrity and security.</p>	

Strategic risk register

Strategic delivery:

Setting standards

Increasing and
informing choice

Demonstrating efficiency
economy and value

Details:

Meeting	Authority
Agenda item	12
Paper number	HFEA (16/11/16) 816
Meeting date	16 November 2016
Author	Paula Robinson, Head of Business Planning

Output:

For information or decision?	For information
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.
Resource implications	In budget
Implementation date	Ongoing
Communication(s)	The risk register is reviewed quarterly by the Corporate Management Group (CMG), and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 21 September, and will review it again at its meeting on 7 December.
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	Annex A: Strategic risk register

1. Latest reviews

- 1.1. CMG reviewed the risk register at its meeting on 7 September. Three of the twelve risks are above tolerance. CMG reviewed all risks, controls and scores. CMG's specific comments are contained in the risk register at Annex A.
- 1.2. The risk register was last discussed at AGC on 21 September. No changes were proposed to the risk scores. Any comments from the Authority will be fed into the Committee's next review on 7 December.

2. Recommendation

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

HFEA strategic risk register 2016/17

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage ¹	Residual risk	Current status	Trend*
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	12 – High	At tolerance	↓ ↔ ↔ ↔
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	12 – High	Above tolerance	↔ ↔ ↔ ↔
Data	D1: Data loss or breach	Efficiency, economy and value	10 – Medium	At tolerance	↔ ↔ ↔ ↔
Data	D2: Incorrect data released	Efficiency, economy and value	9 – Medium	Above tolerance	↓ ↔ ↔ ↔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	9 – Medium	At tolerance	↔ ↔ ↔ ↔
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	9 – Medium	At tolerance	↔ ↔ ↔ ↔
Capability	C1: Knowledge and capability	Efficiency, economy and value	9 – Medium	Above tolerance	↔ ↔ ↔ ↔
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	8 – Medium	Below tolerance	↔ ↔ ↔ ↓
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	8 – Medium	At tolerance	↔ ↔ ↔ ↔
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	8 – Medium	At tolerance	↔ ↔ ↔ ↔
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	8 – Medium	At tolerance	↔ ↔ ↔ ↔
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	4 – Low	At tolerance	↔ ↔ ↔ ↔

* This column tracks the four most recent reviews by AGC, CMG, or the Authority (eg, ↑ ↔ ↓ ↔).

Recent review points are: CMG 18 May ⇒ AGC 15 June ⇒ Authority 6 July ⇒ CMG 7 September/AGC 21 September (no changes to scores)

¹ Strategic objectives 2014-2017:

Setting standards: improving the quality and safety of care through our regulatory activities. (Setting standards – quality and safety)

Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families. (Setting standards – donor conception)

Increasing and informing choice: using the data in the register of treatments to improve outcomes and research. (Increasing and informing choice – Register data)

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

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

CMG overview – summary from September risk meeting

CMG reviewed the risk register and risk scores at its meeting on 7 September. Detailed review of the legal (LC1) risk was undertaken offline with the risk owners.

CMG heard about the Department of Health risk audit recommendation that ALBs and the Department consider risk interdependencies across the health and care system, and heard that the HFEA would be seeking to embed this approach into future management of risk.

With regard to IfQ risks, as we move toward the end of the Programme, perhaps unsurprisingly a number of risks have surfaced or increased. There is still a volume of work to complete, and the separate IfQ report on the agenda gives further information about current challenges. Three new inter-related strategic risk sources, arising due to IfQ, were added to the register in September. These related to the various possible impacts if Electronic Patient Record System (EPRS) providers did not make the necessary changes to their systems to submit clinic treatment data to the new Register structure following IfQ release 2. The risk areas affected were firstly RM1 (the risk of a loss of regulatory authority), because any gaps in data could impact effective regulatory monitoring. Secondly, IfQ1 (the risk to improved information access), since any data that had not been provided would then not be available to provide to patients through Choose a Fertility Clinic. And finally, FV1 (financial viability - risk of overspend) could be impacted if the HFEA were not able to bill clinics for treatments that they had undertaken but not reported to us. CMG heard that this risk was not yet imminent since it would only apply following IfQ release 2, in 2017; however, the impact of the risk could potentially be wide-reaching if it were not managed effectively. CMG heard that the IfQ Programme Board had received proposals for a revised delivery plan and that this would positively affect the proximity of the risk. Work was also underway to develop further mitigation plans for these risks, alongside the finance and compliance teams where needed. CMG agreed that the HFEA was able to tolerate this situation at the current time, however, appropriate mitigation plans and risk monitoring would be essential.

Under item C1 (Knowledge and capability), CMG discussed the impact of the Head of Corporate Governance leaving the organisation in September. Although this would leave the HFEA with a Head level vacancy again, the residual risk level for this risk had previously been raised when there had been two Head vacancies at once, and had not been lowered since that point pending bedding in periods. Because of this, the risk would not increase as a result of having a vacancy again.

CMG reassessed the residual risk likelihood for IfQ3 (delivery of promised efficiencies), and agreed it should be reduced to a score of 2, since, with the mitigations currently in place it was unlikely that the HFEA would not be able to deliver these improvements. This brings this risk to within tolerance, with a score of 8.

All Finance related risks were reassigned to the Head of Finance pending the arrival of the new Director of Finance and Facilities at the beginning of November. Ownership will be revised shortly, to reflect that the new Director has recently started.

CMG also considered operational risks (under a different report) and noted that the main theme of each team's operational risks was resources. This has been the position for some time now and risks in this area were raised by all teams, though resource pressure was particularly being felt in the Legal team at the moment. Other teams have been made aware of these pressures on the Legal team and external support is being sought where useful.

An increase in the number of quality-related operational risks across teams was also noted. This was especially highlighted in a new business planning team risk, rated 'high', that 'unanticipated or uncontrolled risks could become live issues or cause internal incidents'. The importance of ongoing operational risk management with teams, during a busy period, was highlighted to all Heads. The business planning team are also planning to implement further measures to embed risk management in teams and upskill more junior team members, though this also requires the ongoing commitment of Heads.

The Finance team raised as a new, high, operational risk the potential for non-payment of suppliers caused by technical issues with the HFEA being migrated to Barclays internet banking. This has subsequently been escalated with Barclays and is largely resolved, reducing the risk.

AGC feedback – September meeting (21/09/2016):

The committee asked the executive to give more consideration to 'plan B' for the website, in the event of an adverse JR judgment, or in the event of Red Dot (the current, outgoing content management system, which was old and unsupported) failing completely.

CMG discussed this issue and confirmed that the new website was capable of being used in place of the current website, and that if we needed to deploy it before the JR was resolved, the information under dispute could be removed as a short term measure. The new website made use of a different content management system, Umbraco, which was up to date and supported, as well as more stable and reliable than RedDot. This option meant that our communications channels would remain open, and this seemed sufficient mitigation. In addition, the HFEA had a range of other channels for communicating important information to clinics and other stakeholders, including the clinic portal, social media, Clinic Focus, and email. This was felt to provide a sufficient range of options for important communications should the worst happen and access to the current website be lost.

All concerns raised by AGC have been noted and addressed.

Criteria for inclusion of risks:

- Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.
- Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank

Risks are arranged above in rank order according to the severity of the current residual risk score.

Risk trend

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

Risk scoring system

See last page.

Assessing inherent risk

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

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

System-wide risk interdependencies

We also consider whether any HFEA strategic risks or controls have a potential impact for the Department or any other ALBs.

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner	
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇄ ⇄ ⇄ ⇄ Peter Thompson
			Likelihood	Impact	Inherent risk	
			3	5	15 High	
			Residual risk level:			
			Likelihood	Impact	Residual risk	
2	4	8 Medium				
Tolerance threshold:			8 Medium			
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary	
Inspection/reporting failure.		Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Sharon Fensome-Rimmer		At tolerance.	
		Audit of Epicentre conducted to reveal data errors. Queries now routed through Licensing, who hold a definitive list of all licensing details.	Completed October 2015 – Siobhain Kelly		The Head of Corporate Governance and Chief Inspector started in their posts (in March and May 2016 respectively). While any new staff member is bedding into the organisation it is likely that some degree of ownership of controls would sit with both the respective Directors as well as the Heads themselves until fully trained. The Head of Corporate Governance subsequently left the HFEA in September 2016 which left a Head vacancy again (now filled). There will continue to be a period of bedding in for the Chief Inspector.	
Regulatory monitoring processes may be disrupted as a result of the temporary inability of Electronic Patient Record System (EPRS) providers to submit data to the new register structure until their software has been updated. This could impact performance information used in inspection notebooks and RBAT alerts		Proposals on an updated IfQ delivery plan were made to August IfQ Programme Board, these should help address this risk by extending the release date for the EDI replacement by 3 months (IfQ release 2). Mitigation plans for this risk are in the process of being prepared and agreed with SMT as at September.	Mitigation planning in progress in September - Nick Jones			
Monitoring failure.		Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Sharon Fensome-Rimmer			
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Update of compliance and enforcement policy.	Completed following Authority approval of new policy March 2016 - Nick Jones		The need to manage the recent Head vacancy, the continuing training period and also the action plan being implemented in connection with legal parenthood consent issues, has	
		Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer			

Insufficient inspectors or licensing staff	Inspection team up to complement. The new Chief Inspector joined the HFEA in early May 2016.	In place – Nick Jones	raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely) – at least until November 2016.
	Licensing team up to complement following earlier recruitment.	In place – Siobhain Kelly	
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Sharon Fensome-Rimmer	On legal parenthood, a strong set of actions is in place and continues to be implemented.
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins	The inspection team continue to work with colleagues in licensed centres where there are anomalies. The focus is on ensuring all affected patients are informed and appropriately supported.
	Group induction sessions put in place where possible.	In place – Sharon Fensome-Rimmer	
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson	
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Sharon Fensome-Rimmer	
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing rate since efficiency improvements were made in 2013 (acknowledged by the sector).	In place – Sharon Fensome-Rimmer	
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A incidents occur at once.	Resilient staffing model in place.	In place – Sharon Fensome-Rimmer	
	Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Regulatory model RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			↔ ↔ ↔ ↔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	4	8 Medium		
Causes / sources			Mitigations		Timescale and ownership of mitigations	Effectiveness – commentary	
Failures or weaknesses in decision making processes.		Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Siobhain Kelly			At tolerance. Although two additional risk sources exist at present (website outages until the new beta website is live and the plan of work to address legal parenthood consent issues), these are being well managed and/or tolerated, and the overall risk score has not increased.	
		Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – Siobhain Kelly				
		Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Siobhain Kelly				
		Staffing structure for sufficient committee support.	In place – Siobhain Kelly				
		Decision trees; legal advisers familiar.	In place – Siobhain Kelly				
		Proactive management of quoracy for meetings.	In place – Siobhain Kelly				
		New (ie, first application) T&S licences delegated to ELP. Delegations were revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP –the documentation for recording Licensing Officer decisions is complete as at September 2016 and this process is ready for implementation.	In place – Siobhain Kelly Licensing Officer role – ready for implementation September 2016 – Siobhain Kelly Delegations in SOs were put in place - Spring 2016				
Failing to demonstrate competence as a regulator		Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer				
		Inspector training, competency-based recruitment, induction process, SOPs, quality management system (QMS) and quality assurance all robust.	In place – Sharon Fensome-Rimmer				
Effect of publicised grade A incidents.		Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Sharon Fensome-Rimmer				

	SOPs and protocols with Communications team.	In place – Sharon Fensome-Rimmer
	Fairness and transparency in licensing committee information.	In place – Sharon Fensome-Rimmer
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Sharon Fensome-Rimmer
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below).	New work in development as at September 2016
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped.	Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen
	Guidance/induction in handling FOI requests, available to all staff.	In place – Siobhain Kelly
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Sharon Fensome-Rimmer
	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using RedDot). This risk has informed our decisions about which content to move first to the beta version of the new site.	In progress – beta phase February 2016 – Juliet Tizzard
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	In place - Peter Thompson

HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).

Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Siobhain Kelly
Update of compliance and enforcement policy and implementation of new policy and related procedures.	In place – revised policy agreed Spring 2016 – Nick Jones / Sharon Fensome-Rimmer
Seeking the most robust possible assurance from the sector with respect to legal parenthood consent issues, and detailed plan in operation to address identified cases and anomalies.	In progress – Nick Jones
QMS and quality assurance in place in inspection team.	In place – Sharon Fensome-Rimmer

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level:		↔ ↔ ↔ ↔	Juliet Tizzard	
			Likelihood	Impact			Inherent risk
			4	4			16 High
			Residual risk level:				
			Likelihood	Impact			Residual risk
3	4	12 High					
Tolerance threshold:		8 Medium					
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Inability to extract reliable data from the Register.		Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify and cleanse all of the data that will require correction before migration can be done. Decisions have been made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data is being addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones		Above tolerance. The approval process has had to be tightly managed; a summary is set out below. The Department of Health gateway review took place in November 2015 and awarded a high score to the HFEA, but the formal decision on this was still not made by the Government Digital Service board until mid-January (a month later than expected). This meant that the beta (build) stage initially had to proceed at risk (subsequently resolved).		
Reduced ability to provide for patient choice based on CaFC information as a result of EPRS inability to submit/correct data in the new register structure if they do not update their systems in time to comply. This could impact the publication of CaFC data.		Proposals on an updated IfQ delivery plan were made to August IfQ Programme Board, these should help address this risk. Mitigation plans for this risk are in the process of being prepared and agreed with SMT as at September.	In progress - Nick Jones		Approval also carried a number of requirements and conditions which need to be added to the delivery. Owing to these delays, it was necessary to extend the timeline for the private beta phase from March to June 2016.		
Stakeholders dislike or fail to accept the new model for CaFC. Stakeholders not on board with the changes.		In-depth stakeholder engagement and extensive user research completed to inform the programme's intended outcomes, products and benefits. This included, consultation, expert groups and Advisory Board and this continues to be an intrinsic part of programme approach.	In place and ongoing – Juliet Tizzard /Nick Jones				

<p>Cost of delivering better information becomes too prohibitive, either because the work needed is larger than anticipated, or as a result of the approval periods associated with required DH/GDS gateway reviews.</p>	<p>Costs were taken into account as an important factor in consideration of contract tenders and negotiations. Following earlier long timelines and unsuccessful attempts to discuss with GDS, our experience at the Beta gateway has been much improved and feedback was almost immediate. Watching brief being kept.</p>	<p>In place – Nick Jones In place – Nick Jones</p>	<p>The live beta gateway approval in May was much more efficient, with approvals received within days of the assessment taking place. However, there were a number of requirements to address before implementing live beta.</p>
<p>Redeveloped website does not meet the needs and expectations of our various user types.</p>	<p>Programme approach and some dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations. GDS Beta assessment was passed on all 18 points.</p>	<p>In progress – delivery of next stage of user research by end Oct 2016 – Juliet Tizzard</p>	<p>The move to public beta was delayed by an injunction brought by a licensed clinic. We successfully managed to have the injunction lifted, but it meant that we could not issue the new website to public beta testing until August 2016.</p>
<p>Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.</p>	<p>Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted. All GDS approvals sought so far have been granted, albeit with some delays to the earlier ones. Additional sprints of work were incorporated in beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.</p>	<p>In place – Juliet Tizzard In place – Nick Jones (decision received April 2015) In place – Nick Jones</p>	
<p>Resource conflicts between delivery of website and business as usual (BAU).</p>	<p>Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.</p>	<p>In place – Juliet Tizzard</p>	

<p>Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.</p>	<p>Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors. Sound project management practices in place to monitor delivery. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary. Regular contract meetings in place. This remains a challenge.</p>	<p>In place – Juliet Tizzard</p>
<p>New CMS (content management software) is ineffective or unreliable.</p>	<p>CMS options were scrutinised carefully as part of project. Appropriate new CMS chosen, and all involved teams happy with the selection.</p>	<p>In progress – implemented in beta phase, July 2016 – Juliet Tizzard</p>
<p>Benefits not maximised and internalised into ways of working.</p>	<p>During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working. Knowledge handover with the contractors will take place.</p>	<p>In place – Nick Jones</p>

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:		↔ ↔ ↔ ↔	Nick Jones	
			Likelihood	Impact			Inherent risk
			2	5			10 Medium
			Residual risk level:				
			Likelihood	Impact			Residual risk
2	4	8 Medium					
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.		IfQ programme groundwork focused on current state of Register. Extensive planning in place, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen		At tolerance.		
The firm (Avoca) which was scheduled to provide assurance on data migration has gone out of business.		The HFEA has considered other sources of assurance and have now sourced a supplier and is currently going through procurement processes to appoint them.	Pending a successful appointment process, we would expect the new company to begin providing assurance in September/October– Nick Jones		This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.		
Historic data cleansing is needed prior to migration.		A detailed migration strategy is in place, and data cleansing is in progress.	In place – Nick Jones/Dave Moysen				
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.		IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were ‘future proofed’ as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones				
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).		Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen				
System interdependencies change / are not recognised		Strong interdependency mapping done between IfQ and business as usual.	Done – Nick Jones				
Benefits not maximised and internalised into ways of working.		During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working. Knowledge handover with the contractors will take place.	In place – Nick Jones				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:		↔ ↔ ↔ ↓	Nick Jones	
			Likelihood	Impact			Inherent risk
			4	4			16 High
			Residual risk level:				
			Likelihood	Impact			Residual risk
2	4	8 Medium					
Tolerance threshold:			9 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Poor user acceptance of changes, or expectations not managed.		Stakeholder involvement strategy in place and user testing being incorporated into implementation phases of projects.	In place – Nick Jones/Juliet Tizzard		Below tolerance.		
Clinics not consulted/involved enough.		Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place. Workshops were delivered with the sector regarding how information will be collected through the clinic portal. From beta live onwards we will receive feedback and iteratively develop the products.	In place – Nick Jones/Juliet Tizzard		September 2016 - Since, ultimately, we believe that the mitigations that are in place are working effectively and mean that we are on track to achieve the promised efficiencies, we have reduced the level of likelihood for this risk. This in turn brings the risk to below the tolerance threshold of 9.		
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.		Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones		This risk is also affected by GDS approvals and associated requirements (see IfQ1).		
Efficiencies cannot, in the end, be delivered.		Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones				
Cost of improvements becomes too prohibitive.		Contracts only awarded to bidders who made an affordable proposal. Detailed planning for release two (which includes the second iteration of the portal and the introduction of the new EDI interface) is in progress and the HFEA will continue to work within agreed costs.	In place (July 2015) – Nick Jones In progress (September 2016) – Nick Jones				

<p>Required GDS gateway approvals are delayed or approval is not given.</p>	<p>All GDS approvals sought so far have been granted, albeit with some delays to earlier gateways. Our detailed planning includes addressing the requirements laid down by GDS as conditions of alpha and beta phase approval. Additional sprints of work were incorporated into beta, in an attempt to allow sufficient time (and resources) for the remaining GDS gateway review processes and subsequent formal approval mechanisms. The beta timeline was extended by 3 months to compensate for previous and anticipated future delays.</p>	<p>In place – Nick Jones</p>
<p>Benefits not maximised and internalised into ways of working.</p>	<p>During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.</p> <p>Knowledge handover with the contractors will take place.</p>	<p>In place (June 2015) – Nick Jones</p>

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↓ ↔ ↔ ↔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	4	12 High					
Tolerance threshold:			12 High				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Complex and controversial area.		Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson		At tolerance.		
		Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Joanne Anton		Current cases:		
		Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Joanne Anton/Juliet Tizzard		The judgment in 2015 and subsequent cases on consents for parenthood have administrative and policy consequences for the HFEA. Further cases are going through court, although there have been no cases arising from new incidents post the 2015 judgment. The HFEA is unlikely to participate in most of these legal proceedings directly, though the court has required us to provide information and clarification in relation to six legal parenthood cases.		
HFE Act and regulations lead to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.		Panel in place, as above, to get the best possible advice. Case by case decisions regarding what to argue in court cases, so as to clarify the position.	In place – Peter Thompson		Further cases are going through court, although there have been no cases arising from new incidents post the 2015 judgment. The HFEA is unlikely to participate in most of these legal proceedings directly, though the court has required us to provide information and clarification in relation to six legal parenthood cases.		
Decisions and actions of the HFEA and its committees may be contested.		Panel in place, as above.	In place – Peter Thompson				
New guide to licensing and inspection rating (effective from go-live of new website) on CaFC may mean that more clinics make representations against licensing decisions.		Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. consistent decision making at licence committees supported by effective tools for committees Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Siobhain Kelly		A judicial review hearing of one discrete element of the IfQ CaFC project has been set for December. Authority decisions in November may impact on the scope of the JR. We are advised that our case is strong; however, if it were lost then it		
		Well-evidenced recommendations in inspection reports.	In place – Sharon Fensome-Rimmer				

<p>Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.</p>	<p>Scenario planning is undertaken at the initiation of any likely action.</p>	<p>In place – Peter Thompson</p>	<p>may impact on aspects of the presentation of data.</p>
<p>HFEA could face unexpected high legal costs or damages which it could not fund.</p>	<p>If this risk was to become an issue then discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also interdependent risk because DH would be involved in resolving it.</p>	<p>In place – Peter Thompson</p>	
<p>Legal proceedings can be lengthy and resource draining.</p>	<p>Panel in place, as above, enabling us to outsource some elements of the work.</p>	<p>In place – Peter Thompson</p>	
	<p>Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.</p>	<p>In place – Peter Thompson</p>	
<p>Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.</p>	<p>Licensing SOPs, committee decision trees in place.</p>	<p>In place – Siobhain Kelly</p>	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
2	5	10 Medium					
Tolerance threshold:			10 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Confidentiality breach of Register data.		Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen		At tolerance.		
Loss of Register or other data.		As above.	In place – Dave Moysen				
		Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen				
Cyber-attack and similar external risks.		Secure system in place as above, with regular penetration testing.	In place – Dave Moysen				
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.		IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen				
		Deliberate internal damage to infrastructure, or data, is controlled through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones				
Business continuity issue.		BCP in place and staff communication procedure tested. A new BCP is being produced by the Head of IT to reflect the changes to this following changes to infrastructure and the office move.	In place – Morounke Akingbola Update being done by Dave Moysen – September 2016				
Register data becomes corrupted or lost somehow.		Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen				

Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen
Poor records management	TRIM training and guidance/induction in records management in place pending new work on records management to be commenced in autumn 2016 (see below). New work in development as at September 2016	New work in development as at September 2016
	Further work planned on records management in parallel with IT strategy. This piece of work is currently being scoped. Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen	Linked to IT strategy work – in progress – Siobhain Kelly / David Moysen

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			↓ ↔ ↔ ↔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	3	9 Medium					
Tolerance threshold:			8 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Poor record keeping		Refresher training and reminders about good records management practice.	In place – SMT		Above tolerance.		
		TRIM review and retention policy implementation work – part of records management project	To sync in with IT strategy. RM project to start autumn 2016– Dave Moysen/Siobhain Kelly		Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, complexity or deadlines.		
		Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Siobhain Kelly Implementation of actions following Epicentre audit planned and to be completed by November 2016– Siobhain Kelly		In September 2016 we have not yet registered an unusual spike in volumes following on from recess (during which time there were no PQs). However, with the current work on the mitochondria scientific review, due to be published in November, this situation is likely to change in future months. We continue to closely monitor volumes.		
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors		PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, it is occasionally necessary to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data. FOI requests are refused when there are grounds for this.	In place – Juliet Tizzard / Nick Jones				
		PQ SOP revised and log created, to be maintained by Committee and Information Officer/Scientific Policy Manager.	In place - Siobhain Kelly				

Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Siobhain Kelly / Peter Thompson
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work is ongoing to address consent reporting issues	Inspections now routinely sample check a clinic's performance comparing original consent form with the detail held on the Register, to ensure it has been transcribed effectively. Where the error rate is above tolerance the clinic must undertake a full audit and carry out corrections to the Register as necessary – Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Donor conception DC 1: OTR inaccuracy	There is a risk that an OTR applicant is given incorrect data.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
1	4	4 Low					
Tolerance threshold:			4 Low				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Data accuracy in Register submissions.		Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones		At tolerance (which is very low for this risk).		
		Audit programme to check information provision and accuracy.	In place – Nick Jones				
		IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish more efficient processes.	In place – Nick Jones				
		If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones				
Issuing of wrong person's data.		OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones				
Process error or human error.		As above.	In place – Nick Jones				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Donor conception DC 2: Support for OTR applicants	There is a risk that inadequate support is provided for donor-conceived people or donors at the point of making an OTR request.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			↔ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	3	9 Medium					
Tolerance threshold:			9 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Lack of counselling availability for applicants.		Counselling service established with external contractor in place.	In place (June 2015) – Nick Jones		At tolerance.		
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.		Additional member of staff dedicated to handling such enquiries. However, there is currently also one member of staff returning to work from long term sick leave, and this together with work pressures from IfQ delivery means there is still some pressure on team capacity (being discussed by managers).	In place, with ongoing team capacity issue under discussion – Nick Jones		The pilot counselling service has been in place since 1 June 2015, and we will make further assessments based on uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period, and the first such report was provided to the July Authority meeting.		
Risk of inadequate handling of a request.		Trained staff, SOPs and quality assurance in place.	In place – Nick Jones				
		SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – ongoing management of the pilot by Rosetta Wotton.				

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Morounke Akingbola
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	3	9 Medium		
Tolerance threshold:			9 Medium				
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
Fee regime makes us dependent on sector activity levels.		Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Morounke Akingbola		At tolerance. 2015/16 achieved a small under-spend but risk of additional legal costs remains.		
		Fees Group created enabling dialogue with sector about fee levels. Fee increase was agreed and approved by Treasury. This was implemented and the eSET discount ended (April 2016).	In place. Fees Group meeting in October, ongoing – Morounke Akingbola		The increase of per-cycle fees by £5 (to £80) and the end of the small 'eSET discount' for elective single embryo transfer has now been implemented following Treasury approval in February 2016. This should help secure sufficient funds going forward.		
GIA funding could be reduced due to changes in Government/policy		Proposals were made to August IfQ Programme Board for adjustments to the IfQ schedule which would impact when this risk is likely to be felt. Further discussions are needed with Finance to understand the scale of the potential impact of this risk and to plan for an effective mitigation to secure cash flow. These discussions will be ongoing while IfQ release 2 develops further.	Ongoing -Nick Jones		It is too early for us to tell whether this reduces this risk further. The situation will be clearer following IfQ implementation.		
		A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Morounke Akingbola		The potential impact of the IfQ risk here, related to EPRS suppliers and the impact on treatment fees, is not yet fully understood. It is also clear that this would not potentially impact the organisation until 2017, so the risk level is not affected at this time. Meanwhile, the IfQ team will work together closely		
		Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Morounke Akingbola				
Budget setting process is poor due to lack of information from directorates		Detailed budgets for 2016/17 have been agreed with Directors. DH has previously agreed our resource envelope.	In place – Morounke Akingbola				
		Quarterly meetings with directorates flags any shortfall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola				
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required		Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required.	Monthly – Morounke Akingbola				

Annex A

	IfQ Programme Board regularly reviews the budget and costs.	Monthly – IfQ Programme Board	with the finance team and the mitigation for this risk will be updated once more information is gathered and a plan agreed. We will keep this under review.
Upwards scope creep during projects, or emerging during early development of projects eg, IfQ.	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with finance.	Ongoing – Wilhelmina Crown	
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:		↔ ↔ ↔ ↔	Peter Thompson	
			Likelihood	Impact			Inherent risk
			4	4			16 High
			Residual risk level:				
			Likelihood	Impact			Residual risk
3	3	9 Medium					
Tolerance threshold:		6 Medium					
Causes / sources		Mitigations	Timescale and ownership of mitigations		Effectiveness – commentary		
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.		People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins		Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for this risk. Both Head vacancies were initially filled (in March and May 2016 respectively). The Head of Corporate Governance subsequently left in September 2016, and was replaced internally, with associated recruitment activity needed.		
Staff have access to civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.		In place – Rachel Hopkins					
Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.		In place – Rachel Hopkins					
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.		The HFEA was proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson				
Poor morale leading to decreased effectiveness and performance failures.		Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson				
		Staff survey and implementation of outcomes, following up at December 2015 all staff conference.	Survey and staff conference done – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson				

Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources.	In place – Paula Robinson
	Early emphasis given to team-level service delivery planning, with active involvement of team members. CMG will continue to review planning and delivery.	In place – Paula Robinson
	Planning for 2016/17 prioritises IfQ delivery, and therefore strategy delivery, within our limited resources.	In place as part of business planning (2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of CSL.	In place – Peter Thompson
Regarding the recent work on licensing mitochondrial replacement techniques, there is a possible future risk that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	Issue for consideration when applications commence – Juliet Tizzard

Scoring system

The HFEA uses the five-point rating system when assigning a rating to both the likelihood and impact of individual risks:

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

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