

## Authority paper

Strategic delivery	Setting standards	☑	Increasing and informing choice	☑	Demonstrating efficiency, economy and value	☑
<b>Paper title</b>	Information for Quality: recommendations for data, submission and publishing					
<b>Agenda item</b>	7(a)					
<b>Paper number</b>	[HFEA (21/01/2015) 741]					
<b>Meeting date</b>	21 January 2015					
<b>Author</b>	Matthew Watts, Regulatory Policy Manager					
<b>For information or decision?</b>	Decision					
<b>Recommendation</b>	To accept all Advisory Group recommendations with two exceptions					
<b>Resource implications</b>	See additional paper on Information for Quality resourcing					
<b>Implementation</b>	During 2015/16 business year					
<b>Communication</b>	Regular throughout 2015/16					
<b>Organisational risk</b>	High					
<b>Annexes</b>	Annex A: Recommendations to the Authority from the Advisory Group Annex B: Stakeholder's views from public consultation					

## 1. Introduction

- 1.1. The Information for Quality (IfQ) programme is a comprehensive review of the information the HFEA holds, the systems that govern the submission of that data, the uses to which it is put and way in which it is published. This paper sets out a series of recommendations that, if accepted, will be implemented in the 2015/16 business year.
- 1.2. We have long wanted to carry out such work, and it was highlighted in the recent McCracken review (2013) that we proceed with this major review of information requirements 'to reduce unnecessary regulatory burden' on fertility clinics. However, we see it as much more than 'reducing regulatory burden'. IfQ is a fundamental programme of work for the Authority, impacting on each strand of its strategy - setting direction, increasing and informing choice, and demonstrating efficiency, economy and value. It has real significance for our stakeholders. Patients will have access to better information to help them make decisions on accessing treatment. Clinics will also benefit, with improved systems of data submission and the ability to access information to help them provide a better service. Such work is anticipated to yield savings of approximately £1m for the approximately 100 clinics that provide information to the HFEA.
- 1.3. The Authority has been updated on the progress of the programme at each Authority meeting since September 2013. The report of the Advisory Group we established is attached at Annex A, they make a range of recommendations which will be greatly welcomed by clinics, patients and other stakeholders. We heard from such stakeholders during our public consultation late last year, the results of which can be found at Annex B. This paper provides a commentary on the Advisory Group's report, highlighting key points of principle for discussion.

## 2. The Register

- 2.1. Licensed fertility clinics submit information about each cycle of treatment they carry out, such as; patient and donor details, the treatment provided and its outcome. This information is held on a database called the Register. The requirement to keep a Register of Treatments stems from the Human Fertilisation and Embryology Act 1990 (as amended) (the Act).
- 2.2. The Register is an extremely valuable asset to both us and our stakeholders. We use it to:
  - securely hold information about donors and their donations
  - ensure traceability of gametes and embryos
  - provide patient information on success rates
  - monitor clinic performance, and
  - facilitate research into the safety of treatments.
- 2.3. The Advisory Group is of the view that the HFEA has not in the past been explicit about why information is required for the Register and how it is then used. Without an agreed structure to justify the submission of data, we could:
  - collect more information than necessary without a clear purpose for its use and thus increase the burden on clinics, or
  - collect less information than necessary with the effect that we would not have the required information to allow us to use the Register effectively for our stakeholders.

2.4. The Advisory Group therefore sets out a number of criteria for data collection and argues that data should not be submitted to the HFEA unless it can meet at least one of these. Broadly speaking, these criteria are aligned to how we currently use the Register and allow the Authority to ensure that all its stakeholders can take advantage of this resource. We agree that it is important to make these criteria clear to stakeholders.

2.5. There will always be differences in opinion on what data clinics should submit to the HFEA, due to the competing priorities of our stakeholders. The Advisory Group themselves are not yet settled on the specifics of the dataset – this will be agreed at their final meeting in February 2015.

2.6. With these issues in mind, the Advisory Group's recommendations that we should have a system in place to review future additions or deletions to the Register, and a clear set of criteria for data collection seems appropriate. If the Authority agrees that this is the right approach, then the following Advisory Group recommendations should be accepted:

**The HFEA should establish a dedicated standing group to assess any future requests for additions (or deletions) to the dataset, using agreed criteria.**

**Information required for the Register should only be submitted if it meets at least one of the justifications (as set out by the Advisory Group).**

2.7. The Register is the most complete source of data on fertility treatment in the UK but the quality of some data items could be improved. As the Advisory Group report highlights, some fields are not well defined, and others cannot easily be verified or validated. Their recommendations will ensure that stakeholders have access to even better quality information – a key objective in the Authority's ambition to increase and inform choice.

2.8. Another Authority objective is to facilitate research. The Advisory Group shares this commitment and recommends mandating the NHS number for all patients, donors and children born from treatment. Such information is often used in linkage studies to other national databases to monitor the safety of fertility treatments. As a member of the National Information Board, the Authority should be aware that it will be a requirement of NHS treatment that the NHS number is supplied and used. We agree with the Advisory Group that this should also apply to private paying patients though further work may be required to help clinics obtain such information.

2.9. We know that the Authority wish to ensure stakeholders have access to meaningful data, and therefore we recommend the following Advisory Group recommendations are accepted:

**Only data that is clearly defined and that can be validated or verified should be submitted to ensure only accurate and meaningful information is held on the Register.**

**The NHS number should be a mandatory data requirement. Where unavailable, the passport number or unique ID number relevant to the patient's citizenship should be the preferred unique identifier.**

### **3. The submission of information**

3.1. Clinics submit data to the Register via either:

- Electronic Data Interchange (EDI) – software developed by the HFEA in 2005 for clinics. Only data required for the HFEA is entered and

submitted.

- Electronic Patient Records System (EPRS) – various software developed by clinics themselves or by a third party to electronically manage their records, carry out analysis/audit of their data, and submit the relevant information to the HFEA.

There is roughly a 50:50 split between clinics that use EDI and those that use an EPRS.

- 3.2. Clinics also submit information on licence applications through the HFEA Clinic Portal – a password protected extranet. In a similar way to EDI, Clinic Portal allows clinics to review performance against some regulatory requirements.
- 3.3. Clinics must submit data to the HFEA by law, but we know that there are lots of ways in which we can make it easier – we heard first-hand the view of clinics at the 2013 HFEA conference. When they talk of the ‘burden’ of information requirements, clinics are often referring to the data submission process. Our user research with clinic staff showed that those using EDI can find it a frustrating system, for example, data can be submitted even if there is an error in the data, and clinics have no access to the data they submit. We also know that both EDI and EPRS find the reports setting out errors in their data unclear. It’s important we tackle these, and other, issues for both EDI and EPRS users to:

- improve the quality of data we receive
- save clinic and HFEA staff time and effort – time which clinics could spend with patients, and
- help clinics drive up improvements in quality of care provided.

- 3.4. In its strategy, the Authority agreed to demonstrate efficiency, economy and value by improving the methods used to submit and verify data. Making changes to the data submission process will ensure that data is submitted accurately the first time, reduce unnecessary effort, reduce transactional costs and increase satisfaction. The various recommendations made by the Advisory Group on data submission should make a significant difference to the experience of clinics and we recommend that they are accepted:

**The HFEA should reduce the burden of the data submission, correction and verification process. EDI should be redeveloped with causes of error designed out and processes streamlined.**

**Where possible, the HFEA should implement a system of contemporaneous validation of data fields.**

**Error reports should be improved and consolidated into a user-friendly reporting mechanism, with the ability to drill down, print out, and find exactly what and where the error is.**

**Rather than several forms for data submission, EDI should comprise of a single record of treatment.**

**The replacement to EDI should have the functionality to enable clinics to access and query their own data.**

**A system of accreditation should be implemented so that clinics know which EPRS meet good standards of data submission.**

**Training and support should be provided to clinics using EDI to ensure that data is consistently submitted in a high quality format.**

**The HFEA should prioritise the implementation of a secure mechanism for**

**the electronic submission of donor goodwill messages and pen portrait information.**

**Clinic Portal is redeveloped so that information and reports are more accessible and co-ordinated with other tools.**

**Clinic Portal and EDI should be merged into a single point of clinic contact with the HFEA, with the additional functionality of a central messaging system.**

**The successor to EDI should be robust, adaptable and functional enough that it could be used as a stand-alone data management solution, albeit not with the full scope and functionality of an EPRS.**

#### **4. The website**

4.1. The Authority has a statutory duty to provide information to patients, donors, clinics and the general public. Our main tool is the website, receiving about 100,000 visits each month. It is also central to our strategic ambition to increase and inform choice. User research with patients, donors and donor-conceived people found that the information on the website is well written, but it is difficult to navigate and does not reflect a typical patient's journey through fertility treatment. Users also find the tone and language of the website a little dry and unfriendly.

4.2. As noted above, the website is our main method of publishing information for patients, donors and donor-conceived people – as well as for professional stakeholders and it is therefore vital that we improve the website, both in terms of content, tone and accessibility. With this in mind, we recommend that the Advisory Group recommendations regarding the website are accepted:

**The HFEA website should be redeveloped with a more intuitive design to make information more user-friendly, less complex and organised around a typical user journey.**

**Online information about donation should be developed to inform donors and recipients about the options for donation and parenthood.**

**The HFEA should improve how stakeholders access its information, ensuring it is optimised for a variety of devices (such as mobiles or tablets).**

#### **5. Choose a Fertility Clinic**

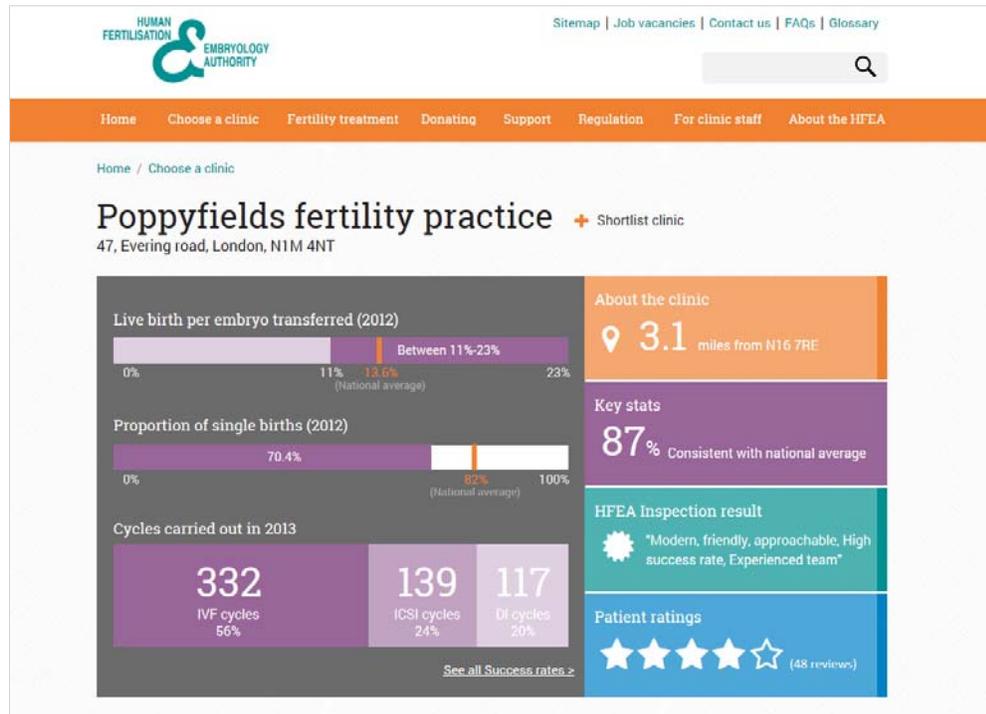
5.1. Choose a Fertility Clinic is our clinic search tool. It provides information about each clinic that we license; its services, success rates and inspection reports. Around 15,000 patients use it each month to help them decide where to go for fertility treatment. For those who have no choice about where to go, Choose a Fertility Clinic helps them find out more about the clinic they have been referred to for treatment.

5.2. The Authority has already agreed, through its strategy, that we will improve presentation of clinic comparison information on Choose a Fertility Clinic. We know that the success rate information is difficult to interpret and can give a false impression of a clinic's performance. This was reinforced by the findings of the user research which showed that the:

- navigation is deep and complex
- advanced search is overwhelming and difficult to use

- statistics and the ranges provided are difficult to understand, and
  - single figure data on clinic websites were seen as more appealing and straightforward.
- 5.3. The challenge with presenting outcome data, particularly for individual clinics, is to make the information meaningful and easy to understand. We tried to do that when Choose a Fertility Clinic was first developed, but it is clear that in the search for statistical sophistication we have overcomplicated matters for users. Finding this balance will be important when redeveloping our website. We therefore recommend the Authority accepts the following Advisory Group recommendation:
- Choose a Fertility Clinic is redesigned with information set out as clearly and simply as possible, and to avoid large amounts of data being spread over several pages.**
- 5.4. From the user research, we know that patients are interested in pregnancy and birth data, but they see the quality of a clinic as being more than just its success rates. Patients said they wanted more information about our assessment of the clinic as the regulator and welcomed the Authority's plans to publish patient experience information (described below). Presenting a broader range of information about each clinic will reduce the over-reliance on outcome data and help patients make a decision based not so much on which is the 'best' clinic, but on which is the best clinic for them. Furthermore, we know that patients want to be able to compare clinics and this is an ambition in the Authority's strategy. We therefore recommend that the Authority accept the following Advisory Group recommendation:
- Choose a Fertility clinic should show that quality is more than pregnancy rates and facilitate comparisons.**
- 5.5. As the Advisory Group highlights, success rates are not the only factor that patients consider when deciding where to have treatment - other information matters too (described below). They also agreed that the online search we provide should facilitate comparisons between clinics, though less emphasis should be placed on success rates, as it is difficult to directly compare one clinic with another based on such data.
- 5.6. The discussion on the weight that should be given to success rates highlighted a concern from the Advisory Group about the name Choose a Fertility Clinic. They argued that by using the word 'choose', patients may be misled into thinking that there are significant differences between clinics in terms of success rates – when this is largely not the case. The Advisory Group therefore recommends in its report that: **the HFEA should change the name of its online clinic search function so that it is not about choice and instead is called 'Find your Fertility Clinic'.**
- 5.7. The Executive agrees that success rates, on their own, can be misleading. Patients often focus on differences of a few percentage points in the success rates of clinics, but these differences may be caused by nothing other than luck. This is why we currently use a range in the success rates on Choose a Fertility Clinic (though this is difficult to understand) and make comparisons with the national average. However, our intention is to move away from privileging success rates above all else in Choose a Fertility Clinic and introducing other measures of quality, such as inspection findings and feedback from other patients.
- 5.8. We provided a mock-up of how a new search tool could look in the IfQ

consultation document<sup>1</sup>. While not suggesting that this is the new design, it attempts to show how we might draw together and balance out the different types of information that we will display:



- 5.9. The Advisory Group – and the respondents to the IfQ consultation – support this move to presenting a range of different quality measures. However, we know that many professionals, both on the Advisory Group and beyond, have serious concerns about how we present success rates and the extent to which patients should be able to compare clinics on that basis. It is for this reason that they wish to move away from the idea of choosing a clinic.
- 5.10. These are reasonable concerns, based on a good understanding of the limitations of statistics. However, given that 60% of cycles are self-funded and some NHS-funded patients have a choice of clinic (albeit limited), patients do wish to *choose* their clinic. Removing the ability to compare or changing the name of the service will not make this desire go away – patients will choose on what information they can find, or they will go elsewhere, to information which is not necessarily balanced. Instead, we should perhaps meet this desire head on by presenting a range of information (success rates, inspection findings, patient feedback etc) and making the measures as meaningful as possible. We should also remind patients that the information cannot tell them which is the best clinic – nor can it tell them what their own chance of success might be.
- 5.11. When we come to build our new search tool, we will think very carefully about how to display the information, and about whether the Choose a Fertility Clinic name – or some other, new name – is the right one. We will involve the people from the Advisory Group in that process. We therefore recommend that the Authority does *not* accept the recommendation to change the name of Choose a Fertility Clinic to 'Find your fertility clinic'.

<sup>1</sup> <http://www.hfea.gov.uk/docs/Binder1.pdf>

**New information to help patients choose a clinic**

- 5.12. The Authority has previously discussed new types of qualitative information which they would like available to patients. Through its strategy, members committed to enhance Choose a Fertility Clinic by including user experience scores and collecting and publishing information regarding donor gamete availability. It is clear from the IfQ consultation that there is support for information along these lines. Such a move would also be in line with broader trends in healthcare, where the NHS Friends and Family Test and other feedback mechanisms are being rolled out across different medical services.
- 5.13. We can collect and display patient experience information in a number of ways, each with their own advantages and disadvantages. Our consultation showed a preference, particularly from lay respondents, for using free text as a means to provide feedback. However, the Advisory Group has instead opted for feedback using aspects of a number of methods, balancing the views of stakeholders. Principally, we believe it should be made as easy as possible, collecting only the necessary information, and be displayed in an understandable format. If the Authority agrees, the Advisory Group's recommendation on patient feedback should be accepted.
- 5.14. Providing details on the type and source of donors a clinic recruits will also be of use to potential patients; we heard support for such information at our 2013 conference. However, the Advisory Group felt that there was a limit to how much information clinics could self-report onto Choose a Fertility Clinic. Information on the average waiting time for donors was seen as disproportionate as it could change on a regular basis, and it was seen as difficult to define an 'average' due to different availability of types of donors. We believe information along these lines should be available, but have carefully listened to the concerns of stakeholders and agree with the Advisory Group's recommendation.
- 5.15. We also know that the cost of treatment is a concern for patients, and an important factor they consider when deciding where to access treatment. We have no remit over the prices that clinics set, but do expect clinics to provide patients with a costed treatment plan before treatment begins. However, there appears to be an appetite for the HFEA to do more. In particular, there were concerns about clinics offering additional tests or treatments after treatment had begun. There is a balance to find between providing useful information to patients, whilst not overburdening clinics. The Advisory Group's recommendation that a question on the transparency of a clinic's costs be included through the patient feedback mechanism seems appropriate. It will allow patients to provide information to future patients about how open a clinic was about their costs and additional treatments they may or may not need.
- 5.16. New information along the lines set out above will help patients make decisions on where to access treatment, alongside existing information on success rates and inspection reports. We recommend that the Authority accepts the following recommendations regarding new qualitative information on Choose a Fertility Clinic:

**Patient feedback should be provided through the HFEA website, using the question of "Would you recommend this clinic?" via a star rating. The average rating, the number of people responding and the number of cycles the clinic carries out must also be provided. We also recommend that patients are able to choose from a number of HFEA-generated statements to summarise their experience. This could be displayed via a word cloud for each clinic. The HFEA must pilot such a system and consider whether any changes are required based on feedback.**

**Self-reported information on a clinic's type of donors, and source, should be provided on Choose a Fertility Clinic.**

**Questions regarding the transparency of treatment costs should be asked through the patient feedback mechanism.**

#### **Outcome data**

- 5.17. While qualitative information is important we know that patients also want access to quantitative outcome data for each clinic. However, as noted above, our user research and consultation findings showed that patients found the data we currently provide on Choose a Fertility Clinic difficult to understand, and supported changing how this is provided.
- 5.18. Replacing live births per cycle started as the headline figure is welcomed by many in the sector because it can be misleading to patients, particularly as some clinics will have top quality staff and facilities, but receive poor prognosis patients. Instead, by using live births per embryo transferred, there would be a greater emphasis on the clinical and embryological practices of the clinic, and would promote the Authority's policy on single embryo transfer as a multiple birth would reduce a clinic's live birth rate.
- 5.19. Conscious that many patients are not successful after their first embryo transfer, we can also use our data to show what a patient's chance of success is over a period of time, for example 2 years. This would help patients when making decisions about whether to have additional cycles of treatment at a particular clinic. Such information would be available as a second headline figure.
- 5.20. The Advisory Group found that the majority of consultation respondents did not support combining both stimulated and unstimulated cycles together in these headline figures. However, after thorough discussion, they recommend that they are combined in the headline data, in part because they are of the view that mode of stimulation is less relevant when using live births per embryo transferred as the headline success rate. Such information may still be available on the next layer of data on Choose a Fertility Clinic.
- 5.21. Whether a patient will have a successful outcome depends on many factors, such as clinic practices and facilities, and the individual characteristics of the patient. However, clinics receive a mix of patients, each with different clinical characteristics. By risk adjusting our success rates for more of the factors that affect outcome, we can lessen the impact of patient case mix on our data.
- 5.22. In line with the Authority's ambition to ensure that patients have high quality information on which to make informed decisions, we recommend that each of the following Advisory Group recommendations on outcome data are accepted:

**Live birth per embryo transferred should be the headline success rate figure on Choose a Fertility Clinic. We also recommend that the HFEA makes clear to users what this information is able to tell them.**

**Cumulative live birth rate from one egg collection, reported over a two year period, should be the second headline success rate figure.**

**The headline success rate figures should include not only stimulated and unstimulated cycles, but all types of treatment, such as intra-cytoplasmic sperm injection (ICSI) and pre-implantation genetic screening (PGS).**

**The HFEA should risk adjust success rates in the future. If additional information is necessary, we recommend that it is submitted by clinics immediately to allow a large enough body of data to be built up for subsequent analysis when the tool is developed. The algorithm used to**

**risk adjust success rates should be published in a peer-reviewed journal.**

**Frozen embryo transfer success rates should be based on patient age at egg collection rather than at patient age of embryo transfer.**

**The HFEA should bring forward the publishing date of clinic statistics so that patients have more up-to-date information.**

#### **National data**

- 5.23. We can make further use of the data we hold by providing additional information on a national basis. This includes providing patients with an indication of the likelihood of success over more than one cycle of treatment, and developing a personalised pregnancy or birth rate predictor tool. Providing such information would build on the Authority's ambition to ensure we use the data in the Register effectively and ensure patients have access to high quality meaningful information. If the Authority agrees, we recommend that the following Advisory Group's recommendations are accepted:

**A personalised predictive pregnancy or birth rate tool should be provided by the HFEA. It should be prospective and, where possible, be based on verifiable and validated data. There will always be a number of other individual factors at play, therefore a disclaimer should be displayed to explain to users that it is not definitive and only provides an indication of pregnancy or birth.**

**The HFEA should provide a national cumulative live birth rate over three cycles of treatment.**

#### **6. Additional points**

- 6.1. The HFEA publishes an anonymised Register, which allows researchers or interested person to review non identifiable Register data. It is a useful source of information, however, we can take a number of steps to avoid duplication of research, promote collaboration and improve its accessibility. We therefore recommend that the following Advisory Group recommendation is accepted:

**The anonymised Register should be made more accessible, with further guidance on how to use it, along with clear definitions of the data fields. When individuals wish to use such information, the HFEA should request details of the research being proposed, along with their contact details to publish on its website. This will avoid duplication and promote collaboration.**

- 6.2. With the exception of whether a patient consents to the disclosure of their information to research, a patient's consent is not submitted to the HFEA and was therefore beyond the scope of this programme. However, our user research and some members of the expert and Advisory Group(s) stated that consent was a significant concern for clinic staff.

- 6.3. Providing informed consent is a fundamental principle in healthcare and the requirement for patients undergoing licensed fertility treatment to provide consent is set out in the Act. The Authority will be aware that the Executive, working with stakeholders, has run several workshops looking at specific aspects of consent and will be updated in due course. The Authority is therefore asked to note the following Advisory Group recommendation:

**The HFEA should look at what can be done to improve the consent process.**

**7. Next Steps**

- 7.1. Subject to Authority agreement, implementation of the IfQ programme will be a major piece of work for the 2015/16 business year. It is important that, having worked closely with stakeholders over the last year, we now put in place the changes they suggest. The additional paper in this item makes further recommendations on implementation that the Authority is asked to approve.

## ANNEX A

### Information for Quality – recommendations to the Authority from the Advisory Group

Dr Alan Thornhill  
Chair of the Advisory Group and member of the Authority

## Chair's foreword

Since 1991, the Human Fertilisation and Embryology Authority (HFEA) has regulated assisted reproduction in the UK under the requirements of the Human Fertilisation and Embryology Act 1990 (as amended). As well as licencing and inspecting fertility clinics, the HFEA maintains a Register of Treatments (the 'Register'), holding data submitted by licenced clinics on each cycle of treatment performed.

The Register is one of the largest and oldest national datasets of its type and the data it holds is used to allow donor-conceived people to access information about their donor, facilitate research into the quality and safety of assisted reproductive techniques, and provide information on success rates through the online search function Choose a Fertility Clinic.

The way in which the HFEA uses and shares this information helps drive improvements in the sector and allows for effective regulation. However, it is clear that changes are required – the process for clinics submitting data is too cumbersome, some of the information clinics are required to submit is ill defined and Choose a Fertility Clinic is complicated, difficult to navigate and its presentation of statistical data requires review. The HFEA has therefore embarked on an ambitious programme, known as Information for Quality (IfQ), to transform the way it collects, uses and publishes information to benefit patients, clinics and the wider public.

There are many stakeholders who submit data to, or use the information from, the Register. We wanted to be as inclusive as possible, and established an Advisory Group of various stakeholders in late 2013. They have driven this programme of work and, with the help of four expert groups comprising clinic staff and professionals, have identified problems and developed solutions. Additionally, we commissioned an independent technical options appraisal of the HFEA's systems and processes infrastructure, and user research. This culminated in a public consultation between 1 October and 12 November 2014, in which stakeholders had the opportunity to provide us with feedback.

Having considered the consultation findings, and the recommendations from each expert group, we discussed and agreed a set of recommendations for the Authority. This report sets these out.

Having been the Person Responsible of a London based fertility clinic, I am all too aware of the importance of maintaining, having access to, and providing high quality information. I was therefore extremely pleased when the Authority asked that I lead this programme, which is key to achieving the HFEA's vision of high quality care for everyone affected by assisted reproduction.

I would like to thank the many people who have contributed to this programme and made this report possible. First, the clinic staff and other stakeholders who joined several expert groups to develop the plans and proposals for improving the way the HFEA collects, uses and publishes information. Drawing on their experiences, they

looked in detail at current issues and developed a series of recommendations on how best to overcome them.

Second, I'd like to thank everyone who responded to our public consultation which set out both our plans and proposals for change. We carefully considered the feedback received and revisited and refined some of our recommendations.

And finally, my thanks go to the Advisory Group. Made up of a mix of stakeholders, each came to the group with their own perspective. This allowed for rich debate; we often agreed in the principles at hand but disagreed on the details. For example, our recommendations for improvements to the information clinics submit will ensure the HFEA receives top quality data – but there are still uncertainties over particular items of data. Similarly, we think that the HFEA could provide additional information on its online search function, Choose a Fertility Clinic, such as patient feedback, the availability of donor sperm and eggs and the cost of treatment, but we had different views on how best to approach these challenges. In particular, I would like to thank those members of the Advisory Group that chaired an expert group. I am grateful for the time and effort they have given to listen to their peers, develop solutions, build consensus, and provide regular updates and a report to the Advisory Group.

The Advisory Group was united in wanting to ensure the HFEA has high quality information, that the process of data submission is made easier and that all data collected is put to good use and accurately reported.

As you will see from this report, there is a lot to do. However, it is clear that the sector is both keen for change and excited by the plans and proposals we set out during our consultation. We have made good progress in understanding the issues and developing ways to overcome them. The Authority must now consider these recommendations before we begin the next phase of this programme: implementation.

## Summary of recommendations

Throughout this report we make recommendations for improvement. A summary of these can be found below.

### The information that clinics submit

1. Information required for the Register should only be submitted if it meets at least one of our justifications.
2. Only data that is clearly defined and that can be validated or verified should be submitted to ensure only accurate and meaningful information is held on the Register.
3. The NHS number should be a mandatory data requirement. Where unavailable, the passport number or unique ID number relevant to the patient's citizenship should be the preferred unique identifier.
4. The HFEA should establish a dedicated standing group to assess any future requests for additions (or deletions) to the dataset, using agreed criteria.

### Consent

5. Although not within scope of this programme, the HFEA should review what can be done to improve the consent process.

### How data is submitted to the HFEA

6. The HFEA should reduce the burden of the data submission, correction and verification process. The HFEA Electronic Data Interchange (EDI<sup>1</sup>) should be redeveloped with causes of error designed out and processes streamlined.
7. Where possible, the HFEA should implement a system of contemporaneous validation of data fields.
8. Error reports<sup>2</sup> should be improved and consolidated into a user-friendly reporting mechanism, with the ability to drill down, print out, and find exactly what and where the error is.
9. Rather than several forms for data submission, EDI should comprise a single record of treatment.
10. The replacement to EDI should have the functionality to enable clinics to access and query their own data.
11. A system of accreditation should be implemented so that clinics know which Electronic Patient Record Systems (EPRS<sup>3</sup>) meet good standards of data submission.
12. Training and support should be provided to clinics using EDI to ensure that data is consistently submitted in a high quality format.

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<sup>1</sup> Software developed by the HFEA for clinics to submit data. Only data required for the HFEA is entered and submitted.

<sup>2</sup> HFEA generated reports which inform clinics of errors in their submitted data, such as missing fields.

<sup>3</sup> Software developed by clinics themselves or a third party to electronically manage their records

13. The HFEA should prioritise the implementation of a secure mechanism for the electronic submission of donor goodwill messages and pen portrait information.
14. Clinic Portal<sup>4</sup> should be redeveloped so that information and reports are more accessible and co-ordinated with other tools.
15. Clinic Portal and EDI should be merged into a single point of clinic contact with the HFEA, with the additional functionality of a central messaging system.
16. The successor to EDI should be robust, adaptable and functional enough that it could be used as a stand-alone data management solution, albeit not with the full scope and functionality of an EPRS.

### How the HFEA website should function

17. The HFEA website should be redeveloped with a more intuitive design to make information more user-friendly, less complex and organised around a typical user journey.
18. Online information about donation should be developed to inform donors and recipients about the options for donation and parenthood.
19. The anonymised Register should be made more accessible, with further guidance on how to use it, along with clear definitions of the data fields. When individuals wish to use such information, the HFEA should request details of the research being proposed, along with their contact details to publish on its website. This will avoid duplication and promote collaboration.
20. The HFEA should improve how stakeholders access its information, ensuring it is optimised for a variety of devices (such as mobiles or tablets).

### How Choose a Fertility Clinic should function

21. Choose a Fertility Clinic should be redesigned with information set out as clearly and simply as possible, avoiding large amounts of data being spread over several pages. It should show that quality is more than pregnancy rates and facilitate comparisons.
22. Live birth per embryo transferred should be the headline success rate figure on Choose a Fertility Clinic. We also recommend that the HFEA makes clear to users what this information is able to tell them.
23. Cumulative live birth rate per egg collection, reported over a two year period, should be the second headline success rate figure.
24. The headline success rate figures should include not only stimulated and unstimulated cycles, but all types of treatment, such as intra-cytoplasmic sperm injection (ICSI) and pre-implantation genetic screening (PGS).
25. Frozen embryo transfer success rates should be based on patient age at egg collection rather than patient age at embryo transfer.
26. The HFEA should risk adjust success rates in the future. If additional information is necessary, we recommend that it is submitted by clinics immediately to allow a large enough body of data to be built up for subsequent analysis when the tool is developed. The algorithm developed to risk adjust success rates should be published in a peer-reviewed journal.
27. A personalised predictive pregnancy or birth rate tool should be provided by the HFEA. It should be prospective and, where possible, be based on verifiable and

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<sup>4</sup> A password-protected extranet where clinics can submit licence applications and review performance against some regulatory requirements.

validated data. There will always be a number of other individual factors at play, therefore a disclaimer should be displayed to explain to users that it is not definitive and only provides an indication of pregnancy or birth.

28. The HFEA should provide a national cumulative live birth rate over three cycles of treatment.
29. The HFEA should bring forward the publishing date of clinic statistics so that patients have more up-to-date information.
30. Patient feedback should be provided through the HFEA website, using the question of "Would you recommend this clinic?" via a star rating. The average rating, the number of people responding and the number of cycles the clinic carries out must also be provided. We also recommend that patients are able to choose from a number of HFEA-generated statements to summarise their experience. This could be displayed via a word cloud for each clinic. The HFEA must pilot such a system and consider whether any changes are required based on feedback.
31. Self-reported information on a clinic's type of donors, and source, should be provided on Choose a Fertility Clinic.
32. Questions regarding the transparency of treatment costs should be asked through the patient feedback mechanism.
33. The HFEA should change the name of its online clinic search function so that it is not about 'choice', and instead is called Find your Fertility Clinic.

## Introduction

The HFEA business plan for 2013/14 set out the work needed to improve the effectiveness of the information it holds and collects including reviewing its forms for data submission, validation rules and verification procedures, enhancing Clinic Portal, reviewing Choose a Fertility Clinic and increasing the transparency of publishable information. The IfQ programme encompasses this work.

In late 2013, the HFEA established an IfQ Advisory Group made up of patients, doctors, embryologists, nurses, data researchers and others. Our terms of reference have been to:

- provide advice to the Authority on a range of strategic and operational issues at all stages of the programme
- help to ensure that the programme takes into account the views of all key stakeholders and that it is balanced and comprehensive
- bring diverse views and perspectives to the framing of the programme
- bring intelligence from our own organisations or sectors to help shape the programme and frame questions for the wider sector
- gather evidence from, and consult with, our own networks so their views are utilised
- advise on the establishment of a number of expert groups relating to specific strands of the programme and help to select appropriate experts for these groups
- advise on practical issues as and when needed.

Throughout this report, we set out a number of recommendations – you will see these in **bold** (a summary is provided in the previous section). These recommendations have been developed as a result of several strands of work we have completed as part of the IfQ programme, outlined below.

### Technical options appraisal

This was an external appraisal of the HFEA's systems, processes and infrastructure in relation to how information is submitted to the HFEA, how it is held on the Register, how this is transformed into reporting mechanisms such as Choose a Fertility Clinic and how it is then published. This did not duplicate the work of the relevant expert groups (discussed below) as it looked specifically at technical and systems infrastructure – for example the suitability of the content management system the HFEA uses to publish its website.

### User research

User research was used in a variety of ways to understand what key users need in order to optimise the usability of the HFEA's systems and resources. For example feedback gained from clinic staff was used to understand the issues with data submission systems.

The research covered many user types and adopted several research techniques such as surveys, follow-up phone calls, focus groups and field visits – different combinations were used for different users.

## Establishing expert groups

We set up four expert groups each led by a member of the Advisory Group to look at specific aspects of the IfQ programme, analysing the current issues and making suggestions for improvement. Each group contained clinic staff or professionals who responded to an article in the HFEA's newsletter for clinics, Clinic Focus. Each group summarised their recommendations in reports to the Advisory Group. The groups were:

- Data Dictionary – led by Professor Alison Murdoch, its scope was to develop and define the data the HFEA requires.
- Data Submission – led by Jason Kasraie, its scope was to deliver effective mechanisms for the submission of data to the HFEA.
- Data Reporting and Analytics – established by Professor Daniel Brison and subsequently led by Dr Abha Maheshwari, its scope was to review the data reports produced by the HFEA to consider if they meet the requirements of the sector and HFEA, and whether there was other information that should be reported.
- Websites and publishing – led by Melissa Asare, its scope was to review the HFEA website so that information for patients and the general public about treatment and licensed clinics is presented in an efficient, accessible, transparent and balanced way.

## Public consultation

It was important that we engaged with the HFEA's stakeholders throughout this process. We informed stakeholders of our progress through a number of professional society publications and the HFEA's newsletters Clinic Focus and e-update. We also ran a public consultation between 1 October and 12 November 2014 to allow all stakeholders to learn more about our plans and proposals and provide us with feedback. We are grateful to all those who responded via our online survey or clinic workshops. We received support for most of our proposals which we discuss later.

The Advisory Group met regularly to hear feedback on each strand of work. This report summarises our recommendations to the Authority on:

- the information that clinics submit
- how data is submitted to the HFEA
- how the HFEA website should function
- how Choose a Fertility Clinic should function.

## The information that clinics submit

Licensed clinics submit details on each cycle of fertility treatment carried out, including patient or donor information, details of the treatment provided and its outcomes. Some of this information is required by law, whilst some is a matter of HFEA policy. It is held on a database called the Register. It is an extremely valuable asset and is one of the largest and oldest of its kind. It contains information on the treatments of UK patients since 1991, allowing donor-conceived people to access information about their donor, facilitating research, and ensuring effective regulation.

Some stakeholders are critical of the information the HFEA requires because the amount submitted is perceived as unjustified and the process for deciding what is submitted, why it is needed or who will carry out any analysis is unclear. Furthermore, once submitted, clinics have no access to that information for their own audit or data analysis.

If clinic staff need to spend time away from patients to submit information, they should be told why this is the case (we discuss how data submission could be made easier, and how clinics can access the data they submit later on in this report). With this in mind, we agreed to set out the scope of the Register. **Only data that meets at least one of the below justifications should be submitted:**

- to meet a legal requirement, for example to enable the HFEA to provide donors, donor-conceived people and their parents with the information to which they are entitled
- to provide prospective and current patients and donors with sufficient, accessible and up-to-date information in order to allow them to make informed decisions
- to provide information that enables the HFEA to assess compliance of individual clinics against agreed standards
- to provide information that enables the HFEA to alert clinics of their own performance changes
- to obtain information about current practice that is considered by the professional groups and other relevant stakeholders to be useful and beneficial, including information on safety
- to provide identifying information that enables linkage studies<sup>5</sup> about children conceived as a result of licensed treatment
- to enable ethically and scientifically approved research.

Having met one of these criteria, it is then important that the data the HFEA receives is of high quality. Some stakeholders have expressed concern that the current data fields are ill defined, and we have therefore developed a 'data dictionary'. This sets out the definitions and characteristics of each piece of data and how it can be verified and validated. **We recommend that only data that is clearly defined and that can be validated or verified should be submitted to ensure only accurate and meaningful information is held on the Register.** On rare occasions, there may be data fields that

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<sup>5</sup> Studies which involve linking together information on different health databases

cannot be validated or verified but are required because of the value attached to the information. We set out below a process by which we can assess the addition of new data.

Using this methodology, and following guidance from the Health and Social Care Information Centre (HSCIC) to ensure our dataset meets good standards of data collection and is compatible with other health data collection systems, we established a draft dataset which we intend to be accredited by the Standardisation Committee for Care Information (SCCI).

## The value of an NHS number

In considering a new dataset, there had been some uncertainty about whether to mandate the collection of the NHS number for all UK patients, donors and children born as a result of treatment. Our public consultation found that while the majority were supportive and agreed in principle to its collection, many highlighted difficulties getting patients to provide this information, particularly if they were funding their treatment privately, in which case clinics would have no way of validating the information.

While we acknowledge that there may be some challenges, the provision of the NHS number is of utmost importance to act as both a unique identifier on the Register, but also to allow for linkage studies to investigate the safety of assisted reproductive techniques. It is therefore essential that this is consistently collected across the sector and should be mandated. This will require change from clinics, but we are confident that its value outweighs the difficulties of collection.

Collecting the NHS number for children born can be more complicated, but for the reasons set out above, we continue to **recommend that the NHS number be a mandatory data requirement**. We suggest the HFEA considers producing guidance for clinics on how best to seek follow-up information from patients (for example, outlining how long clinics should attempt to obtain the information and by what methods).

On rare occasions **where there is no NHS number available, such as when treating an overseas patient, we recommend the passport number or unique ID number relevant to the patient's citizenship be the preferred unique identifier**.

## The dataset

By ensuring that data is clearly defined, verifiable, and that it can be validated, along with removing duplications of data fields, and designing a data submission system that can derive data from existing information, we have slightly reduced the number of fields in the dataset. We sought views on the draft dataset during the consultation and found that stakeholders were supportive of the methodology we applied. However, there were concerns regarding specific data items that were marked for removal and some suggestions for additions. Similar concerns remain between members of the Advisory Group. We therefore intend to meet in February 2015 to finalise the dataset, though there was strong consensus regarding the methodology and principles we have applied.

The dataset will change over time, responding to changes in legislation, priorities for the HFEA, or to facilitate specific research. However, to ensure that the principles and methodologies we have established continue to be applied, **we recommend the HFEA**

**establishes a dedicated standing group to assess any future requests for additions (or deletions) to the dataset, using agreed criteria.** As part of the consideration process, additional questions would be asked; for example the expected benefits, the risks of obtaining this information and the validity and feasibility of data collection.

It is essential that when the new dataset is implemented, and when changes are made to how this information is held, it will remain possible to trace sperm, eggs and embryos between the new and existing Register.

## Consent forms

With the exception of whether a patient consents to the disclosure of their information to researchers, a patient's consent is not submitted to the HFEA, and was therefore beyond the scope of this programme. However, our user research and some members of the expert and Advisory groups stated that consent was a significant concern for clinic staff.

Providing informed consent is a fundamental principle in healthcare and the requirement for patients undergoing licensed fertility treatment to provide consent is set out in the Human Fertilisation and Embryology Act 1990 (as amended). The Advisory Group **recommends that the HFEA reviews what can be done to improve the consent process.** We have been informed that the HFEA, working with stakeholders, has recently completed a series of sector workshops looking at specific aspects of consent. We look forward to hearing its outcomes.

## How data is submitted to the HFEA

When clinic staff describe the 'burden' of HFEA information requirements, it often relates to how data required for the Register is submitted to the HFEA. This is via either:

- Electronic Data Interchange (EDI) – software developed by the HFEA for clinics. Only data required for the HFEA is entered and submitted; clinics may continue to use paper patient records to hold all other information.
- Electronic Patient Records System (EPRS) – software developed by clinics themselves or by a third party to electronically manage their records, carry out analysis/audit of their data and submit the relevant information to the HFEA. This is used by around half of all UK clinics.

Clinics also conduct other transactions via Clinic Portal, a password-protected extranet. Here, clinics can submit applications to the HFEA, such as for a new licence or a special direction for importing/exporting sperm, eggs and embryos. The portal also provides clinics with indicators of performance against some regulatory requirements (such as invoice payments and whether data has been submitted on time).

At the HFEA annual conference in March 2013, we heard firsthand the difficulties and frustrations that clinic staff experience. Alongside an expert group (comprised of clinic staff who submit data) looking specifically at these issues, we commissioned an independent technical options appraisal of the HFEA's systems for data submission and carried out user research with clinic staff.

With these findings in mind, **we recommend that the HFEA reduce the burden of the data submission, correction and verification process. EDI should be redeveloped with causes of error designed out and processes streamlined.** Below we set out specific recommendations for EDI, EPRS and the Clinic Portal.

### Contemporaneous validation, error reporting and a single treatment record

Our aim is to improve the usability of the data submission process and ensure the HFEA receives high quality data. However, the current system requires some improvement to achieve this aim. For example, whether using EDI or EPRS, mandatory information can be submitted despite there being errors in the data. The system is unable to flag these errors until the information has been processed by the HFEA. These are highlighted through HFEA error reports generated by clinics. However, these are complex and do not direct clinic staff to the specific error.

To avoid the submission of poor quality data and reduce time spent finding errors, **we recommend that, where possible, the HFEA implements a system of contemporaneous validation of data fields.**

There will always be some errors in data that require chasing up, however, **we recommend that the reports which set out these errors be improved and consolidated into a user-friendly reporting mechanism, with the ability to drill down, print out, and find exactly what and where the error is.**

We believe that some of these errors can be dealt with by moving away from the concept of having several ‘forms’ of treatment being submitted at specific points of a treatment cycle. Instead, **we recommend a single record of treatment** – thereby removing the need to match forms, cutting down the time needed to enter data, and removing duplications.

### Access to submitted data

If you are being asked to submit information, without either an understanding of why it is needed, or how you may benefit, you may be less concerned about its quality. The improvements to the dataset outlined earlier will help ensure that clinics know why the information is required.

However, we are also mindful that this is clinics’ data, and therefore they should be able to have access to it. EPRs provide such a feature, however, their cost and lack of compatibility with other NHS systems means that EDI remains the only option for some clinics. **We recommend that a replacement for EDI has the functionality to enable clinics to access and query their own data.** We envisage reporting tools being available, potentially drawing on performance indicators set by the professional societies, which clinics can then use to compare their past and current performance. Such a tool will be of great benefit to EDI users and help to drive continuous improvement for outcomes and quality of care.

### Ensuring EPRs submit accurate data

Some EPRs appear to be less effective in submitting Register data – including clinics using the same supplier and across different suppliers. This results in substantial follow-up work for clinics and the HFEA. To drive up the quality of data from EPRs, **we recommend the HFEA implements a system of accreditation so that clinics know which EPRs meet good standards of data submission.** By doing so, both clinics and the HFEA should see a reduction in time spent resolving errors.

### Training, support and provision of donor information

Our user research highlighted that the quality of submitted data, and the process of submission, varied across clinics and between different members of staff at the same clinic; staff who have years of expertise often submit data differently to new staff. When a new EDI is developed, **we recommend the HFEA provides training and support to clinics using EDI, to ensure that data is consistently submitted in a high quality format.** With regards to the technology underpinning these systems, the HFEA should make clear the level of technical support it will provide to clinics, particularly those using an EPR.

**We also recommend that the HFEA prioritises the implementation of a secure mechanism for the electronic submission of donor goodwill messages and pen portrait information.** These are currently provided to the HFEA in hardcopy form via registered mail.

## Clinic portal

While Clinic Portal provides useful performance information, clinics tell us that it could be improved. For example, the ‘traffic light’ indicators that inform clinics of errors in their data are not live – they are run once every month. Therefore, if clinics rectify an error, the indicator will remain red until the system is updated in the following weeks. We know this is a frustration for clinics and therefore recommend that **Clinic Portal is redeveloped so that information and reports are more accessible and co-ordinated with other tools** such as EDI. Owing to the crossover between EDI and the portal, **we recommend merging the two systems into a single point of clinic contact with the HFEA, with the additional functionality of a central messaging system.**

## Flexible data submission

As mentioned earlier, we recommend a standing group to assess new additions (or deletions) to the Register, for example, new data that informs a policy decision or supports research. This group would assess the feasibility and appropriateness of clinics submitting data to the Register indefinitely or for a specific period of time.

However, there may be occasions when individual clinics wish to submit additional information through EDI for their own specific purposes (those using an EPRS can already add or remove fields to their own systems). This would help clinics monitor their own clinical performance and improve outcomes. This could equally apply in scenarios where a group of clinics wish to carry out research and have information submitted to the HFEA, but not be mandated across the sector. **We therefore recommend that the successor to EDI is robust, adaptable and functional enough that it could be used as a stand-alone data management solution, albeit not with the full scope and functionality of an EPRS.**

## Submission only in the event of pregnancy or embryos in storage

In considering improvements to the data submission process, we discussed whether identifiable information about a patient should only be submitted to the HFEA when there is a pregnancy or embryos stored. Some have argued that it is morally unacceptable that there is a central database that identifies those who have difficulty conceiving. A database of donors and people who have had a child through licensed fertility treatment is necessary, but there was less certainty over whether the HFEA needed a database of the infertile. We therefore put this issue out to consultation.

We received a fairly mixed response. On the one hand, the HFEA is not required to hold identifiable patient information if there is no pregnancy or embryos stored and the holding of personal data can be a very sensitive matter to individuals. On the other, the withholding of information such as NHS number would impact on the HFEA’s ability to monitor long-term health outcomes of women and men who have undergone fertility treatment. For example, the HFEA could not facilitate research on failed cycles.

We also noted some practical issues. Firstly, once embryos have been used or destroyed (which could be up to 10 years later), the HFEA would be required to retrospectively remove identifiable information from the Register even though the information might have already been used in research. Secondly, we were concerned

about the impact this would have on the HFEA's ability to trace patients who have moved between clinics. Finally, without the NHS number for all patients, the HFEA would be unable to provide a cumulative live birth rate on Choose a Fertility Clinic (a recommendation we discuss later). For these reasons, we do not recommend such a proposal be implemented.

## How the HFEA website should function

The HFEA has a statutory duty to provide information to patients, donors, clinics and the public about fertility treatment and licensed clinics. Its main tool is its website, receiving over 100,000 visits each month. It is authoritative and impartial, providing tailored information for its main audiences.

We know from feedback and the user research we commissioned that the website is informative, but needs improvement. For example, information for patients does not reflect a typical journey through treatment or cater well for non-standard patients. **We recommend that the website is redeveloped with a more intuitive design to make information more user-friendly, less complex and organised around a typical user journey.** This will involve improving its navigation, updating its content, ensuring that it is relevant for all users and the tone and language is easier to understand.

We also know that prospective patients, and donors in particular, need more information to help them understand all their treatment options – whether that be using a licensed, non-licensed or overseas clinic – and what risks or benefits each may have. In conjunction with the National Donation Strategy Group, **we recommend that online information about donation is developed to inform donors and recipients about the options for donation and parenthood.**

There are also specific changes that can be made to benefit research. The HFEA publishes an anonymised Register which allows researchers or interested persons to review raw, non-identifiable, Register data. Whilst a useful source of information, **we recommend that it is made more accessible, with further guidance on how to use it, along with clear definitions of the data fields. When individuals wish to use such information, we recommend that the HFEA requests details of the research being proposed, along with their contact details to publish on its website.** This will allow those undertaking research to be aware of active research projects using HFEA data, to avoid duplication and promote collaboration.

As these changes are made across the website, **we recommend that the HFEA improves how stakeholders can access its information, ensuring it is optimised for a variety of devices (such as mobiles or tablets).**

## How Choose a Fertility Clinic should function

One of the most visited sections of the HFEA website is the Choose a Fertility Clinic search function, attracting around 15,000 visitors each month. This service provides users with verified information on all licensed fertility clinics in the UK so they can find their nearest clinic offering the treatments they require, recent inspection reports, success rates, multiple birth rates and other information that clinics self-report (such as whether they have female doctors).

Our user research made clear that, while valuable, stakeholders struggle with the complexity of the information, have difficulty finding what they want, make comparisons between clinics and value information other than just success rates. **We recommend that Choose a Fertility Clinic is redesigned with information set out as clearly and simply as possible to avoid large amounts of data being spread over several pages. It should show that quality is more than pregnancy rates and facilitate comparisons.** While Choose a Fertility Clinic cannot provide patients with information on their individual chances of success, it can provide a suite of information to give an indication of clinic performance. We set out specific recommendations below.

### Presenting headline statistical information

Currently, a clinic's headline success rate figures (that is the first information users see) are:

- live births per treatment cycle started
- live births per embryo transferred
- proportion of single births.

We know that users look at this headline data when making decisions, but we do not consider it the most appropriate information. In our public consultation, we suggested using only two headline figures: 'live births per embryo transferred' and 'cumulative live birth rate'. While professional societies were supportive, others were fairly split.

A point often made was that the HFEA should not have any headline figures. Instead users should be able to view whichever measurement of success rates they choose. At first glance, this position is understandable; the consultation findings showed that each figure has a number of advantages and disadvantages. However, our user research found that Choose a Fertility Clinic was complicated to navigate and understand and users want information clearly presented. While we do not suggest removing the ability to interrogate a clinic's data using a number of different metrics, we believe that users need some headline data, based on appropriate metrics, to help them compare clinic performance.

While headline figures cannot tell users their individual chance of pregnancy, we can present the data in such a way that highlights clinics that have good clinical and embryological practices. The current figure of live births per treatment cycle started can disadvantage clinics who receive patients with a poor prognosis, even though they may have top quality staff and excellent facilities. While no metric allows direct comparison

between clinics, we believe a better metric for a well performing clinic would be live births per embryo transferred – this would remove some of the confounding factors (including patient case mix and poor response to stimulation) that live births per cycle started does not address, as well as highlighting clinics which are good at creating and selecting top quality embryos, their clinical practice at transfer, as well as promoting good practice towards single embryo transfer. **We therefore recommend that live birth per embryo transferred is the headline figure on Choose a Fertility Clinic. We also recommend that the HFEA makes clear to users what the information is able to tell them.**

The consultation findings also showed that cumulative live birth rate can be complicated to understand and difficult to define. However, it is seen to provide useful information to patients on their overall chance of achieving a live birth from each egg collection. While live births per embryo transferred gives an indication of success based on an embryo transfer, cumulative success rates provide patients with an indication of success over a period of time. This will be useful for patients as many require more than one embryo transfer procedure before a successful outcome. While the consultation suggested a preference for it be reported over a three year period, we recommend two; we want to ensure that women who have had a birth event are subsequently removed from the cumulative birth rate calculations. Rather than exclude such patients in a statistical formula, we consider two years to be enough time for a fresh and subsequent frozen transfer cycles without a woman having more than one birth event. **We therefore recommend that cumulative live birth rate per egg collection, reported over a two year period, be the second headline figure.**

We believe that these headline figures can be made more useful by including both stimulated and unstimulated cycles. However, the majority of consultation respondents disagreed as it was seen as misleading to combine different types of treatment in one figure.

We are of the opinion that the success rates for stimulated and unstimulated cycles should be displayed separately within the second layer of Choose a Fertility Clinic data. However, because we recommend using live birth per embryo transferred as the headline figure, whether a cycle was stimulated or unstimulated is less relevant to the subsequent data. After thorough discussion **we recommend that the headline figures include not only stimulated and unstimulated cycles, but in fact all types of treatment, such as ICSI and PGS.**

Furthermore, in presenting success rate data, **we recommend the HFEA stops basing frozen embryo transfer success rates on the patient's age at embryo transfer, and instead, uses the patient's age at egg collection.** As highlighted in our consultation, the egg's age is the most important factor to determine whether the cycle will be successful.

## Risk adjustment

There are many factors which impact on the chance of a woman getting pregnant following fertility treatment. The HFEA currently publishes success rate data that adjusts for female age but there are other important factors such as whether there was a previous pregnancy and duration of infertility.

Although we cannot tell a patient their individual chance of getting pregnant, we can improve the quality of information by standardising clinics' success rates through statistical techniques to adjust for these additional factors. This would mean that pregnancy and birth rates were adjusted for a clinic's patient case mix and valid comparisons could be made.

Our consultation found a split in opinion on the appropriateness of risk adjustment. It could provide more accurate data to allow patients to make valid comparisons between clinics; however, there might be several new pieces of data that clinics would be required to submit. We agreed to consider the necessity of additional information at our final meeting in February 2015.

While we recognise that this is a large piece of work, we consider it beneficial information for Choose a Fertility Clinic users and **recommend that the HFEA commits to developing such a tool in the future. If additional information is necessary, we recommend that it is submitted by clinics immediately to allow a large enough body of data to be built up for subsequent analysis when the tool is developed. We recommend that the HFEA publishes the algorithm developed to risk adjust success rates in a peer reviewed journal** for validation and transparency purposes.

## National data

Even with risk adjustment, success rates cannot tell a user about their individual chances of conceiving, as this is dependent on their own circumstances. However, we know that certain factors affect outcomes more than others. With a large enough database, it is possible to develop a personalised predictive pregnancy or birth rate tool, giving users an indication of their chance of conceiving based on information they provide. Though not a guaranteed success rate, it can give a fairly good indication of success based on the outcomes of previous patients.

Providing such a tool on the HFEA website received broad support from stakeholders, although it was highlighted that such personal pregnancy predictors are publicly available online and for the HFEA to develop such a tool, clinics might need to submit additional information.

We found that those tools already available were based on old data, and users could provide contradictory information yet still be provided with a predicted success rate. We considered leaving the development of such a tool to researchers; however, their dataset would be based only on those patients who had consented to the disclosure of their information to research, whereas if the HFEA provided such a tool, it would have the benefit of being based on up-to-date and complete data.

**We therefore recommend that a personalised predictive pregnancy or birth rate tool is provided by the HFEA. It should be prospective and, where possible, be based on verifiable and validated data. There will always be a number of other individual factors at play and we recommend that a disclaimer is displayed to explain to users that it is not definitive and only provides an indication of pregnancy or birth.**

As mentioned earlier, there may be some additional data that clinics are required to submit for the HFEA to provide such a tool – the Advisory Group will consider this at

their final meeting in February 2015. Such information may not be collected by all clinics. We believe it is proportionate that only those clinics that collect the data be required to submit it to the HFEA.

Based on our recommendations so far, it may seem counter intuitive to propose either risk adjustment or a national pregnancy or birth rate tool as it may require additional information to be submitted to the HFEA. However, IfQ is not simply about reducing the amount of data clinics submit – it is about having data submitted for a clear purpose and putting it to good use.

Our consultation findings also found some support for providing a national cumulative live birth rate over three cycles of treatment. This would provide patients with an indication of the likelihood of a successful outcome over more than one cycle of treatment. It could also be used to show how much success rates change after more than three cycles. **We recommend that the HFEA provides a national cumulative live birth rate over three cycles of treatment.**

### Using recent data

Currently, there is a long gap between outcomes and when information is published on Choose a Fertility Clinic. With improvements being made to how data is submitted, **we recommend that the HFEA brings forward the publishing date of statistics so that patients have more up-to-date information.** As these improvements are made, the HFEA should consider whether some of the verification procedures currently in place are required.

### New types of information

Our user research and expert groups highlighted that patients base their decision on where to access treatment on more factors than just success. In its strategy, the Authority has committed to providing some type of information on patient experience and the availability of donor sperm, eggs and embryos. We discussed, and sought views on, how this might be best done. We also considered whether the cost of treatment should be included on Choose a Fertility Clinic.

### Patient experience

Our consultation showed support for providing patient experience information via star ratings, free text, using data from the 'NHS friends and family test', or through information collected on inspection. However there were concerns about how this could be done in a fair and impartial way.

We recommend that patient experience information is provided directly to the HFEA because while clinics may have their own systems to monitor feedback, it is important there is a separate route for patients to provide open and honest feedback to the HFEA.

Some members of the Advisory Group were concerned that clinics might be able to undermine the system by providing positive feedback on their clinic. While this is a possibility, there is only so much we can do to prevent this, such as designing a system that could identify multiple submissions from the same IP address. We considered it

unrealistic to develop a system of patient validation to ensure feedback is only provided by genuine patients.

Following discussion, we acknowledged that there were advantages and disadvantages to each option. For example, free text might give you a real feel for how a clinic operates, but this requires moderation. Ideally, any provision of patient experience information would need to be reliable, validated, of sound methodology and be piloted. While there may be some limitations to the method we recommend, and how this is displayed, we agreed that it would still be of great use to Choose a Fertility Clinic users.

We do not want to design a complicated and unusable system of patient feedback and preferred the simplicity of the NHS friends and family test being applied to fertility clinics, ie, being asked the question: "Would you recommend this clinic?"

Feedback needs to be displayed in a meaningful manner. The consultation findings showed that star ratings were the most favoured method, and we consider it the most appropriate representation of patient experience information alongside headline success rate information. Users answering "Would you recommend this clinic?" would choose between one and five stars and an average star rating would be placed on each clinic's profile. To show how representative this is, the number of respondents and the number of cycles a clinic carries out should be displayed.

Conscious that our consultation findings showed free text to be the favoured method of feedback by lay respondents, we questioned whether we could do more. Clinic staff had concerns – one negative comment might persuade patients to avoid a clinic, even though it was a one-off instance and the clinic otherwise performed well.

The use of a 'word cloud' was seen as a compromise. Rather than writing their own comments, patients would select from a list of statements provided by the HFEA. Those chosen most often would be largest in the 'word cloud' so that attention was drawn to them. Those rarely chosen would be smallest.

There will be further technical issues to consider during implementation. However, **we recommend that patient experience information is provided through the HFEA website, using the question "Would you recommend this clinic?" via a star rating. The average rating, and the number of people responding and the number of cycles the clinic carries out, must also be provided. We also recommend that patients be able to choose from a number of HFEA-generated statements to summarise their experience. This could be displayed via a word cloud for each clinic. The HFEA must pilot such a system and consider whether any changes are required based on feedback.**

### **Availability of donor sperm, eggs and embryos**

Some stakeholders are concerned that patients are not provided with an accurate picture of the availability of donor sperm and eggs (gametes) and embryos in the UK and are subsequently offered treatment abroad by their clinic. The HFEA has been informed that some clinics have a surplus of donor gametes and no waiting lists and believe patients should be fully informed about such options. Thus, the HFEA is committed to providing some type of information about the availability of donor gametes and embryos.

We sought feedback on three pieces of information that may be useful to patients: the type of donors a clinic has (sperm, eggs or embryo), their source (UK, Europe or further afield) and average waiting times. Rather than being information provided by the HFEA, we saw this as self-reported information clinics could update on Choose a Fertility Clinic.

Our consultation showed support for each, though there were concerns about how regularly the availability of donor gametes and embryos can change. If an average waiting time was provided, it would quickly become out of date.

The Advisory Group had differing views. Some argued that it was difficult to define what an average was. A clinic might have a ready supply of one type of donor, but if the patient was looking for a specific ethnicity, it might be much longer than the average, and therefore misleading to a patient. However, others were of the view that patients need this information when making choices of where to have treatment, and that Choose a Fertility Clinic would provide an indication. The provision of such information could be simplified through improvements to the data submission process so that it is not a burden.

While information about the availability of donor gametes and embryos is useful for patients, **we recommend that only self-reported information on a clinic's type of donors, and source, is provided on Choose a Fertility Clinic.** If patients want information on average waiting times, we recommend they speak to individual clinics for the latest information.

### Cost of treatment

Another important factor for patients when choosing a clinic is the cost of treatment. While the HFEA has no remit over the prices that clinics charge, they require that patients be given a costed treatment plan before starting treatment. We considered whether more information could be provided to patients by allowing clinics to self-report the average cost of treatment onto Choose a Fertility Clinic.

Our public consultation showed that stakeholders, particularly patients, were supportive of this, though clinic staff often highlighted practical difficulties of keeping this up to date. Our assessment is that people are concerned about the cost of treatment, but also the transparency of information on costs. For example, we have heard that some patients are unexpectedly recommended additional tests or procedures during treatment, and are unsure about their necessity, thus incurring more costs.

We considered asking clinics to self-report the average cost of a cycle of treatment as defined by the HFEA on Choose a Fertility Clinic. For example, this might include drugs, egg recovery, culture of embryos, and embryo transfer. This would only be an average, but could give patients an indication of what they might be expected to pay. However, as with information on the availability of donor gametes and embryos, this information might regularly change, be complicated to work out if clinics have different packages of treatment, and not be specific enough for patients.

However, the HFEA could help by asking patients to provide an indication of how transparent clinics had been with costs. As part of the patient feedback word cloud, patients could choose statements which indicated whether the clinic was transparent

from the start about the cost of treatment and whether they often suggested additional procedures or tests during treatment.

Although the Advisory Group initially had some concerns about how this could be provided in a meaningful manner, **we recommend that patients are asked about the transparency of costs through the patient feedback mechanism.** Information on the actual cost of treatment should be for clinics to provide on their own websites.

### Choosing or finding your fertility clinic?

We have recommended many changes to the way information about clinics is provided to patients. As a result, users will have more information available to them, statistical data will be more useful and easier to understand, and its presentation and layout will be improved to make it easier to navigate. However, we discussed whether its purpose was to help a user 'choose' or 'find' their clinic.

After thorough discussion we mostly agreed that, while valuable to patients, it was a tool to help find the most appropriate clinic. By using the word 'choose', patients may be misled into thinking there is much to choose from between clinics – particularly when they are looking at two clinics with the same success rates bar a minor percentage difference. This drives a competitive market which was not seen as helpful. For NHS patients, there is rarely any choice available. Furthermore, no metric provides users the ability to directly compare and subsequently choose a clinic, hence why we have recommended risk adjusting success rates.

In essence, we believe this is a tool to help patients find out information about a clinic and seeing if it is right for them and their particular needs. **We therefore recommend that the HFEA change the name of its online clinic search function so that it is not about 'choice', and instead is called Find your Fertility Clinic.**

## ANNEX B

# Information for Quality consultation



**Stakeholder's views**

### 1. Introduction

- 1.1. Information for Quality (IfQ) is an ambitious programme of work to review the data which clinics are required to collect for the HFEA, how that is then submitted to us, the use to which we put that information, and how we then publish it through the website or Choose a Fertility Clinic. Between 1 October and 12 November 2014, the HFEA consulted on a number of proposals for change that had been developed by the IfQ Advisory and Expert Groups. This report sets out these findings.

### 2. Background

- 2.1. In late 2013, we established an Advisory Group made up of patients, doctors, embryologists, nurses, data researchers and others. They have advised – and challenged – us about the direction we should take.
- 2.2. To better understand the practicalities, we established four Expert Groups, each considering specific aspects of the programme. We also used the findings from an external technical options appraisal of our systems, and user research investigating how patients and clinics interact with our website and published information, to inform our next steps.
- 2.3. We produced a consultation document which set out our plans and proposals which we wanted views on. These were compiled by the relevant Expert Group(s), and agreed for consultation by the Advisory Group.
- 2.4. We sought views via an online survey, and two workshops which we held for clinic staff to discuss both the plans and proposals in more depth. This report summarises findings from both.
- 2.5. Each Expert Group should use the relevant findings set out in this document to help formulate their recommendations to the IfQ Advisory Group. In turn, the Advisory Group should consider both this paper, and the recommendations of the Expert Groups, to provide the Authority with its recommendations on how to proceed. Ultimately, the Authority will decide what approach to take at their meeting in early 2015.

### 3. Conclusions

- 3.1. Below are a summary of the conclusions reached based on the findings. Expert Groups should discuss the relevant sections of this document and provide their recommendations to the Advisory Group.
- 3.2. NHS Number
  - There is clear support for collecting the NHS number, though a number of practical difficulties have been raised.
  - The Advisory Group may wish to consider whether they still wish to mandate the collection of the NHS number – their view may differ for NHS and Private patients.
  - Further guidance may be required to help clinics follow up on information from patients.
- 3.3. The revised dataset

- Stakeholders agree with the plans and approach for reviewing the Register.
  - There is disagreement over the purpose of the Register, as some believe the HFEA should use it to collect more information than currently to allow for oversight of other aspects of ART. The Advisory Group should discuss the purpose of the Register at their next meeting.
  - There is still disagreement over particular items of data, and therefore the Expert Group should consider each of these before finalising its dataset.
- 3.4. Submission of identifiable information only when pregnancy or embryos stored
- Despite some support, its impact on traceability, research, and likelihood to increase the information requirements on clinics, suggests that it would not be appropriate to support this proposal.
- 3.5. Headline success rates
- Both live births per embryo transferred and cumulative live birth rate have a number of advantages and disadvantages
  - Some respondents support having multiple metrics to measure success, although going down this path would be contrary to the findings of user research – and such information can still be available but not as the headline figure.
  - Assuming we want to highlight which clinics are good at producing high quality embryos resulting in a birth (the primary aim of Choose a Fertility Clinic), then live births per embryo transferred is the most appropriate headline figure.
  - The definition of cumulative birth rate is not well understood, but is seen as a useful second headline figure to provide. If chosen, further work is needed to define what it is measuring and conveying this in an accurate and understandable way.
- 3.6. Adjust success rates for more factors
- Stakeholders see the benefit of risk adjusting success rates, but note that additional information may be required for it to be done correctly, which might then increase the information requirements of clinics.
- 3.7. Presenting frozen embryo transfer success rates on age of egg collection
- Stakeholders agree that FET success rates should be based on the age at egg collection.
  - Information explaining that other factors affect FET success rates may be useful to include alongside these success rate figures.
- 3.8. Providing a personalised pregnancy/birth tool
- Whilst patients may support this proposal, a large number of stakeholders are concerned that we do not have all the required information to provide the service, and would need to collect more – which many were not happy with.
- 3.9. Presenting stimulated and unstimulated cycles together
- The majority of stakeholders were not supportive of this proposal and wanted both sets of information available. However, if we are concerned about the depth of information we might be providing on Choose a Fertility Clinic, we could instead amalgamate the figures and explain what unstimulated IVF is, and why it can have lower success rates.
- 3.10. Patient experience
- Stakeholders are generally supportive of patient feedback, but want it to be done in a way which is seen as fair.
  - Each of the options, except for Friends and Family, were ranked fairly equal, though a number of respondents highlighted problems with having free-text.
- 3.11. Donor gamete availability
- Information on donor gamete availability is, in principle, welcomed.

- There is concern over how this will be kept up to date when the information can change so quickly but such issues do not seem insurmountable if we make clear that the data is based on averages, and improve how such information is provided.

#### 3.12. Cost of treatment

- This proposal has support from stakeholders, particularly patients, but there are concerns about how it might be implemented.

## 4. Breakdown of who responded

4.1. We received 335 responses. The table below breaks this down by respondent type – not all who started the survey answered each question.

<i>Type of respondent</i>	<i>Percentage</i>	<i>Number</i>
Embryologist	18.8%	63
Other	11.6%	39
Fertility treatment patient (past or present)	9.0%	30
Person Responsible	7.8%	26
Nurse	7.5%	25
Representing a professional organisation	6.6%	22
Another member of clinic staff	6.6%	22
Researcher	6.3%	21
Quality Manager	6.0%	20
Clinic data entry staff member	5.1%	17
Parent of a donor conceived person	4.2%	14
Counsellor	3.6%	12
Donor	2.4%	8
Media	2.1%	7
Donor conceived person	1.5%	5
NHS Clinical Commissioner	1.2%	4

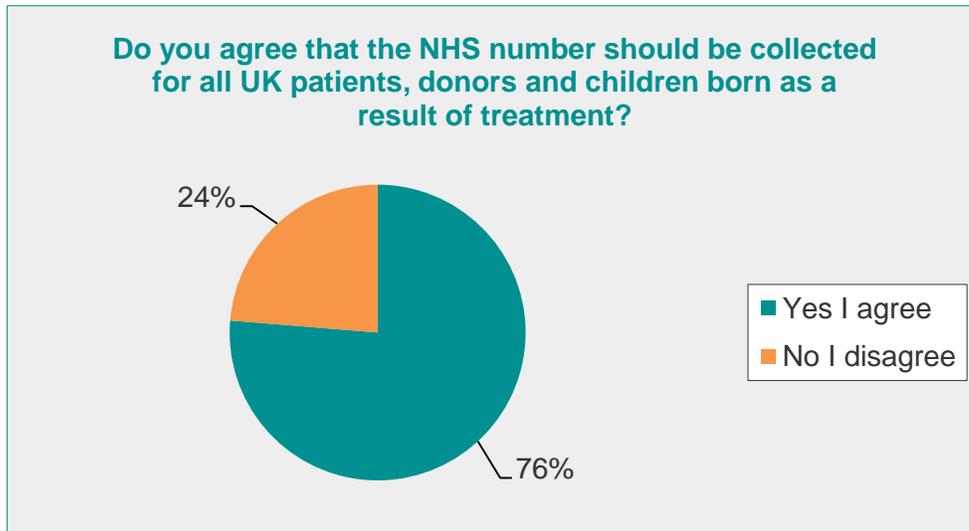
4.2. As the table above shows, we received responses from several organisations. Not all provided their name or provided any responses, but those that did were:

- British Fertility Society
- Association of Clinical Embryologist
- Senior Infertility Nurses Group
- Infertility Network UK
- Representing an independent charity that serves patients, professionals and the broader public.
- The Multiple Births Foundation
- Christian Medical Fellowship
- ESHRE
- Royal College of Nursing: Fertility Nurses Forum

4.3. Of the 'Other' respondents, the majority were specific types of clinic staff or medical professional. This category also included 16 responses from staff at the HFEA.

## 5. Collecting the NHS number

- 5.1. Clinics use the NHS, passport, or possibly driving licence number as a unique identifier when registering patients. We sought views on whether the NHS number should be collected for all UK patients, donors and children because of the value of the Register as a powerful tool for research, for example when used in data linkage studies. We were therefore minded to make the submission of a patient's NHS number (or 'Community Health Index' (CHI) number in Scotland, or 'Health and Care Number' (HCN) in Northern Ireland) mandatory.



N. 270. Yes = 206. No = 64

- 5.2. The pie chart above shows that a clear majority of online survey respondents agreed with this proposal. Of those that disagreed, it is noteworthy that 62% were clinic staff; however, this only represented 26% of all clinic staff responding.

### Reasons for disagreeing

- 5.3. Comments from the online survey highlighted a number of practical difficulties with this proposal. Several respondents suggested that patients are often unaware of their NHS number and envisaged a scenario where the start of treatment would be delayed until such information was obtained, or that patients would be reluctant to provide the information. NHS staff attending our clinic workshops agreed, but highlighted that referrals from GPs often include this information, or alternatively, they could access an NHS Portal to seek such information, thus allowing them to easily access and verify the data.
- 5.4. However, for staff working at private clinics, concerns regarding the practicalities of this proposal were much greater. Private paying patients can be reluctant to provide such information when accessing treatment outside of the NHS. If the HFEA required such information, they would not only struggle to get it, but would have no means of verifying the number – unlike NHS staff, they would be unable to access NHS records, and would not necessarily have a GP referral letter:

*“The private sector cannot verify NHS numbers which therefore makes them meaningless.” A clinic data entry staff member*

*“Verification of this would be extremely difficult operationally for clinics.” A Quality Manager*

- 5.5. There were also particular concerns about seeking the NHS number for children born from treatment. Some staff at our workshops, again often from private clinics, described the difficulty of obtaining information on patients’ treatment outcome, child name and weight. Adding the NHS number to the list of information to follow up on was seen as an additional ‘burden’ on clinics for a process that can be time consuming and often unsuccessful.
- 5.6. However, when we broke down the responses to this proposal by respondent type, we saw that, of the patients, donors, donor conceived persons and their parents who responded, the majority (70%) agreed with this proposal, suggesting they may be happy to provide this information if reasons for providing it were explained. Of those who did not support the proposal, we received only one comment:

*“Fair enough if the patients are being funded by the NHS (so their records already show they are undergoing fertility treatment) but for privately funded patients it feels a bit "Big Brotherish". This will be particularly relevant for patients (couples or single women) who do not want anybody to know they underwent fertility treatment as it could put them off having treatment in the UK and go to less regulated clinics overseas instead.” A parent of a donor conceived person*

- 5.7. There were some comments which noted a principled disagreement with the proposal (such as this not being legally required of the HFEA), but most of the objection was based on the practical difficulties of obtaining and verifying.

### Reasons to agree

- 5.8. Despite these concerns, very few staff at our workshops disagreed in principle with the proposal because it allowed researchers to carry out linkage studies to other national datasets to understand the safety of assisted reproductive technologies (ART). We saw similar supportive comments through the online survey:

*“Research is really important and it will assist with that.” A parent of a donor conceived person*

*“I imagine this could be useful is linking data such as presentation of OHSS with clinic data that might otherwise be unconnected.” A Researcher*

- 5.9. Even where there was concern with the practicalities, respondents understood and agreed with the principle of collecting the NHS number:

*“But may be difficult to achieve. Any guidance from you as to where best to look this up would be beneficial.” An Embryologist*

- 5.10. Both the survey and workshop highlighted a number of other points:
- Overseas patients do not have an NHS number - though it was acknowledged that this was a small proportion of the overall number of patients.
  - The majority of clinic staff at the Manchester workshop were of the view that a lack of NHS number (either due to being from overseas or not having it) should

- not necessarily be a barrier to treatment. Several comments from the online survey suggested that the provision of the NHS number should be optional.
- HFEA Code of Practice guidance note 5.11 (<http://www.hfea.gov.uk/336.html>) requires clinics to verify the identity of anyone having treatment, including examining photographic evidence such as passport or driving licence. Thus they often use this information as the identifier to submit to the HFEA, rather than NHS number.
  - Might there be a risk that different patients using NHS, CHI or HCN number are the same?

### Summary

- 5.11. Despite some of the practical issues, stakeholders agreed in the principle of collecting the NHS number for all patients, donors and children born from treatment. We heard many comments about its benefit as both a unique patient identifier, and its potential to help facilitate linkage studies with other national databases. Furthermore, the National Information Board recently launched its report 'Personalised Health and Care 2020'<sup>1</sup> where they stated that an individual's NHS number must be used to identify patients for all care they receive in the NHS. It is therefore appropriate that the HFEA works in line with this objective.
- 5.12. However, those working in private clinics are particularly concerned that obtaining and verifying the NHS number may add an additional 'burden'. We often heard that the HFEA should consider what more it could do to either search for a patient's NHS number and provide this to clinics, or produce clinic guidance on best practice for following up information with patients. For example, how long should they keep trying to get in touch with patients, and using what methods.
- 5.13. With these issues in mind, it is less clear whether we should mandate, or promote, the use of the NHS number for those accessing privately paid treatment.

### Conclusions

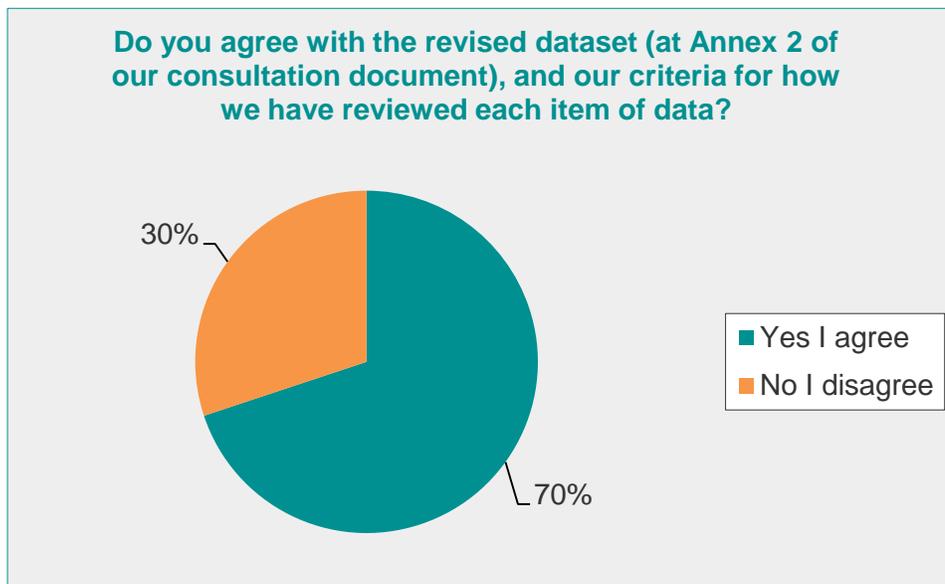
- There is clear support for collecting the NHS number, though a number of practical difficulties have been raised.
- The Advisory Group may wish to consider whether they still wish to mandate the collection of the NHS number – their view may differ for NHS and Private patients.
- Further guidance may be required to help clinics follow up on information from patients.

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<sup>1</sup> Using Data and Technology to Transform Outcomes for Patients and Citizens, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/374539/Personalised\\_Health\\_and\\_Care\\_for\\_All\\_2020\\_-\\_Final\\_Version.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/374539/Personalised_Health_and_Care_for_All_2020_-_Final_Version.pdf)

## 6. The revised dataset

- 6.1. Clinics submit information about each cycle of treatment they undertake, including patient or donor information, details of the treatment provided and their outcome. This information is held as a database that is called the HFEA Register. Some of the information clinics submit is required by law, whilst some is a matter of HFEA policy.
- 6.2. We sought views on the data which clinics are required to submit to us, and items of data that it has been suggested is no longer submitted. We also asked whether there was agreement on how we have reviewed each item of data.



N. 256. Yes = 179. No = 77

- 6.3. The pie chart above shows that the majority of online survey respondents agreed with the dataset and how we reviewed each item of data. This was a broad question, in which respondents could provide comments on a range of fields within the Register. Neither the survey nor workshops suggested concerns with plans for the Register or the approach taken to review the dataset. Instead, we received encouragement and suggestions on how to maximise the work being carried out.

*"...We are pleased to see that there has been liaison with the HSCIC but this should be maintained and developed."* **The Multiple Births Foundation**

- 6.4. The majority of comments highlighted disagreement with the conclusions the Expert Group reached on specific pieces of data – some of which was backed up with an explanation, others of which were not.
- 6.5. Due to the amount of data collected, the consultation document did not set out the many discussions that had already taken place on each data field, however the survey and workshops showed that stakeholders wanted to understand this rationale. This was useful not only in the context of this consultation, but also so that clinic staff could explain this to patients who may be reluctant to provide certain information.

- 6.6. Due to the wide ranging, and detailed, nature of comments received, the Data Dictionary Expert Group should consider the suggestions put forward in each individual response. There were however, some common themes regarding either new data, or data marked for removal from the Register which is set out below.

Data items that may be removed

- 6.7. Cause of Infertility was the most commonly mentioned field in the survey and workshops. The concern was that it is an important field for research purposes and patients appreciated the HFEA collecting, and reporting, this data. However, it was often mentioned that its definition needs improving and was difficult to verify:

*“We need information on cause of infertility but it needs to be improved.”* **A Person Responsible**

*“...without collecting cause of infertility, there is little value to any data presented. Therefore, cause of infertility should be collected, with a granular level of information.”* **Other [unspecified]**

- 6.8. One respondent thought these issues could be overcome:

*“...Some criticise the fertility sector for failing to investigate thoroughly underlying causes of infertility, and for rushing to fertility treatment. Failing to record the cause of infertility may contribute to this problem. Your consultation document states that the cause of infertility is difficult to verify and validate, but this does not preclude the data from being useful for research purposes. The qualification 'reported' can be added when presenting data (as in, 'reported cause of infertility') in order to underline the lack of verifiability. **Representing an independent charity that serves patients, professionals and the broader public.***

- 6.9. We also heard at our workshops that congenital abnormalities was information which patients would want to know about and should continue to be collected by the HFEA. As the Regulator, several thought we should continue to collect this information as part of our role to ensure the safety of those born through ART. However, some staff mentioned that congenital abnormalities are often only present several months after the birth of a child, meaning it may be falsely reassuring for clinics to notify the HFEA that there are none present, when it is too early for them to appear.
- 6.10. Another field that prompted some discussion at the workshops was whether to remove Assisted Hatching – this was also mentioned in the survey:

*“...assisted hatching is not yet considered a technique with proven benefit for the patients. Therefore, I would definitely add it to be able to trace it in the future until the efficacy of the technique is confirmed.”* **An Embryologist**

- 6.11. The argument used above was also played out by a respondent justifying the collection of patient and partner ethnicity – not knowing if something affects outcome should not necessarily mean that the HFEA should not collect the data.
- 6.12. There were concerns over a number of other data fields earmarked for removal, particularly because it was thought that this might affect the HFEA’s ability to ensure traceability of patients, gametes and embryos.

### New pieces of data

- 6.13. The piece of data most commonly suggested for inclusion on the Register was the fertility drugs, and doses, that a woman takes as part of treatment. One fertility treatment patient felt that such information could be linked to outcomes so that they are aware of the impact of such drugs. This was echoed at the workshops, where some felt there was a key role for the Regulator to ensure that women undergo safe treatment and consider the impact of fertility drugs on women's health – either themselves or by facilitating research.
- 6.14. However, some caution was expressed about the amount (and detail) of information the HFEA would need to collect. A similar point was made in the survey about the impact of having a large dataset:

*“Much too detailed. Large units will be able to afford to pay someone to do this - we could not and it would stifle our purpose which is to treat patients.”*  
**A Person Responsible**

- 6.15. The blood type of donors was seen as an additional piece of information that patients and parents of donor conceived persons would find useful in the future for health reasons:

*“I think that blood group should be added to the donor information that is passed on to the recipients, as it may be important for them at a later stage.”*  
**A parent of a donor conceived person**

- 6.16. The collection of information relating to twinning was also mentioned both during the workshops and survey. The Multiple Births Foundation recommended a number of new fields for collection, and this was echoed by some at the workshops:

*“...it is very important to collect information about each baby in a multiple pregnancy. In addition we suggest the following should be collected: reasons for elective termination of the whole pregnancy; with multi fetal pregnancy reduction the number of fetuses in the pregnancy and the number remaining after reduction and outcome for each; if termination or selective feticide is carried out because of chromosomal abnormality or other serious conditions diagnosed during pregnancy including twin to twin transfusion syndrome in monochorionic twins or triplet pregnancies.”*  
**The Multiple Births Foundation**

- 6.17. Other suggestions, though not exhaustive, included:
- Long term psychological outcomes for patients
  - Grade of embryo transferred
  - Capture whether it was a freeze all eggs or embryo
  - BMI
  - Was time-lapse imaging used
- 6.18. There were also concerns about collecting information on when intercourse without contraception started – either because this was difficult to verify, or because it was seen as redundant for single women accessing treatment, or same sex couples. For these patients, it was suggested we ask ‘why are you having treatment?’

## Summary

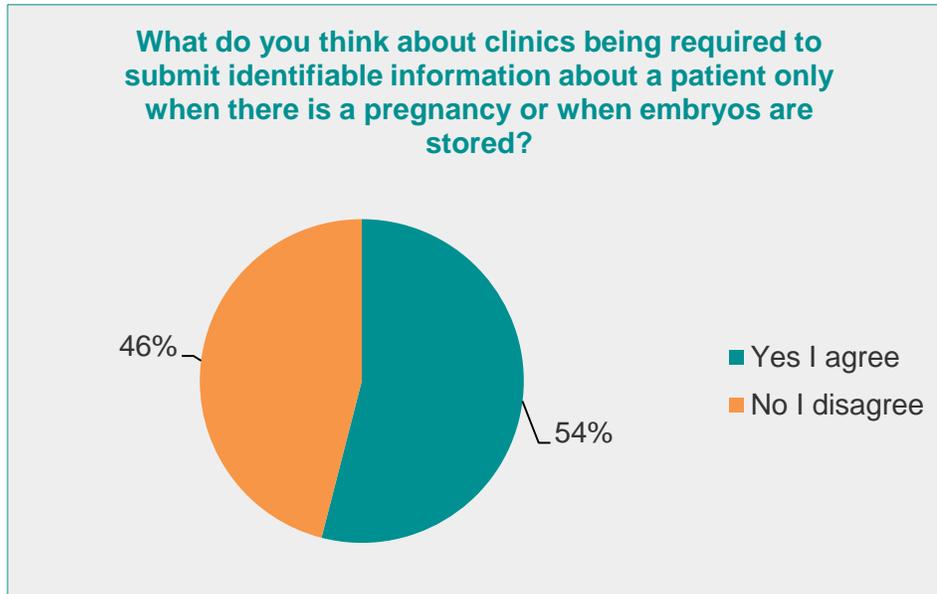
- 6.19. It is clear from both the workshops and survey that stakeholders agree with plans to improve the Register, and the methodology used to reach the revised dataset. However, there is difference in opinion over the specific data items which should be included, such as Cause of Infertility, Congenital Abnormalities and the fertility drugs that women take during treatment.
- 6.20. There are also different opinions about the how the Register should be used. We saw this played out in the workshops and survey, where some believe the HFEA should collect additional information to allow it, or others, to review the safety of ART to a greater extent than currently. Whilst there are advantages to doing so, this has an impact on clinic staff that will spend more time submitting additional information to the HFEA. Furthermore, we know that some stakeholders are concerned the HFEA will hold certain information without a clear purpose as to what it is for, or who will carry out any analysis of it. Such points were picked up by the Data Dictionary Expert Group who noted that before any new data is collected, such issues must be resolved up front.

## Conclusions

- Stakeholders agree with the plans and approach for reviewing the Register.
- There is disagreement over the purpose of the Register, as some believe the HFEA should use it to collect more information than currently to allow for oversight of other aspects of ART. The Advisory Group should discuss the purpose of the Register at their next meeting.
- There is still disagreement over particular items of data, and therefore the Expert Group should consider each of these before finalising its dataset.

## 7. Submission of identifiable data based on whether a pregnancy or embryos stored

- 7.1. Patient and Partner registration forms (which record identifiable information) are sent to the HFEA 10 working days after a patient has confirmed an intention to undergo treatment. The Advisory Group had discussed the appropriateness of the Register holding the identifying information of unsuccessful patients as it was not required by law to do so. Therefore, this question sought views on whether identifiable information should only be submitted to the HFEA when there is a pregnancy or embryos are stored.



N. 248. Yes = 134. No = 114.

### Reasons to Agree

- 7.2. The pie chart above shows that it is more or less evenly split as to whether people accept this proposal. Several comments to the online survey supported the view that, in principle, the HFEA should not be collecting identifiable information on unsuccessful patients, partly due to issues over personal privacy. In particular, the British Fertility Society (BFS) noted:

*"This is consistent with the BFS view that it is inappropriate to hold identifying information on central registers when an outcome is negative"*

### Reasons to disagree

- 7.3. However, the practicality of this proposal was often questioned, with some foreseeing scenarios where staff would have to retrospectively review the information they held to ensure it was correct before submission to the HFEA, and the possibility of this proposal increasing the workload on clinics and resulting in more errors to be dealt with in the future:

*"This may lead to inaccuracies or missing data, it is much easier and more accurate to submit the same data for all patients..."* **An Embryologist**

*“...if identifiable information is required to be submitted at any point it would be practical to do so when registering the patient, thus avoiding another data entry activity” Senior Infertility Nurses Group (SING)*

- 7.4. Of the comments received, the most common themes were that identifiable information on failed cycles is important to collect as part of a duty of care over all patients undergoing treatment, and that identifiable information can help facilitate research on the safety of ART:

*“This would be a failure to protect the health of women who undergo fertility treatment...” Other [unspecified]*

*“...all must be treated the same, regardless of final outcome, This would assist any potential follow up if adverse consequences arise, and would assist profiling and research etc.” Christian Medical Fellowship*

*“...unsuccessful people may have had even more cycles so be of more interest in some research ...” A fertility treatment patient (past or present)*

- 7.5. Staff at our workshops agreed this to be the case, and felt strongly that the HFEA should continue to collect this information. They highlighted that this proposal would hamper the HFEA’s ability to ensure traceability of patients, gametes and embryos as the HFEA would have no record of patients who had several unsuccessful cycles at a number of clinics before achieving a pregnancy.
- 7.6. However, the holding of identifiable data can be a very personal, and sensitive, issue for some individuals, and regardless of the benefits, they will not want the HFEA to hold their details if unsuccessful. When we reviewed the responses given by patients and parents of donor conceived persons, we again saw that views were fairly mixed:

*“...I have a unique name and as such it's hard to maintain anonymity...I therefore STRONGLY support the idea NOT to hold identifiable data unless absolutely necessary...” A fertility treatment patient (past or present)*

*“I think there is importance of keeping identifiable data on women undertaking ivf cycles (successful or not) so that any long term effects of fertility treatment on their health can be monitored.” A fertility treatment patient (past or present)*

### Summary

- 7.7. We received a fairly mixed response to this proposal. Whilst stakeholders could understand the issue being raised, we heard many concerns about its impact on traceability and research on unsuccessful cycles. There were also concerns that this proposal would increase the information requirements of clinics, rather than reduce them as the IfQ programme entails.
- 7.8. We found that, after thorough discussion, each workshop ended with the overwhelming majority disagreeing with this proposal.

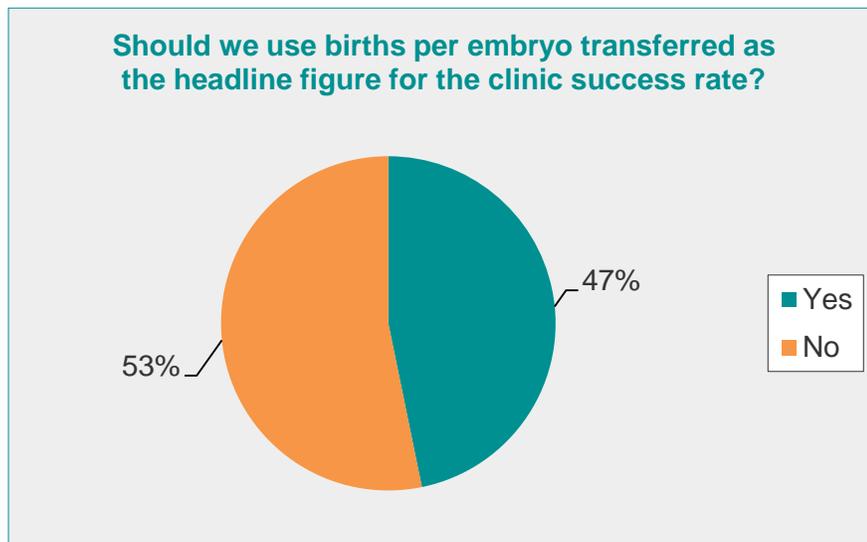
## Conclusions

- Despite some support, its impact on traceability, research, and likelihood to increase the information requirements on clinics, suggests that it would not be appropriate to support this proposal.

## 8. Headline success rates

- 8.1. Choose a Fertility Clinic provides a large amount of data on clinics success rates. The headline figures for each clinic, that is the first set of success rate data the user is shown, are noted below in order. The user can then ‘take a closer look’ to find out even more information about a clinics performance.
- Live births per treatment cycle started
  - Live births per embryo transferred
  - Proportion of single births
- 8.2. Our user research showed that patients can struggle with success rate data on Choose a Fertility Clinic. The amount of data, over several tables and pages, can be overwhelming and complicated. We also know that some stakeholders think that the current metric for ‘success’ is not the most appropriate. We wanted to provide a success metric for patients that is easy to understand, whilst still allowing users to dig deeper into the data if they so wished. Therefore, we sought views on whether Live Births per embryo transferred should be the headline figure for each clinic, with a second headline figure of Cumulative live birth rate – we additionally asked over what time period this should be reported.

### Live births per embryo transferred



N. 234. Yes = 102. No = 116.<sup>2</sup>

### Reasons to agree

- 8.3. As the pie chart above shows, it was fairly split on whether to accept this proposal. Respondents noted that live births per embryo transferred had some benefits such as excluding scenarios of failed to fertilise, creating a more level playing field by showing the quality of labs and their clinicians, and using a more helpful success

<sup>2</sup> Note: total for yes & no do not equal the total number who responded to this question. This is due to an error in consultation questions, where respondents could choose ‘Please enter any comments’ rather than Yes or No. This was quickly rectified, but 16 respondents chose this option, however their comments have still fed into the analysis for this question.

rate figure than is currently presented. Whilst not providing further information, some simply stated that this was the most appropriate measure.

- 8.4. Whilst supportive, several thought that additional information needed to be provided alongside this metric:

*“We also need to present adverse health outcomes (complications) for women and children including OHSS and Low Birth weight and Prematurity data alongside success rate. It is only then we can give a balanced picture to the public and prospective patients about the outcome of IVF per clinic. We need to present both sides of the coin.”* **A Person Responsible**

- 8.5. It was also suggested by several respondents that we amend the metric to ‘term births’. Although not supportive of the proposal, one respondent pointed out:

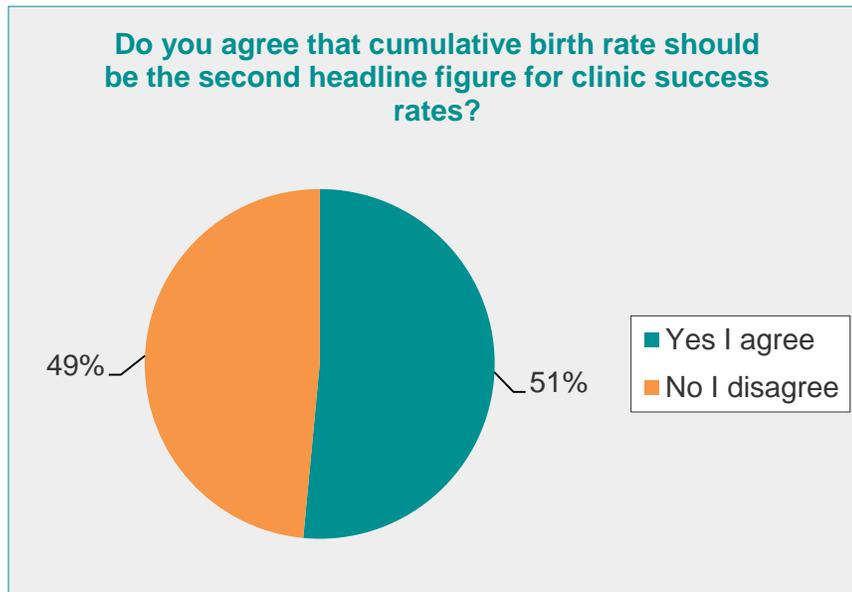
*“...The HFEA must use term births in any headline statistic. There is significant evidence from the HFEA's own database, publicised at ESHRE, that babies born in stimulated IVF are at a higher risk of premature birth and low birth weight. Without term births, the HFEA would be facilitating poor practice.”* **Other [unspecified]**

- 8.6. Of the respondents who identified themselves as being a member of clinic staff, we found that a slight majority (56%) supported using this as the headline figure. Our discussions with clinic staff at the workshops highlighted that they were also fairly supportive of this proposal, particularly as it encouraged single embryo transfer. Responses from several professional organisations were also in favour, including BFS, Association of Clinical Embryologist (ACE), SING, Infertility Network UK (INUK) and Royal College of Nurses Fertility Nursing Forum (RCN).

### Reasons to disagree

- 8.7. However, there were just as many respondents who disagreed with presenting births per embryo transferred as the headline figure. It was suggested that this is a complicated metric for patients to understand, but also that it was slightly misleading as a large proportion of patients will not even reach embryo transfer stage.
- 8.8. When we analysed by respondent type, we saw that a large proportion of those who identified themselves as a patient, donor, donor conceived person or their parent disagreed with this proposal. The majority did not provide a rationale to explain why, or a suggestion of what would be better, however we received a handful of comments which can be summarised as below:
- It conceals the rate of failure prior to embryo transfer
  - It does not show clinics which are good at creating embryos as the ones that fail are not included
  - It could cause clinics to transfer less embryos even though in some cases double embryo transfer may be more effective
  - It is too confusing; patients want to know the odds of success from starting a treatment cycle at a clinic.

## Cumulative live birth rate (including period over which to be reported)



N. 227. Yes = 117. No = 110.

### **Reasons to agree**

- 8.9. The pie chart above shows mixed views on whether to accept this proposal. However, a number of comments were provided to explain why it was favourable. For example, it was seen as being a statistically accurate way to present success rates, but also encourages clinics to have a sensible policy towards single embryo transfers.
- 8.10. We were provided with some comments suggesting that, whilst useful, the metric should be amended so that it gives patients an indication of the likelihood of success after two or three cycles. Responses from SING, BFS and INUK were supportive of the proposal, BFS noted:

*“Given the NICE Guidelines recommend that 3 full cycles of IVF should be provided to women under the age of 40, then the BFS recommends that the cumulative conception over 3 full cycles (ie fresh and their consequent froze cycles) should be shown. To minimize the effect of female age, we recommend that this be limited to 3 full cycles undertaken in within a defined period of time.”*

- 8.11. The BFS also noted that, to ensure multiple births were counted, we should use ‘babies’ per embryo transferred.

### **Reasons to disagree**

- 8.12. However, a number of issues were identified:
- Due to NHS funding criteria, NHS patients are unlikely to continue for further frozen embryo transfers - thus skewing the success rate figures for those clinics mainly treating NHS patients.

- Patients may be concerned that they will be encouraged to undergo additional treatments if a clinic's success rate will be determined over a specific period of time:

*"...this sort of metric allows clinics to encourage patients to undergo multiple treatments that don't or won't lead to success without fear they will affect their success rates..."* **A fertility treatment patient (past or present)**

- It may have the unintended effect of encouraging clinics to overstimulate women to ensure a large number of eggs are collected:

*"I presume you mean cumulative from one stimulation cycle. This would encourage higher degree of stimulation to obtain more eggs - putting patients at increased health risk."* **A Person Responsible**

8.13. The first part of the above quote highlights another issue often raised – how exactly is cumulative birth rate being defined? Respondents wanted clarity in a number of areas, such as:

- How could the figures be presented meaningfully as patient age changes?
- Does it mean fresh and frozen embryos from a single cohort of embryos or multiple attempts at the same centre (either fresh and/or frozen) – how would this work when moving between licensed clinics?
- Once a woman has a child, will she be removed from any further analysis if she attempts further treatment – it may be the individual circumstances of the patient, rather than the clinic, which was the main factor in them becoming pregnant

8.14. Considering the findings above, it is unsurprising that we often heard that using cumulative birth rates was a complicated way of presenting success rates. This was highlighted by both staff at our workshops, and through the online survey:

*"Focus needs to be on the user of the data which in most cases will be the patient. Keep it simple."* **A Quality Manager**

*"I don't understand what it means. This suggests few patients will."* **A Donor**

8.15. When we looked at how patients, donors, and parents of donor conceived persons responded, we saw that it was relatively split. We received only two comments to explain why there was disagreement; they would prefer multiple metrics on which to base their decision, or that it should not be the second headline figure (as noted by a few other respondents in the online survey).

8.16. The second part of this question asked for views on the ideal duration over which cumulative birth rate should be reported. 24% of online survey respondents recommended 1 year; 35% said two years; and 41% said three years (N. 128. 1 year = 31. 2 years = 45. 3 years = 52).

8.17. We also received a mixed set of comments, but they broadly suggested:

- that it should be measured for an indefinite period of time as gametes/embryos can be stored for 55 years
- it should be measured until all embryos are used
- it should be measured per egg collection

- 8.18. Similar views were highlighted at the workshops, although it was noted that it would not be appropriate to have an indefinite period of time as the data would take too long to be updated.

#### Using multiple metrics

- 8.19. We heard several times from discussions at the workshop, and on several questions from the online survey, that we should not have clinic headline figures at all, and that users should be able to view success rate data using whichever metric they wanted.
- 8.20. This position is understandable; the findings show that each metric has a number of advantages and disadvantages. Furthermore, it is true to say that if we promote a certain metric as headline figure, clinics might alter practice to favour that metric.
- 8.21. However, our user research highlighted that people find Choose a Fertility Clinic complicated to navigate and understand, and want information clearly presented. None of our proposals suggest that we intend to remove the ability to dig down into the data in a number of other ways, however we do think that choosing one headline figure will make it much easier for patients to understand the data.

#### **Summary**

- 8.22. Using live birth rate per embryo transferred as headline figure, and cumulative live birth rate as second headline figure is seen as appropriate by workshop delegates, around half of online survey respondents, and several professional bodies.
- 8.23. However, a large proportion of patients did not agree, although it is not clear why as only some explanation, or alternative, was provided.
- 8.24. It was often brought up, throughout the whole survey, and at the workshops, that we should do away with headline figures. This had support from a variety of stakeholders. However, we should bear in mind what our user research showed us – that patients find Choose a Fertility Clinic difficult to understand and navigate, meaning that they often go to clinics' own websites to view a simple presentation of success rates. Whilst not passing judgement on clinics' websites, it sits uncomfortably with the HFEA that our main stakeholders struggle with a website designed to provide impartial and objective data of the sector. Accurate data must be provided in an understandable format.
- 8.25. Bearing this in mind, we should consider the purpose of success rate information on Choose a Fertility Clinic. We have always been clear that its primary purpose is to show to patients where there are good clinics that can produce top quality embryos with positive outcomes, which suggests that births per embryos transferred might be the most appropriate headline figure. However, some see it as a service which is primarily intended to show a patient the likelihood of successful treatment at a particular clinic, which suggests that births per treatment cycle started might be best – although we should note that there are many other factors that can impact on whether a patient becomes pregnant.

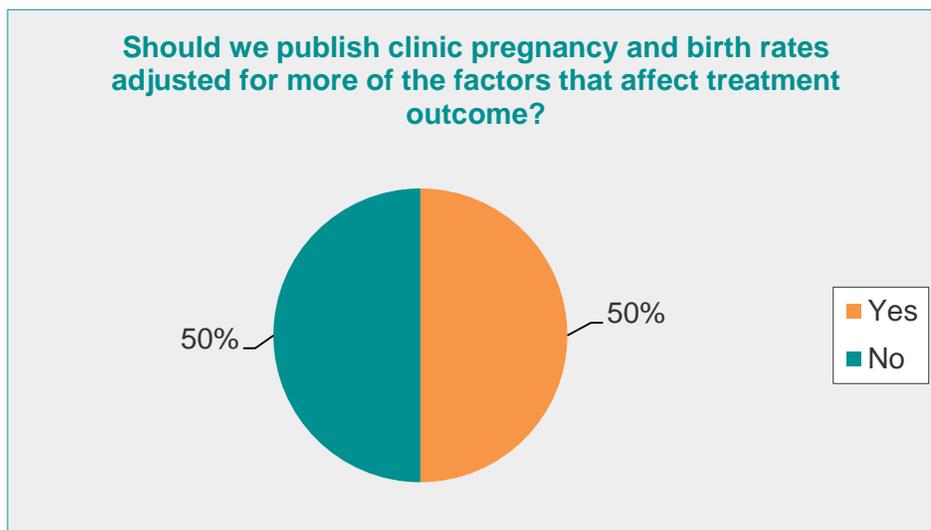
#### **Conclusions**

- Both live births per embryo transferred and cumulative live birth rate have a number of advantages and disadvantages
- Some respondents support having multiple metrics to measure success, although going down this path would be contrary to the findings of user research – and such information can still be available but not as the headline figure.

- Assuming we want to highlight which clinics are good at producing high quality embryos resulting in a birth (the primary aim of Choose a Fertility Clinic), then live births per embryo transferred is the most appropriate headline figure.
- The definition of cumulative birth rate is not well understood, but is seen as a useful second headline figure to provide. If chosen, further work is needed to define what it is measuring and conveying this in an accurate and understandable way.

## 9. Adjusting success rates for more factors

- 9.1. The HFEA provides clinic success rates adjusted for age only; however, the proposal put forward was to adjust for more factors which impact on the chances of pregnancy, such as number of previous pregnancies, number of eggs collected and duration of infertility. By adjusting for individual case mix, the intention was to provide more reliable comparisons between clinics.



N. 228. Yes = 114. No = 114.

### Reasons to agree

- 9.2. The pie chart above shows that online survey respondents were split on whether to accept this proposal. Many of those in support felt that risk adjustments would provide patients with a more accurate picture of their chances of pregnancy. Age was consistently referred to as a reliable risk factor but other suggested areas also included years of infertility, number of previous attempts at treatment and treatment type. One respondent concluded that:

*“This is very admirable and I would support this measure. This should include factors such as ovarian reserve, duration of infertility, previous failures etc...”* **Other [unspecified]**

- 9.3. Some respondents tentatively supported the proposal but cautioned about the complexity and the need to not over simplify complicated calculations. Comments referred to the risk of dealing with small data sets and whether this would actually yield useful results.
- 9.4. When we looked at how those who identified themselves as a patient, donor, donor conceived person or their parent responded, we saw that around half were in favour. They saw this as an opportunity to provide more accurate success rate data:

*“Patients need to know figures that are relevant to them, not a grossed up average.”* **A fertility treatment patient (past or present)**

- 9.5. When we looked at how clinic staff responded, we saw that just over half supported the proposal.

### Reasons to disagree

- 9.6. Conversely those who opposed the proposal felt that there are too many variables for the feature to truly be meaningful. The amount of information, and detail, required was seen as too complex and rather than helping and informing patients, it could be misleading. There were also comments on the HFEA not being in possession of enough information on the factors known to influence success rate – for example AMH reserve. Publishing an adjusted rate could therefore give the numbers credibility where it is not warranted:

*“These factors would only confuse - and will change over time....”* **Person Responsible**

- 9.7. The sentiment from the workshop more or less mirrored the views from the online responses. Overall, delegates liked the idea of risk adjustment, but the reality of having the right data to do so was thought to be probably insurmountable given the number of variables involved. They mostly agreed that age was the only factor which could give reliable information. There was also concern that patients could suffer from ‘knowledge paralysis’ faced with good, but increasingly complex information. Others talked about their approval of using the differentiation by age but anything more would be cumbersome and actually make it more difficult for patients to understand.

### Summary

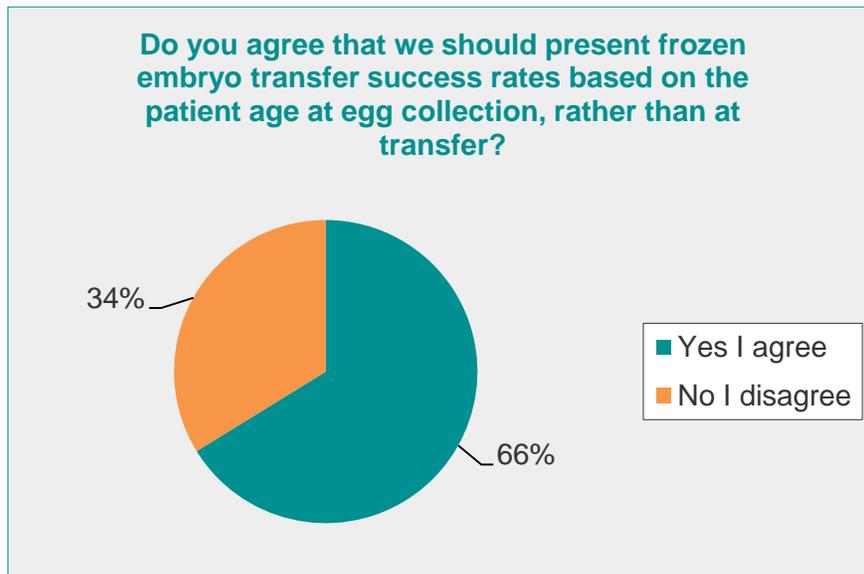
- 9.8. On balance, it is clear that there is the will to provide patients with the right tools to help them make assessments about their chance of pregnancy. If the correct data is available to do this, risk adjusting would be a way to achieve this. However, it does appear that the HFEA is not in possession of some of the information needed, and thus new information may need to be submitted by clinics. There is also the issue of numbers being so small in certain clinics that the data become less meaningful.

### Conclusions

- Stakeholders see the benefit of risk adjusting success rates, but note that additional information may be required for it to be done correctly, which might then increase the information requirements of clinics.

## 10. Presenting frozen embryo transfer success rates

- 10.1. Success rates for frozen embryo transfer (FET) are currently shown by the age of the patient at transfer. There is a suggestion that it is better to show success rates by the age of the patient at the time of egg collection because this is the key factor that affects outcome.



N. 231. Yes = 153. No= 78.

### Reasons to agree

- 10.2. The pie chart above shows that the majority of respondents agreed with this proposal. They often stated that the egg's age was the most important factor for FET. Doing otherwise would give an inaccurate view on success rates:

*"It is a well-established biological fact that the patient's age at egg collection has a greater impact upon the success of their treatment than the patient's age at embryo transfer." **Representing an independent charity that serves patients, professionals and the broader public.***

*"This gives the "age" of the egg and is the most important factor in defining whether treatment is successful or not." **Retired assisted conception doctor.***

- 10.3. One respondent felt that it would also demonstrate a clinic's ability and record of egg collection:

*"It is good because we will be able to demonstrate to the public that we have done well in terms of egg collection" **Reproductive medicine doctor***

- 10.4. The majority of staff at our workshops also agreed with this proposal for similar reasons though questioned what would happen when embryos frozen on different dates are thawed and used in treatment. As well as this, some were unsure how this proposal would work when using donor eggs.

### Reasons to disagree

- 10.5. Those that disagreed were concerned this would mislead patients to think the focus was on the age of the egg alone:

*“The age of the 'uterus' at transfer is surely relevant in measuring success as social freezing becomes more popular.” **Quality Manager***

*“...although younger age for eggs is good for genetic problems and does play a large part in success, it doesn't solve the increased risks an older age at transfer can pose - increased medical problems, blood pressure, uterine problems (fibroids) increased risk of miscarriage unrelated to embryo age. I think it would give false hope to patients...” **A fertility treatment patient (past or present)***

- 10.6. A slight majority of those identifying themselves as patients, donors, donor conceived person or their parents agreed with this proposal. Though not many comments were provided, those that disagreed explained they wanted to have the data for both egg age, and age of transfer, available to them so that they could make their own decisions on treatment.

*“Both will be important considerations for patients making decisions about their future plans.” **A fertility treatment patient (past or present)***

### Summary

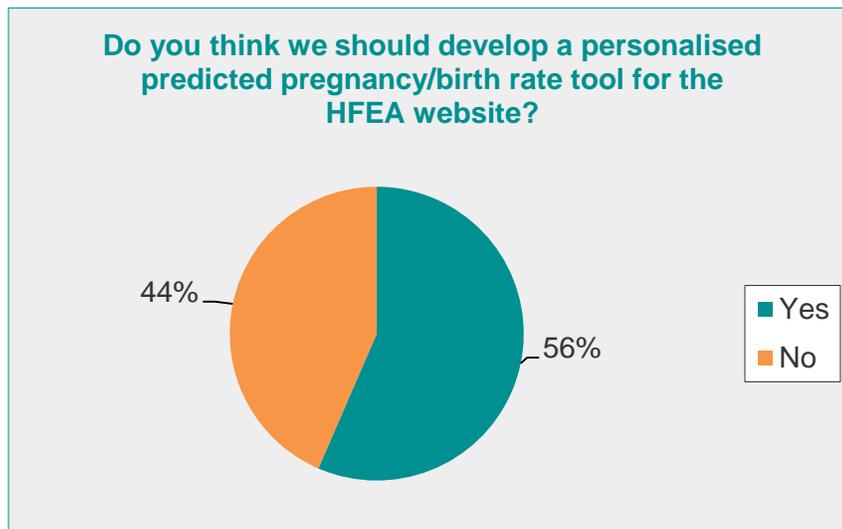
- 10.7. There is an acceptance that the importance of a patient's age at egg collection eclipses that of her age at egg transfer. This is supported by the overall consensus of the online respondents and delegates who attended the workshop.
- 10.8. However it was often noted that other factors affect outcomes, and it is important to make clear to patients that just using 'younger' eggs, does not mean that using them as an older patient will guarantee a successful outcome due to a number of other factors at play.

### Conclusions

- Stakeholders agree that FET success rates should be based on the age at egg collection.
- Information explaining that other factors affect FET success rates may be useful to include alongside these success rate figures.

## 11. Personalised pregnancy/birth rate tool

11.1. The HFEA provides patients with clinic specific success rates based on their data submissions. We indicate whether a clinic is either below, in line with, or above the national average. Although there is a publicly available tool already, there was a suggestion that it may be advantageous for the HFEA to also provide a personalised pregnancy/birth rate calculator on our website. Although not clinic specific, this would be based on national data and would give an indication of a patients personal chance of conceiving, irrespective of the clinic they attend.



N. 232. Yes = 131. No = 101.

### Reasons to agree

11.2. The pie chart above shows a slight majority of online survey respondents agreed with this proposal. Some felt that such a tool would offer patients the ability to understand their individual chances of a successful pregnancy. A couple of respondents felt that the HFEA is in the best position to offer such a resource:

*"I think that since the Register is such a big source of information, managing it to provide information to the patients would be its best exploitation."*

**Embryologist**

*"...this is the most significant advance HFEA could possibly make for their website. Not only will it help patients do their own research more effectively, but it will prevent clinics becoming bias towards optimising for one particular set of patients." A fertility treatment patient (past or present)*

11.3. We found a large proportion of patients, donors, donor conceived persons and their parents supported this proposal – often because it gave them personalised data. However, whilst supportive, some were cautious of how this might be done, and how to explain it accurately. Similarly, some clinics staff considered the

predictor tool to be useful but with some reservation – approximately half were in favour. They wanted to be assured that the resource could offer accurate and meaningful information, and that the outcome should not be presented as if that was the correct diagnosis of the patient.

### Reasons to disagree

- 11.4. However, the value of such a resource was challenged by those respondents who chose to comment on this question. They felt that such a resource would propagate false hope in women because it not only required individuals to self report information, but also the HFEA dataset does not contain enough data fields on which to make these predictions. Others felt that it was a task that was not within the remit of the HFEA, particularly as there was already a similar tool available on the internet:

*“This presupposes that the HFEA understands the treatment protocol and aim of treatment, which it does not” Other [unspecified]*

*“The HFEA has a role as a regulator, less so as a clinical advice service.”  
An Embryologist*

- 11.5. There was also a concern that providing a predictor tool would expose the HFEA to a levy of blame should the prediction be wrong, raising the number of complaints it receives.
- 11.6. In both workshops, staff understood the principle of giving patients accurate and individual information, but following discussion, were not supportive of the proposal. They felt that the HFEA would hold insufficient data to support it, and therefore HFEA data collection would have to increase – thus increasing the data burden on clinics. There were also issues around patients self-assessing their situation but not actually knowing the medical facts themselves or speaking to a professional.

### Summary

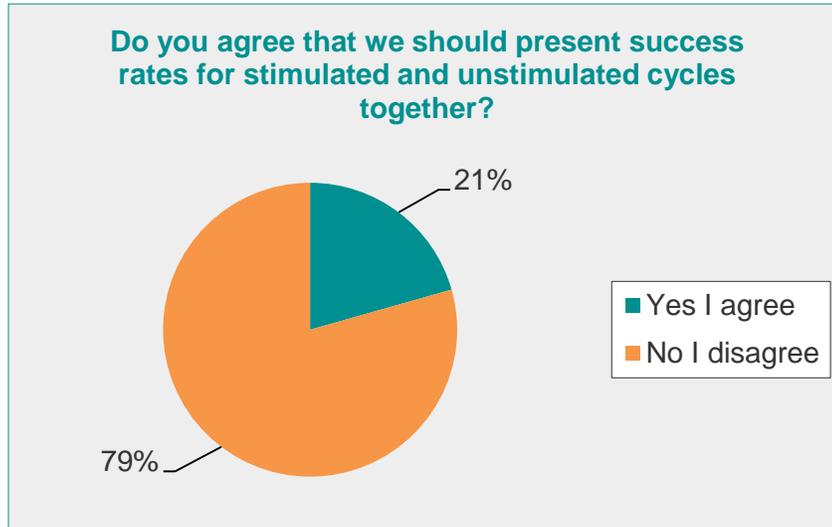
- 11.7. Providing a predictor tool, although a good aspiration, appears to have many issues which make it a difficult resource for HFEA to provide as we do not hold all the information that might be required to accurately provide the resource. Furthermore, it was suggested that such a resource is already available online – it is possible that patients agreed with this proposal because they weren't aware it already existed. Our user research noted that the HFEA does not need to provide everything about infertility on its website, and the use of 'piggy backing' or sign posting to other sites might be appropriate.

### Conclusions

- Whilst patients may support this proposal, a large number of stakeholders are concerned that we do not have all the required information to provide the service, and would need to collect more – which many were not happy with.

## 12. Stimulated and unstimulated success rates

12.1. Success rate data for stimulated cycles (involving the use of fertility drugs) are currently separated from unstimulated cycles. To give a more accurate picture of activity in a particular clinic, it was suggested that we combine them in the headline figure.



N. 233. Yes = 48. No = 185.

### Reasons to disagree

12.2. As the pie chart above shows, the majority of respondents disagree with this proposal. When we reviewed the comments from the survey and workshop we heard that it was important to keep them separate as they were very different types of figures/patient groups, and that patients needed this separated so they could make an informed choice. At the workshops, we heard that amalgamating them together could hide a clinic's poor success rate at unstimulated cycles:

*"To present them together would be unscientific and deeply flawed." Other [unspecified]*

*"No, if patients are looking to access natural/ unstimulated treatment they will want to understand their chances of pregnancy for either stimulated or unstimulated treatment in order to make an informed decision." An Embryologist*

*"... [patients] really need to appreciate up front the differing success rates, and having this data in black and white in front of them will help manage expectations." A parent of a donor conceived person*

*"I'm in a minority group and as such if you only choose to publish the most common data I will not be able to find the answers I want." A fertility treatment patient (past or present)*

12.3. The majority of clinic staff and patients, donors, donor conceived persons and their parents disagreed with the proposal. Some also thought that, as well as separating them out, we should ensure to use terminology such as 'Natural' rather than unstimulated. However, it was noted that it is difficult to define 'Natural' and 'Mild' IVF. For some, the lack of clear definition meant that the information should not be collected (bearing in the mind the plans for having a clearly defined data dictionary).

#### Reasons to agree

12.4. A minority of respondents supported the proposal. Reasons included:

- A clinics headline figure should encompass both
- It is still a success despite whether a stimulated or unstimulated cycle

12.5. Furthermore, The BFS noted that if we used live birth per embryo transferred as the main headline figure, then the mode of stimulation would not matter.

#### Summary

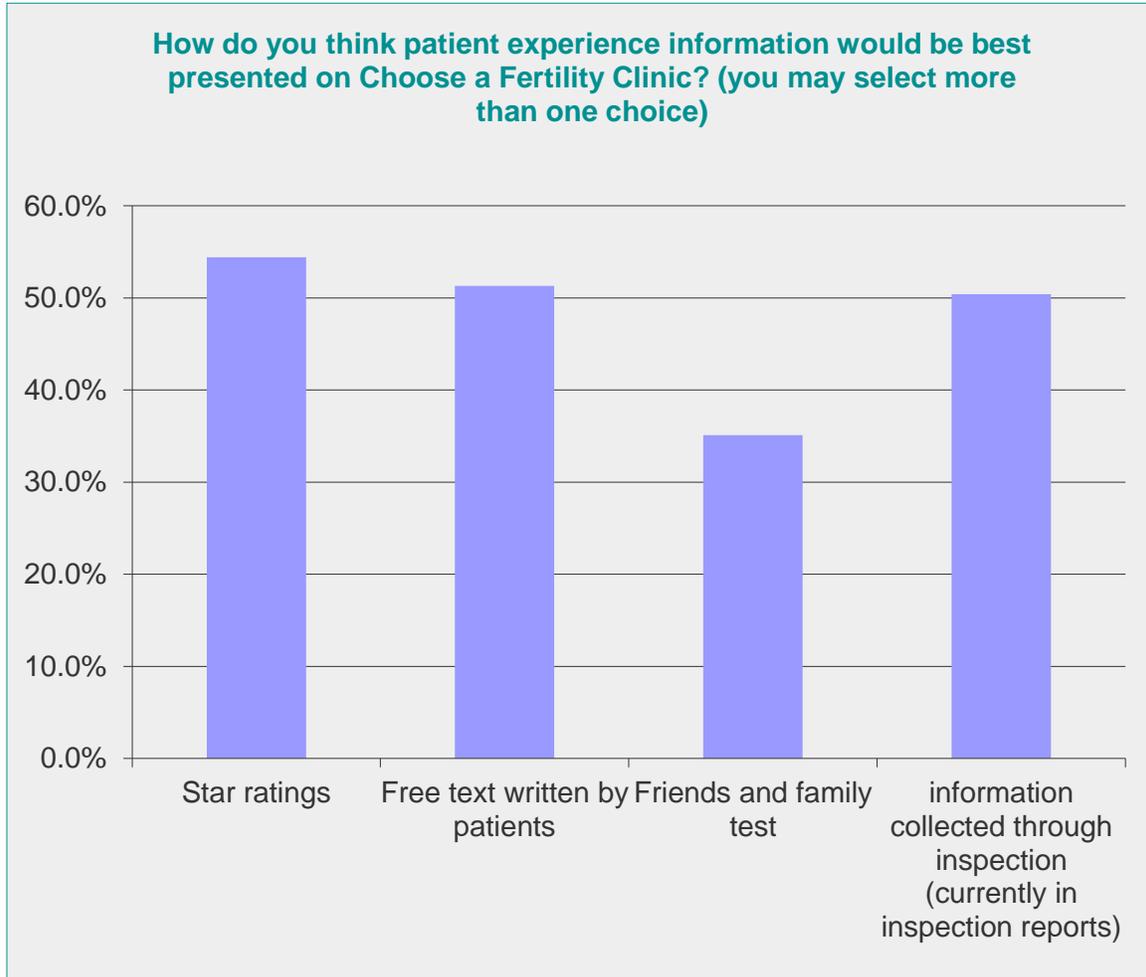
12.6. Both the workshops, and online survey, showed that the majority of respondents disagreed with this proposal as patients should be able to view the differing success rates for stimulated and unstimulated cycles. However, depending on whether we use live births per embryo transferred as the headline figure, this may be less of an issue.

#### Conclusions

- The majority of stakeholders were not supportive of this proposal and wanted both sets of information available. However, if we are concerned about the depth of information we might be providing on Choose a Fertility Clinic, we could instead amalgamate the figures and explain what unstimulated IVF is, and why it can have lower success rates.

## 13. Patient experience

13.1. As highlighted in the Authority's strategy, the HFEA is committed to providing patient experience information on Choose a Fertility Clinic. This question sought views on how we might do this.



Star ratings = 124. Free text = 117. Friends and Family= 80. Inspection = 115.

13.2. The chart above shows that the most often selected method for providing patient experience information was star ratings. When we looked at the results based on those identifying themselves as a patient, donor, donor conceived person or their parent, we saw that the most often chosen response was (in order):

- free text
- information collected on inspection
- star rating (only one behind)
- friends and family test

13.3. One respondent wrote, with great detail and passion, why it was important to have an outlet to share patient experience information. They supported using free text:

*“All of these would be good but free text written by patients who the clinic cannot identify is absolutely vital... as otherwise they will be afraid to say*

*what they really think. Fertility patients rarely dare to complain however much they might want to. I mentioned this at a support group meeting and there was a heart felt unanimous chorus of agreement. We want to warn other patients about particular clinics but unless we meet them personally we wouldn't dare try. Clinics hold our entire future in their hands and the lives of our children - if we've already had embryos created. We are afraid to complain in case we or our embryos are made to suffer for it. Some clinics are ruthless in their pursuit of good success rates and wealth. If we seem to be getting in their way we have no idea what they might do - so we keep quiet. If we were able to safely say how we really felt about how they'd treated us fertility treatment in this country would be revolutionized. At last they would stop being able to get away with things that they should never have been able to get away with in the first place. There are some truly good clinics and clinicians out there and we need to be able to tell each other which these are. Once we can, those clinics and clinicians that leave a lot to be desired will start to put their patients first at last!"* **A fertility treatment patient (past or present)**

- 13.4. Despite their support for free text, we heard several comments both through the survey and workshops about heading down a path of a 'Trip Advisor' type of feedback service. There was real concern that clinics could be targeted deliberately through negative feedback and that it could be seen as insensitive to treat the experience at a fertility clinic as you would a city break or condition of a hotel. Several noted that the people who often give feedback are those who are either very positive or negative:

*"Against free text as usually gives the extremes only and would be a huge task to undertake regularly. The objectives of the website should remain factual so no personal experiences and no self-assessment tools (in my opinion)"* **A fertility treatment patient (past or present)**

*"Any sort of 'trip advisor' review may result in misuse by patients or clinics. How would this be monitored and by who?"* **An Embryologist**

- 13.5. Also not particularly welcomed was the use of the friends and family test. This may be because, as one respondent put it, it is insensitive to ask people whether they would recommend something as emotional as fertility treatment to their friends or family. However, the BFS noted that it did not make sense for the HFEA to 'reinvent the wheel' since NHS organisations use the friends and family test, and the HFEA could ask private clinics to provide the same data in a different format.
- 13.6. Some respondents at our workshops thought that using the information collected through inspection was a fair and objective method – it was the second most chosen option of those identifying themselves as clinic staff. One respondent (not clinic staff) commented:

*"The other options are too open to manipulation / being skewed by people with strong opinions so HEFA should stick to the facts. If people want an opinion from other patients there are a million and one other websites they can find it on."* **A parent of a donor conceived person.**

13.7. Star ratings were the preferred option of clinic staff (although those responding to the survey often wanted more information on how it might work). At our workshops, some thought that the HFEA could use its own patient questionnaire to highlight a number of areas on which patients could rate a clinic, and then publish this on its website as a star rating. It was questioned how the HFEA might verify that a patient had actually had treatment at the clinic. Some, however, had concerns about what a star rating system would result in:

*“Star ratings create a league table mentally. Not all patients have freedom to access all centres dependent upon funding”* **Person Responsible**

13.8. A number of other points were raised by respondents through the survey and workshops:

- Ensuring that patient experience is gathered in a uniform way eg, questions should be asked at the same point of treatment
- Being mindful that responses usually come from people who have had extremely good or bad experiences
- Adopted methods are quantifiable and auditable
- That there is a difference in what the private and NHS clinics provide:

*“The questions for rating need to relate to factors which can be applied fairly to both NHS & Private centres, eg, physical environment of a private centre likely to be much nicer than an NHS, due to funding available to spend on decor, furniture, etc.”* **Quality Manager**

13.9. The Association of Clinical Embryologists advocated further development of HFEA patient feedback questionnaire:

*“Increased use of HFEA questionnaires, ensuring that clinics are not selecting patients who are more likely to give positive feedback. Perhaps not just before a clinic is due an inspection, perhaps make forms available at all times”*

13.10. Other suggestions included the HFEA highlighting clinics that have been identified as following best practice by patients, ie those recommending single embryo transfer to reduce multiple births should get highlighted as 'highly compliant'.

13.11. Despite the question being posed as 'how' patient information could be displayed, several respondents opposed its introduction – often because they thought it was out of the HFEA's remit, and that other channels to provide this information already exist.

### Summary

13.12. The HFEA is committed to providing some type of patient feedback system. Often where there are concerns, it is about how it could be done in a fair and impartial format.

13.13. It is clear that patients are supportive of having patient experience information available to them. Each method of feedback has advantages and disadvantages, but overall, patients wanted to provide free text – something which clinic staff in particular were concerned about. However, there may be a way of combining each

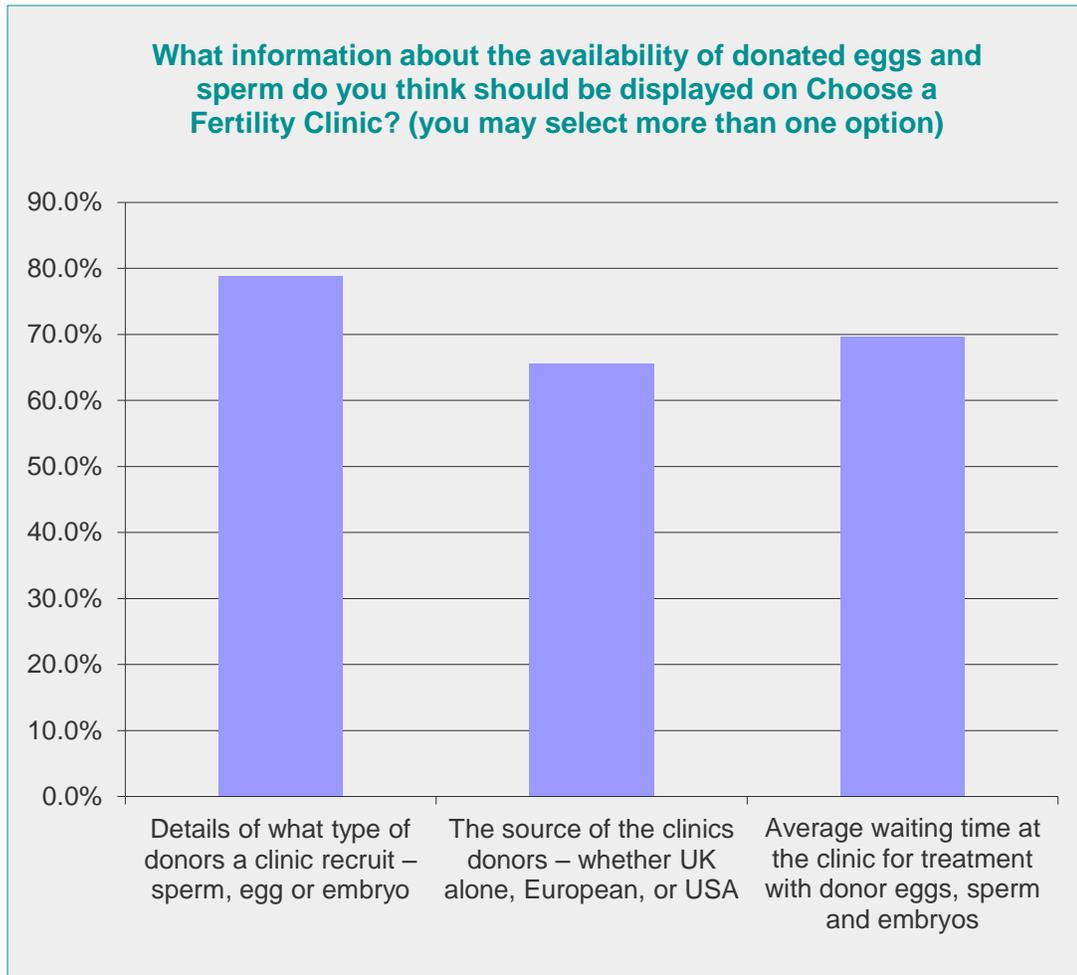
method to seek feedback in a fair way. For example, using the Friends and Family test, but supplemented by additional questions which would be presented by star ratings.

### Conclusions

- Stakeholders are generally supportive of patient feedback, but want it to be done in a way which is seen as fair.
- Each of the options, except for Friends and Family, were ranked fairly equal, though a number of respondents highlighted problems with having free-text.

## 14. Donor gamete availability

14.1. The HFEA only provides information on whether a clinic recruits, or provides treatment with, donor gametes. However, it was suggested that we should do more, and is an issue that the Authority has included as part of its Strategy. This question therefore asked what information should be made available on clinics donor availability through Choose a Fertility Clinic.



Type of donors = 179. Source = 149. Waiting time = 158.

14.2. There was general support to publish availability of types of donors, the source in which they come from and average waiting time. We did not receive any comments from patients, donors, donor conceived persons or their parents to suggest there were issues with the proposal which was reflected in some of the comments:

*“Can't agree more that there is a huge gap here. Is there a way to also include information on independent egg/sperm donor sources as well as those managed by a specific clinic. Also, can you include availability of anonymous or open identity donors and the amount of information that's*

*available to patients and offspring.” A fertility treatment patient (past or present).*

- 14.3. Although, there was overall support for such a feature this was closely followed by concerns of the practicalities. This usually stemmed from the point of how to monitor the “average” waiting time, particularly as donor gamete availability changes regularly, and the difficulty of keeping this up to date. According to some respondents the issue is heightened when dealing with patients who want particular types of donors.

*“There is no “average” waiting time for a donor – too many variables such as ethnicity and the recipients own specific requirements. An average wait time would be misleading, inaccurate and difficult to verify or validate.”*  
**Clinic staff – Donor Coordinator**

*“Given that the availability of donor gametes can change regularly, unless this information was kept up to date we are not sure that it would be a good idea to include on the Choose a Fertility Clinic.”* **Infertility Network UK**

- 14.4. Alternatives included having a link on Choose a Fertility Clinic to the clinic's own web page which detailed out the latest information. There was also a slight concern that the HFEA was stepping out of its remit and the National Gamete Donation Trust should be the organisation to publish such information or alternatively clinics publish it themselves on their websites.

### Summary

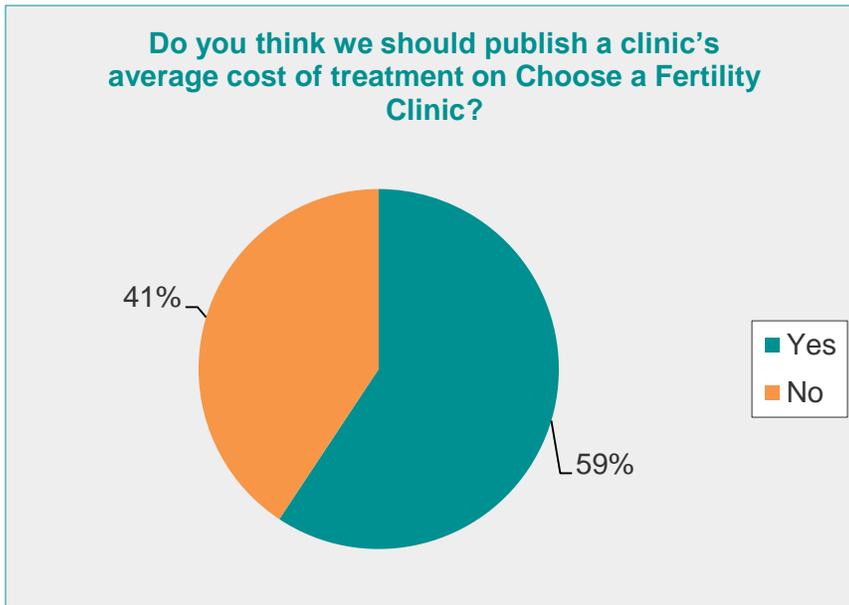
- 14.5. The HFEA is committed to providing information on donor gamete availability on its website. On balance it can be seen that, in principle, this would be welcomed. Each of the options on how we might do this had support from professionals and patients.
- 14.6. There is some concern about how the HFEA can provide this information in a useful and meaningful way, with some clinic staff explaining that the donor gamete availability can change quickly and will need to be updated regularly. However, we did not hear many principled disagreements, and it seems that the practical difficulties are driving concerns. Saying that, we intend to improve the usability of Choose a Fertility Clinic as part of the IfQ programme, such that it should be easier for clinics to update any clinic specific information.

### Conclusions

- Information on donor gamete availability is, in principle, welcomed.
- There is concern over how this will be kept up to date when the information can change so quickly but such issues do not seem insurmountable if we make clear that the data is based on averages, and improve how such information is provided.

## 15. Cost of treatment

15.1. The HFEA is not an economic regulator, and therefore has no control over the amount clinics charge patients. However, to help patients understand how much they might be expected to pay, we provide guidance to clinics stating that they should provide a costed treatment plan before patients start treatment. We know cost is an important issue for patients and therefore asked whether the average cost of treatment should be included on Choose a Fertility Clinic.



N. 236. Yes = 140. No = 96.

### Reasons to agree

15.2. As the pie chart above shows, information on the cost of treatment was welcomed by a majority of online survey respondents. Moreover, the majority of those identifying themselves as patients, donors, donor conceived persons and their parents supported this proposal. Some, however, thought that there were other means by which patients could be provided with greater information on costs, such as a range (the maximum or minimum cost of treatment) or a history (based on details of how much previous patients had paid – possibly through a patient feedback system).

15.3. We also found that just over half of clinic staff agreed with the proposal. They expressed views such as:

*“Yes definitely, this needs far more clarity, so many patients are given a price, then asked to pay for 'essential extras' once their treatment has started...”* **An Embryologist**

*“Yes, this needs far more clarity...”* **ACE**

15.4. We also heard some staff at the workshops agree with the proposal. They suggested we publish agreed areas of treatment (such as consultation, drugs and IVF/ICSI/IUI treatment) and ask clinics to self report the cost onto Choose a Fertility Clinic.

15.5. There were also suggestions on how this could be applied to NHS treatment:

*“For NHS cycles, it is essential that the cost paid by the CCG is included in any calculation. Otherwise the HFEA would be distorting the IVF market and would be open to challenge.” Other [specified]*

### Reasons to disagree

15.6. However we also heard a number of concerns with this proposal. Some of this was based on a lack of clarity as to what it would entail and how would it be done. Some comments included:

*“This will become more challenging and will depend on what is included, e.g. PGS, time lapse, embryo glue, endometrial scratch, immune therapy, hysteroscopy and how it is decided what is and isn't included”. A doctor*

15.7. Rather than clarifying the cost for patients, some argued that it could in fact add to confusion as it was difficult to define an ‘average’ treatment. Several respondents felt that patients need different treatments and medications according to their own circumstances and the proposal for an average would be difficult to achieve in an objective, accurate and comparable way.

15.8. Several people at our workshops and through the survey thought it was not within the remit of the HFEA to provide this information. Instead, we could provide a link to the pricing options of individual clinic’s webpages.

### Summary

15.9. Publishing the average cost of fertility treatment is in general supported, particularly by patients. A range of stakeholders appreciate that cost is an important factor for patients. However, there is apprehension about how this might be accurately presented on Choose a Fertility Clinic in order to provide comparable data, and some concern about whether it is within the HFEA’s role to provide such information.

15.10. It is likely that such information would be self reported by clinics, and be an optional piece of data they provide. A consensus would need to be reached about what is included in the ‘average’ treatment.

### Conclusions

- This proposal has support from stakeholders, particularly patients, but there are concerns about how it might be implemented.