

Authority meeting - agenda

Date: 28 June 2017

Venue: HFEA Offices, 10 Spring Gardens, London SW1A 2BU

Agenda item	Time
1. Welcome, apologies and declaration of interests	11:30am
2. Minutes of 10 May 2017 HFEA (28/06/17) 839 For decision	11:35am
3. Chair's report (verbal)	11:40am
4. Chief Executive's report (verbal)	11:50am
5. Committee chairs' updates (verbal)	12:00pm
6. Performance report HFEA (28/06/17) 840 For information	12:15pm
Lunch	12:45pm
7. Information for quality programme: update HFEA (28/06/17) 841 For information	13:30pm
8. Donor information requests HFEA (28/06/17) 842 For information	13:45pm
9. Improving embryo research HFEA (28/06/17) 843 For decision	14:05pm
10. Treating trans patients and donors HFEA (28/06/17) 844 For decision	14:35pm
11. Updates to the Code of Practice in October 2017 HFEA (28/06/17) 845 For decision	15:10pm
12. Any other business	15:30pm
13. Meeting close	15.35pm

Minutes of Authority meeting

10 May 2017

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

Details:

Meeting Authority

Agenda item 2

Paper number HFEA (28/06/17) 839

Meeting date 28 June 2017

Author Erin Barton - Inspections, Logistics and Projects Officer

Output:

For information or decision? For decision

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

Resource implications

Implementation date

Communication(s)

Organisational risk Low Medium High

Annexes

Minutes of the Authority meeting on 10 May 2017 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire (Chair) Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore Anita Bharucha Bobbie Farsides
Apologies	Ruth Wilde Dr Andy Greenfield	
Observers	Steve Pugh (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Paula Robinson Richard Sydee Catherine Drennan	Rosetta Wotton Joanne Triggs Erin Barton

Members

There were 9 members at the meeting, 6 lay members and 3 professional members.

1. Welcome, apologies and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members and members of the public to the third meeting of 2017. As with previous meetings, it was audio-recorded and the recording was made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.
- 1.2.** Apologies were received from Dr Andy Greenfield and Ruth Wilde.
- 1.3.** Declarations of interest were made by:
 - Anthony Rutherford (Person Responsible at a licensed centre)
 - Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
 - Yacoub Khalaf (Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 15 March 2017

- 2.1.** Members agreed the minutes of the meeting held on 15 March, for signature by the Chair of the meeting.

3. Chair's report

- 3.1.** The Chair provided members with a summary of events that she attended since the Authority meeting on 15 March 2017.
- On 16 March, we held our Annual Conference where we launched our new strategy for 2017-20. The day was a huge success with other 300 attendees. The Chair thanked staff who volunteered on the day and those who attended.
 - On 29 March, she chaired our Remuneration Committee with Margaret Gilmore and Anita Bharucha. In the evening, the Chair was invited to take part in the Progress Educational Trust debate held at the Royal College of Obstetricians and Gynaecologists about fertility treatment add-ons.
 - On 19 April, the Chair, along with the Chief Executive, visited the Frances Crick Institute and met Kathy Niakan and Robin Lovell-Badge to talk about Kathy's HFEA licensed research using gene editing techniques.
 - On 2 May, she chaired the Appointments Committee with Margaret Gilmore and Anita Bharucha where they agreed to renew the appointments of Elizabeth Haxby and Samuel Stein to our independent Appeals Committee.
 - On 4 May, the Chair, along with the Chief Executive visited Hull IVF Clinic and met Stephen Maguiness and Christine Leary.
- 3.2.** Finally, the Chair thanked members for their contributions over the past business year.

4. Chief Executive's report

- 4.1.** The Chief Executive advised members that on 21 March he attended the Audit and Governance Committee, and on 29 March he attended the Remuneration Committee to discuss our restructure proposals. We received Cabinet Office approval for a small voluntary redundancy scheme and are now looking to recruit to a number of new roles to ensure that we are organised to meet our strategic ambitions over the next three years.
- 4.2.** On 13 April, the Chief Executive attended the Health and Care Leaders Senior Talent board meeting, and on 18 April he was interviewed by South Korean TV about gene editing research.
- 4.3.** On 3 May, the Chief Executive spoke at the NHS BT Senior Leadership Development programme event in Leamington Spa.

Press coverage

- 4.4.** The Chief Executive informed members that it had been a busy few weeks in terms of media interest in the fertility sector.
- 4.5.** Daily Mail investigation into IVF clinics: The Daily Mail published several articles last week as part of an investigation into practices at a number of licensed fertility clinics. The paper made allegations about egg donation, egg freezing and OHSS. We issued a statement in response which was quoted in the Mail saying that we would investigate any allegations and will take regulatory action where we judge that it is merited. The Chief Executive advised that it would be inappropriate to comment further on the substance of the allegations until we have investigated and reported our findings to a Licence Committee.

- 4.6.** In addition, we will be assessing the extent to which there are wider lessons for the regulatory regime and the sector as a whole. The Chief Executive informed members that he had written to all PRs and would report back to the Authority.
- 4.7.** Treatment add ons: The Chair participated in a recent PET debate on treatment add ons which led to a number of stories in the media. This is a key part of our new strategy and was discussed at our recent annual conference.
- 4.8.** Woman's Hour: The Director of Strategy and Corporate Affairs appeared on Woman's Hour to discuss how patients make decisions about what to do with their embryos after treatment. She raised the issue of promoting embryo research to patients, which is a key element of our new strategy.

5. Committee Chairs' updates

- 5.1.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 30 March and 27 April. It considered five preimplantation genetic diagnosis (PGD) applications in March and one request for Special Directions, all of which were approved. At the April meeting, five PGD applications and one request for Special Directions were considered. The minutes have not yet been published. The Chair noted that the volume and complexity of their workload had increased, and thanked members for their contribution.
- 5.2.** The Deputy Chair of the Licence Committee advised members that the committee met on 4 May to consider one research licence renewal, one interim inspection report, two executive updates and one additional report. The minutes have not yet been published.
- 5.3.** The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) met four times since the Authority last met; on 24 March, 6 and 21 April, and 5 May. The panel considered four renewal applications, six interim inspection reports, seven licence variations, and one application for HLA tissue typing, all of which were approved. The Licensing Officer approved four licence variations. She advised members that the new Head of Planning and Governance was no longer a member of the Executive Licensing Panel, and that the Head of Regulatory Policy had taken over as Deputy Chair.
- 5.4.** The Chair of Audit and Governance Committee (AGC) advised members that the committee met on 21 March and, aside from the usual standing items and updates from internal and external audit, the committee received reports on:
- Finance and resources, from the Director of Finance and Resources
 - Strategic risks, from the Head of Business Planning (now Planning and Governance)
 - Contracts and procurement, and the whistle blowing policy, from the Head of Finance
 - Information standards
 - Cyber security, Information Governance Group activities, resilience and business continuity management, and an update on the IfQ programme, from the Director of Compliance and Information
 - A final report on board effectiveness which the Chief Executive will circulate to members, to get their views on the two recommendations relating to internal communication and training for new members.

- 5.5.** On IfQ, the Chair of AGC advised members that the committee will continue to monitor progress and expenditure on the data submission project and will be looking at benefits realisation for the IfQ programme once it has been concluded.
- 5.6.** The Chair informed members that, as previously mentioned, the Remuneration Committee met on 29 March and the Appointments Committee met on 2 May.

6. Performance report

- 6.1.** The Chief Executive introduced this item, advising members of the proposed changes to the existing strategic performance report, which reported on both organisational performance and progress against our strategy.
- 6.2.** Members will retain oversight of the overall health of the organisation and its performance through the performance report, which will continue to come to every Authority meeting and will include meaningful KPIs and other metrics relating to key management areas including:
- Our finances
 - The efficiency of our licensing processes
 - Information
 - Our staffing.
- 6.3.** These main performance indicators may change over time as new measures become available or become more important.
- 6.4.** We will report on strategy progress differently, through a series of Authority agenda items across the year. These themed reports will provide greater context, detail, narrative and impact.
- 6.5.** The Director of Compliance and Information summarised activity and performance within his directorate. Since the last Authority meeting, the 2016/17 inspection year had concluded and all planned inspections had been completed, alongside various additional inspections and new licence applications.
- 6.6.** The Director of Compliance and Information reassured members that we investigate all allegations made by whistleblowers and patients, and that the recent reports in the Daily Mail will be investigated thoroughly following our usual process. All material evidence will be formally reviewed and discussed with the clinic concerned, who will be provided with a draft report which they may comment on. This report will be presented to a licensing committee and appropriate regulatory action may be taken.
- 6.7.** Members heard that the problems with videoconferencing and the telephone system which were affecting committees had been resolved. Meetings will be brought back onsite cautiously and the IT team will be working with members individually to overcome any barriers to holding an effective meeting.
- 6.8.** One of the red performance indicators in the report related to the percentage of PGD applications processed within three months. There were only two applications, one of which was processed one day outside of the KPI which made the overall percentage drop dramatically. This was not a concern and was partly due to staff changes within the organisation.

- 6.9.** The Director of Compliance and Information informed members that the Statutory Approvals Committee had been issued with Office 365 with the aim of making the process of agreeing minutes more straightforward. The IT team will be providing further instructions to support its use.
- 6.10.** The Director of Strategy and Corporate Affairs informed members that the Annual Conference was attended by 300 members of the sector, including both senior staff and people who had not previously attended one of our conferences. The feedback was very positive, with 70% of respondents reporting that their expectations had been met or exceeded. Attendees particularly enjoyed the Chair's speech on showing leadership within clinics and the speech was published on the Clinic Portal for everyone who could not attend. Attendees also responded well to the workshops which were run and attended by members. The two most popular focussed on support for transgender patients and providing good emotional support for patients. Feedback also provided some ideas for next year's conference including live streaming of talks, using different types of technology and other improvements with regards to the venue.
- 6.11.** We made the greatest impact on Twitter in one day than ever before, on the day of the conference. This was affected by the Chair's announcement that we had issued the first licence to perform mitochondrial donation in the UK. Our tweets on the day received over 9000 views which grew our social media following.
- 6.12.** The Director of Finance and Resources informed members that we ended the financial year with a surplus of just over £1m, which is primarily due to treatment activity being higher than forecasted.
- 6.13.** Members were interested in using the findings of our planned study into the various factors affecting the demand for treatment to predict our future income more accurately and, if appropriate, adjust our treatment fee. Any adjustments would need to take into consideration the views of our fees stakeholder group which in the past has preferred a stable fee for a reasonable period time over fluctuation, and would need to be approved by the Treasury.
- 6.14.** Our year-end accounts have been produced in draft and will be audited by the National Audit Office over a period of two weeks, before being presented to the AGC on 13 June for sign off. Restrictions on government bodies while in purdah will delay parliamentary sign off until July, but this will hopefully take place before parliamentary recess.
- 6.15.** Following discussion, members noted the latest performance report and endorsed our proposed approach to ensuring the Authority retains good oversight of both organisational management and strategic progress.

7. Information for Quality: update

- 7.1.** The Director of Compliance and Information reminded members that the IfQ programme is a comprehensive review of the information that we hold, the systems that govern the submission of data, the uses to which it is put and the ways in which the information is published. It includes:
- The redesign of our website and Choose a Fertility Clinic (CaFC) function
 - The redesign of the 'clinic portal' used for interacting with clinics
 - Combining data submission functionality
 - A revised dataset and data dictionary which will be accredited

- A revised Register of treatments, which will include the migration of historical data contained within the existing Register
- The redesign of our main internal systems that comprise the Authority's Register and supporting IT processes.

- 7.2.** The Director of Compliance and Information advised members that the main focus was preparing the site for launch following the successful resistance of a legal challenge. The team has largely completed the creation of new rich content for the website including video clips and animations as well as a home page news feed.
- 7.3.** Clinics have now completed the verification of their outcome data ready for publication on CaFC. The Government Digital Service (GDS) provided feedback that we must address before we can proceed to live stage. This included the necessity of thorough security penetration testing which has now been completed, and the completion of an exercise and report as to the accessibility of the website to all users. The recommendations in this report are being addressed and publication is planned to take place following the final GDS assessment in May 2017.
- 7.4.** The majority of remaining work relates to the data submission component of the programme. Progress has been made with regards to data migration and external reports have shown our processes to be working well. Further work on the clinic front-end experience requires the support of contracted developers to progress. We plan to release the new system to current 'EDI' users, which is around half of all licensed clinics, in September 2017. It will take longer to roll the system out to clinics using third party suppliers to submit data.
- 7.5.** IfQ will formally close when the website is launched although the Authority and AGC will continue to receive progress reports on the remaining data submission project work. There will be an IfQ closure report to reflect on lessons learned and benefits realised as part of the programme.
- 7.6.** The original programme of £1.227m has all been accounted for with a slight overspend. The remaining work will be delivered as a project within our 2017-18 Business Plan commitments and an additional expenditure of £350,000 will be required. This additional expenditure is consistent with our new strategy and organisational restructure which includes a small two person development team who will procure a programme of development and continuous improvement of our systems.
- 7.7.** The Director of Strategy and Corporate Affairs informed members that changes have been made to CaFC based on the decisions made by the Authority in November 2016, following the successful resistance of a legal challenge referred to earlier. These changes are not visible to the public yet but they will be ready to publish shortly. We are presenting top level performance based on births per embryo transferred for patients having fresh IVF under the age of 38. We have produced an animation for the home page of CaFC which is designed to help patients to view success rates in context and consider other measures of performance, such as patient ratings and inspection reports, as equally important.
- 7.8.** Work has been done to improve accessibility of the website following recommendations from our GDS assessment. We have passed the plain language assessment and will be publishing a kitemark on that. Internal audit has approved our process for producing corporate information, and we are going through the process of acquiring the Information Standard which is a government standard for patient facing information. We have been working with NHS Choices

which is the main referrer into our website, to create a smooth transition from their website to our own.

7.9. Members were interested in how we will continue to monitor performance and demonstrate effectiveness particularly in relation to CaFC. The Director of Strategy and Corporate Affairs advised members that this would be covered later in the meeting as part of our Communication Strategy for 2017-2020.

7.10. Members noted:

- the intention to launch the HFEA website and CaFC, as live, in the next few weeks
- the activities necessary for completing the data submission project
- the budget expectations, and the capital cover consequences.

8. Pre-HFEA voluntary contact register

8.1. The Donor Information Manager informed members that the Department of Health (DH) is no longer funding the pre-HFEA voluntary contact register, the Donor Conceived Register (DCR) service, which to date has been managed by the National Gamete Donation Trust (NGDT), and has asked us to determine how to support the service.

8.2. There are two options for the future delivery of the pre-HFEA voluntary contact register:

1. To absorb part of the service into our mainstream activities, or
2. To contract out the entire service to another suitable organisation.

Absorbing into mainstream activities

8.3. The costs associated with bringing the service in-house would include additional salary costs of circa £28,000 plus an estimated £7,000 for overheads. Further costs would include the DNA analysis, and counselling and intermediary support. In both cases a new contract would need to be negotiated and it is not certain that the existing arrangements and costings could be maintained.

8.4. It makes sense to users to have all donor conception services under one roof, although the databases and processes vary in significant respects and this may confuse users to have such different systems side by side.

8.5. This option also presents the challenge of effectively integrating part of the service into our work. We would still need to contract out both the DNA analysis, and counselling and intermediary work, as the Opening the Register team are not qualified for this purpose. It would be difficult to acquire an additional member of staff whilst still operating within our headcount controls and whilst we have some of the expertise required to run the service, we do not have the capacity. The only way to create capacity would be to divert HFEA staff away from their core duties. There are also implications for other areas of the HFEA for example with stakeholder management, media and communications, and Freedom of Information requests.

Contracting out to another organisation

8.6. If we decide to continue to contract another organisation to run the voluntary contact register, we will go through a tender process to allow other organisations to bid for it, which would require

some staff time. Based on the DCR's current operating costs, this arrangement is likely to cost around £26,000 each year.

- 8.7.** Contracting out the service would maintain the distinction between the HFEA register and the DCR and if the current supplier were to bid for the service successfully, there would be continuity of service for its users. The HFEA would retain oversight of the service to ensure service users' needs are met.
- 8.8.** Members were concerned about the implications of diverting staff and resources away from other core functions, especially during a period of organisational change.
- 8.9.** Members were also interested in the continuity of service and contacts for users, if the current supplier were to bid for the service successfully. They were assured that there would be a range of performance metrics and a formal feedback mechanism within any agreement to ensure that the quality of service is maintained.

Decision

- 8.10.** Members stressed that the priority is to maintain a high quality service for donors and donor-conceived people, and felt that this could be best achieved by contracting out the entire service to another suitable organisation.
- 8.11.** Members asked the Executive to do some further work to estimate the likely increase in the number of registrants and ongoing costs, to decide on the most suitable type of contract.

9. Communications strategy 2017-2020

- 9.1.** The Head of Engagement gave an overview of our new communications strategy for 2017-2020, which is closely aligned to our strategic objectives of providing patients with information to make informed choices and raising the quality of care by encouraging patients to give feedback on their treatment.
- 9.2.** The strategy has six main audiences: patients, clinics, donors, donor-conceived people and their parents, the public and HFEA staff. The main audience for this strategy is patients.

Patients

- 9.3.** From our research, we know that:
 - Patients don't always find the HFEA when looking for information early in their treatment pathway but go to other sources such as NHS Choices or Mumsnet
 - Only one third (36%) of patients surveyed were aware of the CaFC service on the website
 - The website is our most commonly used resource by patients. We have an average of 110,000 visitors to the HFEA website each month
 - 49% of patients said they thought the HFEA was impartial and 61% said we are authoritative.
- 9.4.** As part of our new strategy, we will:
 - Get to patients earlier in their fertility journey by working alongside NHS Choices
 - Market the benefits of our new website and CaFC service
 - Increase our use of social media including Twitter

- Make better use of rich media including animations and videos
- Run campaigns to improve care by providing patients with better information to challenge clinics on controversial issues and make informed choices
- Continue to engage in qualitative face to face communication with patients by attending fertility shows
- Make an impact with our partnership working with patient organisations on campaigns like treatment add ons so we can make maximum impact.

9.5. We know our approach to social media is working and we will continue to take this approach to increase our following on Twitter and engage with stakeholders. We will also consider developing other social media tools such as Facebook.

Clinics

9.6. The strategy also focuses on our communications with clinics to improve practice by setting out what we expect of clinics and what information they should give to their patients. We also aim to reach patients by encouraging clinics to give our information to their patients and to direct patients to our website. We will produce marketing materials for clinics and brief our inspectors who are in regular contact with clinics.

Media management

9.7. We know that the media helps us by maintaining our reputation and showing that we are knowledgeable about the sector. We will generate media interest by:

- Running campaigns, starting with a major campaign around treatment add ons which we will use to generate media opportunities including broadcast interviews and magazine features
- Making better use of data, and looking at ways of releasing data to create maximum coverage and to reach as many people as possible. We can release data contained in the trends report at different times rather than in one go to provide more media opportunities.

How we will know how we've done

9.8. We have developed a new set of metrics, and will continue to add more, to enable Authority members to monitor the success of the new communications strategy.

9.9. Members were asked to consider the new strategy, in particular:

- Do you agree to making patients our main focus for this strategy?
- Do you agree with our suggested approach to media management?
- Is social media important to the HFEA?

9.10. Members were assured that, although not a main focus in our communications strategy, work was being done to direct geneticists and researchers to specific areas of our website which may be less visible now due to the website's new focus on patients.

9.11. Some members asked whether more could be done to reach patients earlier through their GPs but heard that online digital marketing is a far more efficient and cost-effective way to reach our demographic. We know that many patients being referred for fertility treatment look online for information and often use NHS Choices. We aim to reach more patients by developing a good information pathway from NHS Choices to our website.

- 9.12.** Members were keen to ensure that the HFEA can be easily found through search engines, and to market the benefits of our new website and CaFC service where appropriate, for example during interviews or other media appearances.
- 9.13.** Members advised a cautious approach to the use of Facebook and wanted clarity around what we expect to achieve. Facebook creates a new platform for patients and the public to ask questions, and this must be monitored carefully. Members heard that Facebook would be beneficial in running campaigns alongside other patient organisations, such as Fertility Network UK who currently use Facebook successfully to reach patients. We will use Facebook in a selective way and develop our approach over time.
- 9.14.** Some members requested guidance on how they could help to support the social media strategy, for example by retweeting posts from our account.

Decision

- 9.15.** Following discussion, members agreed with the focus of the new communications strategy and the suggested approach. The Executive agreed to continue to work to deliver the strategy with the help of a subgroup of members.

10. Any other business

- 10.1.** The Chair of the meeting confirmed that the next meeting will be held on Wednesday 28 June at 10 Spring Gardens, London, SW1A 2BU. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

11. Chair's signature

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

Signature

Chair

Date

Performance report

Strategic delivery:

- Safe, ethical effective treatment
 Consistent outcomes and support
 Improving standards through intelligence

Details:

Meeting	Authority
Agenda item	6
Paper number	HFEA (28/06/17) 840
Meeting date	28 June 2017
Author	Paula Robinson, Head of Planning and Governance

Output:

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

1. Introduction

- 1.1. The attached paper summarises our performance up to the end of April 2017, with financial data from May.
- 1.2. Following discussion of the new format at the May Authority meeting, we have continued with the new style of report. We will work with staff over the next few months, particularly once the Information for Quality Programme work has been completed, to review all of our current indicators. This will include consideration of the indicators themselves, and the associated targets. Over time, we would like to develop more measures of quality and performance, as opposed to quantity.

2. Reviewing performance

- 2.1. The Corporate Management Group (CMG) reviewed the April data at its June performance meeting.
- 2.2. Overall performance remains good.

3. Recommendation

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

Dashboard – April data

People – capacity

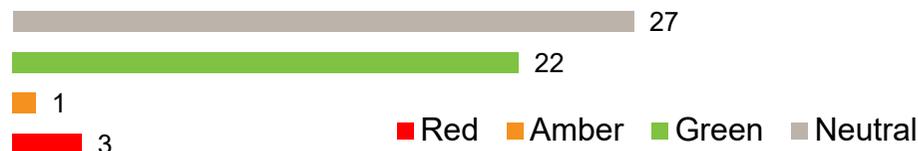
Establishment leavers per month

(% turnover for the year).

KPI: 5 - 15% establishment turnover

↑
Leavers: 0
(15.8%)

Overall performance – RAG status (all indicators)



Information – OTR efficiency

Opening the Register requests responded to within 20 working days

(Number on time/ number due)

KPI: 100%

★
100%
(13/13)

Licensing end-to-end

Length of the whole inspection and licensing process

KPI: ≤ 70 working days

★
63 days

Money – budget

Summary Financial Position - May 2017

£0000	Year to Date £			Full Year £		
	Actual	Budget	Variance	Forecast	Budget	Variance
Income	900	1,088	(189)	6,230	6,230	-
Expenditure	695	964	270	5,784	5,784	-
TOTAL Surplus / (Deficit)	205	124	81	446	446	-
Commentary						

The year to date (YTD) position (May 2017) shows a significant surplus against the planned budget. We have seen an under recovery of income, primarily due to GIA not yet being drawn down from DH, offset by significant underspends in staff costs - where we are currently carrying a number of vacancies - and in areas where spend is more volatile such as legal costs.

At present we continue to forecast to budget. A review of YTD spend will be undertaken at the end of quarter 1 and discussed in detail with Directorates in order to inform any decision to revise the year end forecast.

Overall performance – April 2017

We reviewed the overall performance picture at the CMG meeting on 14 June. Most indicators are on track, which demonstrates the commitment of our staff during an extremely busy period.

We noted a slight upward trend in establishment turnover, taking it just over our ideal range of 5-15%. The picture is complicated by the organisational changes that are in progress and the continued use of some contingency labour during delivery of the IfQ programme. Figures for May are higher still (19.2%, compared to 15.8% in April) and we expect the trend to continue upwards in the short term. We will continue to pay particular attention to this indicator and we will discuss any further needed actions if the trend continues beyond the summer.

We noted an apparent decrease, over the past 4 months, in the numbers of critical and major non-compliances on inspection. It is too early to say whether this indicates a sustained improvement in clinics' regulatory performance, but we will continue to monitor this.

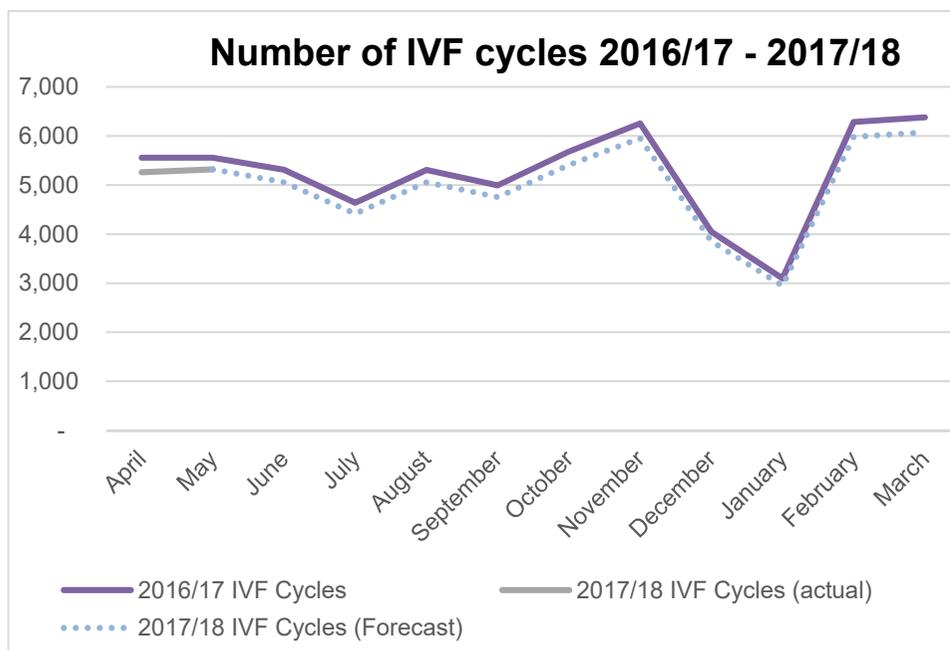
We received additional information about the top pages visited on the current (outgoing) website, compared to the new (beta) website. This was of interest because it shows a very different picture between the two sites. On the old site, the top pages are surrogacy, the home page, IUI and IVF. On the new site, the top pages are consent forms and guidance, the home page, CaFC, and CaFC clinic search. It may be that patients are mostly still using the old site, while centre staff are more aware of the new site and are interested in how their own clinic looks on it, as well as looking for information about consent forms and guidance. Once the new site is live, we plan to review our indicators, and will make more use of analytics showing how people are using the site, which pages they are interested in, and so on. This will inform our ongoing maintenance of the site itself and the content of other information that we produce for patients and clinics.

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

- Total number of outstanding (unresolved) form errors in the system. Our target is to decrease this number. If the number increases by more than 5%, we rate this indicator as red. For April, the number rose by 6% (to 2,525). This is attributable to the CaFC pre-publication verification process, which required focused attention by both centre staff and register team staff.
- Average number of working days from day of inspection to the day the draft report is sent to the PR. Our target is to send 90% of inspection reports to the clinic within 20 working days. In April, there were two reports due, and these were sent at 21 and 28 working days. The first of these was due to seeking legal advice on a difficult storage consent question, while the other was due to the interim inspection subsequently being combined with a change of premises, causing complexities in completing the report within the KPI timeframes.
- Annualised rolling average figure – percentage of all PGD applications processed within 3 months for the year to date. Our target is for 100% of applications to be processed within three months (66 working days). Owing to delays in PGD processing earlier in the rolling year, this measure is at 75%, although the average number of working days for processing remains well within target, at 60 working days.

Delays in PGD processing usually occur at the peer review stage. Typically, the cause is either a poor quality application, or a complex multi-type application. Either can prolong the timeline considerably and involve more processing effort. Although there was a period of temporary cover in Compliance, earlier in the year, this did not contribute significantly to delays in processing times. Clinics have recently been sent feedback about how they can improve their PGD application quality. It is also worth noting that the proportion of PGD applications that can be regarded as 'complex' (featuring multiple types) is increasing, since most of the more straightforward conditions have already been considered, and are on the PGD list already.

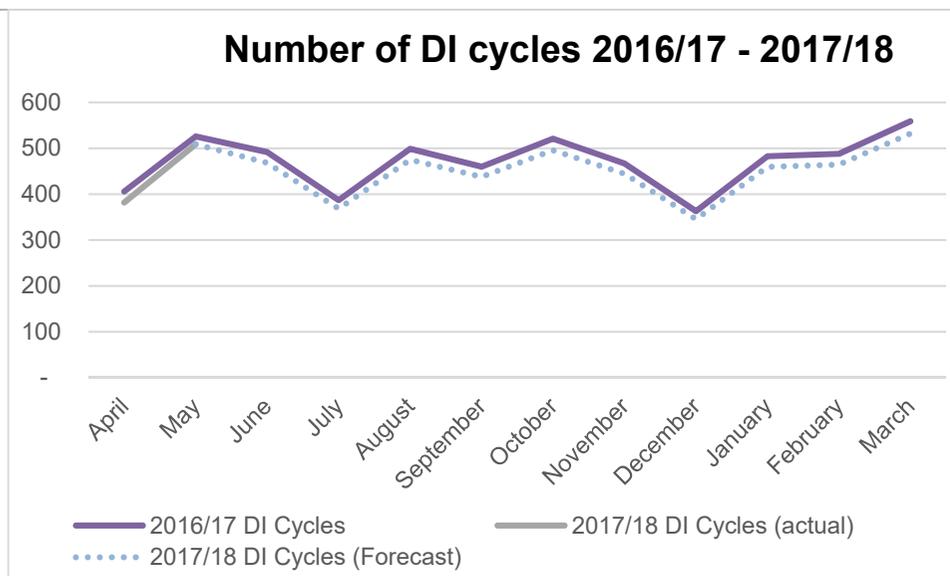
Budget status – May data



IVF Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2016/17 IVF Cycles	11,115	889,174	63,111	5,048,854
2017/18 IVF Cycles	10,581	846,480	60,080	4,806,433
Variance	534	42,694	3,030	242,421

YTD volumes for IVF cycles in the first 2 months of this financial year are 5% below those undertaken in 2016/17. Extrapolating that position across the financial year would see a fall in income, compared to 2016/17, of c£240k. The 2017/18 income budget was prudently predicated on a reduction in volume of 3%.

It is too early to suggest whether this indicates a likely trend for the remainder of this financial year, we will review the position at the end of Q1 before making any amendments to the overall income forecast.



DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2016/17 DI Cycles	932	34,950	5,651	211,913
2017/18 DI Cycles	891	33,413	5,383	201,878
Variance	41	1,538	268	10,034

DI cycles have followed the pattern of IVF cycles for the start of this financial year, with a fall of c5% when compared to 2016/17.

Although fees from DI cycles are a much smaller proportion of licence income it is useful to note the overall trend in activity within the sector.

HFEA Income & Expenditure

May-2017

Management commentary

£000	Year to Date £			Full Year £		
	Actual	Budget	Variance	Forecast	Budget	Variance
Income						
Grant-in-aid	-	156	(156)	938	938	-
Licence Fees	882	931	(49)	5,286	5,286	-
Other Income	8	1	7	6	6	-
Seconded Salary reimbursed	10	-	10	-	-	-
Total Income	900	1,088	(189)	6,230	6,230	-
Revenue Costs						
Salaries (excluding Authority)	456	585	130	3,513	3,513	-
Staff Travel & Subsistence	38	33	(5)	200	200	-
Other Staff Costs	9	23	14	138	138	-
Authority & Other Committees costs	40	50	11	301	301	-
Facilities Costs incl non-cash	64	115	51	690	690	-
IT costs Costs	15	21	6	125	125	-
Legal / Professional Fees	51	106	55	637	637	-
Other Costs	22	30	8	180	180	-
Total Revenue Costs	695	964	270	5,784	5,784	-
TOTAL Surplus / (Deficit)	205	124	81	446	446	-

Income

As previously stated licence fee income is 5% below 2016/17 position for the first two periods of 2017/18. Overall income is down against budget, GIA is yet to be drawn down for Q1.

Expenditure

Year to date is significantly below budget at period 2 across most categories of spend. This is partly explained by a straight line approach to budget profiling for some costs (Legal & Professional Fees, Facilities costs) where actual incurred spend is more volatile.

Salary costs to date are significantly below budget, this is due to a combination of new posts yet to be filled and general staff churn. This underspend position is likely to continue until we reach full establishment, not anticipated until the tail end of Quarter 2.

Overall position

Although our YTD position has seen a drop in income compared to 2016/17 this is offset by current underspends in staff costs; as a result these early figures suggest we are on track to a surplus position at year end.

Forecast

Forecast remains to budget for both income and expenditure at this time. The resources team will be meeting with each Director once the first quarter results are finalised, to review expenditure plans and revise forecasts where necessary. We will also take a view as to whether the income forecast should be downgraded in line with the emerging activity trend.

People – key performance and volume indicators

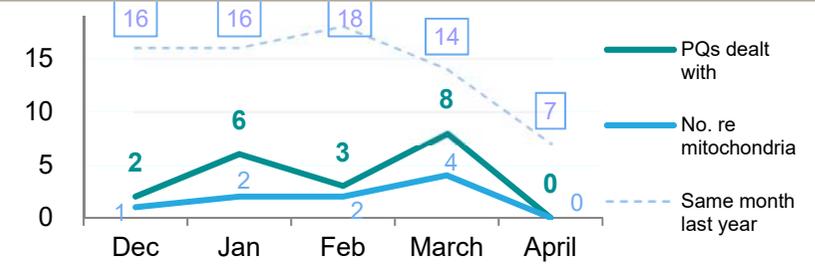
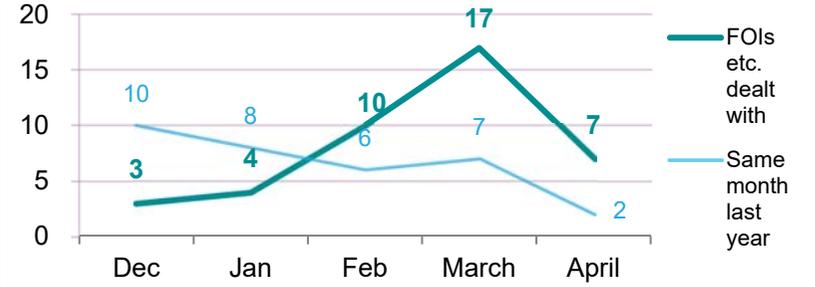
Indicator	Score	RAG	Recent trend ¹	Notes																		
Current headcount by month Headcount/ establishment	61/67	↔	<p>Headcount vs establishment</p> <table border="1"> <thead> <tr> <th>Month</th> <th>Headcount</th> <th>Establishment</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>62</td> <td>67</td> </tr> <tr> <td>Jan</td> <td>61</td> <td>67</td> </tr> <tr> <td>Feb</td> <td>62</td> <td>67</td> </tr> <tr> <td>Mar</td> <td>61</td> <td>67</td> </tr> <tr> <td>Apr</td> <td>61</td> <td>67</td> </tr> </tbody> </table>	Month	Headcount	Establishment	Dec	62	67	Jan	61	67	Feb	62	67	Mar	61	67	Apr	61	67	Overall volume (capacity) indicator. The gap between the number of permanent staff and our headcount is partly filled by staff on IfQ related contract work. The remaining vacancies arise from organisational change and should be filled in the coming months.
Month	Headcount	Establishment																				
Dec	62	67																				
Jan	61	67																				
Feb	62	67																				
Mar	61	67																				
Apr	61	67																				
Turnover: Establishment ('unplanned') leavers per month (% establishment turnover for the year).	15.8%	↑	<p>Turnover vs target range (5-15%)</p> <table border="1"> <thead> <tr> <th>Month</th> <th>Turnover (%)</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>10.9%</td> </tr> <tr> <td>Jan</td> <td>12.4%</td> </tr> <tr> <td>Feb</td> <td>12.4%</td> </tr> <tr> <td>Mar</td> <td>14.1%</td> </tr> <tr> <td>Apr</td> <td>15.8%</td> </tr> </tbody> </table>	Month	Turnover (%)	Dec	10.9%	Jan	12.4%	Feb	12.4%	Mar	14.1%	Apr	15.8%	KPI range: 5-15% turnover for the rolling year The public sector average is 10% (Expert HR & CIPD research 2013) which therefore forms the basis of our target. This is worked out on a rolling basis each month.						
Month	Turnover (%)																					
Dec	10.9%																					
Jan	12.4%																					
Feb	12.4%																					
Mar	14.1%																					
Apr	15.8%																					

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

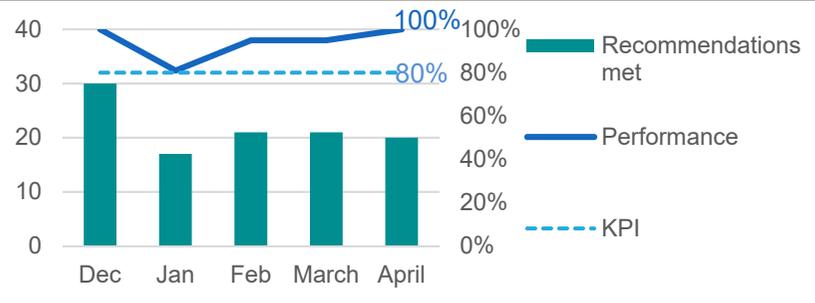
Indicator	Score	RAG	Recent trend ¹	Notes												
Staff sickness absence rate (%) per month.	1.5%	★	<p>Sickness absence</p> <table border="1"> <thead> <tr> <th>Month</th> <th>Sickness absence rate (%)</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>1.0%</td> </tr> <tr> <td>Jan</td> <td>1.4%</td> </tr> <tr> <td>Feb</td> <td>0.4%</td> </tr> <tr> <td>Mar</td> <td>1.1%</td> </tr> <tr> <td>Apr</td> <td>1.5%</td> </tr> </tbody> </table>	Month	Sickness absence rate (%)	Dec	1.0%	Jan	1.4%	Feb	0.4%	Mar	1.1%	Apr	1.5%	<p>KPI: Absence rate of ≤ 2.5%.</p> <p>Public sector sickness absence rate average is eight days lost per person per year (3.0%).</p>
Month	Sickness absence rate (%)															
Dec	1.0%															
Jan	1.4%															
Feb	0.4%															
Mar	1.1%															
Apr	1.5%															

Information – key performance and volume indicators

Indicator	Score	RAG	Recent trend	Notes																		
Number of emailed public enquiries received (cw same month last year)	200	↓	<p>Number of emailed public enquiries received</p> <table border="1"> <thead> <tr> <th>Month</th> <th>This year</th> <th>Last year</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>160</td> <td>193</td> </tr> <tr> <td>Jan</td> <td>170</td> <td>248</td> </tr> <tr> <td>Feb</td> <td>200</td> <td>259</td> </tr> <tr> <td>March</td> <td>208</td> <td>242</td> </tr> <tr> <td>April</td> <td>200</td> <td>224</td> </tr> </tbody> </table>	Month	This year	Last year	Dec	160	193	Jan	170	248	Feb	200	259	March	208	242	April	200	224	Volume indicator.
Month	This year	Last year																				
Dec	160	193																				
Jan	170	248																				
Feb	200	259																				
March	208	242																				
April	200	224																				
Percentage of Opening the Register requests responded to within 20 working days	100%	★	<p>Percentage of Opening the Register requests responded to within 20 working days</p> <table border="1"> <thead> <tr> <th>Month</th> <th>Number of requests</th> <th>% within 20 days</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>25</td> <td>100%</td> </tr> <tr> <td>Jan</td> <td>14</td> <td>100%</td> </tr> <tr> <td>Feb</td> <td>17</td> <td>100%</td> </tr> <tr> <td>March</td> <td>19</td> <td>100%</td> </tr> <tr> <td>April</td> <td>13</td> <td>100%</td> </tr> </tbody> </table>	Month	Number of requests	% within 20 days	Dec	25	100%	Jan	14	100%	Feb	17	100%	March	19	100%	April	13	100%	<p>KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)</p>
Month	Number of requests	% within 20 days																				
Dec	25	100%																				
Jan	14	100%																				
Feb	17	100%																				
March	19	100%																				
April	13	100%																				

Indicator	Score	RAG	Recent trend	Notes
Number of requests for contributions to Parliamentary questions	0	↓		Volume indicator. Last year's numbers were notably high, for a period. Many of those PQs related to the work we were then doing on the mitochondria scientific review.
Number of Freedom of Information (FOI), Environmental Information Regulations (EIR) and Data Protection Act (DPA) requests	7	↓		Volume indicator. There does not appear to be any trend or predictability in the volume or focus of our FOI (and other) requests.

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend ²	Notes
Recommendations met by clinics following earlier inspections (No. met that month / No. due to be met that month)	100%	★		KPI: 80% of recommendations due that month, completed on time by clinics.

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

Indicator	Score	RAG	Recent trend ²	Notes																								
Average number of critical/major recommendations at clinics in inspection reports that were considered by ELP/LC that month	6	↓	<table border="1"> <caption>Recent trend data for critical/major recommendations</caption> <thead> <tr> <th>Month</th> <th>Total</th> <th>Critical</th> <th>Major</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>5</td> <td>2</td> <td>3</td> </tr> <tr> <td>Jan</td> <td>22</td> <td>2</td> <td>20</td> </tr> <tr> <td>Feb</td> <td>14</td> <td>1</td> <td>13</td> </tr> <tr> <td>March</td> <td>11</td> <td>0</td> <td>11</td> </tr> <tr> <td>April</td> <td>6</td> <td>0</td> <td>6</td> </tr> </tbody> </table>	Month	Total	Critical	Major	Dec	5	2	3	Jan	22	2	20	Feb	14	1	13	March	11	0	11	April	6	0	6	Volume indicator. It is too early to know whether this downward trend since January means that sector performance is improving. We will monitor over time.
Month	Total	Critical	Major																									
Dec	5	2	3																									
Jan	22	2	20																									
Feb	14	1	13																									
March	11	0	11																									
April	6	0	6																									
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	63	★	<table border="1"> <caption>Recent trend data for working days</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>113</td> </tr> <tr> <td>Jan</td> <td>77</td> </tr> <tr> <td>Feb</td> <td>76</td> </tr> <tr> <td>March</td> <td>53</td> </tr> <tr> <td>April</td> <td>63</td> </tr> </tbody> </table>	Month	Working days	Dec	113	Jan	77	Feb	76	March	53	April	63	KPI: Less than or equal to 70 working days.												
Month	Working days																											
Dec	113																											
Jan	77																											
Feb	76																											
March	53																											
April	63																											
Monthly percentage of PGD applications processed within three months (66 working days).	100%	★	<table border="1"> <caption>Recent trend data for PGD applications</caption> <thead> <tr> <th>Month</th> <th>Performance (%)</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>60%</td> </tr> <tr> <td>Jan</td> <td>100%</td> </tr> <tr> <td>Feb</td> <td>50%</td> </tr> <tr> <td>March</td> <td>45%</td> </tr> <tr> <td>April</td> <td>100%</td> </tr> </tbody> </table>	Month	Performance (%)	Dec	60%	Jan	100%	Feb	50%	March	45%	April	100%	KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application.												
Month	Performance (%)																											
Dec	60%																											
Jan	100%																											
Feb	50%																											
March	45%																											
April	100%																											

Indicator	Score	RAG	Recent trend ²	Notes												
Average number of working days taken.	0 (none due in April)	-	<table border="1"> <caption>Working days (Recent trend)</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>62</td> </tr> <tr> <td>Jan</td> <td>52</td> </tr> <tr> <td>Feb</td> <td>57</td> </tr> <tr> <td>March</td> <td>67</td> </tr> <tr> <td>April</td> <td>0</td> </tr> </tbody> </table>	Month	Working days	Dec	62	Jan	52	Feb	57	March	67	April	0	Unusually, no applications were due to be completed in April. This is because it was not possible to submit applications in January, when the clinic portal was closed for a period for necessary IfQ work.
Month	Working days															
Dec	62															
Jan	52															
Feb	57															
March	67															
April	0															
Annualised (rolling year) percentage of PGD applications processed within three months (66 working days)	75%	↓	<table border="1"> <caption>Performance (Recent trend)</caption> <thead> <tr> <th>Month</th> <th>Performance</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>89%</td> </tr> <tr> <td>Jan</td> <td>90%</td> </tr> <tr> <td>Feb</td> <td>87%</td> </tr> <tr> <td>March</td> <td>77%</td> </tr> <tr> <td>April</td> <td>75%</td> </tr> </tbody> </table>	Month	Performance	Dec	89%	Jan	90%	Feb	87%	March	77%	April	75%	KPI: As above. (Annualised score). Dips in monthly performance across the preceding year impact on the annualised figure. Complex applications (multiple types) sometimes result in unavoidable processing delays, and the relative proportion of complex conditions being applied for is increasing.
Month	Performance															
Dec	89%															
Jan	90%															
Feb	87%															
March	77%															
April	75%															
Average number of working days taken.	60	★	<table border="1"> <caption>Working days (Recent trend)</caption> <thead> <tr> <th>Month</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Dec</td> <td>56</td> </tr> <tr> <td>Jan</td> <td>54</td> </tr> <tr> <td>Feb</td> <td>56</td> </tr> <tr> <td>March</td> <td>59</td> </tr> <tr> <td>April</td> <td>60</td> </tr> </tbody> </table>	Month	Working days	Dec	56	Jan	54	Feb	56	March	59	April	60	
Month	Working days															
Dec	56															
Jan	54															
Feb	56															
March	59															
April	60															

Information for Quality programme: update

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

Details:

Meeting	Authority
Agenda item	7
Paper number	HFEA (28/06/17) 841
Meeting date	28 June 2017
Author	Nick Jones, Director of Compliance and Information

Output:

For information or decision?	For information
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Recommendation	<p>The Authority is asked to Note:</p> <ul style="list-style-type: none"> • The HFEA Website GDS assessment, and arrangements for launch • Progress on the new data submission system • The progress with data migration and assurance • Budget update and spending to date • Key risks and issues
----------------	---

Resource implications	The IfQ Programme budget has now been expended. The budget for remaining work has been established at £350,000
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Implementation date	During 2017–18 business year
---------------------	------------------------------

Communication(s)	Regular, range of mechanisms
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Organisational risk	<input type="checkbox"/> Low <input type="checkbox"/> Medium <input checked="" type="checkbox"/> High
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Annexes:	None
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1. Background

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

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

1.2. This paper updates Members on:

- Completing the programme
- Work in progress
- Programme budget
- Risks and issues

2. The IfQ programme

2.1. It has been agreed by the Authority that the Programme will close when the new HFEA website is launched. The completion of the treatment data submission system, and associated infrastructure will continue as a defined project which we will continue to report to the Authority.

2.2. This paper sets out the path to conclusion of that residual work. As with IfQ, the project is progressing in line with 'agile' principles required by the Government Digital Service (GDS).

3. Work in progress

HFEA Website and choose a fertility clinic

3.1. The Government Digital Service provided feedback in early May 2017 to be addressed before we can proceed 'to live'. This included the necessity of thorough security penetration testing; the completion of an exercise and report as to the accessibility of the website to all users; and confirmation of our arrangements for continual improvement, and active management, of the website.

- 3.2.** The required work to satisfy GDS standards was completed and an assessment by GDS took place on 7 June 2017. We were very pleased to receive a positive assessment and the HFEA website was passed to go live, subject to the submission of further documentation. We expect that submission to have been completed by the time the Authority meets, with launch scheduled for then or close to the meeting. The Director of Strategy and Corporate Affairs will demonstrate the website features at the meeting and confirm launch arrangements accordingly.

Release 2 – data submission component

- 3.3.** The website launch is a key milestone, and creates significant capacity to finish off the remaining commitments – clinics' submission of treatment information to the HFEA. This project is picking up speed following the focus on the website, and the Portal before that. Very good progress is being made on the 'front end' experienced by users and we have begun sharing the outputs of this with users. This work will yield benefits in terms of both making user interaction more friendly and provide greater flexibility to incorporate more complex submission elements. Similarly, engagement with clinics' suppliers of patient record systems is ongoing and positive.
- 3.4.** That said, we continue to need the support of externally commissioned expertise (contracted in developers) to progress. Our plan to release the new system to current 'EDI' users remains September 2017.

Register data migration

- 3.5.** As reported regularly, over the last 12 months, the Register has been subject to a thorough overhaul, and cleansing exercise – in preparation of migration of the data to a new Register to enable all the benefits of the data submission system to be realised.
- 3.6.** Data Migration is progressing at a slower pace than originally planned following the focus of resources on other activities within the organisation; this includes greater emphasis on the website (CaFC) and the transfer of knowledge from staff leaving the organisation to colleagues, some of whom are involved in the data migration effort.
- 3.7.** Nevertheless, the goal of completing a significant milestone relating to the data migration – the third 'trial load' is on track for completion in July 2017.
- 3.8.** We appointed a third party (Northdoor plc) to provide assurance that we are compliant with our own data migration strategy – commissioned in 2015/16. Northdoor has now completed its second data migration audit and the Audit and Governance Committee (AGC) was appraised of the findings of this (interim) audit, by a senior member of the Northdoor team, at its meeting on 13 June 2017.
- 3.9.** AGC received an assessment that the processes being followed by the team were robust; that the team were applying themselves to the task diligently and carefully; good progress was being made but there was more work to do; and as far as comparators go from Northdoor's experience in supporting organisations through similar approaches, our team's work was described 'as good as we have seen.' An important observation made

related to progress being hindered by the team's focus being diverted to other tasks, and that data migration exercises were usually made more efficient when the team had an undisturbed focus. The team now has more capacity resulting in data migration activity being the main priority for several of its number, and is welcomed by them.

4. Programme budget

- 4.1.** The IfQ programme budget has now closed; with final expenditure (subject to final accounts) of £1.276m compared to our planned programme budget of £1.227m. That expenditure includes substantial work (to end March 2017) on the data submission project, although, as noted above, there is a considerable amount of work still to complete.
- 4.2.** The budget for completion of the data submission project has been established at £350,000 for the 17/18 financial year. The budget is in line with capital expenditure expectations - such expenditure is on investment, or development, of the IT system estate provided by contractors on short-term contracts, and some programme management resource (delivered by internal secondees).

Budget this F/Y	Planned spend	Actual to date	Monthly Variance
£350,000 (17/18)	£40,000 (April 17)	c. £37,700 (awaiting finance nominal report) (April 17)	c. £2,300

5. Risks and issues

- 5.1.** Risks are reviewed regularly, the latest review on 12 May 2017 and several new risks to the project were identified. The main area of risk relates to staffing, particularly given the departure of colleagues from the organisation further to the organisational change programme.
- 5.2.** The top five risks to the project have been identified as:
- Workload and lack of resources
 - Loss of knowledge within the IT team
 - Data migration supported by only a few people, often diverted to other work (now addressed – see paragraph 3.7 above)
 - Reliance on external contractors, which means there is a risk of contractors leaving at short notice
 - Key IT knowledge will soon be transferred to contractors

5.3. The principal mitigation activities relate to:

- Retaining our existing external contractors by close monitoring, support and documenting procedures and processes
- Recruiting additional (short-term) expertise to provide extra capacity during the forthcoming period of organisational change.

6. Recommendation

The Authority is asked to note:

- The HFEA Website GDS assessment, and arrangements for launch
- Progress on the new data submission system
- The progress with data migration and assurance
- Budget update and spending to date
- Key risks and issues

Donor information requests

Strategic delivery:

Safe, ethical
effective treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting

Authority

Agenda item

8

Paper number

HFEA (28/06/2017) 842

Meeting date

28 June 2017

Author

Rosetta Wotton, Donor Information Manager

Output:

For information or
decision?

For information

Recommendation

The Authority is asked to note:

- the update on OTR performance and figures
- the timely and supportive way in which they are handled
- the second-year evaluation of the pilot support service and the informal positive feedback received from service users
- the requirement to decide on the future of the support service at the Authority meeting in January 2018

Resource implications

In budget

Implementation date

OTR service ongoing

Communication(s)

OTR service on website

Organisational risk

Low

Medium

High

1. Introduction

- 1.1.** This paper brings the Authority up to date on the activity regarding donor information requests (known as Opening the Register (OTR)) over the last year and, in particular, the second year of the pilot support and intermediary service.

2. Background

- 2.1.** The Human Fertilisation and Embryology Act requires the Authority to keep a *Register* of information about donors and treatments involving the use of donor gametes and embryos in the UK. It also records the notified births resulting from these treatments.
- 2.2.** Donor-conceived people and donors have a statutory right of access to information held on the Register as follows:
- 16-year-old donor-conceived people can find out:
 - if they are donor-conceived
 - non-identifying information about their donor
 - the number, gender and year of birth of any donor-conceived genetic siblings
 - if their donor has removed their anonymity
 - if they might be related to an intended spouse or partner
 - 18-year-old donor-conceived people can find out:
 - identifying information about their donor (if the donor is identifiable)
 - identifying information about their donor-conceived genetic siblings, if both sides consent (via Donor Sibling Link (DSL))
 - Donors can:
 - find out the number, gender and year of birth of any children conceived from their donation
 - remove their anonymity - which is relevant to those who donated before the law changed on 1 April 2005
- 2.3.** Parents have no statutory rights to access Register information although in 2004 they were granted discretionary access rights to the following information:
- non-identifying information about their donor
 - the number, gender and year of birth of any donor-conceived genetic siblings
 - if their donor has removed their anonymity (since 2005)
- 2.4.** Applications by donor-conceived people, donors and parents for Register information are known as Opening the Register (OTR). The HFEA has had a process in place for dealing with OTR applications by parents and donors since

2005, and donor-conceived people since 2007 (when the first cohort of donor-conceived people on our Register turned 16). Applicants submit the relevant application form with proof of identity and address by post to us. We return their identity documents within 5 working days and respond to their application within 20 working days – both by special delivery post. We retain a copy of their identity documents for 5 years to enable applicants who wish to re-apply for updated information at a later date to do so with more ease.

- 2.5.** The OTR service is provided primarily by a small dedicated team (the Donor Information Manager and Donor Information Officer), with some additional support provided by two other members of the Register Team. All OTR staff have completed a 30-hour Introduction to Counselling Skills course. The Donor Information Manager has worked in the OTR team for 6 years and, in addition to counselling skills training, she has completed an accredited mediation course and Samaritans training on handling challenging contacts. She has also attended BICA study days and numerous Donor Conception Network conferences.

3. HFEA strategy 2017-2020

- 3.1.** The HFEA strategy 2017-2020, puts patients (including donors and donor-conceived people) and the quality of care and support they receive at the centre of our work. The following elements are relevant to this paper:

Vision: High quality care for everyone affected by fertility treatment

- Improve the emotional experience of care before, during and after treatment or donation
- Donors, parents and donor-conceived people to understand how their information is stored and how they can access it

What we will do:

- Focus efforts on support before, during and after treatment for patients, donors and donor-conceived people
- Make excellent support a core message

- 3.2.** The OTR service is fundamental in the achievement of these strategy objectives. Recent improvements to the service contribute further to this aim.

Application forms

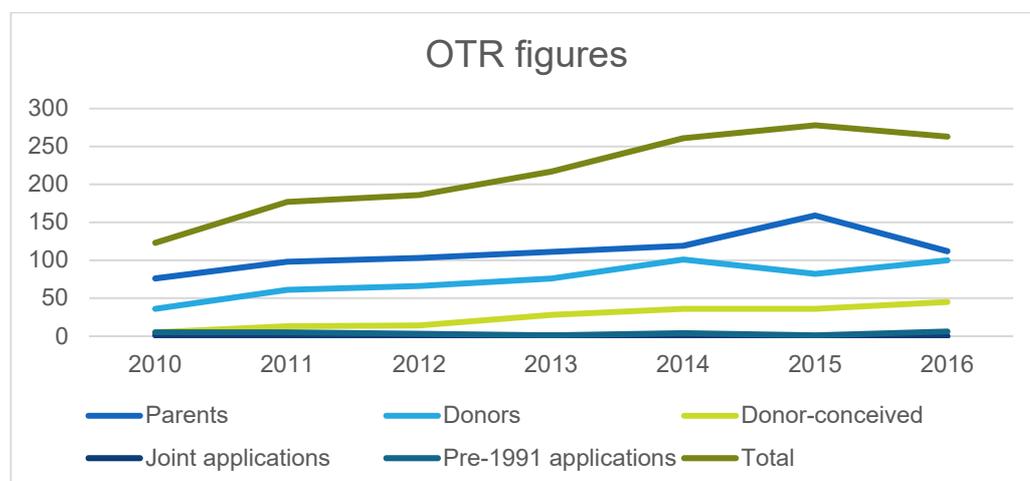
- 3.3.** We have improved the information and guidance on our application forms, and added a tick-box section to the donor re-registration form and all the donor-conceived application forms (applying for information about their donor/siblings, joining DSL and joint application to see if they are related) to provide applicants with the opportunity to indicate that they are interested in finding out more about our support service before we process their application.

Support and intermediary service

- 3.4.** In April 2013 the Nuffield Council on Bioethics report ‘Donor conception: ethical aspects of information sharing’ made recommendations relating to donor information and support for applicants to the Register. The McCracken review of the HFEA in 2013 also recognised the importance of this work.
- 3.5.** Support for Register applicants was also identified as a high priority by a group of key stakeholders in June 2013 as no established, professional practice existed for providing support to those accessing donor identifying information from the HFEA Register, and potentially making contact with a donor.
- 3.6.** In March 2014 the Authority agreed a three-year pilot to provide enhanced support services at a national level. A contract to deliver such a service to people affected by donation was awarded to PAC-UK in 2015, an adoption support agency with relevant expertise and suitably qualified staff.
- 3.7.** We delivered a two-day training event to PAC-UK in May 2015 and developed a suite of leaflets to compliment, or act as an alternative to, the support service which launched on 1 June 2015.
- 3.8.** We fund a limited number of 1-hour contact sessions, which can be delivered flexibly, for:
- adult donor-conceived people who have or are considering applying for identifying information about their donor; or are considering joining DSL and making contact with their donor-conceived sibling(s)
 - donor-conceived people over the age of 16 who have or are considering applying for non-identifying information about their donor
 - donors considering re-registering to be an identifiable donor
 - donors who are aware that an adult person conceived from their donation has applied for their identifying information.

4. Performance

- 4.1.** The volume of OTR applications we receive each year is dependent on several factors including: the cumulative number of people eligible to access Register information, and the cultural shift towards openness around donor conception. While the OTR service is currently delivered by a small dedicated team, when the post 2005 cohort of donor-conceived people start turning 18 in 2023 (and can access identifying information about their donor), the service will become a much larger part of our organisation’s function.
- 4.2.** We have seen a steady rise year-on-year in the number of OTR applications handled, with over double the amount in 2015 compared to 2010 (see table below). While we still saw an increase in OTR applications from donors and donor-conceived people in 2016, there was a decrease in the total number of OTRs in 2016 compared with 2015 due to a reduced number from parents.



	2010	2011	2012	2013	2014	2015	2016
Parents	76	98	103	111	119	159	112
Donors	36	61	66	76	101	82	100
Donor-conceived	5	13	14	28	36	36	45
Joint applications	1	-	-	1	-	-	-
Pre-1991 applications	5	5	3	1	4	1	6
Total	123	177	186	217	261	278	263

- 4.3.** In addition, since launching in 2010, 137 adult donor-conceived people have joined DSL, our voluntary contact register, whereby registrants agree to us sharing their name and contact details with any of their donor-conceived genetic siblings who have also joined. Numbers registering are still small - 11 per year in 2011 and 2012, increasing to 21 per year in 2013 and 2014, 24 in 2015 and 27 in 2016 – but will likely grow significantly in the coming years (20 people have already joined DSL so far this year). In 2015 we made the first DSL match and there were four further matches in 2016.
- 4.4.** We have also received 165 applications in total from anonymous donors (those who donated after the HFEA was set up but before 1 April 2005) to remove their anonymity, which is just under 1% of anonymous donors with live birth outcomes. Between 2011 and 2015 there were slight increases year-on-year in such applications however; numbers are disappointingly low dipping to only nine doing so in 2016.
- 4.5.** In 2013 a first application for identifying information from an adult donor-conceived individual with an identifiable donor was received. In total 11 applications of this nature have been received, and so far, nine of these cases have led to the release of the donor's identifying details.

- 4.6.** In each case we offered and coordinated support and intermediary assistance to the donor-conceived people and donors concerned.

Feedback

- 4.7.** As part of the OTR service, applicants are provided with a link to an online confidential feedback questionnaire. A summary of the feedback received since the last update to the Authority in July 2016 will be provided in a presentation when the Authority meets on 28 June 2017.

5. Support service evaluation

- 5.1.** At the time of agreeing the three-year pilot support and intermediary service in 2014, the Authority asked that the HFEA retained control over the quality of any service provided and evaluated the service during the course of the pilot.
- 5.2.** We developed an evaluation framework for this purpose and an evaluation of the service is presented to the Authority on an annual basis in July 2016, June 2017 (here) and a final paper in January 2018.
- 5.3.** The evaluation of the second year of the service covers:
- The cost of the service
 - The level of demand for the service and its value to users
 - The quality of the service provided by the contractor

Cost

- 5.4.** The Authority set aside a capped budget of £50,000 for the duration of the pilot. This amount covers the cost of PAC-UK's initial service set up and training, and from then on a 'pay as you go' arrangement for each session provided at a fixed rate (£99 + VAT). The initial set up and training cost was £7248 and the total anticipated charge for sessions (inclusive of VAT) provided over the first two years (period 1 June 2015 – 31 May 2017) is £1782 (£594 in year one, rising to £1188 in year two).
- 5.5.** This second sum would indicate that the amount set aside for the pilot will be more than sufficient for the remainder of the pilot.

Demand

- 5.6.** In the first year of the service we referred a total of just seven cases for HFEA-funded support to PAC-UK. Six of the seven cases referred contacted PAC-UK within its first year and four received support (several of these cases were ongoing into the second year of the service).
- 5.7.** However, the second year of the service has seen an increase in referrals for HFEA-funded support to PAC-UK, with us referring 18 cases:
- Four referrals concerned sperm donors – two whose identifying details were requested and two who were considering removing their anonymity.

- Fourteen referrals concerned donor-conceived people – two referrals were for those who had requested their donor's identifying details, three following a sibling match on DSL, four for people considering applying for donor/sibling information, four for people considering joining DSL and one for a person who'd obtained identifying donor information from us several years previous.

Out of the 18 referrals, eight people (associated with ten referrals as two people were referred twice for separate reasons) contacted PAC-UK within its second year and seven received support.

This increase may be due to the addition of the tick-box section about accessing support on all the donor-conceived application forms and the donor re-registration application form.

- 5.8.** It is difficult to assess the level of demand for the remainder of the pilot, but given the increase in the past year, we'd expect a similar amount or a further increase this year.
- 5.9.** As of 2016 there were over 20,500 children aged 16 or above conceived following donor treatment between 1991 and 2005, and who had therefore reached the age where they could access non-identifying information about their donor(s) and donor-conceived genetic siblings from the Register.
- 5.10.** There were also over 4,000 additional people aged 18 or above in 2016. Out of this number of adults, only the small percentage whose donor(s) had removed their anonymity could access identifying information about them, and only those who have donor-conceived genetic siblings would be eligible to join Donor Sibling Link. The rate of donors re-registering is also very low.
- 5.11.** As noted above, the cohort of people eligible to seek funded services is therefore small and many may not know they are donor-conceived. Of those who do know, some may not be interested in accessing information at all and some may not feel a need for professional support. Where anonymous donors are concerned, many who contact the HFEA are not aware that they can request information on the outcome of their donation, let alone re-register as identifiable.
- 5.12.** The support service is also available on a self-funded basis to those who are not eligible for HFEA-funded support (e.g. parents etc.) but there has not been any demand in this area. This may be down to several factors including; a lack of awareness of the existence of the service, the cost to those self-funding (£89 per session) and the availability of free informal support from charitable organisations such as Donor Conception Network.

Quality

- 5.13.** A new online system is now in place to obtain feedback from all users once cases are closed. There are still wrinkles to iron out as there is frequently a long gap between counselling sessions and it can be difficult to know when the case should be closed.

- 5.14.** We have not received any formal feedback about the service, which may be because the number of people taking up the service is still small and some referrals are ongoing. Despite a lack of formal feedback, the informal feedback received from users in correspondence with the HFEA continues to be positive. Users have expressed gratitude that such a service exists and have found it extremely helpful.
- 5.15.** We have not received any formal complaints from users regarding the service, and PAC-UK met their overall KPIs where users were concerned in the second year of the pilot.
- 5.16.** The quality of the relationship between the HFEA and PAC-UK goes from strength to strength (e.g. ease of interactions, PAC-UK's level of engagement and commitment; whether we have had to chase information). This period of service delivery has gone smoothly and included; the handover of the support service management within PAC-UK to another service manager following the former's retirement, and enhancements in the way the service is delivered through improved administrative solutions.
- 5.17.** Those referred to PAC-UK for the service have been compliant with including necessary details concerning preferred time, location and face to face versus telephone counselling when contacting PAC-UK, and this has meant that a counsellor can be allocated directly and simply with little intrusion by the administrative process.
- 5.18.** It is very encouraging that all informal user feedback continues to be positive following support sessions. The HFEA and PAC-UK continue to share a common goal of providing an excellent service to all concerned.

Looking ahead

- 5.19.** As the current three-year pilot support and intermediary service will come to an end on 31 May 2018, the Executive will bring a final paper to the Authority in January 2018 with an evaluation of the pilot as a whole, and options going forwards.

6. Recommendation

- 6.1.** The Authority is asked to note:
- the update on OTR performance and figures.
 - the timely and supportive way in which they are handled.
 - the second-year evaluation of the pilot support service and the informal positive feedback received from service users.
 - the requirement to decide on the future of the support service at the Authority meeting in January 2018.

Improving embryo research

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

Details:

Meeting	Authority
Agenda item	9
Paper number	HFEA (28/06/2017) 843
Meeting date	28 June 2017
Author	Jessica Watkin, Policy Manager

Output:

For information or decision?	For decision
Recommendation	<ul style="list-style-type: none"> To improve the information and support available to patients when making decisions about what to do with their embryos. To encourage better collaboration between treatment clinics and research centres (with the development of a new Clinic Portal facility and annual workshops) Not to change our policy on consent for the time being.
Resource implications	If recommendations accepted, further staff time to collect information from research centres and draft patient information. Some design costs for patient information, though expected to be low.
Implementation date	For Clinic Portal information, aim to publish in the autumn
Communication(s)	Communications aimed at clinics and patients to be carried out later in the year, after the information about research projects has been published on Clinic Portal.
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High

Annexes

1. Introduction

- 1.1.** Safe, ethical and effective fertility treatment is a central ambition in our strategy to 2020 and one way of achieving this is by encouraging world-class research and clinical trials. Through our strategy, we want:
- clinics to be more research-focused, with proper testing of new techniques before they are offered to patients
 - patients to be aware of research they could take part in, and to understand the benefits of research
 - easier patient donation of embryos for research, and research centres to have access to those donated embryos.
- 1.2.** IVF could not have come into existence without good quality embryo research, carried out in the UK since the 1960s, when Professor Robert Edwards started his pioneering work. Building on this work, the UK has continued to enjoy a reputation for high quality research, supported since the 1990s by our robust yet permissive regulatory framework. However, there are relatively few embryo research projects going on in the UK at present and a low number of embryos donated to those projects.
- 1.3.** We know from talking to patients, clinic staff and researchers that there is great potential to improve embryo research in the UK; more patients would like to donate their embryos to research than currently do and researchers would be able to widen the scope and quality of their research if more patients donated their embryos to them.
- 1.4.** However, there are a number of issues that need to be addressed before we can make those improvements:
- Whilst some clinics have close collaborations with research centres and can provide donated embryos to the laboratory, most clinics do not have these arrangements.
 - Clinics without research collaborations feel they do not have the time or resources to enter these arrangements. In 2016, only 1 in 5 clinics recruit embryo donors for research.
 - Whilst many patients would be open to donating their embryos, they need more information about research and, crucially, much better emotional support in making what are difficult personal decisions about donation.
 - Our current policy of requiring patients to give consent to the use of their embryos in a specific research project (rather than to embryo research in general) can compound the issues in clinics without research collaborations and may unnecessarily limit how those embryos which are donated are used in the research project.
- 1.5.** This paper sets out a number of recommendations to address these issues.

2. Background

The regulatory and licensing framework

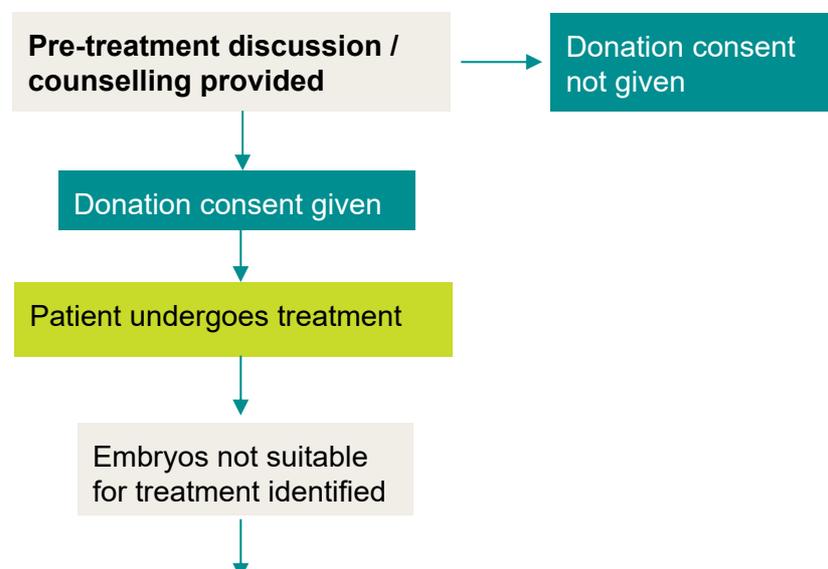
- 2.1.** Research using human embryos can only take place under an HFEA licence. We will only grant a licence if it meets the requirements in the Human Fertilisation and Embryology Act 1990 and our policies, including that:
- the use of human embryos, rather than animal embryos or other tissue, is necessary
 - patients have given effective consent to the use of their embryos in research. (Our current policy requires that the gamete providers consent to the use of their embryos for *specific* projects of research, rather than to research more generally.)
 - the research been approved by a research ethics committee, which considers patient information and consent
 - the purpose of the research meets those in the legislation, ensuring that it is done for appropriate reasons, such as to development new fertility treatment or enhance understanding human development and disease.
- 2.2.** When we receive an application for a research licence, we seek advice from a peer reviewer before submitting it to the licence committee for consideration. Once approved, we publish a lay summary of the research (currently written by the applicant) on our website. We are currently working with research centres to make improvements to current lay summaries, which we expect to re-publish in the summer.
- 2.3.** We have already made some improvements to the application process to make it clearer for applicants and peer reviewers. We have updated:
- the research application form to clarify what we need from applicants, to remove any unnecessary questions, and to advise them on how to write a good lay summary
 - the peer review form to bring it in line with the approach taken by organisations such as the Medical Research Council (MRC) and to ensure that it provides the relevant information the Licence Committee needs to make a judgement about the appropriateness of granting a licence.
- 2.4.** We have also updated guidance in General Directions 0008 to clarify what constitutes ‘a properly constituted ethics committee’, to be used when a research project has not been before a research ethics committee. This will be formally considered by the Authority as part of the Code of Practice update (agenda item 11 of this meeting).
- 2.5.** Lastly, we are developing a short briefing for research ethics committees about our licensing and inspection responsibilities, to avoid any duplication.

The embryo research landscape

- 2.6.** There are relatively few embryo research projects in the UK and a very low number of embryos being donated to research.
- 2.7.** In 2016, only 1727 embryos were donated out of the approximately 300,000 embryos created that year. Around 25% of all embryos created are used in treatment, 50% destroyed because they are unsuitable for treatment and 25% stored for future use.
- 2.8.** Those embryos that are donated tend to come from a small number of clinics: in 2016, approximately only 1 in 5 of treatment clinics supplied researchers with embryos. At the time of writing, there are 21 licensed research projects across 19 laboratories in the UK. Eight of those research projects are externally funded by institutions such as the Medical Research Council (MRC), the Wellcome Trust or the EU, with the remainder being funded locally, by, for example, the clinics itself.
- 2.9.** From our research (see section 3), we know that more patients would like to donate their embryos to research and research teams would welcome more embryos for their research.

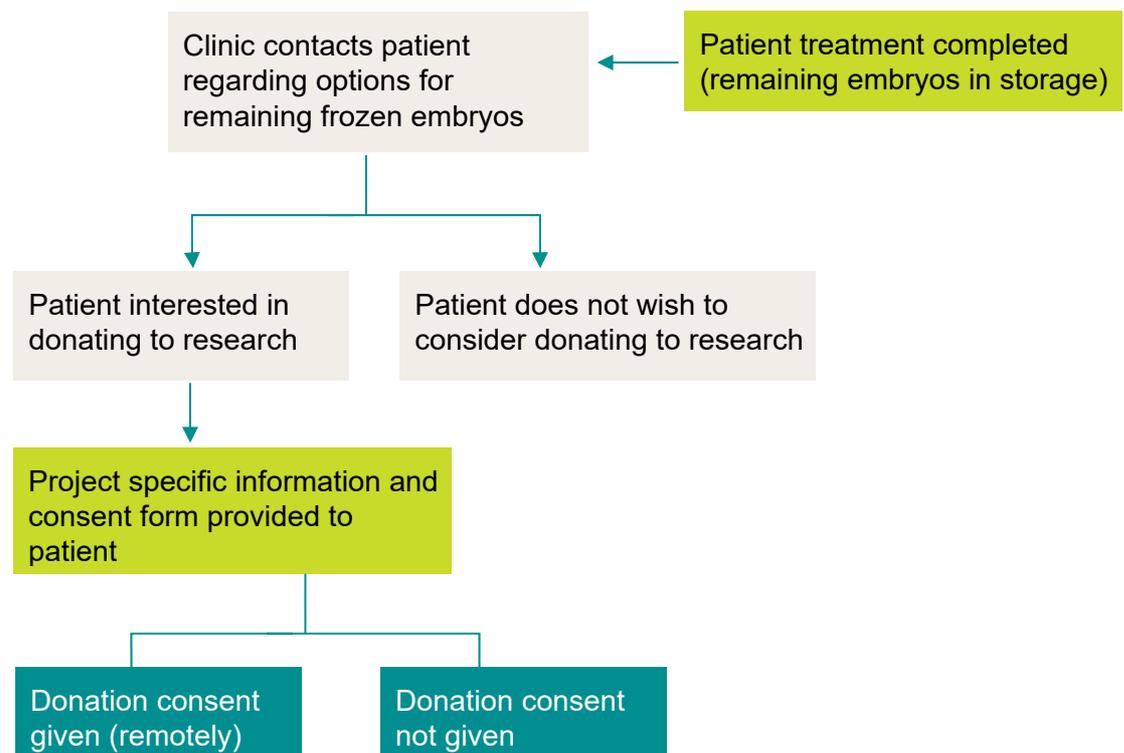
How and when can patients donate their embryos?

- 2.10.** In 2016, around 80% of embryos donated to research were frozen and come from patients who have completed their treatment. The rest were fresh embryos donated during treatment because they are not suitable for use in transfer. Occasionally, embryos are created during a research project from donated eggs and sperm.
- 2.11.** For fresh embryo donation, the supplying clinic is close to the research team so that the embryos can be transported immediately. The patient is asked to consider donating fresh embryos before treatment starts and only embryos unsuitable for treatment (for example, poor quality embryos) are donated.



Embryos donated (with consent provided)

2.12. For frozen embryo donation, the patient is asked about donating to research after treatment has finished, but before the end of the storage period (normally 10 years). However, given that the patient is unlikely to have face-to-face contact with their clinic at this stage, they are asked to consider donating their embryos to research via a letter, normally alongside an invoice for the annual storage fee. If the patient is interested in donating their embryos to research, they will be sent information materials and a consent form, and given the option of discussing the research.



2.13. If the clinic where the patient's embryos are stored doesn't have any links with a research project, it can be difficult for patients to donate embryos, even if they try to identify a research project themselves. This is because it might not be financially or logistically feasible for a research team to arrange transportation for a single or small number of embryos from a clinic.

3. Patient and professional attitudes

3.1. We have explored the views and experience of patients, as well as clinic and laboratory staff, both to gather evidence and to discuss possible solutions to the barriers identified. This evidence gathering has included:

- A survey for patients
- A survey for clinic and laboratory staff
- Discussions with clinic staff at our Licensed Centres Panel; with representatives of patient organisations and professional bodies
- A dedicated workshop at our 2016 annual conference
- Discussions with research funders and regulators

Patients

3.2. We ran a survey in April and May and recruited patients via our own channels and through patient organisations such as Donor Conception Network and Fertility Network UK.

3.3. The survey received 188 responses from patients who are:

- at the start of the IVF journey (3%);
- currently receiving treatment (22%); or
- have finished treatment (75%).

3.4. We asked respondents whether or not they had donated embryos to research. The high number who said yes (which is much higher than the proportion of all patients who have donated) suggests that the survey sample is weighted towards those who actively support research. However, it does suggest that more patients would be willing to donate than currently do.

Yes, I have donated	33%
No, but I would consider it	50%
No and I would not consider it	17%

Total answered: 188

3.5. Many respondents see the value of research, with most of those who gave comments saying either that past research helped them conceive or they felt compelled to 'give something back' from successful treatment:

'I benefited from medical research to have two beautiful girls and felt it was only right to contribute to the research story'

'I strongly believe that we are only able to undergo IVF because of past research and the success of IVF can only be further improved if research continues, for which embryos are needed.'

- 3.6.** However, a significant minority felt that research was not for them or felt ambivalent about it. A few cited faith reasons, but most felt this way because they had such a strong connection with their embryos:
- 'I agreed to donate any of my eggs which were unsuitable for treatment, but felt an emotional connection to my embryos and therefore did not want them to be subjected to research.'*
- 'I very much support using donated embryos for research - I think it's probably some feelings about the embryo having potential of life that makes me feel uneasy. If I knew that the embryo wasn't viable I would definitely donate. I'm too old to use my frozen embryo [sic] but can't quite give it up'*
- 3.7.** Of those patients who were invited to consider donation to research, the majority of respondents (83%) felt they were given enough time to make the decision. Most reported being able to make a decision that was right for them and were quite clear about their views. But a number reported feeling confused and overwhelmed by the decision about what to do with their frozen embryos:
- 'it didn't feel right to discard them - after all I was instrumental in creating life. That should be respected more. At least by donating them to someone else, they had a chance to survive. This was an awful decision and took me three years to come to.'*
- 'I feel that I need more counselling/ support [...]. I feel that the giving life to potential life is important, but need to understand the implications of my children's genetic full siblings being part of a different family to ours. I also believe in the importance of medical research to advance our understanding and would definitely support my embryos being donated to research rather than discarded'*
- 3.8.** That said, the majority of respondents (58%) said they would prefer to donate their embryos to research rather than allow them to perish - many suggested that if they could not be used for their treatment, they would not want them to be 'wasted'. *'...so much effort went in to making them!! Ideally, my first choice would be to a family/ person... My second choice is to donate to research'*. Only 6% said that they would prefer their embryos to be discarded.
- 3.9.** The survey also revealed that opportunities to donate are limited. If a clinic does not have a prior agreement with a research team, they are unlikely to raise the possibility of donating embryos to research with patients. In addition, where those agreements do not exist, a patient might struggle to donate their embryos, even if they wish to. One respondent wrote: *'We wanted to donate embryos for research but our unit didn't have any research projects active; and when I rang around a few others I couldn't find anywhere who could take [them]'*.
- 3.10.** The comments suggested that a significant number of patients would welcome more information. For some, this meant information about a particular research project that they might consider donating their embryos to. For others, this meant more general information about embryo research; some patients were not aware that their embryos would have been suitable for research and a few thought that age restrictions applied to donating to research. Others felt unable

to make a decision because of lack of understanding about what is involved: *'I just feel confused about it and would to hear more about it'*.

- 3.11.** When asked whether they would support a consent process which allowed them to donate to research in general, rather than a specific research project, most were in favour:

I would feel comfortable with consenting to my embryos being used for any approved embryo research project	50%
I would feel comfortable with consenting to my embryos being used for a broad range of approved embryo research projects, with the option of opting out of certain types of research or putting conditions on my donation	21%
I would only feel comfortable with consent to my embryos being used for a specific approved embryo research project	8%
I don't know if I would prefer to donate my embryos to a specific project or to any approved embryo research project	21%

Total answered: 175

Professionals in clinics and laboratories

- 3.12.** We published a set of surveys for clinics and researchers, to identify issues and barriers to establishing collaborations between clinics and researchers and any other issues that might explain the relatively low level of embryo research. We received very few responses (just 34), which is itself perhaps indicative of fertility clinics' interest in embryo research. We also had one to one discussions with clinics and researchers actively involved in embryo research.

- 3.13.** The key findings were:

- A greater number of embryos would improve the quality and scope of research.
- Collaboration between treatment clinics and research centres could be greatly improved. Whilst research centres have very constructive relationships with their collaborating clinic, establishing those collaborations in the first place can be challenging and requires a significant amount of effort from committed staff.
- Facilitating links between supplying clinics and researchers would be welcomed by all.

- 3.14.** There were mixed views about consent. Some strongly favoured a shift to a generic model of consent. However, only half of survey respondents favoured a

shift to generic consent. However, this appears to be on the basis of assumptions about patients' wishes, which is not necessarily borne out by the responses to our patient survey (see paragraph 3.11):

'Patients should be able to decide if they are comfortable with the specific fate of their embryos'.

'If patients are to give their embryos to research it is important that they understand the way in which these embryos will be used and the implications of this'.

3.15. Others identified the following difficulties with our current requirement to get specific consent for embryo donation to research:

- Staff and resources (including the complexity of consent process). The level of commitment required can be a disincentive to establish collaborations with researchers.
- There is a risk that consent might become invalid if the project changes significantly. Indeed, we heard examples of when this has happened.
- Specific consent makes imports impossible. Some researchers we spoke to said that they have difficulty in sourcing certain rare embryos (particularly early stage ones) and the option of importing these from overseas would be helpful.

4. Improving the availability of embryos

4.1. Our research suggests that, beyond the work we have already done to improve the licence application and consideration process, we can do more to improve embryo research in the UK. The solutions fall into three areas:

- Raising patient awareness and understanding
- Facilitating collaboration between clinics
- Reviewing the consent process

Raising patient awareness and understanding

4.2. Although survey results suggest that patients understand the value of research, they would welcome more and better general information to help them make the decision about what to do with their embryos. There is also a clear need for more emotional support for patients in making these difficult decisions. We have had early discussions with Fertility Network UK about how to provide this.

4.3. To address this need, we propose making further improvements to our website, to cover this area in more breadth and detail. This would include information on:

- the value and benefits of research and how it is monitored
- examples of research and its outcomes (including the clear lay summaries which we are currently developing)
- personal stories/interviews with patients
- what to expect if they decide to donate and how to withdraw their consent.

- 4.4.** We also propose developing a patient leaflet for those considering frozen embryo donation, who will have finished treatment and no longer have face-to-face contact with the clinic. These would be sent to patients along with the invoice for annual storage fees and provide information about all the alternatives to continued storage.

Facilitating collaboration between clinics

- 4.5.** We believe that we could make a positive impact by facilitating the establishment of collaborations between clinics and researchers for the supply of embryos. At present, these are organised directly between research teams and clinics and we have been told that this can take a lot of work.
- 4.6.** We propose gathering information from research centres recruiting embryo donors and publishing it on the Clinic Portal for clinics to see. This would enable researchers to advertise their need for embryos and help establish collaborations. The information they would provide would include the following:
- contact details and details of their research
 - their embryo requirements (eg, how many, what type)
 - details of any compensation or support available for administrative work involved in establishing a collaboration and taking consent (for example, they may have funding for research nurses to take consent).
- 4.7.** We also propose hosting a workshop to support collaborations and enable researchers to ‘pitch’ their research to clinics.

Consent

- 4.8.** The Act does not require a patient to consent to the donation of their embryos for use in a *particular* project of research, except where the research involves the derivation of embryonic stem cells, research using identifiable embryos or research involving human admixed embryos.
- 4.9.** As noted earlier, there was support for a generic model of consent from many patients and clinic staff. However, there are a number of benefits and disadvantages with changing the consent regime, not least the effort involved for us and for clinics/laboratories in implementing the change:

Specific consent	Generic consent
<p>Pros</p> <ul style="list-style-type: none"> • Patients know exactly what would happen to their embryos and the particular nature and purpose of the research they are donating to. • Shows strong regard for the special status of embryos, as distinct from other cells or tissues 	<p>Pros</p> <ul style="list-style-type: none"> • More patients able to donate to research • Easier for staff to explain and take consent • Imports possible (particular benefit where rare, early stage embryos are sought)

<ul style="list-style-type: none"> • Consent process is resource-intensive • If the research project is abandoned or changes significantly, the embryos can no longer be used as the consent will be invalid 	<ul style="list-style-type: none"> • Could deter some patients from donating • Resources required to store embryos before they are transported to researchers • May appear that we are treating embryos no differently from other cells or tissues. • Would require changes to licence conditions, meaning all research licences would need to be re-issued and accepted by them
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Discussion

4.10. It seems clear from our research that the main barrier to more patients donating their embryos to research is the lack of collaboration between fertility clinics and research centres. Where these collaborations exist (in approximately 20% of clinics), they work well. However, in most clinics the possibility of donating to research is not being raised with patients or, where it is, the clinic is not able to make the donation happen for those patients who would consent. Our current system of consent is further compounding the problem.

4.11. How should we go about addressing these issues and in what order? Our recommendation is to start with clinic/laboratory collaborations. Without creating these connections, any changes we make to patient information and support or to consent would be relatively pointless. In fact, it could be counterproductive, raising expectations amongst patients and causing work for clinics in implementing a new consent approach.

4.12. Our strategic aim is to encourage and facilitate embryo research; whether a shift in consent from specific to generic would do that is an open question. Given the other proposals set out in this paper, we recommend delaying any decision on consent until the impact of those other proposals is known. It is hoped that better information for patients and an online tool to enable better collaboration between treatment clinics and research centres will deliver the improvements that we seek. If they do have an impact but are hampered by the consent process, we can then return to the issue of consent.

5. Recommendations and next steps

- 5.1.** The Authority is asked to consider and decide on the proposals set out below
- To improve the information and support available to patients when making decisions about what to do with their embryos.
 - To encourage better collaboration between treatment clinics and research centres (with the development of a new Clinic Portal facility and annual workshops)

- Not to change our policy on consent for the time being.
- 5.2.** If these recommendations are agreed, we will review their impact over the next year and report to the Authority.

Treating trans patients and donors

Strategic delivery	<input checked="" type="checkbox"/> Safe, ethical, effective treatment	<input type="checkbox"/> Consistent outcomes and support	<input type="checkbox"/> Improving standards through intelligence
Details			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (28/06/2017) 844		
Meeting date	28 June 2017		
Author	Anjeli Kara		
Output			
For information or decision?	For decision		
Recommendation	Agree to the proposed amendments to the Code of Practice. These changes will be introduced in October 2017.		
Resource implications	Within budget		
Implementation date	2 October 2017		
Communication(s)	Code of Practice, Chair's Letter and Clinic Focus article		
Organisational risk	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Medium	<input type="checkbox"/> High
Annexes	Annex A: Guidance note 4 (page 12) Annex B: Guidance note 5 (page 18) Annex C: Guidance note 6 (page 39) Annex D: Guidance note 11 (page 67) Annex E: Guidance note 17 (page 83) Annex F: Guidance note 29 (page 99) Annex G: Guidance note 30 (page 104) Annex H: Guidance note 31 (page 116)		

1. Overview

- 1.1. In recent years, equality issues concerning trans people have been increasingly prominent in public policy. The [Transgender Equality report](#) published by the House of Commons Women and Equalities Committee in 2016 highlighted significant concerns about the lack of awareness and consideration of health professionals in treating trans patients, and the need for government bodies to aim to improve the lives of trans people. Over the last 18 months, we have also received an increasing number of enquiries from fertility clinics and the public about providing fertility services to trans people. These enquiries have generally focussed on fertility preservation and treatment options, which consent forms should be used, which documents are required as proof of identification, and legal parenthood queries. Though the number of trans patients are small, clinics are keen to provide a better service.
- 1.2. While our Code of Practice currently refers to gender reassignment and other protected characteristics under references to the Equality Act 2010, and we remind clinics of their obligation not to discriminate under equalities legislation, we do not have adequate patient information, guidance for the sector, or a way for a trans patient to record their consent.
- 1.3. To address this, we set up a small internal working group to look at the guidance and information we could provide to clinics and patients. This working group has engaged with members of the trans community, gender identity clinics and fertility clinics with experience of treating trans patients, to gain insight into the area and explore the issues entailed. Taking on board the experiences of patients, professionals, those who work with trans people or are trans, and independent legal advice, we identified several ways to address the issues faced by clinics when treating trans patients and our lack of patient information.
- 1.4. We have already made some improvements for the benefit of trans patients. In April 2017 we published a suite of [gender-neutral consent forms](#) that removed references to 'male' and 'female', and published patient information on the [beta version of our website](#) (see [Authority paper HFEA\(18/01/17\)824](#), for more information).
- 1.5. For October's update to the Code of Practice, we have drafted new guidance for clinics on how they should provide care and treatment for trans patients, based on the opinions gathered while conducting this work. That guidance is set out at annexes A-H and covers:
 - the general treatment of trans patients and donors
 - disclosing information about a patient's gender reassignment or any other information pertaining to their gender history
 - verifying trans patient identity, and
 - legal parenthood.

2. Background

- 2.1.** People who identify as trans desire to live as a person of the gender they most closely associate with, which differs from the gender they were labelled at birth. For some this may mean a social transition without medical intervention, while others may undergo hormonal and/or surgical interventions.
- 2.2.** There are multiple terms used to recognise trans people and terminology in the area is ever-evolving. For inclusivity, this paper uses the term ‘trans’ to refer to all trans identities. This includes persons who identify as ‘non-binary’ (ie, identify as somewhere, either fixed or moveable, on the male-female continuum) and ‘non-gendered’ (ie, neither male, female, nor on the male-female continuum). A list of terms used by experts in the field that are commonly used in this paper are listed at Table 1.

Table 1: List of trans terminology

Term	Definition
Gender	The designation of ‘male’ or ‘female’.
Gender identity	The gender that a person may associate themselves with. This may be male, female, somewhere along the continuum of male-female, or non-gendered.
Gender presentation	How a person chooses to outwardly express their gender to others.
Gender dysphoria	Discomfort or distress experienced by a trans person that is caused by a discrepancy between a person’s gender identity and the gender they were assigned at birth.
Non-binary	A person who identifies as somewhere, either fixed or moveable, on the male-female continuum.
Non-gendered	A person who does not identify as a male, female, or on the male-female continuum.
Trans person	A person who has a gender identity that differs from the gender they were assigned at birth.
Transitioning	The process by which a person changes their gender presentation to bring it in line with their gender identity. This may involve hormonal and/or surgical treatment, but need not.
Acquired gender	The gender a person is legally recognised as, that differs to the gender they were assigned at birth.

The Equality Act 2010 and the Gender Recognition Act 2004

- 2.3.** The two principal statutes that offer specific protection to trans people are the Gender Recognition Act 2004 and the Equality Act 2010.
- 2.4.** The Gender Recognition Act 2004 was pioneering in providing trans people with formal legal recognition of their acquired gender. This recognition is possible from the issue of a full gender recognition certificate (GRC) by a Gender Recognition Panel (GRP). A GRC will be issued if the GRP is satisfied that a person has (or has had) a gender identity disorder, and has either lived in

the acquired gender for the preceding two years (and intends to continue to live in the acquired gender until death), or has been recognised under the law of another country as having changed gender.

- 2.5.** Once a full GRC has been issued, a person's acquired gender legally becomes their new identity. For example, if a female transitions to male, their gender legally becomes male. However, the GRC does not re-write the gender history of a person (ie, erase the fact that they were previously legally recognised as another gender).
- 2.6.** Although the GRC is proof that a person has acquired a new identity, it must be noted that legislation (such as the Equality Act 2010) makes it clear that legal protection against discrimination is possible without physically appearing to have transitioned. Essentially, intention to be trans alone is enough.
- 2.7.** Under the Equality Act 2010, gender reassignment is one of the nine protected characteristics. A person is considered to be protected if they are proposing to undergo, are undergoing or have undergone a process (or part of the process) of gender reassignment, by either changing their physical or physiological attributes.
- 2.8.** The Equality Act 2010 also deals with discrimination, harassment and victimisation in providing services. It is therefore unlawful, under the Act, for a licensed clinic to discriminate against a trans person that requires their service by:
 - (a) not providing them with the service,
 - (b) terminating the existing provision of a service,
 - (c) providing the service on less favourable terms than those persons who do not share the protected characteristic of gender reassignment, or
 - (d) subjecting the trans person to any other detriment.
- 2.9.** As mentioned above, the current Code of Practice refers to gender reassignment and other protected characteristics under references to the Equality Act 2010 (see guidance notes 11 (Donor recruitment, assessment and screening) and 29 (Treating people fairly)), and we also remind clinics of their obligation not to discriminate under equalities legislation. However, there are information gaps that exist pertaining to the provision of better care for trans people seeking fertility services and this is the focus of the remainder of this paper.

3. General information on treating trans patients

- 3.1.** Historically, there has been an assumption that gender is binary – that is, defined as either male or female – and we have established processes and practices based on these assumptions. While this helps clinics (and the general healthcare sector) to deliver safe and appropriate care for most patients,

gender identity and the traditional definitions of gender are evolving and do not always fit into 'male' or 'female' stereotypes.

Fertility preservation and treatment options

- 3.2.** It is important to recognise that a trans person can approach a clinic at various stages of their transition, depending on how they choose to transition. For example, a trans person may present at a clinic prior to hormonal or surgical interventions to preserve their fertility (with the intention of using their eggs or sperm later in treatment with a partner and/or a surrogate), while another trans person who lives in their acquired gender permanently without medical intervention may present at a clinic at the time they wish to receive fertility treatment.
- 3.3.** As a result, we need to consider the treatment and storage options that are available to a trans person, based on their individual circumstance. For this reason, we have set out at Table 2 instances when a trans person may approach a clinic and which treatment or storage services may be necessary.

Table 2: Instances when a trans patient may come to a clinic

Stage and service
Visiting a clinic prior to gender reassignment (ie, hormonal or surgical interventions)
To store eggs, sperm or tissue If a trans person is pre-pubertal, they will store ovarian or testicular tissue for use in treatment at a later date. If a trans person is post-pubertal, they will store eggs or sperm for use in treatment at a later date.
Visiting a clinic after gender reassignment (ie, hormonal or surgical interventions)
To use stored eggs, sperm or tissue in treatment Treatment may be with partner, using a donor and/or surrogate.
To extend storage period
To donate eggs or sperm to others
Visiting a clinic living as their acquired gender, without medical intervention
To use eggs, sperm or tissue in treatment Treatment may be with partner, using a donor and/or surrogate.
To store eggs, sperm or tissue
To donate eggs or sperm to others

- 3.4.** To provide high quality care for trans patients, it is important to meet their information needs and ensure that information provided is tailored accordingly. Given that a trans person may visit a clinic prior to gender reassignment, we propose clinics should inform a trans patient that they may need to be screened as a donor at the time of egg or sperm collection. This is because their eggs or sperm will be used in another person's treatment (ie, with their partner or via a surrogate) when they return for treatment in the future.

- 3.5.** Certain trans patients, depending on their individual circumstance, may also be considered prematurely infertile as they are due to undergo gender reassignment. As a result, some trans patients may be able to store their gametes beyond 10 years, provided appropriate consent is in place and a medical practitioner has certified in writing that they meet the medical criteria for premature infertility. Ensuring a clinic considers whether a trans patient meets the criteria for extended storage, provides trans patients with viable treatment options.
- 3.6.** In addition to receiving relevant information about treatment, storage and/or donation, trans patients should also be given additional information on which consent forms should be completed. We propose that clinics should use information obtained through their discussions with trans patients to chart the potential treatment and storage options available to the patient – both in the short term and long term – before determining which consent forms need to be completed.
- 3.7.** It is also important to recognise the sensitivities of treating trans patients, and identify practical ways of accommodating their needs with dignity and respect. Speaking to gender identity clinics and clinics that have treated trans patients, practical solutions to treating patients sensitively could include:
- asking a trans patient how they would like to be addressed
 - taking time to explain why gender at birth may be noted in medical records
 - avoid making assumptions when referring to gender (eg, if a telephone enquiry is received regarding sperm storage, avoid assuming the caller is male – instead, ask the caller how they would like to be addressed), and
 - taking privacy and sensitivity into consideration (eg, avoid asking a trans male undergoing an egg collection to wait in room full of women also awaiting egg collection).

Recommendations

- 3.8.** The draft Code of Practice guidance annexed to this paper recommends that:
- clinics should inform a trans person that depending on the treatment options available to them, they may be screened as a donor at the time of egg or sperm collection
 - clinics should consider whether a trans patient may meet the requirements for extended storage periods due to premature infertility
 - use information obtained through their discussions with trans patients to determine which consent forms need to be completed, and
 - identify practical ways of accommodating the needs of trans patients with dignity and respect.

The Authority is asked to agree to the proposed changes to guidance notes 4 (Information to be provided prior to consent), 5 (Consent to treatment, storage, donation, training and disclosure of information), 17 (Storage of gametes and embryos), 29 (Treating people fairly), and 31 (Record keeping and document control).

4. Disclosing information about a patient's gender reassignment or any other information pertaining to their gender history

- 4.1.** The Gender Recognition Act 2004 provides a range of protection to trans people, including the disclosure of information. For example, it is a criminal offence for an individual to disclose information gathered in an official capacity about a person's application for a GRC, or about the gender history of a person who has a GRC. Therefore, if a licensed clinic was informed by a person that they had a GRC, the clinic and its staff would not be able to disclose the person's gender history unless it was for one of the following exceptions where disclosure does not constitute an offence:
- (a) If the information does not enable the person to be identified
 - (b) If the person has consented to the disclosure, or
 - (c) If the person making the disclose does not know or believe that a full GRC has been issued.
- 4.2.** Compliance with the Data Protection Act 1998 is also key. Under the Act, gender reassignment and any information relating to a person's gender history is considered to be a special category of private information that requires considerable protection (ie, 'sensitive personal data'). This information must not be processed, shared or disclosed unless certain requirements under the Data Protection Act 1998 can be met, or consent has been obtained from a trans person.
- 4.3.** Other ways of justifying the processing of this information would include:
- where it is necessary to safeguard a trans person (or others)
 - where it is necessary for legal proceedings
 - where it is necessary for the exercise of functions under statute, or
 - where it is necessary for medical purposes.
- 4.4.** Provided requirements of the Gender Recognition Act 2004 and the Data Protection Act 1998 are met, it is possible for a clinic to lawfully disclose information regarding a person's gender reassignment and relating to a person's gender history. To ensure clinics meet these requirements, we propose encouraging clinics to consider circumstances where they may need to disclose a person's gender history in order to determine whether they should

seek the person's consent (eg, to those within the centre who need to know of a trans patient's gender history to deliver safe and appropriate care).

- 4.5.** If it is decided that consent should be obtained, the clinic must inform trans patients of instances where they may need to disclose their gender history and why this is necessary. For example, clinics have an obligation to inform donors that certain information about them will be submitted to us and held on the Register, and that this may potentially be disclosed to anyone born as a result of their donation. In the case of a trans donor, clinics should also convey that anyone born as a result of their donation may work out that their donor is trans at the age of 18, based on the identifying information we disclose (eg, where a trans woman donated sperm and registered with the clinic and us in her acquired female gender. On disclosure of her identifying information it will be apparent to the person born as a result of her donation that the she is a trans woman having donated sperm).

Record keeping

- 4.6.** In accordance with the Data Protection Principles published by the information Commissioner, records of personal information should accurately reflect a person's current details. There is therefore a requirement to ensure the integrity of past records is maintained while ensuring current records are up-to-date.
- 4.7.** When recording information about a trans patient who has obtained a GRC, we propose clinics should ensure records are accurate and up-to-date to reflect the patient's newly acquired identity in a manner that does not necessarily erase pre-existing records containing the patient's previous identity.
- 4.8.** An example of how this could work in practice can be drawn from the UK birth registrar maintained by the Registrar General for England and Wales, who have created a separate Gender Recognition Register (GRR) and have a 'dual record' system for trans patients. In essence, the fact that a GRC has been issued obliges the Registrar to make an entry in the GRR, and to mark the original entry referring to the birth of a trans person to show that the original record has been superseded. This ensures caution is exercised when the previous record is accessed, and informs Registrar users that another entry is available for the same patient, but – crucially – refrains from linking the two.
- 4.9.** The Authority also has an obligation to ensure that certain information is included in the Register. We propose setting out that clinics should inform us that a patient has transitioned to their acquired gender if they have provided eggs or sperm for use in donor treatment, and have consented to the disclosure of this information to us.

Recommendation

- 4.10.** The draft Code of Practice guidance annexed to this paper recommends that:
- clinics should consider when it might be necessary for it to disclose a person's gender history

- if a clinic decides that it might need to disclose a person's gender history, they must obtain consent to disclose that information and inform the trans patient why it is necessary
- clinics should ensure records of trans patients are accurate and updated to reflect their acquired identity, and
- clinics should inform us that a patient has transitioned to their acquired gender if they have provided eggs or sperm for use in donor treatment and how to do this.

The Authority is asked to agree to the proposed changes to guidance notes 5 (Consent to treatment, storage, donation, training and disclosure of information), 11 (Donor recruitment, assessment and screening), 29 (Treating people fairly), 30 (Confidentiality and privacy) and 31 (Record keeping and document control).

5. Proof of identification

- 5.1.** Clinics are required to take reasonable steps to verify the identity of patients, partners (if applicable) and prospective donors by asking for appropriate identification. The purpose of doing so is to ensure that a patient, partner or donor is who they say they are, and to ensure that the data reported to the Authority and held on the Register about the treatment received is correct. If clinics fail to obtain satisfactory evidence of identity, we require clinics to consider whether they should offer treatment to patients, or accept a donor's gametes or embryos for treatment.
- 5.2.** Our stakeholder engagement work highlighted that clinics are unsure of what identification should be requested from a trans person to verify their identity, and that this can affect their ability to treat patients well. For example, failing to verify identity makes it difficult for a clinic to allow a trans patient to use their stored eggs, sperm or tissue in treatment, as a trans patient may appear physically different to the way they did at the time of storage.
- 5.3.** Under the Gender Recognition Act 2004, a trans person does not need to undergo gender reassignment to be legally considered as their acquired gender (ie, a different gender to that which they were at birth). For example, if a trans person was legally recognised as male at birth and subsequently identified as a female, she can be legally recognised as female without undergoing gender reassignment.
- 5.4.** For these reasons, we propose clinics verify the identity of trans patients in line with the other government organisations, such as the Passport Office. Principally, in cases where a trans patient has changed their name (eg, has changed their name by deed poll or has obtained a GRC), or has changed their physical appearance (eg, has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at

birth) since their previous consultation, examination or donation, centres should:

- ask for evidence of their previous name (eg, a passport or photocard driving licence) and verify details against the patient's medical records and
- ask for evidence of their new name, by providing one of the following:
 - a birth or adoption certificate in an acquired gender
 - a Gender Recognition Certificate, or
 - a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed poll).

5.5. We also propose clinics ensure that a patient's records are updated to accurately reflect their new identity.

Recommendations

5.6. The draft Code of Practice guidance annexed to this paper recommends that:

- clinics verify trans patient identity in line with the above, and
- clinics ensure medical records of trans patients are updated to reflect their acquired identity.

The Authority is asked to agree to the proposed changes to guidance notes 4 (Information to be provided prior to consent), 5 (Consent to treatment, storage, donation, training and disclosure of information), 11 (Donor recruitment, assessment and screening) and 31 (Record keeping and document control).

6. Legal parenthood

6.1. Several enquiries from fertility clinics about caring for trans patients have revolved around legal parenthood – namely whether transitioning affects the legal status of a trans patient as a parent and what legal parenthood consent forms trans patients should complete when having treatment with their partners.

6.2. Under the Gender Recognition Act 2004, the fact that a person's gender has changed and become the acquired gender under law, does not affect the status of the person as the mother, father or second legal parent of an existing child. For instance, where a woman has had a child and subsequently transitions to become a trans man, and obtains a GRC, he remains the mother of his existing child. Where for example a trans woman uses her sperm in her female partner's treatment, provided she and her partner have met the relevant statutory requirements and provided the necessary consents, she will be the second legal parent of the child. This is because what is of relevance is the identity of the trans patient at the time treatment takes place, rather than their identity at the time their eggs or sperm were stored.

Recommendation

- 6.3.** The draft Code of Practice guidance annexed to this paper recommends that:
- clinics should make sure a trans patient is aware of their legal parenthood status.

The Authority is asked to agree to the proposed changes to guidance note 6 (Legal parenthood).

7. Recommendations and next steps

- 7.1.** The Authority is asked to consider and agree to the recommendations made throughout this paper, and agree to the proposed changes to the Code of Practice that are set out at Annex A.
- 7.2.** All proposed changes are subject to Plain Language checks, and will be incorporated in the October 2017 update to the Code of Practice.
- 7.3.** As mentioned above, the gender-neutral consent forms and patient information were launched on the beta version of our website and promoted via Clinic Focus. This new work to provide guidance on treating trans patients will be communicated to our clinics and stakeholders in the same manner.

Annex A – Guidance note 4 (Information to be provided prior to consent)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

4. Information to be provided prior to consent

Version 5.0

Mandatory requirements

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

12 General Conditions

- (1) The following shall be conditions of every licence granted under this Act -
... (c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with,...

13 Conditions of licences for treatment

- (6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

13A Conditions of licences for non-medical fertility services

- (3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.

Schedule 3 - Consent to use or storage of gametes, embryos or human admixed embryos etc

- 3 (1) Before a person gives consent under this Schedule -

- (a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and
- (b) he must be provided with such relevant information as is proper.

Licence conditions

T58 Prior to giving consent gamete providers must be provided with information about:

- a. the nature of the treatment
- b. its consequences and risks
- c. any analytical tests, if they are to be performed
- d. the recording and protection of personal data and confidentiality
- e. the right to withdraw or vary their consent, and
- f. the availability of counselling.

T59 The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.

NOTE For the mandatory requirements pertaining to consent, see [guidance note 5 – consent to treatment, storage, donation, training and disclosure of information](#).

Directions

0005 – Collecting and recording information for the HFEA

HFEA guidance

Information to provide

Interpretation of mandatory requirements 4A



The law requires appropriate information to be provided when:

- (a) a woman or couple seeks treatment with donated gametes, mitochondria or embryos (including mitochondrial donation)
- (b) an individual or couple seeks treatment that will create embryos in vitro
- (c) an individual or couple seeks to store their gametes or embryos (for exceptions, see Schedule 3 of the HFE Act 1990 (as amended), paragraphs 9 or 10)
- (d) an individual or couple seeks to donate their gametes, mitochondria or embryos for the treatment of others (including mitochondrial donation)
- (e) an individual seeks to donate their gametes for use in non-medical fertility services
- (f) an individual or couple seeks to donate their embryos for research purposes, or for training people in embryo biopsy, embryo storage or other embryological techniques
- (g) an individual seeks to provide their gametes or cells for the creation of embryos or human admixed embryos for research (for exceptions, see mandatory requirements outlined in [guidance note 22 – research and training](#))
- (h) a woman provides embryos (obtained by lavage) for any purpose

- (i) written notice is served by a man or a woman consenting to the man being treated as the legal father of any child born as a result of the woman's treatment, or
- (j) written notice is served by a woman, or her female partner, consenting to the partner being treated as the legal parent of any child born as a result of the woman's treatment.

Information must always be provided before consent is given to treatment, storage, provision or donation (cases (a) to (h) above) or treatment is provided or continued (cases (i) and (j) above). In the case of donors wishing to donate gametes or embryos for use in mitochondrial donation and patients wishing to undergo treatment involving mitochondrial donation, the above information must be provided by a clinic licensed to offer mitochondrial donation.

Distinguishing the provision of information from the offer of counselling

4.1 The provision of information should be clearly distinguished from the offer of counselling.

See also

[Guidance note 3 – Counselling](#)



Information for those seeking treatment

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

- (a) the centre's policy on selecting patients
- (b) the centre's statutory duty to take account of the welfare of any resulting or affected child
- (c) the expected waiting time for treatment
- (d) fertility treatments available
- (e) the likely outcomes of the proposed treatment (data provided should include the centre's most recent live birth rate and clinical pregnancy rate per treatment cycle, verified by the HFEA, and the national live birth rate and clinical pregnancy rate per treatment cycle)
- (f) the nature and potential risks of the treatment, including the risk of children conceived having developmental and birth defects
- (g) the possible side effects and risks to the woman being treated and any resulting child, including ovarian hyperstimulation syndrome (OHSS)
- (h) in the case of fresh egg donation, the screening requirement of the donor and the risk of infection for the recipient
- (i) the availability of facilities for freezing embryos, and the implications of storing embryos and then using embryos
- (j) the importance of informing the treatment centre about the eventual outcome of the treatment (including if no live birth results)
- (k) the centre's complaints procedure, and
- (l) the nature and potential risks (immediate and longer term) of IVF/ICSI with in vitro matured eggs, including reference to the clinic's experience.

Information about the cost of treatment

4.3 Before treatment, storage or both are offered, the centre should also give the person seeking

treatment or storage, and their partner (if applicable) a personalised costed treatment plan. The plan should detail the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The centre should give patients the opportunity to discuss the plan before treatment begins.

Further information to provide

4.4 There are different kinds of information centres should give, where appropriate, to patients, patients' partners and donors prior to obtaining consent to treatment, storage or donation. Centre staff should familiarise themselves with all the appropriate information to provide. This information is contained in the following list of guidance notes:

- 5 – Consent to treatment, storage, donation, and disclosure of information
- 6 – Legal parenthood
- 7 – Multiple births
- 8 – Welfare of the child
- 9 – Preimplantation genetic screening (PGS)
- 10 – Embryo testing and sex selection
- 11 – Donor recruitment, assessment and screening
- 12 – Egg sharing arrangements
- 14 – Surrogacy
- 15 – Procuring, processing and transporting gametes and embryos
- 17 – Storage of gametes and embryos
- 20 – Donor assisted conception
- 21 – Intra-cytoplasmic sperm injection (ICSI)
- 22 – Research and training
- 29 – Treating people fairly
- 30 – Confidentiality and privacy
- 33 – Mitochondrial donation

Additional information for treating trans patients

- 4.5** The centre should be aware that there are multiple terms used to refer to trans people and that terminology in this area is evolving. For inclusivity, this Code of Practice uses the term 'trans' to refer to all trans identities, including persons who consider themselves 'non-binary' (ie, identify as somewhere, either fixed or moveable, on the male-female continuum) and 'non-gendered' (ie, neither male, female, nor on the male-female continuum).
- 4.6** The centre should be aware that under the Gender Recognition Act 2004, a trans person can be legally recognised as their acquired gender if they have a full gender recognition certificate (GRC) that has been issued by a Gender Recognition Panel (GRP). A GRC will be issued if the GRP is satisfied that a person has (or has had) a gender identity disorder, and has either lived in the acquired gender for the preceding two years (and intends to continue to live in the acquired gender until death), or has been recognised under the law of another country as having changed gender.
- 4.7** The centre should be aware that under the Equality Act 2010, a trans person does not need to undergo gender reassignment to have the protected from discrimination on the grounds of gender reassignment. For example, if a trans person who was male at birth subsequently identifies as a female, and chooses to live in her female identity permanently without any medical intervention, she will have the protection of the Equality Act. The law recognises a person's

intention without the person undergoing gender reassignment.

- 4.8** Before treatment or storage is offered to a trans person, the centre should consider the treatment and storage options that are available to the patient, depending on their individual circumstances. For example, if a trans person is visiting the clinic prior to gender reassignment they will be seeking options for fertility preservation (ie, storage of either testicular or ovarian tissue, or eggs or sperm depending on whether they have undergone puberty); or if a trans person is visiting the clinic after gender reassignment they may be seeking ways to use their preserved tissue, eggs or sperm in treatment with a partner and/or a surrogate, or extend their storage periods due to premature infertility.
- 4.9** Before treatment, storage or both are offered, the centre should inform a trans person that depending on the treatment options they may wish to pursue in the future, they may need to be screened as a donor at the time of egg or sperm collection and explain the reasons why.
- 4.10** Before treatment, storage or both are offered to a person who is yet to undergo gender reassignment or who is not yet living in their acquired gender, the centre should inform them that should they change their identity before returning for further treatment, it will be necessary for them to provide evidence of their acquired identity and to verify that they are the person previously treated.
- 4.11** The centre should recognise the sensitivities of treating trans patients, and find practical ways of accommodating their needs with dignity and respect. For example, rather than making assumptions about how a trans patient would like to be addressed, centres should ask how they would prefer to be addressed. Centres may also need to explain why gender at birth may be noted in medical records, should avoid making assumptions when referring to gender (eg, if a telephone enquiry is received regarding sperm storage, avoid assuming the caller is male), and should take privacy and sensitivity into consideration (eg, avoid asking a trans male undergoing an egg collection to wait in room full of women also awaiting egg collection).

See also



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

Guidance note 6 – Legal parenthood

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 17 – Storage of gametes and embryos

Guidance note 29 – Treating people fairly

Guidance note 30 – Confidentiality and privacy

Responsible use of the centre's website

- 4.12** In line with the Advertising Standards Authority's Code, the centre should ensure that the information provided on its website complies with the following guidance. This also applies to other relevant marketing communications of the centre and associated satellite and transport centres.
- The information should include the most recent data available from the past three years.
 - The website should provide the live birth rate per treatment cycle, and not highlight a high success rate that applies only to a small, selected group of patients.

- (c) The data should show split by maternal age and, if appropriate, by treatment type.
- (d) The website should provide raw numbers rather than just percentages.
- (e) The website should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.).
- (f) The centre's published success-rate data should refer to the HFEA as the source of national information.
- (g) The website must state clearly that information on success rates is of limited value in comparing centres and choosing where to seek treatment. It should include a link to the HFEA's advice on success rates: www.hfea.gov.uk/fertility-clinics-success-rates.html
- (h) If the website refers to comparative costs, it should indicate the likely total cost for a typical cycle, based on the actual costs for recent patients, not individual items in tariffs.

Other legislation, professional guidelines and information

Legislation

Data Protection Act 1998

Equality Act 2010

Gender Recognition Act 2004

Professional guidelines

Advertising Standards Authority: UK code of non-broadcast advertising, and direct and promotional marketing (CAP Code)

National Institute for Health and Care Excellence: Fertility problems – assessment and treatment [CG156] (2013)

One at a Time: Better outcomes from fertility treatment

Clinic Focus articles

Clinic Focus article: Risks – how much do you tell your patients? (May 2015)

Annex B – Guidance note 5 (Consent to treatment, storage, donation, training and disclosure of information)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

5. Consent to treatment, storage, donation, training and disclosure of information

Version 10.0

Mandatory requirements

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

12 General Conditions

- (1) The following shall be conditions of every licence granted under this Act -
... (c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with...

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc

- 1 (1) A consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.

(2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability (a “person unable to sign”), and any notice under paragraph 4 by a person unable to sign varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the person unable to sign, in the presence of the person unable to sign and in the presence of at least one witness who attests the signature.

(3) In this Schedule “effective consent” means a consent under this Schedule which has not been withdrawn.
- 2 (1) A consent to the use of any embryo must specify one or more of the following purposes -
 - (a) use in providing treatment services to the person giving consent, or that person and another specified person together,
 - (b) use in providing treatment services to persons not including the person giving consent,

- (ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or
- (c) use for the purposes of any project of research,
and may specify conditions subject to which the embryo may be so used. ...
- (2) A consent to the storage of any gametes, any embryo or any human admixed embryo must -
 - (a) specify the maximum period of storage (if less than the statutory storage period),
 - (b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and
 - (c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,
and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.
- (2A) A consent to the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.
- (2B) In relation to Scotland, the reference in sub-paragraph (2)(b) to the person lacking capacity is to be read as a reference to the person -
 - (a) lacking capacity within the meaning of the Age of Legal Capacity (Scotland) Act 1991, or
 - (b) being incapable within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000.
- (3) A consent under this Schedule must provide for such other matters as the Authority may specify in directions.
- (4) A consent under this Schedule may apply -
 - (a) to the use or storage of a particular embryo or human admixed embryo, or
 - (b) in the case of a person providing gametes or human cells, to the use or storage of -
 - (i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and
 - (ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.
- (5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to -
 - (a) a particular embryo or particular embryos, or
 - (b) a particular human admixed embryo or particular human admixed embryos.

Procedure for giving consent

- 3 (1) Before a person gives consent under this Schedule -

- (a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and
 - (b) he must be provided with such relevant information as is proper.
- (2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 and, if relevant, paragraph 4A below.

Use of gametes for treatment of others

- 5
- (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.
 - (2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.
 - (3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

In vitro fertilisation and subsequent use of embryo

- 6
- (1) A person's gametes or human cells must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for one or more of the purposes mentioned in paragraph 2(1)(a), (b) and (c) above.
 - (2) An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) (a), (b), (ba) and (c) above of the embryo.
 - (3) An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each relevant person in relation to the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents. ...
 - (3E) For the purposes of sub-paragraphs (2), (3) and (3B) each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A") -
 - (a) each person whose gametes or human cells were used to bring about the creation of embryo A,
 - (b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and
 - (c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.
 - (4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

Embryos obtained by lavage, etc

- 7
- (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in

accordance with the consent.

- (2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.
- (3) Sub-paragraphs (1) and (2) do not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.
- (4) An embryo taken from a woman must not be used to bring about the creation of any embryo in vitro or any human admixed embryo in vitro.

Storage of gametes and embryos

- 8 (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.
- (2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents...
- (2C) For the purposes of sub-paragraphs (2) and (2A) each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A") -
 - (a) each person whose gametes or human cells were used to bring about the creation of embryo A,
 - (b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and
 - (c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.
- (3) An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent.
- (4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraphs 4A(4), 16 and 20.

Cases where consent not required for storage

- 9 (1) The gametes of a person ("C") may be kept in storage without C's consent if the following conditions are met.
- (2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.
- (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -
 - (a) the treatment is likely to cause a significant impairment of C's fertility, and
 - (b) the storage of the gametes is in C's best interests.
- (4) Condition C is that, at the time when the gametes are first stored, either -
 - (a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or
 - (b) C has attained that age but, although not lacking capacity to consent to the storage

of the gametes, is not competent to deal with the issue of consent to their storage.

- (5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes-
- (a) given consent under this Schedule to the storage of the gametes, or
 - (b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.
- (6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications -
- (a) for sub-paragraph (4), substitute -

“(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.”, and
 - (b) in sub-paragraph (5), for “becoming competent to deal with the issue of consent to the storage of the gametes” substitute “acquiring such capacity”.
- 10 (1) The gametes of a person (“P”) may be kept in storage without P’s consent if the following conditions are met.
- (2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.
 - (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -
 - (a) the treatment is likely to cause a significant impairment of P’s fertility,
 - (b) P lacks capacity to consent to the storage of the gametes,
 - (c) P is likely at some time to have that capacity, and
 - (d) the storage of the gametes is in P’s best interests.
 - (4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.
 - (5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule -
 - (a) given consent to the storage of the gametes, or
 - (b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.
 - (6) In relation to Scotland -
 - (a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,
 - (b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and
 - (c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.
- 11 A person’s gametes must not be kept in storage by virtue of paragraph 9 or 10 after the

person's death.

Interpretation

22 ... (6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991

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

Licence conditions

T57 Gametes or embryos must not be used in the provision of treatment services (except in the use of gametes in the course of providing basic partner treatment services or non-medical fertility services) unless effective consent is in place from each gamete provider in accordance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

Directions

0006 – Import and export of gametes and embryos

0007 – Consent

HFEA guidance

Consent to use and storage of gametes and embryos

Interpretation of mandatory requirements 5A



It is generally unlawful to procure, store or use gametes or embryos without written, effective consent from the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created). There are, however, limited circumstances in which it may be possible to store a person's gametes without their consent – where the person is expected to undergo medical treatment likely to cause a significant impairment of his or her fertility, provided certain other legal requirements are met. These exemptions are set out in paragraphs 9 and 10 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) (see 5G). However, these exemptions do not permit gametes to be stored or used without consent where the gamete provider lacks capacity to give consent and is not expected to gain or regain it.

Gametes from a person who has died (including cases of brain stem death) cannot be stored or used once the consent given by that person has expired. While a patient can give consent while alive to the storage and use of their gametes after their death, storage and use is only possible for the duration of the consent.

The provisions of the Human Tissue Act 2004, which allow next of kin to give consent to procure, store or use other body tissues of the deceased, do not apply to gametes.

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

The use of donor gametes or embryos to create more families than a donor has consented to is a breach of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

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

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

If gametes or embryos are to be transferred to a centre outside the UK, requirements set out in General Direction 0006 are met. These include that the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created) has given written, effective consent to the export of the gametes or embryos to the country in which the receiving centre is situated. Such consent must then be provided to the centre receiving the gametes or embryos.

If gametes or embryos are to be transferred into the UK from a centre outside the UK, the requirements set out in General Direction 0006 must be met. These include the requirement that the gamete provider (or in the case of an embryo, both people who provided the gametes from which the embryo was created) has given written, effective consent to the transfer of the gametes or embryos to the UK, and has not withdrawn that consent.

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

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

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

5.1 The centre should obtain written, effective consent from a person before it carries out the following procedures:

- (a) using their gametes for their own treatment or their partner's treatment, or
- (b) using their gametes for research and training.

5.2 When a woman is to undergo an egg or embryo transfer, the centre should:

- (a) obtain her consent to the proposed number of eggs or embryos to be transferred, and
- (b) record her consent in her medical records.

5.3 The centre should establish and use documented procedures to ensure that no activity involving the handling or processing of gametes or embryos is carried out without the appropriate consent having been given. This should include a documented assurance process to ensure that all relevant consent forms have been properly and correctly completed before treatment.

5.4 If, following treatment, the centre discovers errors in the consent provided by a patient or their partner, the centre should:

- (a) take all reasonable steps to notify the affected patient at the earliest opportunity
- (b) assess the error(s) and potential impact, and consider the remedial actions that should be taken
- (c) take all reasonable steps to support any affected patients (and their partner(s), if relevant) and offer independent legal assistance where necessary, and
- (d) report any error(s) as an adverse incident.

NOTE Consent to legal parenthood is subject to specific legal requirements. Centres should familiarise themselves with guidance note 6, which contains guidance and mandatory requirements relevant to legal parenthood.

5.5 If the centre becomes involved in a case where a partner or family member of a deceased person intends to make an emergency application to the High Court to permit harvesting of gametes without valid consent, the centre should notify the HFEA as soon as it becomes aware of this.

See also



[Guidance Note 6 – Legal parenthood](#)

[Guidance note 15 – Procuring, processing and transporting gametes and embryos](#)

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

Procedure for obtaining consent

Interpretation of mandatory requirements 5B



The law requires that before a person consents to the procedures outlined in box 5A, they should be given:

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

5.6 Centres should ensure that, before a person gives consent, they are given the information outlined in guidance note 4.

5.7 The centre should ensure that the person giving consent is able to give their consent freely. The centre should not pre-complete consent forms on behalf of the person giving consent. For

example, a person giving consent to the storage of their gametes and/or embryos should be free to choose how long to consent to store for, within what is permitted by regulations. The centre should not restrict storage consent to tie in with payment or funding arrangements. Contractual agreements covering payment or funding should be separate to consent. Further information on removing gametes and embryos within the storage period is outlined in guidance note 17.

- 5.8** The centre should inform anyone providing gametes that they can, if they wish, specify extra conditions for storing or using their gametes (or embryos created using them).
- 5.9** The centre should give anyone seeking treatment or considering donation or storage enough time to reflect on their decisions before obtaining their consent. The centre should give them an opportunity to ask questions and receive further information, advice and guidance.
- 5.10** If the possibility of donating gametes or embryos (including mitochondrial donation) for the treatment of others, or donating embryos for research or training purposes, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.
- 5.11** The centre should ensure that consent is:
- (a) given voluntarily (without pressure to accept treatment or agree to donation)
 - (b) given by a person who has capacity to do so, and
 - (c) taken by a person authorised by the centre to do so.

A child under the age of 16 is only able to provide consent if it has been established that he or she is 'Gillick competent'.

- 5.12** The centre should ensure that anyone giving consent has been:
- (a) given enough information to enable them to understand the nature, purpose and implications of the treatment or donation
 - (b) given a suitable opportunity to receive proper counselling about the implications of the proposed procedures
 - (c) given information about the procedure for varying or withdrawing consent, and
 - (d) given information in writing that is correct and complete.
- 5.13** Treatment centres should take all reasonable steps to verify the identity of anyone accepted for treatment, including partners who may not visit the centre during treatment. If a patient's identity is in doubt, the centre should verify their identity, including examining photographic evidence such as a passport or a photocard driving licence. The centre should record this evidence in the patient's medical records. Centres should re-verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment.
- 5.14** Where a patient has changed their name (eg, where someone has changed their name by deed poll, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation, centres should take all reasonable steps to verify the patient's identity. This is to ascertain that a patient presenting for treatment or donation is the same person the centre previously engaged with or treated.

Centres should verify a patient's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the person's medical records. This can be a sensitive issue, and centres should take care to address identity issues with consideration. As evidence of their new name, centres should ask the person to provide one of the following:

- (a) a marriage certificate, or
- (b) evidence of a change in name (such as via deed poll)

For trans patients:

- (c) a birth or adoption certificate in an acquired gender
- (d) a Gender Recognition Certificate, or
- (e) a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed poll).

Centres must ensure that a patient's records are updated to accurately reflect their new identity.

- 5.15** To avoid the possibility of misrepresentation or mistake, the centre should check the identities of patients (and their partners, if applicable) against identifying information in the medical records. This should be done at each consultation, examination, treatment or donation. If the partner of a patient who is having treatment has not visited the clinic throughout the treatment, or does not return with the patient for subsequent treatment, centres should take reasonable steps to find out whether the patient's partner still consents to the treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is still valid.
- 5.16** The centre should consider the needs of people whose first language is not English and those who face other communication barriers. Where consent is obtained, the centre should record:
- (a) any difficulties in communicating the implications of giving consent and providing other information to the person (eg, language barriers or hearing impairment), and
 - (b) an explanation of how these difficulties were overcome (eg, the use of an independent interpreter). (This guidance is based on a paragraph taken from The Human Tissue Authority's Code of Practice on Consent (2008)).
- 5.17** The centre should establish and follow documented procedures to obtain written informed consent.

See also

[Guidance note 3 – Counselling](#)

[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 11 – Donor recruitment, assessment and screening](#)

[Guidance note 17 – Storage of gametes and embryos](#)

[Guidance note 22 – Research and training](#)

[Guidance note 23 – The quality management system](#)

[Guidance note 29 – Treating people fairly](#)

[Guidance note 31 – Record keeping and document control](#)

HFEA consent forms



HFEA guide to consent

Recording consent and related information

Interpretation of mandatory requirements 5C



The law requires consent, or any subsequent variation or withdrawal of consent, to be in writing and signed by the person giving consent, except in the following situation:

If the person giving consent, or varying or withdrawing consent, has the mental capacity to do so but cannot sign because of illness, injury or physical disability (for example, quadriplegia), they can direct someone to sign on their behalf, provided that:

- (a) the person giving consent, or varying or withdrawing consent is present at the time, and
- (b) the signature is also witnessed, and attested to by at least one other person.

5.18 The centre should keep a copy of a person's signed consent form(s) (either electronically or as a hard copy) so that a copy can be made available to them upon request.

5.19 The centre should ensure that it documents in the medical records that:

- (a) relevant information, as outlined in guidance note 4, has been provided to the person, and
- (b) the person has been offered counselling before giving consent.

See also



[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 31 – Record keeping and document control](#)

HFEA consent forms

Additional consent requirements for storing gametes and embryos

Interpretation of mandatory requirements 5D



Written consent to the storage of gametes, embryos or human admixed embryos must:

- (a) specify the maximum period of storage (if less than the statutory storage period), and
- (b) state what should be done with the gametes, embryos or human admixed embryos if the person giving the consent dies or cannot, because of mental incapacity, withdraw or vary the terms of the consent.

In relation to b), where consent is given following the application of the parental consent provisions in Schedule 3, the consent needs only to specify what is to be done with the embryo or the human admixed embryo if the person to whom the consent relates dies.

The consent may also specify conditions under which the gametes, embryos or human admixed embryos may remain in storage.

In certain limited circumstances involving premature infertility, gametes and embryos can be stored

beyond the statutory maximum storage period.

Gametes first placed in storage before 1 August 1991

Gametes first placed in storage before 1 August 1991, and which have been kept lawfully, may continue to be stored for an extended period beyond the 10-year statutory maximum storage period without the written consent of the gamete provider (if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied). The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period must be calculated from 1 August 1991.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage between 1 August 1991 and 1 October 2009

Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period without the written consent of the gamete provider (if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied). The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period begins on the date that the gametes were stored. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

Embryos first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period but only if both people whose gametes were used to bring about the creation of the embryo confirm in writing that they have no objection to the extension (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are satisfied). The Schedule to these Regulations set out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage after 1 October 2009

Gametes or embryos first placed in storage after 1 October 2009 may continue to be stored beyond the statutory maximum storage period, to a maximum of 55 years, but only with the written consent of the gamete provider or the people whose gametes were used to bring about the creation of the embryo (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 are satisfied). The same conditions apply to any extension of the statutory storage period for gametes and embryos first stored earlier than 1 October 2009, if the gamete provider (or people whose gametes were used to bring about the creation of the embryo) have provided consent under those Regulations.

- 5.20** The centre should normally ask patients to give consent to storage at the same time as consent to the use of gametes and embryos. However, the centre should accommodate anyone seeking long-term storage of gametes who may wish to consent to storage separately from consent to use.
- 5.21** Before the centre obtains consent from anyone wishing to store gametes or embryos for more than 10 years, it should explain that storage can only continue beyond 10 years if a medical practitioner has certified in writing that the gamete provider, their partner, or the person who the

gametes or embryos have been allocated to, meet the medical criteria for premature infertility **or are likely to become prematurely infertile**.

5.22 The centre should have regard to their obligations to help trans patients. Trans patients, particularly those of a younger age, may be able to store their gametes beyond the statutory 10 years, depending on their individual circumstances and if they can comply with the requirements of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. This includes the need to obtain a written opinion from a registered medical practitioner certifying that they are, or are likely to become prematurely infertile. Giving consideration to whether the patient meets the criteria for extended storage will help to ensure that trans patients have viable treatment options in the future.

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

See also

[Guidance note 6 – Legal parenthood](#)

[Guidance note 17 – Storage of gametes and embryos](#)

HFEA consent forms



Interpretation of mandatory requirements 5E

The law requires the centre to ensure that consent to the use of any embryo (not a human admixed embryo) must specify one or more of the following uses for the embryo:

- (a) providing treatment for the person giving the consent, or, where applicable, that person and another named person together
- (b) providing treatment for others
- (c) training centre staff in embryo biopsy, embryo storage or other embryological techniques, or
- (d) contributing to a specified research project.

In relation to human admixed embryos, the law requires that consent to their use must specify use for a research project.

The consent may also specify conditions for how the embryo may be used.

5.24 Consent to the use of gametes or embryos for the treatment of others should state the number of families that may have children using the donated gametes or embryos.

5.25 When an individual gives consent to the use of gametes for the treatment of others, the centre need not get consent from the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.



- 5.26** Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:
- (a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
 - (b) referred to information on the HFEA's website on this issue, and
 - (c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

See also

[Guidance note 20 – Donor assisted conception](#)

[Guidance note 22 – Research and training](#)

HFEA consent forms



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

- 5.27** The person obtaining consent should ensure that a gamete provider's consent is recorded so that different conditions can be placed on:
- (a) the use or storage of the gametes, and the use and storage of embryos created for the gamete provider's own treatment, and
 - (b) the use of eggs or sperm, and the use and storage of embryos created for the treatment of the recipient(s)

These conditions should be able to be varied independently of each other.

- 5.28** The person obtaining consent should tell the gamete provider and recipient(s) that the gamete provider may withdraw or vary their consent up to when the gametes or embryo(s) are:
- (a) transferred to a woman
 - (b) used in a research project (defined as being under the control of the researchers and being cultured for use in research)
 - (c) used for training, or
 - (d) allowed to perish.

The possible consequences of this should:

- (e) be made clear to the gamete provider and the recipient(s) before the treatment begins, and
- (f) be set out in the written patient information included with the benefits in kind agreement.

The person obtaining consent should tell the gamete provider and recipient(s) that consent to providing gametes solely for use in mitochondrial donation treatment cannot be withdrawn or varied once the patient's nuclear DNA has been inserted into the egg or embryo.

See also

[Guidance note 12 – Egg sharing arrangements](#)



HFEA consent forms

Consent to examination and treatment

5.29 Everyone has the right to withhold or give consent to examination and treatment. Unless there are exceptional circumstances, the centre may not examine, treat or receive gametes from people without first obtaining their consent. The only exceptional circumstance likely to arise during fertility treatment is:

- (a) where the procedure is necessary to save the patient's life, and
- (b) the treatment cannot be postponed, and
- (c) the patient is unconscious or mentally incapacitated so cannot indicate their wishes.

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

Consent to the presence of observers

5.31 If a member of the centre's team wishes an observer to be present when a patient is being examined, treated or counselled, they should explain why beforehand and state who the observer is. The centre should give the patient appropriate information about the proposed observation and ask them whether they consent to the observer's presence.

Consent to disclose identifying information

Interpretation of mandatory requirements 5F



Patients have the right to decide what identifying information should be disclosed and to whom. Centres should obtain a patient's written consent before disclosing information relating to their treatment (or providing gametes for a partner's treatment), or the storage of gametes or embryos.

In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or gamete/embryo storage. For example, consent would be needed from a patient's partner if they could be identified through disclosure of information about the patient's treatment.

If a child born as a result of treatment could be identified, consent must be obtained from the parent(s), unless identification is necessary in disclosing information about the patient's treatment. Once a child born as a result of treatment is considered competent to consent, then their consent (if given) will override the consent of the parent(s).

5.32 Before obtaining consent to disclose information, the centre should give the person enough information for them to make a properly informed decision, including:

- (a) precisely what information is to be disclosed
- (b) the terms on which it is to be disclosed
- (c) the reasons for disclosure (eg, to keep the person's GP informed about the fertility treatment)
- (d) the implications of disclosure, in particular the fact that, once it is disclosed, the information will be subject no longer to the special provisions of the HFE Act 1990 (as amended) but only to the general law of confidentiality, and

(e) the categories of people to whom the information is to be disclosed.

5.33 The centre should seek consent to disclosure to the following categories of people:

- (a) the patient's GP or the patient's partner's GP
- (b) other healthcare professionals outside the centre (so they can provide the patient or the patient's partner with the best possible medical care)
- (c) auditors or administrative staff outside of the centre (so they can perform their functions in connection with the centre's licensable activities), and
- (d) medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).

5.34 Information about gender reassignment and information relating to a person's gender history is, for Data Protection purposes, classed as 'sensitive personal data'; a category of private information which centres must take care to protect. Centres should be aware that it is an offence under the Gender Recognition Act 2004 to disclose information that centres have obtained in an official capacity about a person who has applied for a gender recognition certificate (GRC) or the gender history of someone who has obtained a GRC, unless consent has been obtained from that person.

The centre should consider circumstances where they may need to disclose a person's gender history (eg, to those within the centre who need to know of a trans patient's previous identity to deliver safe and appropriate care) to determine whether they need to obtain the person's consent to disclosure of this information. This should be discussed in detail with the person and any consent obtained should be filed with their medical records. Centres dealing with requests for disclosure of this information may wish to seek advice from information law specialists before disclosing any information.

5.35 The centre should renew consent to disclosure if the nature of treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used instead of the patient's own, or if the patient moves from unlicensed to licensed fertility treatment).

5.36 The centre should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:

- (a) the precise terms upon which it was disclosed and for which consent has been given, and
- (b) that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.

See also

[Guidance note 30 – Confidentiality and privacy](#)

HFEA consent forms



Cases where consent is not required for storage

Interpretation of mandatory requirements 5G



Gametes may be stored without consent if the conditions in paragraph 9 or 10, of Schedule 3 of the HFE Act 1990 (as amended) are met.

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

Paragraph 9 sets out the conditions that must be met before the gametes of a person who is **under the age of 18** can be stored without their consent.

Condition A is that the gametes are lawfully taken from the person before they reach the age of 18 years.

Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the person is expected to undergo medical treatment and that in the opinion of the registered medical practitioner:

- (a) the treatment is likely to cause a significant impairment of their fertility, and
- (b) the storage of the gametes is in the person's best interests.

Condition C is that, at the time when the gametes are first stored, either:

- (a) the person has not reached the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or
- (b) the person is 16 years old, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to storage. A registered medical practitioner must actively establish that the person is not competent to deal with the issues arising in relation to consent to the storage of their gametes.

NOTE In relation to Scotland for Condition C, the test is whether, at the time the gametes were first stored, the person has capacity within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991.

Condition D is that the person has not, since becoming competent to deal with the issue of consent to the storage of the gametes:

- (a) given consent to the storage of the gametes, or
- (b) given written notice to the centre that they do not wish their gametes to continue to be stored.

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

Paragraph 10 sets out the conditions that must be met before the gametes of a person who is **16 years or over** may be stored without their consent.

Condition A is that the gametes are lawfully taken from or provided by the person after they have reached the age of 16 years.

Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the person is expected to undergo medical treatment and that in the opinion of the registered medical practitioner:

- (a) the treatment is likely to cause a significant impairment of their fertility,
- (b) the person lacks capacity to consent to the storage of the gametes,
- (c) the person is likely at some time to have that capacity, and
- (d) the storage of the gametes is in their best interests.

Condition C is that, at the time when the gametes are first stored, the person lacks capacity to consent to their storage.

Condition D is that the person has not subsequently, at a time when he or she has capacity to give a consent:

- (a) given consent to the storage of the gametes, or
- (b) given written notice to the centre that they do not wish their gametes to continue to be stored.

Gametes stored in compliance with these paragraphs may be used only if the person from whom they were collected gives written effective consent to their use (and has sufficient capacity and competence to do so). If the patient dies before providing this consent, the gametes can no longer remain in storage.

5.37 Before a centre can store a patient's gametes without their consent, the centre must ensure that each of the conditions set out in either paragraph 9 or 10 of Schedule 3 of the 1990 Act (whichever is applicable in the circumstances) are met. The centre should ensure that it documents its decision to store the patient's gametes in the absence of consent and records the evidence relied upon to establish that each of the conditions have been met.

5.38 When assessing a patient's competence to consent, the centre should follow current guidance produced by the Department of Health, the General Medical Council and other professional bodies.

5.39 When assessing whether it is in a child's best interests to store their gametes, the centre should refer to applicable General Medical Council guidance and consider the child's short- and long-term best interests. When the child is competent to give consent, the centre should seek their consent to the continued storage of the gametes.

5.40 The centre should provide written information about the proposed procedures that children and young people can read and understand easily. This information should be given by a member of staff experienced in communicating with children.

Competence

5.41 If the centre's staff doubt someone's competence to consent to a proposed procedure, or to the storage or use of gametes or embryos, they should:

- (a) refer to the Mental Capacity Act 2005 (England and Wales), or the Age of Legal Capacity (Scotland) Act 1991 and the Adults with Incapacity (Scotland) Act 2000, and
- (b) follow the current guidelines of professional bodies. If they remain in any doubt, the centre should seek legal advice.

Variation and withdrawal of consent

Mandatory requirements

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

Schedule 3

Variation and withdrawal of consent

- 4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.
- (1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “egg A” and “egg B” have the same meanings in this paragraph as in that regulation).
- (1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.
- (2) Subject to sub-paragraph (3) to (3B), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used -
- (a) in providing treatment services,
- (aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or
- (b) for the purposes of any project of research.
- (3) Where the terms of any consent to the use of an embryo (“embryo A”) include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).
- (3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “embryo A” and “embryo B” have the same meanings in sub-paragraph (3B) as in that regulation).
- (3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.
- 4A (1) This paragraph applies where -
- (a) a permitted embryo, the creation of which was brought about in vitro, is in storage,
- (b) it was created for use in providing treatment services,
- (c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation (“P”) gives the person keeping the embryo notice withdrawing P’s consent to the storage of the embryo, and
- (d) the embryo was not to be used in providing treatment services to P alone.
- (2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P’s withdrawal of consent.
- (3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.
- (4) Storage of the embryo remains lawful until -

- (a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or
 - (b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.
- (5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.

Interpretation of mandatory requirements 5H



The law allows consent to be varied or withdrawn at any point until gametes or embryos (other than human admixed embryos) are used to provide treatment services, or used for a research project or for training.

Consent to providing eggs, embryos or sperm solely for use in mitochondrial donation treatment cannot be withdrawn or varied once the patient's nuclear DNA has been inserted into the egg or embryo.

Consent to the use of any human admixed embryo can be varied or withdrawn until the embryo has been used for a research project.

If someone wishes to withdraw consent to the storage or use of gametes, embryos or human admixed embryos, they must do so in writing, except if they are unable to do so because of illness, injury or incapacity. In these cases, they can direct someone to sign on their behalf, provided that the person withdrawing consent is present at the time, and that the signature is also witnessed and attested to by at least one other person.

If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment (created from their gametes), the law requires the centre to take all reasonable steps to notify the intended recipient(s).

The law allows embryos to be stored for 12 months from the date that the centre receives written withdrawal of consent, or less if the centre receives written signed consent from all intended recipients for the embryos to be destroyed.

This 12-month 'cooling off' period must not extend beyond the end of the period for which valid consent exists.

5.42 The centre should check the identity of anyone withdrawing or varying consent against identifying information held in the medical records. The centre should also ensure that the person withdrawing or varying consent has been given sufficient information to enable them to make an informed decision about doing so.

5.43 The centre should have procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment. In this situation the centre should stop treatment and notify all relevant parties. Centres should provide information about counselling or mediation services as appropriate.

See also

HFEA consent forms



HFEA guide to consent

Other legislation, professional guidelines and information

Legislation

Age of Legal Capacity (Scotland) Act 1991

Adults with Incapacity (Scotland) Act 2000

Data Protection Act 1998

Equality Act 2010

Gender Recognition Act 2004

Mental Capacity Act 2005

Consent to examination and treatment

Department of Health: Reference guide to consent for examination or treatment (second edition, 2009)

General Medicines Council: Consent – patients and doctors making decisions together (2008)

Human Tissue Authority: Code of Practice – 1: Consent (2014)

Office of the Public Guardian: Code of Practice – Mental Capacity Act (2013)

Royal College of Obstetrics and Gynaecologists: Obtaining valid consent [Clinical Governance Advice No.6] (third edition, 2015)

General information

Department of Health: Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health (2004)

Clinic Focus articles

Clinic Focus article: Harvesting sperm from deceased men (October 2012)

Chief Executive letter CE(12)02 (May 2012) – Extension of storage of gametes and embryos where one of the gamete providers is deceased

Chief Executive letter CE(16)02(a) (July 2016) – Changes to the interpretation of several regulations

Annex C – Guidance note 6 (Legal parenthood)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

6. Legal parenthood

Version 7.0

Mandatory requirements

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

PART 2: PARENTHOOD IN CASES INVOLVING ASSISTED PRODUCTION

Meaning of "mother"

33 Meaning of "mother"

- (1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.
- (2) Subsection (1) does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.
- (3) Subsection (1) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

Application of sections 35 to 47

34 Applications of sections 35 to 47

- (1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as "W") as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.
- (2) Subsection (1) has effect subject to the provisions of sections 39, 40 and 46 limiting the purposes for which a person is treated as the child's other parent by virtue of those sections.

Meaning of "father"

35 Women married [to a man] at time of treatment

- (1) If –
 - (a) at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination, W was a party to a marriage [with a man], and
 - (b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage, then, subject to section 38(2) to (4), the other party to

the marriage is to be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).

- (2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1)(a).

36 Treatment provided to woman where agreed fatherhood conditions apply

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but -

- (a) the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,
- (b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed fatherhood conditions (as set out in section 37) were satisfied in relation to a man, in relation to treatment provided to W under the licence,
- (c) the man remained alive at that time, and
- (d) the creation of the embryo carried by W was not brought about with the man's sperm, then, subject to section 38(2) to (4), the man is to be treated as the father of the child.

37 The agreed fatherhood conditions

- (1) The agreed fatherhood conditions referred to in section 36(b) are met in relation to a man ("M") in relation to treatment provided to W under a licence if, but only if, -
- (a) M has given the person responsible a notice stating that he consents to being treated as the father of any child resulting from treatment provided to W under the licence,
 - (b) W has given the person responsible a notice stating that she consents to M being so treated,
 - (c) neither M nor W has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of M's or W's consent to M being so treated,
 - (d) W has not, since the giving of the notice under paragraph (b), given the person responsible -
 - (i) a further notice under that paragraph stating that she consents to another man being treated as the father of any resulting child, or
 - (ii) a notice under section 44(1)(b) stating that she consents to a woman being treated as a parent of any resulting child, and
 - (e) W and M are not within prohibited degrees of relationship in relation to each other.
- (2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.
- (3) A notice under subsection (1)(a), (b) or (c) by a person ("S") who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

38 Further provision relating to sections 35 and 36

- (1) Where a person is to be treated as the father of the child by virtue of section 35 or 36, no

other person is to be treated as the father of the child.

- (2) In England and Wales and Northern Ireland, sections 35 and 36 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.
- (3) In Scotland, sections 35 and 36 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.
- (4) Sections 35 and 36 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the man's child.

39 Use of sperm, or transfer of embryo, after death of man providing sperm

- (1) If -
 - (a) the child has been carried by W as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,
 - (b) the creation of the embryo carried by W was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in W after his death,
 - (c) the man consented in writing (and did not withdraw the consent) -
 - (i) to the use of his sperm after his death which brought about the creation of the embryo carried by W or (as the case may be) to the placing in W after his death of the embryo which was brought about using his sperm before his death, and
 - (ii) to being treated for the purpose mentioned in subsection (3) as the father of any resulting child,
 - (d) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (3) as the father of the child, and
 - (e) no-one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the man is to be treated for the purpose mentioned in subsection (3) as the father of the child.
- (2) Subsection (1) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.
- (3) The purpose referred to in subsection (1) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.
- (4) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

40 Embryo transferred after death of husband etc. who did not provide sperm

- (1) If -
 - (a) the child has been carried by W as a result of the placing in her of an embryo,
 - (b) the embryo was created at a time when W was a party to a marriage with a man],
 - (c) the creation of the embryo was not brought about with the sperm of the other party to

- the marriage,
- (d) the other party to the marriage died before the placing of the embryo in W,
 - (e) the other party to the marriage consented in writing (and did not withdraw the consent) –
 - (i) to the placing of the embryo in W after his death, and
 - (ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,
 - (f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and
 - (g) no-one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.
- (2) If -
- (a) the child has been carried by W as a result of the placing in her of an embryo,
 - (b) the embryo was not created at a time when W was a party to a marriage or a civil partnership but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,
 - (c) a man consented in writing (and did not withdraw the consent) –
 - (i) to the placing of the embryo in W after his death, and
 - (ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,
 - (d) the creation of the embryo was not brought about with the sperm of that man,
 - (e) the man died before the placing of the embryo in W,
 - (f) immediately before the man's death, the agreed fatherhood conditions set out in section 37 were met in relation to the man in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,
 - (g) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and
 - (h) no-one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.
- (3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.

- (4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.
- (5) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

Cases in which woman to be other parent

42 Woman in civil partnership [or marriage to a woman] at time of treatment

- (1) If at the time of the placing in her of the embryo or the sperm and eggs or of her artificial insemination, W was a party to a civil partnership [or marriage with another woman], then subject to section 45(2) to (4), the other party to the civil partnership [or marriage] is to be treated as a parent of the child unless it is shown that she did not consent to the placing in W of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).
- (2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1).

43 Treatment provided to woman who agrees that second woman to be parent

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but -

- (a) the embryo or the sperm and eggs were placed in W, or she was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,
- (b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed female parenthood conditions (as set out in section 44) were met in relation to another woman, in relation to treatment provided to W under that licence, and
- (c) the other woman remained alive at that time, then, subject to section 45(2) to (4), the other woman is to be treated as a parent of the child.

44 The agreed female parenthood conditions

- (1) The agreed female parenthood conditions referred to in section 43(b) are met in relation to another woman ("P") in relation to treatment provided to W under a licence if, but only if, -
 - (a) P has given the person responsible a notice stating that P consents to P being treated as a parent of any child resulting from treatment provided to W under the licence,
 - (b) W has given the person responsible a notice stating that W agrees to P being so treated,
 - (c) neither W nor P has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of P's or W's consent to P being so treated,
 - (d) W has not, since the giving of the notice under paragraph (b), given the person responsible -
 - (i) a further notice under that paragraph stating that W consents to a woman other than P being treated as a parent of any resulting child, or
 - (ii) a notice under section 37(1)(b) stating that W consents to a man being treated as the father of any resulting child, and

- (e) W and P are not within prohibited degrees of relationship in relation to each other.
 - (2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.
 - (3) A notice under subsection (1)(a), (b) or (c) by a person (“S”) who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.
- 45 Further provision relating to sections 42 and 43
- (1) Where a woman is treated by virtue of section 42 or 43 as a parent of the child, no man is to be treated as the father of the child.
 - (2) In England and Wales and Northern Ireland, sections 42 and 43 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.
 - (3) In Scotland, sections 42 and 43 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.
 - (4) Sections 42 and 43 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman’s child.
- 46 Embryo transferred after death of civil partner [or wife] or intended female parent
- (1) If -
 - (a) the child has been carried by W as the result of the placing in her of an embryo,
 - (b) the embryo was created at a time when W was a party to a civil partnership [or marriage with another woman],
 - (c) the other party to the civil partnership [or marriage] died before the placing of the embryo in the woman,
 - (d) the other party to the civil partnership [or marriage] consented in writing (and did not withdraw the consent) –
 - (i) to the placing of the embryo in W after the death of the other party, and
 - (ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,
 - (e) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other party to the civil partnership [or marriage] to be treated for the purpose mentioned in subsection (4) as the parent of the child, and
 - (f) no one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the other party to the civil partnership is to be treated for the purpose mentioned in subsection (4) as a parent of the child.
 - (2) If -
 - (a) the child has been carried by W as the result of the placing in her of an embryo,
 - (b) the embryo was not created at a time when W was a party to a marriage or a civil partnership, but was created in the course of treatment services provided to W in the

United Kingdom by a person to whom a licence applies,

- (c) another woman consented in writing (and did not withdraw the consent) -
 - (i) to the placing of the embryo in W after the death of the other woman, and
 - (ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,
 - (d) the other woman died before the placing of the embryo in W,
 - (e) immediately before the other woman's death, the agreed female parenthood conditions set out in section 44 were met in relation to the other woman in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,
 - (f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other woman to be treated for the purpose mentioned in subsection (4) as the parent of the child, and
 - (g) no one else is to be treated -
 - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3), or
 - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the other woman is to be treated for the purpose mentioned in subsection (4) as a parent of the child.
- (3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.
- (4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the deceased woman's particulars to be entered as the particulars of the child's other parent in a relevant register of births.
- (5) In the application of subsections (1) and (2) to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

48 Effect of sections 33 to 47

- (1) Where by virtue of section 33, 35, 36, 42 or 43 a person is to be treated as the mother, father or parent of a child, that person is to be treated in law as the mother, father or parent (as the case may be) of the child for all purposes.
- (2) Where by virtue of section 33, 38, 41, 45 or 47 a person is not to be treated as a parent of the child, that person is to be treated in law as not being a parent of the child for any purpose.
- (3) Where section 39(1) or 40(1) or (2) applies, the deceased man -
 - (a) is to be treated in law as the father of the child for the purpose mentioned in section 39(3) or 40(4), but
 - (b) is to be treated in law as not being the father of the child for any other purpose.
- (4) Where section 46(1) or (2) applies, the deceased woman -
 - (a) is to be treated in law as a parent of the child for the purpose mentioned in section 46(4), but
 - (b) is to be treated in law as not being a parent of the child for any other purpose.
- (5) Where any of subsections (1) to (4) has effect, references to any relationship between two

people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.

- (6) In relation to England and Wales and Northern Ireland, a child who –
- (a) has a parent by virtue of section 42, or
 - (b) has a parent by virtue of section 43 who is at any time during the period beginning with the time mentioned in section 43(b) and ending with the time of the child's birth a party to a civil partnership with the child's mother, is the legitimate child of the child's parents.
- (7) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 33(1) or sections 35 to 47, read with this section –
- (a) affects the succession to any dignity or title of honour or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or
 - (b) affects the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.
- (8) In relation to Scotland –
- (a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of its holder or affect the succession to any such title, coat of arms or dignity or its devolution, and
 - (b) where the terms of any deed provide that any property or interest in property is to devolve along with a title, coat of arms, honour or dignity, nothing in those provisions is to prevent that property or interest from so devolving.

References to parties to marriage or civil partnership

49 Meaning of references to parties to a marriage

- (1) The references in sections 35 to 47 to the parties to a marriage at any time there referred to –
- (a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but
 - (b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.
- (2) In subsection (1)(a) “judicial separation” includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

50 Meaning of references to parties to a civil partnership

- (1) The references in sections 35 to 47 to the parties to a civil partnership at the time there referred to –
- (a) are to the parties to a civil partnership subsisting at that time, unless a separation order was then in force, but
 - (b) include the parties to a void civil partnership if either or both of them reasonably believed at that time that the civil partnership was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.
- (2) The reference in section 48(6)(b) to a civil partnership includes a reference to a void civil

partnership if either or both of the parties reasonably believed at the time when they registered as civil partners of each other that the civil partnership was valid; and for this purpose it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.

- (3) In subsection (1)(a), “separation order” means -
- (a) a separation order under section 37(1)(d) or 161(1)(d) of the Civil Partnership Act 2004 (c. 33),
 - (b) a decree of separation under section 120(2) of that Act, or
 - (c) a legal separation obtained in a country outside the United Kingdom and recognised in the United Kingdom.

Further provision about registration by virtue of section 39, 40 or 46

51 Meaning of “relevant register of births”

For the purposes of this Part a “relevant register of births”, in relation to a birth, is whichever of the following is relevant -

- (a) a register of live-births or still-births kept under the Births and Deaths Registration Act 1953 (c. 20),
- (b) a register of births or still-births kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49), or
- (c) a register of live-births or still-births kept under the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I.14)).

52 Late election by mother with consent of Registrar General

- (1) The requirement under section 39(1), 40(1) or (2) or 46(1) or (2) as to the making of an election (which requires an election to be made either on or before the day on which the child was born or within the period of 42 or, as the case may be, 21 days from that day) is nevertheless to be treated as satisfied if the required election is made after the end of that period but with the consent of the Registrar General under subsection (2).
- (2) The Registrar General may at any time consent to the making of an election after the end of the period mentioned in subsection (1) if, on an application made to him in accordance with such requirements as he may specify, he is satisfied that there is a compelling reason for giving his consent to the making of such an election.
- (3) In this section “the Registrar General” means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or (as the case may be) the Registrar General for Northern Ireland.

Interpretation of references to father etc. where woman is other parent

53 Interpretation of references to father etc.

- (1) Subsections (2) and (3) have effect, subject to subsections (4) and (6), for the interpretation of any enactment, deed or any other instrument or document (whenever passed or made).
- (2) Any reference (however expressed) to the father of a child who has a parent by virtue of section 42 or 43 is to be read as a reference to the woman who is a parent of the child by virtue of that section.
- (3) Any reference (however expressed) to evidence of paternity is, in relation to a woman who is a parent by virtue of section 42 or 43, to be read as a reference to evidence of

parentage.

- (4) This section does not affect the interpretation of the enactments specified in subsection (5) (which make express provision for the case where a child has a parent by virtue of section 42 or 43).
- (5) Those enactments are -
- (a) the Legitimacy Act (Northern Ireland) 1928 (c. 5 (N.I.)),
 - (b) the Schedule to the Population (Statistics) Act 1938 (c. 12),
 - (c) the Births and Deaths Registration Act 1953 (c. 20),
 - (d) the Registration of Births, Deaths and Marriages (Special Provisions) Act 1957 (c. 58),
 - (e) Part 2 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49),
 - (f) the Congenital Disabilities (Civil Liability) Act 1976 (c. 28),
 - (g) the Legitimacy Act 1976 (c. 31),
 - (h) the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)),
 - (i) the British Nationality Act 1981 (c. 61),
 - (j) the Family Law Reform Act 1987 (c. 42),
 - (k) Parts 1 and 2 of the Children Act 1989 (c. 41),
 - (l) Part 1 of the Children (Scotland) Act 1995 (c. 36),
 - (m) section 1 of the Criminal Law (Consolidation) (Scotland) Act 1995 (c. 39), and
 - (n) Parts 2, 3 and 14 of the Children (Northern Ireland) Order 1995 (S.I. 1995/755 (N.I. 2)).
- (6) This section does not affect the interpretation of references that fall to be read in accordance with section 1(2)(a) or (b) of the Family Law Reform Act 1987 or Article 155(2)(a) or (b) of the Children (Northern Ireland) Order 1995 (references to a person whose father and mother were, or were not, married to each other at the time of the person's birth).

58 Interpretation of Part 2

- (2) For the purposes of this Part, two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships -
- (a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and
 - (b) include the relationship of a child with his adoptive, or former adoptive, parents, but do not include any other adoptive relationships.

Licence conditions

T58 Prior to giving consent gamete providers must be provided with information about:

- a. the nature of the treatment
- b. its consequences and risks

- c. any analytical tests, if they are to be performed
 - d. the recording and protection of personal data and confidentiality
 - e. the right to withdraw or vary their consent, and
 - f. the availability of counselling.
- T59 The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.
- T60 A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- T61 A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.
- T62 The reference in licence conditions T60 and T61 above to the intended second parent is a reference to:
- a. any man with respect to whom the agreed fatherhood conditions in Section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61, and
 - b. any woman with respect to whom the agreed female parenthood conditions in Section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61.
- T63 In the case of treatment services using donated gametes, or embryos created using donated gametes, the person receiving treatment and any intended second parent, must be provided with information about:
- a. the importance of informing any resulting child at an early age that they were born as a result of such treatment, and
 - b. suitable methods of informing such a child of that fact.
- T64 In cases where the nominated second parent withdraws their consent to be treated as the parent of any child born to a named woman, the PR must:
- a. notify the woman in writing of the receipt of the notice from the second parent, and
 - b. ensure that no treatment services are provided to the named woman until she has been notified of the second parent’s withdrawal of consent.
- T65 If a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this.

Directions

0007 – Consent

HFEA guidance

Legal parenthood and parental responsibility

6.1 The centre should provide information to people seeking treatment about legal parenthood, or should direct those people to suitable sources of information. This information should include who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation. Nationals or residents of other countries, or individuals treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the United Kingdom. In particular, if people are seeking treatment as part of a surrogacy arrangement that involves nationals or residents of other countries, the centre should:

- (a) make clear to those involved that the legal and immigration implications are complex; and
- (b) advise them to seek their own legal advice.

6.2 The centre should seek to ensure that people seeking treatment understand:

- (a) the difference in law between legal parenthood and parental responsibility; and
- (b) the implications of this for themselves and any child born as a result of treatment.

6.3 A person recognised as the legal parent of a child may not automatically have parental responsibility. Legal parenthood gives a lifelong connection between a parent and a child, and affects things like nationality, inheritance and financial responsibility. A person with parental responsibility has the authority to decide about the care of the child while the latter is young, for example for medical treatment and education.

6.4 A woman who carries and gives birth to a child as a result of treatment will be the legal mother of that child. Where the woman is married to a man and they are seeking treatment together using the husband's sperm (or embryos created using the husband's sperm), the husband will automatically be the legal father of any resulting child. However, there are cases where the woman's partner may not automatically be the legal parent of the resulting child.

If the woman is married or in a civil partnership at the time of the treatment, her spouse or civil partner will generally be the child's legal parent. If the woman is not married or in a civil partnership with her partner, and the woman is being treated using donor sperm (or embryos created using donor sperm), the consent of both the woman and her partner is needed for the partner to be recognised as the child's legal parent.

For further details about establishing legal parenthood, see below.

6.5 A child's legal mother automatically has parental responsibility. The position of the father or other legal parent depends on factors including their marital status, what is recorded on the birth certificate, and whether the family court has made an order.

6.6 In any case in which people seeking treatment have any doubts or concerns about legal parenthood or parental responsibility for a child born as a result of treatment services, or where a centre has concerns about the understanding of the people seeking treatment, the centre should advise them to seek their own legal advice.

See also

HFEA consent forms

HFEA guide to consent

[Guidance note 27 – Adverse incidents](#)

[Human Fertilisation and Embryology Act 2008 explanatory notes](#)



General procedures for obtaining consent

6.7 The centre should record whether a person receiving treatment is married or in a civil partnership in their notes, and should explain to the person why this is relevant. If a person is having treatment with their partner, the centre should record whether they are married or in a civil partnership with one another (or with someone else). This may affect who will be the second legal parent of any child born following treatment and whether consent is required to make the partner the child's legal parent.

For more information on what to do if a woman who is married or in a civil partnership returns for subsequent treatment without her husband, wife or civil partner present, see paragraphs 6.14 and 6.18.

6.8 Where consent is required for the partner to be the child's legal parent, the centre should establish and use documented procedures to obtain written, effective consent to legal parenthood. Failure to carry out the following steps could mean that the partner is not legally recognised as the child's legal parent and it may be necessary for the partner to apply for a declaration of parentage through the Courts.

6.9 Consent to the partner being the legal parent must be obtained from **both** the woman receiving treatment and her partner.

6.10 Consent to legal parenthood must be obtained from the woman receiving treatment and her partner **before** sperm and egg transfer, embryo transfer, or insemination takes place.

6.11 Consent should be obtained and recorded using the correct HFEA consent forms. The woman must complete the form that pertains to her, and her partner must complete the form that pertains to them.

For more information on which consent to legal parenthood forms should be used and what you should do to make sure consent is taken properly, see the HFEA guide to consent.

6.12 The consent forms must be properly and correctly completed, signed and dated. The centre should retain the original signed consent forms and ensure that a copy is provided to those who have given consent.

6.13 The centre should ensure that there is documented evidence in the medical records that information about legal parenthood and an offer of counselling must be provided to the person giving consent before consent is obtained. The centre should ensure that there is documented evidence in the medical records that this has happened.

6.14 The centre should ensure that consent to legal parenthood is:

- (a) given voluntarily
- (b) given by a person who has the capacity to do so, and
- (c) taken by a person authorised by the centre to do so.

If the person giving consent is unable to complete the consent form because of physical illness, injury or disability they may direct someone else to complete and sign it for them. However, if the person is consenting to being registered as the legal parent of any child born as a result of treatment after their death, only they can sign that part of the form.

6.15 The centre should ensure that any person giving consent declares that:

- (a) they were given enough information to understand the nature, purpose and implications of receiving treatment (or their partner receiving treatment) following consent
- (b) they were given a suitable opportunity to receive proper counselling about the implications of receiving treatment (or their partner receiving treatment) following consent
- (c) they were given information about the implications and procedure for varying or withdrawing consent, and
- (d) the information they have given in writing is correct and complete.

6.16 When obtaining consent to register the partner posthumously as the parent, the centre should ensure that the partner consents to their details and identifying information about treatment being disclosed to either the Registrar General for England and Wales, the Registrar General for Scotland or the Registrar for Northern Ireland, as appropriate.

6.17 If the woman receiving treatment withdraws or varies her consent to her partner being the child's legal parent, the partner must be notified of this in writing. If the woman's partner withdraws or varies their consent to being the child's legal parent, the woman must be notified of this in writing.

6.18 When anyone gives, withdraws or varies consent to legal parenthood, the centre should check their identity against identifying information held in the medical records. If there is doubt about a patient's identity, the centre should take steps to verify this, including examining photo identification such as a photocard driving licence or passport. The centre should record this evidence in the medical records.

6.19 There are very serious implications for patients, their partners and resulting children if consent to legal parenthood is not obtained properly, not recorded accurately or not recorded at all. Inaccuracies or errors on consent to legal parenthood forms may cause doubt about the parental status of the patient's partner, which may only be determined by the partner applying for a declaration of parentage in the courts.

For more information on how to avoid making mistakes when obtaining consent to legal parenthood, see the HFEA guide to consent.

6.20 In cases where a centre identifies anomalies in legal parenthood consent that may have an impact on the legal parenthood of any child born as a result of treatment, the centre should:

- (a) take all reasonable steps to notify the affected patient at the earliest opportunity
- (b) assess the error(s) and potential impact, and consider the remedial actions that should be taken, and
- (c) take all reasonable steps to support any affected patients (and their partner(s), if relevant) and offer independent legal assistance where necessary.

The centre should also seek independent legal advice and must inform the HFEA in writing of any anomalies or deficiencies in legal parenthood consent that it discovers by sending a completed adverse incident form within the incident reporting timescales set out at guidance note 27.

See also



[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 5 – Consent to treatment, storage, donation, training and disclosure of information](#)

HFEA consent forms

HFEA guide to consent

Legal parenthood when the woman has a husband

Interpretation of mandatory requirements 6A



Where a woman married to a man is seeking treatment using her husband's sperm or embryos created using her husband's sperm, the husband will automatically be the legal father of any child born as a result of the treatment, and will have parental responsibility.

Where a woman married to a man is seeking treatment using sperm other than that of her husband, or an embryo created using sperm other than that of her husband, her husband will be treated as the father of any child born as a result of that treatment (and will have parental responsibility) unless:

- (a) at the time the sperm and eggs or embryos were placed in her, or she was inseminated, a judicial separation or separation order was in force, or
- (b) it is shown that the husband did not consent to the placing in her of the sperm and eggs or embryos, or to her insemination.

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

6.21 When a woman who is married returns for subsequent treatment without her husband present, the centre should establish whether the couple are still seeking treatment together. They should also ensure that the original consent form completed by her husband during the first treatment is still valid and effective.

For more information on what a centre should consider when a patient returns for subsequent treatment, see the HFEA guide to consent.

6.22 If a woman married to a man is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

- (a) ascertain whether the husband consents to the treatment 'as a question of fact' (see box 6B), taking into account the duty of confidentiality to the woman (it may not be appropriate to contact him if he is unaware his wife is having treatment), and
- (b) obtain a written record of the husband's position. If the husband consents, he should complete the relevant consent form. If he does not consent 'as a question of fact' (see box 6B), the centre should take all practical steps to obtain evidence of this.

- 6.23** If the centre cannot obtain a written record of the husband's consent or lack of consent, it should record the steps taken to establish whether he consents to the treatment in the medical records.
- 6.24** A woman who is still married may wish to be treated with a new partner (with her new partner's sperm or with donor sperm or a donor embryo). If she wishes her new partner to be registered as the legal parent of any child born from this treatment, then evidence to show that her husband does not consent to the treatment must be obtained in order for the woman's new partner to be the legal parent of any child born as a result of the treatment. It should not be assumed that the biological father will necessarily be the second legal parent if the patient is still married or in a civil partnership with another person.

The law relating to legal parenthood can be complex, this may mean that clinics and patients need to take independent legal advice to ensure that all necessary actions are taken to enable the new partner to be the second legal parent.

Interpretation of mandatory requirements 6B



Establishing lack of consent by the husband 'as a question of fact'

To prove that the husband of a woman undergoing treatment does not consent to this treatment, their lack of consent requires a basis in fact (for example, if the patient and her husband are separated – but there is no judicial separation or separation order in force – and the latter is unaware of the treatment). The patient's husband may be considered the legal father or parent of the child if they support the treatment in any way, for instance if they help the patient to attend appointments to receive treatment. Any form declaring their lack of consent may not by itself remove their status as the legal father or parent if they do consent 'as a question of fact'. If there is a factual basis for the husband not consenting, centres should obtain evidence of this, for instance evidence that the couple are about to start divorce proceedings.

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

See also

HFEA consent forms

HFEA guide to consent



Legal parenthood when the woman has a civil partner or wife

Interpretation of mandatory requirements 6C



Where a woman in a civil partnership or same-sex marriage is seeking treatment using donor sperm, or embryos created using donor sperm, the woman's civil partner or wife will be treated as the legal parent of any resulting child unless, at the time of placing the embryo or sperm and eggs in the woman, or of her insemination:

- (a) a judicial separation or separation order was in force, or
- (b) it is shown that the civil partner or wife did not consent to the placing in her of the sperm and eggs, or embryos, or to the insemination.

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

NOTE The provisions relating to same-sex marriages are not in force in Northern Ireland.

6.25 When a woman who is married or in a civil partnership returns for subsequent treatment without her wife or civil partner present, the centre should establish whether the couple are still seeking treatment together. They should also ensure that the original consent form completed by her wife or civil partner during the first treatment is still valid and effective.

For more information on what a centre should consider when a patient returns for subsequent treatment, see the HFEA guide to consent.

6.26 If a woman in a civil partnership or same-sex marriage is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

- (a) ascertain whether the civil partner or wife consents to the treatment 'as a question of fact' (see box 6D), taking into account the duty of confidentiality to the woman seeking treatment (it may not be appropriate to contact her if she is unaware her civil partner or wife is having treatment), and
- (b) obtain a written record of the civil partner or wife's position. If the civil partner or wife consents, she should complete the relevant consent form. If the civil partner or wife does not consent 'as a question of fact' (see box 6D), the centre should take all practical steps to obtain evidence of this.

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

6.28 A woman who is still married or in a civil partnership may wish to be treated with a new partner (with donor sperm or a donor embryo). If she wishes her new partner to be registered as the legal parent of any child born from this treatment, then evidence to show that her civil partner or wife does not consent to the treatment must be obtained in order for the woman's new partner to be the legal parent of any child born as a result of the treatment. It should not be assumed that the biological father or mother will necessarily be the second legal parent if the woman being treated is still married or in a civil partnership with another person.

The law relating to legal parenthood can be complex, this may mean that clinics and patients need to take independent legal advice to ensure that all necessary actions are taken to enable the new partner to be the second legal parent.

Interpretation of mandatory requirements 6D



Establishing lack of consent by wife or civil partner 'as a question of fact'

To prove that the wife, or civil partner of a woman undergoing treatment does not consent to this treatment, their lack of consent requires a basis in fact (for example, if the patient and her wife, or civil partner are separated – but there is no judicial separation or separation order in force – and the latter is unaware of the treatment). The patient's wife, or civil partner may be considered the legal parent of the child if they support the treatment in any way, for instance if they help the patient to attend appointments to receive treatment. Any form declaring their lack of consent may not by itself remove their status as the legal parent if they do consent 'as a question of fact'. If there is a factual basis for

the wife, or civil partner not consenting, centres should obtain evidence of this, for instance evidence that the couple are about to start divorce proceedings.

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

See also

HFEA consent forms

HFEA guide to consent



Legal parenthood: unmarried male partner

Interpretation of mandatory requirements 6E

The following rules apply only if the woman having treatment:



- (a) is neither married nor in a civil partnership, or
- (b) is married or in a civil partnership but her husband/wife/civil partner is not a legal parent because there is a judicial separation or separation order in force, or because the husband/wife/civil partner does not consent to the treatment (see 6.17 and 6.21).

Where a woman is seeking treatment using her unmarried male partner's sperm, or embryos created using her partner's sperm, her male partner will automatically be the legal father of any child born as a result of the treatment.

Where a woman is seeking treatment using donor sperm, or embryos created with donor sperm, her male partner will be the legal father of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

- (a) both the woman and the male partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the male partner being treated as the legal father
- (b) neither consent was withdrawn (or superseded with a subsequent written notice) before insemination/transfer, and
- (c) the patient and male partner are not close relatives (within prohibited degrees of relationship to each other, as defined in section 58(2), HFE Act 2008).

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also

HFEA consent forms

HFEA guide to consent



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

Interpretation of mandatory requirements 6F



The following rules apply only if the woman having treatment:

- (a) is neither married nor in a civil partnership, or
- (b) is married or in a civil partnership but her husband/wife/civil partner is not a legal parent because there is a judicial separation or separation order in force or because the husband/wife/civil partner does not consent to the treatment (see 6.17 and 6.21).

Where a woman is being treated together with a female partner (not her civil partner or wife) using donor sperm, or embryos created with donor sperm, the female partner will be the other legal parent of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

- (a) both the woman and her female partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the female partner being treated as the parent of any resulting child
- (b) neither consent was withdrawn (or superseded with a subsequent written note) before insemination/transfer, and
- (c) the patient and female partner are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), part 2, HFE Act 2008).

For more information on what legal parenthood consent forms must be used and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also



HFEA consent forms

HFEA guide to consent

Parenthood after death of a man providing sperm

Interpretation of mandatory requirements 6G



A husband or male partner who has provided sperm for the treatment of their wife or female partner can be registered as the father of any child born as a result of treatment after their death, if the following conditions are met:

- (a) the man had given written consent for his sperm, or embryos created using his sperm, to be used after his death in the treatment of his wife or partner
- (b) the man had given written consent to being registered as the father of any resulting child
- (c) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the man's details to be entered in the relevant register of births, and
- (d) no-one else is to be treated as the father or parent of the child.

The treatment can involve insemination of sperm, transfer of sperm and eggs, or transfer of embryos created before or after the man's death. The centre must ensure that partners are given an opportunity to consent to this.

See also

HFEA consent forms

HFEA guide to consent



Parenthood after death of a partner who has not provided sperm

Interpretation of mandatory requirements 6H



A partner (husband, wife, civil partner or other partner) who has not provided sperm for the treatment of their wife, civil partner or female partner can be registered as the father or parent of any child born as a result of treatment after their death, if the following conditions are met:

- (a) the treatment involved the transfer to the woman of an embryo after the death of the partner
- (b) the embryo was created when the partner was alive,
- (c) the partner had given written consent for the embryo to be placed in the woman after their death
- (d) the partner had given written consent to being registered as the father or parent of any resulting child
- (e) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the partner's details to be entered in the relevant register of births, and
- (f) no-one else is to be treated as the father or parent of the child.

The centre must ensure that partners are given an opportunity to consent to this.

Legal parenthood: surrogacy

Interpretation of mandatory requirements 6I



Surrogate mother

The woman who gives birth to the child (in this case the surrogate) is the legal mother when the child is born. She will also have parental responsibility.

Husband, wife or civil partner of the surrogate mother

If the surrogate is married or in a civil partnership at the time of insemination/transfer, her husband, wife or civil partner will be the legal father or parent of any child born as a result of her treatment (and will have parental responsibility), unless:

- (a) there is a judicial separation or a separation order in force, or
- (b) it is shown that her husband, wife or civil partner did not consent to the placing of the sperm and eggs, or embryos, in her, or to her insemination.

Establishing lack of consent 'as a question of fact'

For these purposes, lack of consent requires a basis in fact (for example, if the surrogate and her husband, wife or civil partner are separated and the latter is unaware of the treatment). The surrogate's husband, wife or civil partner will be the legal father or parent of the child if they support the surrogacy arrangement. Any consent form declaring their lack of consent may not by itself remove their status as the legal father or parent if they do consent, 'as a question of fact'. If there is a factual

basis for the husband, wife or civil partner not consenting, centres should obtain evidence of this.

Parenthood in these circumstances can be complex and case-specific, and any dispute is ultimately for the family court or births registrar (or both) to determine.

Intended parents

The intended parents are those who intend to raise the child following a surrogacy arrangement.

If both the surrogate and her husband/wife/civil partner are the legal parents of the child, neither intended parent will be a legal parent when the child is born (and neither will have parental responsibility).

If the surrogate is neither married nor in a civil partnership, if she and her husband/wife/civil partner are judicially separated, or if her husband/civil partner does not consent to her treatment), then one of the intended parents will be the legal parent when the child is born, and will acquire parental responsibility when registered on the birth certificate. The options for which intended parent is the legal parent at birth are as follows:

- (a) if the intended father provides his sperm for the surrogacy arrangement, he will be the legal father at common law when the child is born, if no one else is nominated.
- (b) an intended father who is not the biological father (ie, an intended father using donor sperm or, in a male same-sex couple, the partner of the biological father) will be the legal father when the child is born if, at the time the eggs and sperm, or embryos, are placed in the surrogate or she is inseminated, all the following conditions apply:
 - (i) both the surrogate and the intended father nominated as a parent have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to him being the legal father
 - (ii) neither consent has been withdrawn (or superseded by a subsequent written consent) before the insemination/transfer, and
 - (iii) the surrogate and intended father nominated are not close relatives (within prohibited degrees of relationship to each other, as defined in section 58(2), HFE Act 2008).
- (c) the intended female parent (or one of them if the intended parents are a female same-sex couple) will be the other legal parent when the child is born if, at the time the eggs and sperm, or embryos, are placed in the surrogate or she is inseminated, all the following conditions apply:
 - (i) both the surrogate and the intended female parent have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to her being the other legal parent of any resulting child
 - (ii) neither consent has been withdrawn (or superseded by a subsequent written consent) before the insemination/transfer, and
 - (iii) the surrogate and intended female parent are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), HFE Act 2008).

Parental orders

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

To be able to apply for a parental order, one or both of the intended parents must be a gamete provider, and they must be a couple (married, civil partners or living together as partners). Other conditions also apply, and centres should advise those involved in a surrogacy arrangement to seek

their own legal advice to ensure they will be able to secure their family's legal status after the child is born.

For more information on what legal parenthood consent forms must be used in surrogacy arrangements and on how to ensure consent is taken properly, see the HFEA guide to consent.

See also

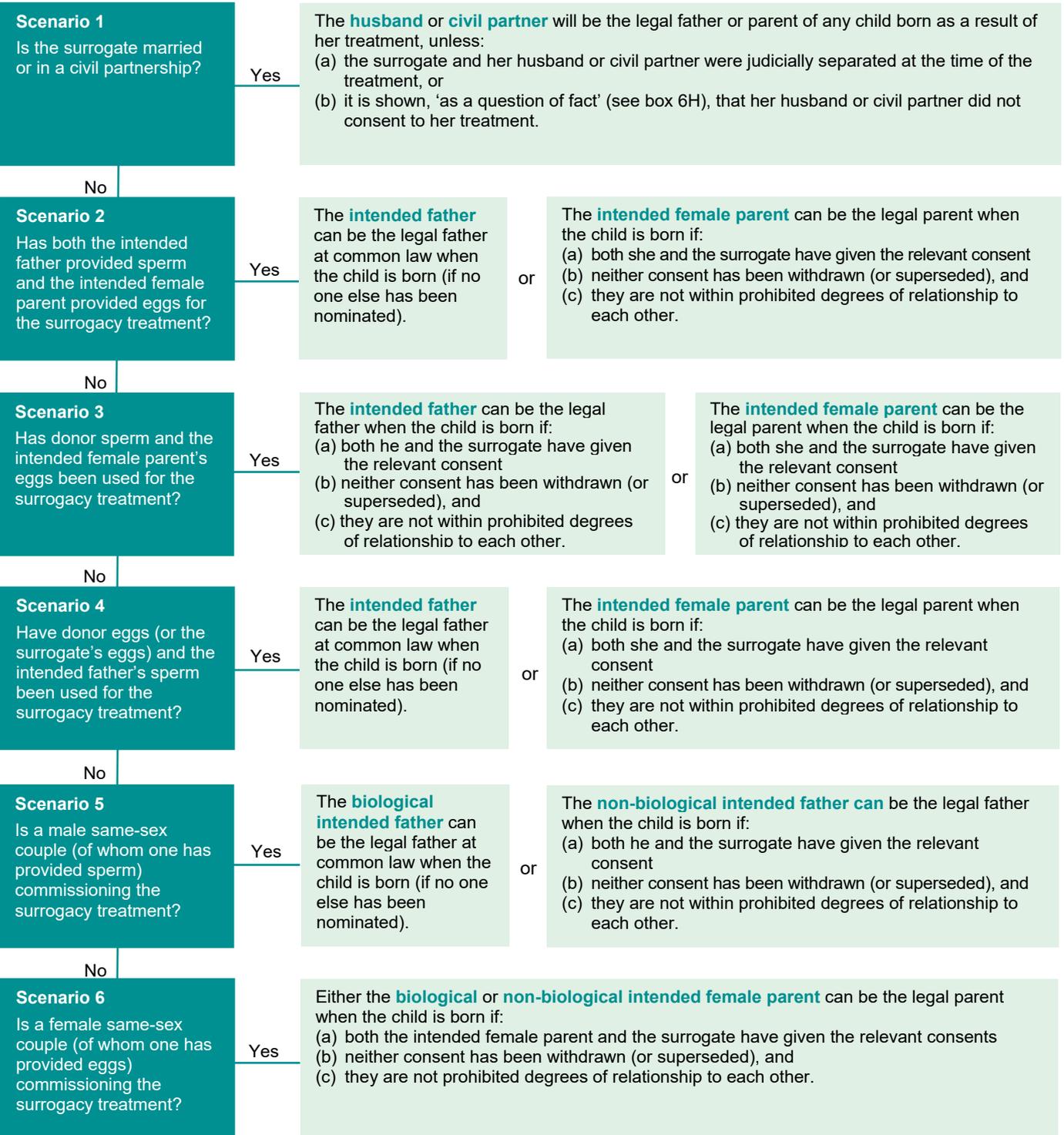
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6.29 The decision tree on the following page provides a guide to some aspects of legal parenthood and surrogacy. It summarises some of the relevant legal positions but is not intended to replace advice on the individual facts of a specific surrogacy arrangement. Centre should advise people involved in surrogacy arrangements to seek their own legal advice.

Decision tree: Legal parenthood in surrogacy arrangements



See also

[Guidance note 14 – Surrogacy](#)



Legal parenthood: trans patients

6.30 The Gender Recognition Act 2004, provides trans people with a formal mechanism by which they can be legally recognised in their acquired gender. People will be issued with a gender recognition certificate (GRC) that will include details of their acquired gender identity.

The centre should be aware that obtaining a GRC does not affect the status of the person as the mother, father or second legal parent of an existing child. What is relevant in determining legal parenthood is the gender identity of the trans patient at the time of treatment which results in the birth of a child. For example, where a woman has had a child and subsequently transitions to become a trans man, and obtains a GRC, he remains the mother of his existing child. Where for example a trans woman uses her sperm in her female partner's treatment, provided she and her partner have met relevant statutory requirements and provided the necessary consents, she will be the second legal parent of the child.

See also

Guidance note 4 – Information to be provided prior to consent

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

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People not to be treated as parents

Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 2008

Part 2

41 Persons not to be treated as father

- (1) Where the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to the 1990 Act (consent to use of gametes for purposes of treatment services or non-medical fertility services) was used for a purpose for which such consent was required, he is not to be treated as the father of the child.
- (2) Where the sperm of a man, or an embryo the creation of which was brought about with his sperm, was used after his death, he is not, subject to section 39, to be treated as the father of the child.
- (3) Subsection (2) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

47 Woman not to be other parent merely because of egg donation

A woman is not to be treated as the parent of a child whom she is not carrying and has not carried, except where she is so treated -

- (a) by virtue of section 42 or 43, or
- (b) by virtue of section 46 (for the purpose mentioned in subsection (4) of that section),

or

(c) by virtue of adoption.

34 Application of sections 35 to 47

(1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as “W”) as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.

54 Parental orders

(1) On an application made by two people (“the applicants”), the court may make an order providing for a child to be treated in law as the child of the applicants if—

- (a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,
- (b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and
- (c) the conditions in subsections (2) to (8) are satisfied.

(1A) For the purposes of this section, neither of the following is to be treated as a person whose gametes were used to create an embryo (“embryo E”)—

- (a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;
- (b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

Interpretation of mandatory requirements 6J



A sperm donor is not to be treated as the father of any child resulting from the use of his sperm in the treatment of others.

An egg donor is not to be treated as the parent of any child resulting from the use of her egg(s) unless her egg(s), or embryos created from her egg(s), are used in treating a civil partner or other female partner (subject to the requirements in sections 42, 43 or 46 of the HFE Act 2008, where relevant) or the resulting child is adopted by the egg donor.

Section 54 of the HFE Act 2008 is amended by the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 to provide that, where a child has been born following treatment involving mitochondrial donation, a person who donated the mitochondria is not eligible to apply for a parental order on the basis of that donation alone.

Information provision and counselling

Mandatory requirements

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

Section 13

Conditions of licences for treatment

- (6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.
- (6B) The reference in subsection (6A) to the intended second parent is a reference to -
- (a) any man as respects whom the agreed fatherhood conditions in section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman being treated, and
 - (b) any woman as respects whom the agreed female parenthood conditions in section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman to be treated.
- (6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about -
- (a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and
 - (b) suitable methods of informing such a child of that fact.

Schedule 3ZA: Circumstances in which offer of counselling required as condition of licence for treatment

Part 2: Events in connection with which counselling must be offered

4. A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.
5. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.
6. A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.
7. The woman for whom the treatment services are provided gives the person responsible a notice

under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

Interpretation of mandatory requirements 6K

The law states that, where a woman who has consented to her male or female partner being treated as the legal parent of any child born as a result of her treatment, and the partner has consented to being the legal parent, treatment may continue after the point at which consent is given only if the woman and her partner:

- (a) have had a suitable opportunity to receive proper counselling about the implications of treatment in these circumstances, and
- (b) have been given proper information.

When people seek treatment using donor gametes or embryos, they must be given information about:

- (a) the importance of informing any resulting child, at an early age, that they were conceived using the gametes of a person who is not their parent, and
- (b) suitable methods of telling the child this.

See also

[Guidance note 3 – Counselling](#)

[Guidance note 4 – Information to be provided prior to consent](#)

Notification of withdrawal of consent to parenthood

Mandatory requirements

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

Section 13

Conditions of licences for treatment

- (6D) Where the person responsible receives from a person (“X”) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of X’s withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman (“W”), the person responsible -
 - (a) must notify W in writing of the receipt of the notice from X, and
 - (b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.
- (6E) Where the person responsible receives from a woman (“W”) who has previously given notice under section 37(1)(b) or 44(1)(b) of the 2008 Act that she consents to another person (“X”) being treated as a parent of any child resulting from the provision of treatment services to W -

- (a) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of the withdrawal of W's consent, or
- (b) a notice under section 37(1)(b) or 44(1)(b) of the 2008 Act in respect of a person other than X, the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b).

Interpretation of mandatory requirements 6L



If a person withdraws their consent to being treated as the legal parent of any child resulting from the treatment of their partner, the person responsible (PR) must notify the partner in writing of this. The partner must not be treated with sperm and eggs, or with embryos, or be inseminated, until she has been notified in this way.

If a woman withdraws her consent to her partner being treated as the legal parent of any child resulting from the woman's treatment, or notifies the centre that she wishes a different person to be treated as the legal parent of any child resulting from her treatment, the PR must notify the partner in writing of this.

Consent can be withdrawn only before sperm and egg or embryo transfer, or insemination.

6.31 The PR should ensure that the written notification they issue explains and refers to the relevant parts of the legislation regarding legal parenthood and withdrawal of consent.

See also

HFEA consent forms

HFEA guide to consent



Other legislation, professional guidelines and information

Legislation

[Equality Act 2010](#)

[Gender Recognition Act 2004](#)

General information

[CE Letter CE\(14\)01: Ensuring consent to legal parenthood is properly taken](#)

[CE Letter CE\(14\)02: Follow-up on legal parenthood audit](#)

Annex D – Guidance note 11 (Donor recruitment, assessment and screening)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

11. Donor recruitment, assessment and screening

Version 9.0

Mandatory requirements

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

Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc.

Use of gametes for treatment of others

- 5
- (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.
 - (2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.
 - (3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

31ZD Provision to donor of information about resulting children

- (1) This section applies where a person ("the donor") has consented under Schedule 3 (whether before or after the coming into force of this section) to -
 - (a) the use of the donor's gametes, or an embryo the creation of which was brought about using the donor's gametes, for the purposes of treatment services provided under a licence, or
 - (b) the use of the donor's gametes for the purposes of non-medical fertility services provided under a licence.
- (2) In subsection (1) -
 - (a) "treatment services" do not include treatment services provided to the donor, or to the donor and another person together, and
 - (b) "non-medical fertility services" do not include any services involving partner-donated sperm.
- (3) The donor may by notice request the appropriate person to give the donor notice stating -

- (a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,
 - (ab) the number of persons in respect of whom the donor is a mitochondrial donor,
 - (b) the sex of each of those persons, and
 - (c) the year of birth of each of those persons.
- (4) Subject to subsections (5) and (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.
- (5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within paragraphs (a) to (c) of subsection (3).
- (6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible—
- (a) has notified the donor that the information concerned is not held, or
 - (b) has failed to comply with the request within a reasonable period.
- (7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible—
- (a) has notified the donor that the information concerned is not held, or
 - (b) has failed to comply with the request within a reasonable period.
- (8) In this section “the appropriate person” means—
- (a) in the case of a donor who consented as described in paragraph (a) of subsection (1)—
 - (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or
 - (ii) the Authority, and
 - (b) in the case of a donor who consented as described in paragraph (b) of subsection (1)—
 - (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or
 - (ii) the Authority.
- (9) In this section “the relevant statutory provisions” has the same meaning as in section 31ZA.

Conditions of licences for treatment

- 13 (9) Persons or embryos that are known to have a gene, chromosome or mitochondrion

abnormality involving a significant risk that a person with the abnormality will have or develop -

- (a) a serious physical or mental disability,
- (b) a serious illness, or
- (c) any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Licence conditions

T52 Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely

- a. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg, superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)
- b. the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:
 - HIV 1 and 2: Anti-HIV – 1, 2
 - Hepatitis B: HBsAg and Anti-HBc
 - Hepatitis C: Anti-HCV-Ab
 - Syphilis: see (d) below
- c. the centre must devise a system of storage which clearly separates:
 - quarantined/unscreened gametes and embryos,
 - gametes and embryos which have tested negative, and
 - gametes and embryos which have tested positive.
- d. a validated testing algorithm must be applied to exclude the presence of active infection with *Treponema pallidum*. The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific *Treponema* confirmatory test is non-reactive. The donor whose specimen test reacted on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use
- e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)
- f. This requirement has been removed.
- g. HTLV-1 antibody testing must be performed for donors living in or originating from high-

prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas, and

- h. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi).
- i. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

T53 The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:

- a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge,
- b. blood samples must be obtained within a timeframe specified by the Authority, and
- c. donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, quarantining of the gametes and re-testing of a repeat blood sample is not required. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

T55 Potential donors that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

- a. a serious physical or mental disability
- b. a serious illness, or
- c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

Directions

0001 – Gametes and embryo donation

0005 – Collecting and recording information for the HFEA

HFEA guidance

Advertising

11.1 Advertising and publicity materials should be designed and written with regard to the sensitive issues involved in recruiting donors.

See also

[Guidance note 13 – Payments for donors](#)



Age of prospective donors

11.2 Centres should refer to the relevant professional guidelines on age limits before accepting gametes for the treatment of others.

NOTE Current professional guidelines state that eggs should not be taken from donors aged 36 or over, and sperm should not be taken from donors aged 41 or over.

11.3 For donated eggs, the relevant age limit should be observed unless there are exceptional reasons not to do so. The centre should record any such reasons in the patient's medical records.

11.4 For donated sperm, the relevant age limit should normally be observed. However, due to less substantial evidence on age limits for sperm donors, centres should assess the possible effect of the donor's age on a case-by-case basis. The centre should record in the patient's medical records the reasons for using a donor above the recommended age limit.

11.5 For donated embryos, the guidance above applies to both gamete providers.

11.6 Gametes for the treatment of others should not be taken from anyone under the age of 18.

General enquiries to be made

11.7 The recruiting centre should take reasonable steps to verify the identity of the prospective donor by asking for appropriate identification (eg, passport or photocard driving licence). Failure to obtain satisfactory evidence of identity should be taken into account in deciding whether to accept their gametes or embryos for treatment.

11.8 Where a donor has changed their name (eg, where someone has changed their name by deed poll, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation, centres should take all reasonable steps to verify the donor's identity. This is to ascertain that a donor presenting for donation is the same person the centre previously engaged with or treated.

Centres should verify a donor's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the donor's medical records. This can be a sensitive issue for donors and centres should take care to address identity issues with consideration. As evidence of their new name, centres should ask donors to provide one of the following:

- (a) a marriage certificate, or
- (b) evidence of a change in name (such as via deed poll)

For trans donors:

- (c) a birth or adoption certificate in their acquired gender
- (d) a Gender Recognition Certificate, or
- (e) a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed poll).

Centres must ensure that a donor's records are updated to accurately reflect their new identity.

- 11.9** When obtaining gametes or embryos for the treatment of others (whether directly from a donor, from another licensed centre or from a foreign supplier), the centre should take appropriate steps to discover whether gametes from that donor have been obtained for use in licensed treatment before and, if so:
- establish which centre is the primary centre for that donor
 - notify that centre that it proposes to use that donor's gametes
 - seek authorisation to do so, if appropriate, and
 - ensure that the limit of 10 families per donor will not be exceeded.

Family and other relevant history

- 11.10** Before a prospective donor provides gametes, the recruiting centre should take their medical and family histories, and details of previous donations. The centre should encourage prospective donors to provide as much other non-identifying biographical information as possible, so that it may be available to prospective recipients, parents and resulting children. If a prospective donor cannot give a full and accurate family history, the centre should record this fact and take it into account in deciding whether or not to accept their gametes or embryos for treatment.
- 11.11** The centre should seek the prospective donor's consent to approach their GP for further factual information if it suspects the donor might be unsuitable. The centre should always seek further information if:
- information provided by the patient suggests there are risk factors that may affect anyone treated using their gametes or any child born as a result
 - the prospective donor has failed to provide any information requested
 - the information provided by the prospective donor is inconsistent, or
 - there is evidence of deception.
- 11.12** If the prospective donor refuses to give such consent, the centre should take this into consideration when deciding whether to accept that donor. Such refusal should not in itself be grounds for not accepting the donor. The centre should discuss with the prospective donor their reason for refusing.

See also

HFEA consent forms



Suitability as a donor

Interpretation of mandatory requirements 11A

A donor must not be selected because they are known to have a particular gene, chromosome or mitochondrial abnormality that, if inherited by any child born as a result of the donation, may result in that child having or developing:



- a serious physical or mental disability
- a serious illness, or

(c) any other serious medical condition.

11.13 The use of gametes from a donor known to have an abnormality as described above, should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

11.14 If a centre determines that it is appropriate to provide treatment services for a woman using a donor known to have an abnormality as described above, it should document the reason for the use of that donor.

See also

[Guidance note 10 – Embryo testing and sex selection](#)



11.15 Before accepting gametes for the treatment of others, the recruiting centre should consider the suitability of the prospective donor. In particular, the centre should consider:

- (a) personal or family history of heritable disorders
- (b) personal history of transmissible infection (as outlined in Department of Health guidance, there should be no specific restrictions on donations from men who have sex with men (MSM), the centre should assess the risks and benefits of accepting donations from each such individual – ie, document MSM behaviour)
- (c) the level of potential fertility indicated by semen analysis (where appropriate)
- (d) the implications of the donation for the prospective donor and their family, especially for any children they may have at the time of donation or in the future, and
- (e) the implications for any children born as a result of the donation, in the short and long term.

11.16 Centres are not expected to match the ethnic background of the recipient to that of the donor. Where a prospective recipient is happy to accept a donor from a different ethnic background, the centre can offer treatment, subject to the normal welfare of the child assessment.

11.17 A centre should not perform treatment that involves mixing gametes (eg, through insemination, IVF or ICSI) of close relatives who are genetically related, including between:

- (a) grandfather and granddaughter
- (b) grandmother and grandson
- (c) father and daughter
- (d) mother and son
- (e) brother and sister
- (f) half-brother and half-sister
- (g) uncle and niece
- (h) aunt and nephew
- (i) uncle and half-niece
- (j) aunt and half-nephew

11.18 The restriction described in 11.16 does not include treatment that involves replacing the gametes of close relatives who are genetically related (eg, sister-to-sister egg donation).

See also

[Guidance note 8 – Welfare of the child](#)

[Guidance note 20 – Donor assisted conception](#)

11.19 The centre should ensure that its procedures for recruiting donors are fair and non-discriminatory.

See also

[Guidance note 29 – Treating people fairly](#)

Conditions placed on a donation

11.20 The centre should inform anyone providing gametes that they can, if they wish, specify extra conditions for storing or using their gametes (or embryos created using them).

11.21 However, some conditions imposed by donors may be incompatible with the Equality Act 2010. The Equality Act prohibits service providers (such as clinics) from discriminating by treating people less favourably because of various protected characteristics. The protected characteristics are:

- (a) age
- (b) disability
- (c) gender reassignment
- (d) marriage and civil partnership
- (e) pregnancy and maternity
- (f) race
- (g) religion or belief
- (h) sex
- (i) sexual orientation.

11.22 When deciding whether or not to recruit donors who place conditions on the use of their gametes or embryos, the centre should judge whether this will result in less favourable treatment because of a protected characteristic (eg, if it will reduce the choice of donors for a particular person by virtue of a protected characteristic).

See also

[Guidance note 29 – Treating people fairly](#)

Medical and laboratory tests

11.23 In addition to meeting the requirements set out in licence conditions, donors of gametes and embryos should be screened in accordance with current professional guidance produced by the relevant professional bodies.

- 11.24** Centres should screen potential donors both before accepting them as donors, and before using the donated gametes and embryos in treatment.
- 11.25** In addition to meeting the mandatory requirements outlined in this guidance note, the centre should quarantine donated gametes and embryos in line with guidance from the relevant professional bodies.

People considered unsuitable as donors

- 11.26** A prospective donor should not be accepted if the centre:
- concludes that a recipient or any child born as a result of treatment using the donor's gametes is likely to experience serious physical, psychological or medical harm, or
 - cannot get enough further information to conclude there is no significant risk.
- 11.27** The Equality Act prohibits service providers (such as clinics) from discriminating by treating people less favourably because of various protected characteristics. The protected characteristics are listed at paragraph 11.21. Centres that consider a person unsuitable to donate due to one or more of these protected characteristics are likely to be in breach of the Equality Act and exposing themselves to liability.

See also

[Guidance note 8 – Welfare of the child](#)

[Guidance note 29 – Treating people fairly](#)

[Guidance note 30 – Confidentiality and privacy](#)



- 11.28** When the centre decides that a prospective donor is unsuitable to donate, it should record the reasons and explain them to the prospective donor. The centre should present the reasons for the decision sensitively and answer any questions in a straightforward and comprehensive way.
- 11.29** The centre should offer counselling to all prospective donors who are considered unsuitable for any reason. When the centre refuses to accept a prospective gamete donor because of physical or psychological problems that require separate treatment or specialist counselling, the centre should provide reasonable assistance to the individual to obtain relevant treatment or counselling.
- 11.30** If information affecting the suitability of a prospective donor becomes known after the selection process, the centre should review the prospective donor's suitability and take appropriate action.

Unsuspected heritable conditions in donors

- 11.31** At registration, donors should indicate whether or not they wish to be notified if the centre learns (eg, through the birth of an affected child) that they have a previously unsuspected genetic disease or they are a carrier of a harmful inherited condition. They should also be asked whether or not they would like their primary care physician to be informed. Their wishes should be recorded in the donors' medical records.

- 11.32** If a centre learns that a donor has a previously unsuspected genetic disease or is a carrier of a harmful inherited condition, the centre should:
- notify the primary centre (where there is one) and the HFEA immediately (the primary centre should immediately notify other centres who have received gametes obtained from that donor)
 - inform patients who have had a live birth as a result of treatment with gametes from that donor, and offer these patients appropriate counselling
 - carefully consider when and how a woman who is pregnant, as a result of treatment with gametes from that donor, is given this information, and
 - refer to the donor's medical records to establish whether, and in what way, they would like to be given the information. If the donor has indicated that they would like to be given such information, the centre should notify their primary care physician, so that the donor can be referred for the appropriate medical care and counselling. If the donor has indicated that they would not like their primary care physician to be informed, the centre should contact the donor directly.
- 11.33** The centre should tell gamete donors that they should inform the centre if, after the donation:
- they discover they are affected by an unsuspected genetic disease, or
 - they find they are a carrier of a harmful recessively inherited condition (eg, through the birth of an affected child).

The centre should then proceed as indicated above.

See also

[Guidance note 15 – Procuring, processing and transporting gametes and embryos](#)



Information for prospective donors

- 11.34** Before any consents or samples are obtained from a prospective donor, the recruiting centre should provide information about:
- the screening that will be done, and why it is necessary
 - the possibility that the screening may reveal unsuspected conditions (eg, low sperm count, genetic anomalies or HIV infection) and the practical implications
 - the scope and limitations of the genetic testing that will be done and the implications for the donor and their family
 - the importance of informing the recruiting centre of any medical information that may come to light after donation that may have health implications for any woman who receives treatment with those gametes or for any child born as a result of such treatment
 - the procedure used to collect gametes, including any discomfort, pain and risk to the donor (eg, from the use of superovulatory drugs)
 - the legal parenthood of any child born as a result of their donation
 - the restriction on using gametes and embryos from an individual donor when the number of families that have already had children as a result of treatment using such gametes or embryos has reached 10 (or any lower figure specified by the donor)
 - what information about the donor must be collected by the centre and held on the HFEA Register

- (i) the fact that the centre or the HFEA (or both) may disclose non-identifying information about the donor, for example to prospective recipients or to the parents of donor-conceived children
- (j) the HFEA's obligation to disclose non-identifying information (and identifying information if donation took place after 31 March 2005), to someone who applies for such information if:
 - (i) the applicant is aged over 16 (to access non-identifying information) or 18 (to access identifying information), and
 - (ii) the applicant appears to have been conceived using the donor's gametes, or embryos created using the donor's gametes
- (k) the importance of supplying up-to-date contact information so that they can be informed if and when disclosure of identifiable information will be made
- (l) the importance of the information provided at 11.29 and 11.30 to people born as a result of their donation
- (m) the possibility that a donor-conceived person who is disabled as a result of an inherited condition that the donor knew about, or ought reasonably to have known about, but failed to disclose, may be able to sue the donor for damages
- (n) the procedure for donors to withdraw consent for the use of their gametes, or embryos created with their gametes, and
- (o) the fact that if the donor is an egg donor who is not a patient, she is free to withdraw from the donation process after preparation for egg recovery has begun without incurring a financial or other penalty.

11.35 Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:

- (a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
- (b) referred to information on the HFEA's website on this issue, and
- (c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

11.36 Centres must consider whether there may be additional information requirements for trans donors and provide relevant information tailored to their specific needs and circumstances. Where the donor is transitioning, the purpose for which they are intending to donate their gametes will determine what kind of information centres should provide and the consent requirements. For example, a trans donor who is consenting to donate their gametes for use in someone else's treatment, may require different information from a trans patient who is being screened as a donor for the use of their gametes in a surrogacy arrangement.

See also

[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

[Guidance note 12 – Egg sharing arrangements](#)

[Guidance note 20 – Donor assisted conception](#)



Giving donors information about children born as a result of their donation

Interpretation of mandatory requirements 11B



If donors of gametes and embryos ask, centres must provide the following information about any children born as a result of their donation:

- (a) number
- (b) sex, and
- (c) year of birth.

If the centre is unable to provide this information, it should direct donors to the Authority.

- 11.37** The centre should inform donors and potential donors that they may ask at any time how many children have been born as a result of their donation.
- 11.38** The centre should inform donors seeking information about children born as a result of their donation that they may find counselling, or similar support services, helpful in considering the implications of receiving such information.
- 11.39** The centre should inform anonymous donors seeking information about children resulting from their donation that they have the right to re-register as identifiable, if they wish.

Informing donors about information available to donor-conceived people

- 11.40** The centre should inform donors that anyone born as a result of their donation will have access to the following non-identifying information provided by them, from the age of 16:
 - (a) physical description (height, weight, and eye, hair and skin colours)
 - (b) year and country of birth
 - (c) ethnic group
 - (d) whether the donor had any genetic children when they registered, and the number and sex of those children
 - (e) other details the donor may have chosen to supply (eg, occupation, religion, **gender history** and interests)
 - (f) the ethnic group(s) of the donor's parents
 - (g) whether the donor was adopted or donor conceived (if they are aware of this)
 - (h) marital status (at the time of donation)
 - (i) details of any screening tests and medical history
 - (j) skills
 - (k) reason for donating
 - (l) a goodwill message, and
 - (m) a description of themselves as a person (pen portrait).
- 11.41** The centre should also inform donors who register or re-register after 31 March 2005 that anyone born as a result of their donation will have access to the following identifying information, from the age of 18:
 - (a) full names (and any previous names)

- (b) date of birth, and town or district where born, and
- (c) last known postal address (or address at time of registration).

- 11.42** The centre should inform identifiable donors that it will make a reasonable attempt to contact and forewarn them before disclosing identifiable details to anyone born as a result of their donation. The centre should encourage donors to provide up-to-date contact details to facilitate this.
- 11.43** The centre should advise trans donors that information disclosed by the HFEA to anyone born as a result of their donation may reveal the donor's gender history (eg, where a trans woman donated sperm and registered with the clinic and the HFEA in her acquired female gender. On disclosure of her identifying information, it will be apparent to the person born as a result of her donation that she is a trans woman having donated sperm).
- 11.44** The centre should inform donors who are, or will be, transitioning that following their donation, they have the option to notify the clinic or HFEA that they have transitioned and may, if they wish, provide details of their acquired identity so that the HFEA Register can be updated. This will allow anyone conceived as a result of their donation at age 18 to find out about the donor's current identity.
- 11.45** The centre should inform donors that the HFEA is lawfully obliged to disclose the information set out at 11.43 and 11.44 to anyone conceived as a result of their donation.

See also



Guidance note 4 – Information to be provided prior to consent

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

Guidance note 11 – Donor recruitment, assessment and screening

Guidance note 20 – Donor assisted conception

Guidance note 30 – Confidentiality and privacy

Provision of counselling to those considering donation

Interpretation of mandatory requirements 11C



All prospective donors must be given a suitable opportunity to receive proper counselling. Where embryos are to be donated, the recruiting centre must offer counselling to each person whose gametes were used to create the embryos.

- 11.46** If the possibility of donating gametes or embryos for the treatment of others, or for research or training, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.

Consent

Interpretation of mandatory requirements 11D

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

- (a) their gametes for the treatment of others or for non-medical fertility services, or
- (b) embryos created with their gametes for the treatment of others.

Those giving consent can specify conditions for the use of their gametes and embryos.

The use of donor gametes or embryos to create more families than a donor has consented to is a breach of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

- 11.47** Where someone intends to donate gametes or embryos for the treatment of others, the centre should ensure it obtains written consent to do so from that person. Such consent should include the number of families that may have children using the donated gametes or embryos.
- 11.48** Centres should aim to make best use of donated sperm within the maximum number of families the donor has consented to (up to the 10-family limit).
- 11.49** If the donor has consented to using the sperm for more than one family, the recruiting centre should not allow patients to reserve more sperm than is reasonable for one family allocation.
- 11.50** Where the centre uses sperm from donors who have been recruited at another centre, the centre should take reasonable steps to assure itself that patients have not reserved more sperm than is reasonable for one family allocation.
- 11.51** The centre is not required to obtain the consent of the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.

See also

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

Monitoring and complying with the 10-family limit

- 11.52** The centre should establish documented procedures to ensure that if the number of families created using gametes (or embryos created using donated gametes) from a particular donor has reached 10 (or any lower figure specified by the donor), that those gametes or embryos are not used or distributed for use in further treatment.
- 11.53** Before authorising a secondary centre to use gametes (or embryos created using gametes) from a particular donor, the primary centre should ensure that no more than 10 families (or any lower figure specified by the donor) at any time:
 - (a) have had live births as a result of treatment using that donor's gametes
 - (b) have embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer, or
 - (c) are being treated using that donor's gametes (or embryos created using gametes).

11.54 If a centre uses gametes (or embryos created using gametes) from a particular donor who was recruited by another centre, it should notify that primary centre each time a new patient has:

- (a) a live birth as a result of treatment using that donor's gametes, or
- (b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

Where a centre uses the sperm of a donor in pronuclear transfer and where the donor will consequently be genetically related to any child born, a) and b) must be complied with. In the case of egg donors who have donated their mitochondria only, or sperm donors who have donated for pronuclear transfer where they will not be genetically related to the child, clinics do not need to comply with the above.

11.55 The primary centre for a particular donor should notify any secondary centres having or using gametes (or embryos created using gametes) from that donor, within two working days, when it becomes aware that six families (The six-family alert applies where the donor has not specified a family limit lower than 10) have had:

- (a) a live birth as a result of treatment using that donor's gametes, or
- (b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

After this, gametes (or embryos created using gametes) from that donor should not be used without authorisation from the primary centre, unless they are used to treat a family who already has a child using that donor. However, if recipients have already begun or had medical, surgical or obstetric treatment (such as ovarian stimulation or egg collection) when the notification is given, this should be allowed to continue.

11.56 When using gametes (or embryos created using gametes) from a particular donor authorised in this way by a primary centre, a secondary centre should notify the primary centre each time a woman starts or ends relevant treatment.

11.57 Relevant treatment situations are where the woman has:

- (a) begun, but not completed, a treatment cycle (eg, ovarian stimulation)
- (b) received treatment (insemination or embryo transfer) and is awaiting confirmation of pregnancy
- (c) a confirmed ongoing pregnancy
- (d) embryos created that have not yet been transferred (eg, placed in storage), or
- (e) received treatment but has not reported the outcome.

11.58 Primary centres should notify secondary centres, and vice versa, when embryos created using a donor's gametes are removed from storage and allowed to perish, donated to research or used for training.

See also

[Guidance note 17 – Storage of gametes and embryos](#)



Benefits in kind

- 11.59** Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for the treatment of others.
- 11.60** The centre should, as appropriate, treat gamete providers donating for benefits in kind in the same way as other potential gamete donors.

See also

[Guidance note 12 – Egg sharing arrangements](#)



Other legislation, professional guidelines and information

Legislation

[Data Protection Act 1998](#)

[Equalities Act 2010](#)

[Gender Recognition Act 2004](#)

Professional guidelines

[Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society and Royal College of Obstetricians and Gynaecologists: UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors \(2008\)](#)

[British Infertility Counselling Association: Guidelines for good practice in infertility counselling \(third edition, 2012\)](#)

[Department of Health \(Advisory Committee on the Safety of Blood, Tissues and Organs\): Donor selection criteria for men who have had sex with men \(2013\)](#)

Clinic Focus articles

[Information on HTLV screening, issued in Clinic Focus \(November 2010\)](#)

[Clinic Focus article: Photographs of donors \(May 2014\)](#)

[Clinic Focus article: Pathology tests \(July 2014\)](#)

[Clinic Focus article: Zika virus \(what it means for donors and fertility patients\) \(February 2016\)](#)

[Clinic Focus article: Updated guidance on Ebola \(March 2016\)](#)

Annex E – Guidance note 17 (Storage of gametes and embryos)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

17. Storage of gametes and embryos

Version 9.0

Mandatory requirements

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

- 1 Meaning of "embryo", "gamete" and associated expressions
 - (4) In this Act (except in section 4A) -
 - (a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,
 - (b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and
 - (c) references to gametes are to be read accordingly.
- 3 Prohibitions in connection with embryos
 - (1) No person shall bring about the creation of an embryo except in pursuance of a licence.
 - (1A) No person shall keep or use an embryo except -
 - (a) in pursuance of a licence, or
 - (b) in the case of-
 - (i) the keeping, without storage, of an embryo intended for human application, or
 - (ii) the processing, without storage, of such an embryo in pursuance of a third party agreement.in pursuance of a third party agreement.
 - (3) A licence cannot authorise -
 - ...(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use
- 4 Prohibitions in connection with gametes

- (1) No person shall -
 - (a) store any gametes...
except in pursuance of a licence.
- (2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.

14 Conditions of storage licences

- (1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos
 - (a) that gametes of a person shall be placed in storage only if -
 - (i) received from that person,
 - (ii) acquired in circumstances in which by virtue of paragraph 9 or 10 of Schedule 3 that person's consent to the storage is not required, or
 - (iii) acquired from a person to whom a licence or third party agreement applies,
 - (aa) that an embryo taken from a woman shall be placed in storage only if -
 - (i) received from that woman, or
 - (ii) acquired from a person to whom a licence or third party agreement applies,
 - (ab) that an embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence or third party agreement applies,
 - (ac) that a human admixed embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies,
 - (b) that gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies,
 - (ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,
 - (c) that no gametes, embryos or human admixed embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish, and
 - (d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.
- (2) No information shall be removed from any records maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.
- (3) The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.
- (4) The statutory storage period in respect of embryos is such period not exceeding ten years

as the licence may specify.

- (4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.
- (5) Regulations may provide that subsection (3), (4) or (4A) above shall have effect as if for ten years there were substituted -
 - (a) such shorter period, or
 - (b) in such circumstances as may be specified in the regulations, such longer period, as may be specified in the regulations.

14A Conditions of licences: human application

- (1) This section applies to -
 - (a) every licence under paragraph 1 or 1A of Schedule 2,
 - (b) every licence under paragraph 2 of that Schedule, so far as authorising storage of gametes or embryos intended for human application, and
 - (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.
- (2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.
- (3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.
- (4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.

41 Offences

- (1) A person who -
 - (b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence, is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.
- (2) A person who -
 - (a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,...
 - (b) keeps any gametes in contravention of section 4(1)(a) of this Act,...
 is guilty of an offence.

Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc

Storage of gametes and embryos

- 8 (1) A person's gametes must not be kept in storage unless there is an effective consent by

that person to their storage and they are stored in accordance with the consent.

- (2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

Cases where consent not required for storage

- 9 (1) The gametes of a person (“C”) may be kept in storage without C’s consent if the following conditions are met.
- (2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.
- (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -
- (a) the treatment is likely to cause a significant impairment of C’s fertility, and
- (b) the storage of the gametes is in C’s best interests.
- (4) Condition C is that, at the time when the gametes are first stored, either -
- (a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or
- (b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.
- (5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes -
- (a) given consent under this Schedule to the storage of the gametes, or
- (b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.
- (6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications -
- (a) for sub-paragraph (4), substitute -
- “(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.”, and
- (b) in sub-paragraph (5), for “becoming competent to deal with the issue of consent to the storage of the gametes” substitute “acquiring such capacity”.
- 10 (1) The gametes of a person (“P”) may be kept in storage without P’s consent if the following conditions are met.
- (2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.
- (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner -
- (a) the treatment is likely to cause a significant impairment of P’s fertility,
- (b) P lacks capacity to consent to the storage of the gametes,

- (c) P is likely at some time to have that capacity, and
 - (d) the storage of the gametes is in P's best interests.
- (4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.
- (5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule -
- (a) given consent to the storage of the gametes, or
 - (b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.
- (6) In relation to Scotland -
- (a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,
 - (b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and
 - (c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.

11 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death

Regulations

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996

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

Licence conditions

- T50 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the centre must:
- a. carry out the following biological tests to assess the risk of cross contamination:
 - HIV 1 and 2: Anti-HIV – 1, 2
 - Hepatitis B: HBsAg and Anti-HBc
 - Hepatitis C: Anti-HCV-Ab
 - b. devise a system of storage which clearly separates:
 - quarantined/unscreened gametes and embryos,
 - gametes and embryos which have tested negative, and
 - gametes and embryos which have tested positive.
 - c. perform HTLV- 1 antibody testing for patients living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas

- d. in certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi)

Positive results will not necessarily prevent the use of the partners' gametes.

- T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:
- a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and
 - b. blood samples must be obtained within a timeframe specified by the Authority
- T75 Centres must ensure that all storage processes are carried out under controlled conditions.
- T76 Gametes of a person must be placed in storage only if -
- a. received from that person,
 - b. acquired in circumstances in which by virtue of paragraph 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or
 - c. acquired from a person to whom a licence or third party agreement applies.
- T77 Embryos taken from a woman must be placed in storage only if -
- a. received from that woman, or
 - b. acquired from a person to whom a licence or third party agreement applies.
- T78 Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.
- T79 No gametes or embryos must be kept in storage for longer than the statutory storage period and, if stored at the end of the period, must be allowed to perish.
- T80 The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.
- T81 The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.
- T82 Regulations may provide that licence conditions T80 and T81 must have effect as if for ten years there were substituted -
- a. such shorter period, or
 - b. in such circumstances as may be specified in the relevant Regulations, such longer period, as may be specified in the relevant Regulations.
- T83 Gametes or embryos which are or have been stored must not be supplied to a person otherwise than in the course of providing treatment services, unless that person is a person to whom a licence applies.
- T85 A documented risk assessment must be undertaken to determine the fate of all stored gametes and embryos following the introduction of any new donor/patient selection or testing criterion or any significantly modified processing step that enhances safety or quality.

Directions

0007 – Consent

HFEA guidance**Facilities and documented procedures**

- 17.1** The centre should establish documented procedures to ensure that all storage and handling of gametes and embryos comply with licence conditions, regulations, and relevant patient and donor consent.
- 17.2** The centre should ensure that the storage facilities for gametes and embryos:
- (a) are dedicated for the purpose, and adequate for the volume and types of activities
 - (b) are designed to avoid proximity to ionising radiation (radioactive material), any known potential source of infection, or chemical or atmospheric contamination, and
 - (c) have a storage-location system that minimises the amount of handling required to retrieve gametes and embryos.
- 17.3** The centre should also have emergency procedures to deal with damage to storage vessels, failure of storage conditions or both.
- 17.4** The centre's documented procedures should also ensure that:
- (a) gametes and embryos are stored under controlled conditions that are validated and monitored
 - (b) gametes and embryos are packaged for storage in a way that:
 - (i) prevents any adverse effects on the material
 - (ii) minimises the risk of contamination
 - (c) records are kept indicating every occasion when gametes and embryos are handled during storage and release, and by whom
 - (d) records are kept indicating that gametes and embryos meet requirements for safety and quality before release, and
 - (e) risk assessments (approved by the person responsible) are done to determine the fate of all stored material whenever any of the following is introduced:
 - (i) a new donor selection criterion
 - (ii) a new criterion for testing donors, patients' partners or patients
 - (iii) a new processing step to enhance safety, quality or both
 - (iv) a new procedure for appropriate disposal of gametes and embryos.

Safety of equipment used to store cryopreserved gametes and embryos

- 17.5** Centres should store gametes and embryos in a designated area. Access to this area should be limited to staff authorised under the terms of the centre's licence. Cryopreservation dewars

should be fitted with local alarms and be linked to an auto-dial or similar facility, (eg, a link to a fire alarm board) to alert staff to non-conformities outside normal working hours.

- 17.6** The centre should have adequate staff and funding for an ‘on-call’ system for responding to alarms out of hours, and adequate spare storage capacity to enable transfer of samples if a dewar fails.
- 17.7** A centre storing gametes and/or embryos for patients whose future fertility may be impaired by a medical condition or procedure should divide individual patients’ samples into separate storage vessels, in case of dewar failure.

See also

[Guidance note 26 – Equipment and materials](#)



Screening and storage of samples to prevent cross-contamination

Interpretation of mandatory requirements 17A



The law requires centres to obtain blood samples for HIV 1 and HIV 2, hepatitis B and hepatitis C screening from patients and their partners within three months before they first provide their gametes for use in treatment. Where the same person provides gametes for further treatment of their partner, the centre must obtain new blood samples within two years of the previous sampling. Patients who have screening tests at one licensed clinic and then move to another do not have to have repeat screening tests if within these timescales. However, individual clinics must decide whether the appropriate screening has taken place in the required timeframe. These screening requirements apply to individuals who provide gametes, or embryos created with their gametes, that will be processed or stored.

Where treatment involves the use of gametes, or embryos created with gametes, from two people who are not in an intimate physical relationship:

- (a) the person providing the gametes to the woman being treated must be screened according to licence condition T52 on donor screening
 - (b) the centre, in discussion with the patient, should consider the merit of additional donor screening in line with guidance by professional bodies.
- 17.8** The centre should ensure that no gametes or embryos are placed in storage unless the people who provided the gametes have been screened in accordance with current recommended professional guidelines.
- 17.9** Centres should:
- (a) assess the risks of cross-contamination during the quarantine period
 - (b) put procedures in place to minimise these risks, and
 - (c) document the rationale for the chosen quarantine procedures.

See also

[Guidance note 15 – Procuring, processing and transporting gametes and embryos](#)



[Guidance note 19 – Traceability](#)

[Guidance note 20 – Donor assisted conception](#)

Storing ovarian and testicular tissue

Interpretation of mandatory requirements 17B



Ovarian and testicular tissue, as cells of the germ line, fall within the definition of gamete in the Human Fertilisation and Embryology Act 1990 (as amended) and so are subject to the same storage requirements as sperm and eggs.

HFEA-licensed clinics currently storing ovarian or testicular tissue can continue to do so without a licence from the Human Tissue Authority (HTA) until the tissue is to be used. If a patient's own tissue is to be transplanted (known as autologous transplant), it must be transferred at the time of use to an HTA-licensed facility for processing and/or distribution to the transplant facility. Details of HTA-licensed facilities are on the HTA website.

An HTA licence is not needed to store ovarian or testicular tissue intended for fertility treatment (eg, in vitro maturation of gametes). HFEA centres licensed to store gametes can store, process and use ovarian or testicular tissue to extract gametes for patients' own use in licensed fertility treatment, subject to the same conditions that apply to the use of sperm and eggs.

Storing gametes and embryos following mitochondrial donation

17.10 Only centres that are licensed to undertake mitochondrial donation can store gametes or embryos following maternal spindle transfer or pronuclear transfer.

Information for those seeking storage of gametes or embryos

17.11 If the treatment involves the creation of embryos in vitro, the centre should give people seeking treatment information about the availability of facilities for freezing embryos, and about the implications of storing and then using stored embryos.

17.12 When a centre enters into a contractual agreement with a patient regarding the practicalities of storage (eg, an agreement to pay storage fees or store whilst funding is available) the patient should be given enough information to understand the terms and conditions of the agreement and the steps the centre will take if these terms and conditions are broken. This agreement should be separate from the consent provided by the patient – see guidance note 5 – information for those seeking storage of gametes or embryos. Depending on the terms of the agreement, the centre should provide information about the circumstances in which the patient's gametes or embryos could be removed from storage before their consent expires. For example, that the centre may only continue to store the patient's gametes or embryos for the period specified in their consent if the patient, or their funding provider, continues to pay the storage fees.

17.13 If there is an intention to store gametes or embryos, or where this possibility arises during treatment, in addition to relevant information about treatment and donation, the centre should give those providing the gametes or embryos relevant information about:

- (a) the possible deterioration or loss of viability of gametes or embryos as a result of storage, and the potential risk of cross-contamination between samples

- (b) statutory storage periods for gametes and embryos which permit patients to store for a maximum of 10 years, and regulations for extending storage periods up to a maximum of 55 years. In the case of embryos, patients should also be given relevant information about the requirement for both gamete providers to consent to any extension of storage
- (c) the likelihood of a live birth resulting from previously cryopreserved embryos or gametes, and
- (d) screening tests to be done, the cost of these, the reason for them and the implications of the tests for the gamete providers.

Oncology patients and other patients requiring long-term storage should be given specific information tailored to their needs and circumstances. Where relevant, this should include information appropriate for children and young people. This information should include the options available if the patient dies and, in particular:

- (i) the consequences for posthumous use in cases where they have not provided written consent to their gametes or embryos being used in the treatment of a named partner in the event of their death, and
- (ii) the maximum storage period, subject to satisfying the regulations and the fact that gametes or embryos cannot be used posthumously for longer than the storage period to which the gamete provider has consented.

Centres treating trans patients should consider the information needs of these patients and ensure that information provided is tailored accordingly. In addition to receiving relevant information about treatment, donation and the points raised in 17.13, these patients (particularly in the case of young trans patients) may need to be given more or different information including information about:

- their future treatment options once they have transitioned
- the requirements that must be met for the extension of storage beyond the statutory storage period of ten years, and
- screening requirements which may be dependent on their future treatment options (eg, if it is likely that they may use their gametes in a surrogacy arrangement or be donated to a future partner for their treatment).

Centres should use information obtained in these discussions to guide them in determining what consent forms need to be completed and the appropriate screening requirements.

17.14 The centre should ensure that, before someone consents to gametes or embryos being stored, they are told:

- (a) the options available if a person providing gametes or resulting embryos dies or becomes mentally incapacitated
- (b) that it may be possible to register a deceased partner as the parent of a child resulting from treatment, and the conditions for doing so, and
- (c) that it is unlawful to store embryos and gametes beyond the period of consent, the centre having a legal obligation to dispose of them once consent has expired.

See also

[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

[Guidance note 11 – Donor recruitment, assessment and screening](#)



HFEA consent forms

Treatment using cryopreserved eggs or embryos

17.15 The centre should ensure that the following sets of eggs or embryos are only transferred during the same treatment cycle in exceptional circumstances, with an upper limit of 2% of all cases:

- (a) fresh eggs and eggs that have been cryopreserved, or
- (b) embryos that have been created using cryopreserved eggs, and embryos created using fresh eggs, or
- (c) cryopreserved embryos that have been created using cryopreserved eggs and cryopreserved embryos that have been created using fresh eggs.

The circumstances justifying such a transfer should be specified in the patient's notes.

Consent to storage and cases where consent is not required for storage

Interpretation of mandatory requirements 17C



The law requires the centre to obtain written informed consent from a person before it stores their gametes or embryos created with their gametes.

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

Gametes stored following the application of these paragraphs may be used only if the person from whom they were collected gives written effective consent to their use (and has sufficient capacity and competence to do so).

In certain limited circumstances involving premature infertility, gametes and embryos can be stored beyond the statutory maximum storage period.

Gametes first placed in storage before 1 August 1991

Gametes first placed in storage before 1 August 1991, and which have been kept lawfully, may continue to be stored for an extended period beyond the 10-year statutory maximum storage period without the written consent of the gamete provider (if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied). The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period must be calculated from 1 August 1991.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage between 1 August 1991 and 1 October 2009

Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period without the written consent of the gamete provider (if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied). The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate

period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period begins on the date that the gametes were stored. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

Embryos first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period but only if both people whose gametes were used to bring about the creation of the embryo confirm in writing that they have no objection to the extension (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are satisfied). The Schedule to these Regulations set out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage after 1 October 2009

Gametes or embryos first placed in storage after 1 October 2009 may continue to be stored beyond the statutory maximum storage period, to a maximum of 55 years, but only with the written consent of the gamete provider or the people whose gametes were used to bring about the creation of the embryo (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 are satisfied). The same conditions apply to any extension of the statutory storage period for gametes and embryos first stored earlier than 1 October 2009, if the gamete provider (or people whose gametes were used to bring about the creation of the embryo) have provided consent under those Regulations.

For guidance about steps to take when consent is not required, see [guidance note 5 – Consent to treatment, storage, donation, and disclosure of information](#).

See also

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

HFEA consent forms



Extension of storage

Interpretation of mandatory requirements 17D

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 regulations') allows gametes or embryos to be stored for longer than the

10 year standard storage period, up to a maximum of 55 years, if one of the gamete providers, their partner, or the person who the gametes or embryos have been allocated to, meet(s) the medical criteria for premature infertility.

To store gametes or embryos for an extended period, the centre must obtain the gamete provider's written consent to extended storage beyond 10 years and a written statement from a registered medical practitioner that one of the gamete providers, their partner, or the person who the gametes or embryos have been allocated to, is prematurely infertile or likely to become prematurely infertile. The statement from the medical practitioner must be renewed for every 10 year storage period beyond the initial statutory period.



- 17.16** The centre should inform patients wishing to store gametes or embryos for more than 10 years of the medical criteria for extended storage, including the 2009 regulations and how these regulations are satisfied. Patients should be aware that, if they satisfy the regulations, they can provide consent to extended storage when their gametes or embryos are first placed in storage or at a later date in the first 10 years.
- 17.17** To satisfy the regulations for extended storage periods, the centre should seek a written medical opinion towards the end of the 10-year standard storage period to certify that one of the gamete providers, their partner, or the person who the gametes or embryos have been allocated to, is prematurely infertile or likely to become prematurely infertile.
- 17.18** The centre should seek the written medical opinion on premature infertility whilst the gamete provider is alive. However, if the gamete provider (who has provided consent to extended storage) dies before a medical opinion is in place, the medical opinion may be sought after death based on evidence that the person would have satisfied the premature infertility criteria when they were alive.
- 17.19** When the criteria for extended storage have been met, the centre can store the gametes and embryos for a further 10 years from the date the criteria are met. The centre can extend the storage period by further 10 year periods (up to the maximum of 55 years) if it is shown at any time within each extended storage period that the criteria continue to be met.

See also

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)
[HFEA consent forms](#)



Disputes involving the withdrawal of consent to storage

Mandatory requirements

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

Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc

4A (1) This paragraph applies where -

- (a) a permitted embryo, the creation of which was brought about in vitro, is in storage,
- (b) it was created for use in providing treatment services,
- (c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation ("P") gives the person keeping the embryo notice withdrawing P's consent to the storage of the embryo, and
- (d) the embryo was not to be used in providing treatment services to P alone.

(2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P's withdrawal of consent.

- (3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.
- (4) Storage of the embryo remains lawful until-
 - (a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or
 - (b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.
- (5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.

Interpretation of mandatory requirements 17E



If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment (created from their gametes), the law requires the centre to take all reasonable steps to notify the intended recipient(s).

The law allows embryos to be stored for 12 months from the date that the centre receives written withdrawal of consent, or less if the centre receives written signed consent from all intended recipients for the embryos to be destroyed. This 12-month 'cooling off' period must not extend beyond the end of the period for which valid consent exists.

For guidance about the withdrawal of consent see [guidance note 5 – Consent to treatment, storage, donation, and disclosure of information](#).

See also



[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

HFEA consent forms

Storage review

17.20 The centre should establish documented procedures to ensure that:

- (a) reviews of stored gametes and embryos are done at least once every two years to:
 - (i) reconcile the centre's records with material in storage
 - (ii) review the purpose and duration of storage, and
 - (iii) identify any action needed
- (b) if the number of families created using gametes (or embryos created using donated gametes) from a particular donor has reached 10, those gametes or embryos are not used or distributed for use in further treatment.

See also

[Guidance note 11 – Donor recruitment, assessment and screening](#)

[Guidance note 20 – Donor assisted conception](#)

17.21 The centre should operate a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes or embryos in storage. The centre should ensure the bring-forward system links to clinical processes regarding extension of storage periods.

End of storage

Interpretation of mandatory requirements 17F

No centre may keep embryos or store gametes after the expiry of the legal maximum storage period, or the period specified when the embryos or gametes were stored if shorter. Storing embryos or gametes beyond the relevant period is a criminal offence, punishable by a prison sentence, fine or both.

17.22 The centre should make efforts to stay in contact with patients who have gametes or embryos in storage for their own treatment, and with any woman to be treated with stored gametes or embryos (where she is not a gamete provider.) The centre should also explain to gamete providers and current patients the importance of informing the centre of any change in their contact details, including that their gametes or embryos may be removed from storage if they do not keep their contact details up to date.

17.23 The centre should establish and use documented procedures to contact patients who have gametes or embryos in storage for their own treatment when the end of the permitted storage period is approaching. The centre should use all contact details available to them, including at least one written form of contact. Patients should be provided with information about the options available to them as the end of their permitted storage period approaches. They should be given enough notice to enable them to consider those options and to access appropriate advice. Options could include the donation of the gametes or embryos for research, training or for the treatment of others. If contact with the patient is not possible, the centre should record the steps it has taken in the patient's medical records.

Other legislation, professional guidelines and information

Legislation

[Data Protection Act 1998](#)

[Equality Act 2010](#)

[Gender Recognition Act 2004](#)

Professional guidelines

[Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society and Royal College of Obstetricians and Gynaecologists: UK guidelines](#)

for the medical and laboratory screening of sperm, egg and embryo donors (2008)

Department of Health: Guidance on the microbiological safety of human organs (2011)

The Human Tissue Authority: The regulator for human tissue and organs

Clinic Focus articles

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

Annex F – Guidance note 29 (Treating people fairly)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

29. Treating people fairly

Version 6.0

HFEA guidance

Treating people fairly

Interpretation of mandatory requirements 29A



The law, mainly the Equality Act 2010, protects people who have a 'protected characteristic' (including centre staff, current and prospective patients, and donors) from less favourable treatment than others who do not have that characteristic. There are nine protected characteristics:

- (a) age
- (b) disability
- (c) gender reassignment
- (d) marriage and civil partnership
- (e) pregnancy and maternity
- (f) race
- (g) religion or belief
- (h) sex
- (i) sexual orientation.

Equality law applies to both NHS and private centres, as employers and providers to the public of goods, facilities or services (paid for or free of charge).

The law protects people by prohibiting the following:

- (a) Direct discrimination: where, because of a protected characteristic, a person with that characteristic is treated less favourably than others who do not share that characteristic.
- (b) Discrimination by perception: where a person who is thought to have a protected characteristic is treated less favourably than others, even though they do not, in fact, have that characteristic.
- (c) Discrimination by association: where a person is treated less favourably than others because of their association with someone who has a protected characteristic.
- (d) Discrimination arising from disability: where a person with a disability is treated less favourably than others because of something that is a result of their disability.

- (e) Combined discrimination: where a person who has two protected characteristics is treated less favourably than others who have neither of those characteristics.
- (f) Harassment: where a person experiences unwanted conduct related to a protected characteristic (other than characteristics (d) and (e)) that violates their dignity or creates an intimidating, hostile, degrading or offensive environment for them, or is intended to do so.
- (g) Victimisation: where a person is treated badly because they have made or supported a complaint or grievance under the Equality Act.
- (h) Indirect discrimination: where a rule, policy or practice applies to everyone but disadvantages people who have a protected characteristic.

For some protected characteristics and in some contexts, unequal treatment may be justified if it is a proportionate way of achieving a legitimate aim.

The law requires reasonable adjustments to be made for people with a disability, including finding a way around arrangements that disadvantage them, helping them overcome disadvantage caused by physical features of the premises, and providing auxiliary aids (for example, extra equipment).

The law also requires those carrying out a public function to consider the need to eliminate prohibited conduct, promote equal opportunities, and encourage good relations between people with protected characteristics and those without.

The Human Rights Act 1998, which gives effect to the rights guaranteed in the European Convention for the Protection of Human Rights and Fundamental Freedoms, is also relevant to broader issues of equality, discrimination and human rights.

- 29.1** The person responsible should ensure that the centre's systems, policies and procedures comply with current equality legislation and guidance. A list of relevant legislation is included in the 'Other legislation, professional guidelines and information' section at the end of this guidance note.
- 29.2** Centres should ensure that staff, donors, patients and other visitors to the centre are treated fairly and with respect for their dignity and human rights. Centre staff should have received up-to-date training and be able to show they are competent in their obligations under equality law.
- 29.3** Attitudes towards assisted conception, gamete donation, embryo testing, mitochondrial donation and the use of gametes and embryos may vary significantly between individuals, cultures and religions. All healthcare professionals should be sensitive to this; the person responsible should ensure employees have access to training and support to help them identify and meet the widest possible range of patients' and donors' needs and preferences.
- 29.4** The Equality Act 2010 prohibits service providers (such as clinics) from discriminating against service users (patients and donors) by treating them less favourably because of a protected characteristic. Centres that consider a person unsuitable for treatment, donation or storage or stop providing services, provide services on less favourable terms than they do for other service users who do not share that protected characteristic, or subject the service-user to any other detriment due to one or more of these protected characteristics, will be in breach of the Equality Act and therefore likely to be at risk of regulatory sanction or other legal liability.
- 29.5** Gender reassignment is a protected characteristic under the Equality Act 2010. A person has the protected characteristic of gender reassignment if they are proposing to undergo, are undergoing or have undergone a process (or part of the process) of gender reassignment, by changing their physical or physiological attributes. The protected characteristic also includes an

intention to transition or state of mind; the person need not have taken any steps toward gender reassignment to be protected.

- 29.6** Centres should be aware that for some patients, gender identity and gender may be distinct and different. Centres treating trans patients or donors with gender dysphoria or gender identity disorder should ensure that they take account of the particular needs of these patients and make appropriate changes to relevant processes and practices to accommodate their needs.
- 29.7** Centres should ensure that all business and clinical structures and functions show respect for equality and diversity. Centres should review policies and procedures regularly to ensure they reflect equality and diversity adequately. Centres should also consider having equality policies.
- 29.8** Centres should put in place suitable procedures for monitoring and auditing the number and quality of services they provide for people with protected characteristics.
- 29.9** Centres should provide or arrange investigations and treatments based on professional assessment and clinical judgment. They should take into account the needs and preferences of prospective or current patients, donors and others visiting the centre, including any reasonable adjustments, aids or help they may need.
- 29.10** Centres must decide fairly whether to offer or refuse treatment. Staff at a centre should not refuse or delay treatment because they believe that what a patient has done or not done has contributed to their condition. The reasons for any refusal, delay or interruption of treatment should be fully documented.
- 29.11** As outlined in Department of Health guidance, there should be no specific restrictions on donations from men who have sex with men (MSM). The centre should assess the risks and benefits of accepting donations from each such individual – ie, document MSM behaviour.
- 29.12** The person responsible for an NHS centre should consider relevant policies of their primary care trust or NHS board before refusing treatment.
- 29.13** Staff at the centre must not harass or victimise patients or donors by allowing their own personal views or judgments (For instance, their views about a patient's age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation) to adversely affect their professional relationship with the patients or donors, or the treatment they provide or arrange. Staff should challenge colleagues if they believe that their behaviour does not comply with this guidance, or with the relevant legislative requirements. (This guidance is based on a paragraph taken from Good Medical Practice. (GMC, 2006))
- 29.14** Centres carrying out a public function should consider taking positive action to help people overcome disadvantage or to meet their needs, where this is consistent with centres' duties towards others.

Conscientious objection

Mandatory requirements

38 Conscientious objection

- (1) No person who has a conscientious objection to participating in any activity governed by this Act shall be under any duty, however arising, to do so.
- (2) In any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming to rely on it.
- (3) In any proceedings before a court in Scotland, a statement on oath by any person to the effect that he has a conscientious objection to participating in a particular activity governed by this Act shall be sufficient evidence of that fact for the purpose of discharging the burden of proof imposed by subsection (2) above.

29.15 The centre should give prospective employees a full description of the centre's activities, and at the interview draw their attention to the provision that anyone who has a conscientious objection to participating in a particular activity done in the centre must not be obliged to do so.

29.16 If a staff member has a conscientious objection to providing a particular licensed activity governed by the Act, they should inform the person responsible. The person responsible should ensure that the patient, patient's partner or donor is given information on or referred to alternative sources of the treatment.

29.17 The person responsible should satisfy themselves that the staff member has a conscientious objection to providing a particular licensed activity, and is not unlawfully discriminating against a patient on the basis of a protected characteristic.

29.18 If all staff at the centre conscientiously object to providing a particular licensed activity, the person responsible should:

- (a) try to refer the person to another centre for treatment, and
- (b) provide the patient with a written explanation of why the centre cannot treat them.

29.19 The person responsible should record:

- (a) the reason(s) for the conscientious objection of any member of staff
- (b) their efforts to provide the particular activity at the centre, and
- (c) if that activity cannot be provided at the centre, efforts they have made to ensure the patient receives treatment elsewhere.

Addressing communication barriers

29.20 The centre should consider the needs of people whose first language is not English and those who face other communication barriers. Where consent is obtained, the centre should record any difficulties in communicating the implications of giving consent and in providing other information to the person (eg, language barriers or hearing impairment) and an explanation of how these difficulties were overcome (eg, the use of an independent interpreter). (This guidance is based on a paragraph taken from the Human Tissue Authority's Code of Practice on Consent (2008)).

See also

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)



Guidance note 23 – The quality management system

29.21 The centre should ensure it establishes and accommodates the preferred means of communication of any patient or donor with a disability. If appropriate, it should consider providing information in a variety of formats such as large print, 'easy read' or Braille.

Other legislation, professional guidelines and information

Legislation

[Equality Act 2010](#)

[Gender Recognition Act 2004](#)

[Human Rights Act 1998](#)

General guidelines

The [Equality and Human Rights Commission](#) was established under the Equality Act 2006 to champion equality and human rights for all, and to work to eliminate discrimination. Among other things, its website, provides practical information for businesses to help them meet their obligations, including a summary of relevant law. Case studies illustrate the various forms of discrimination. The Commission produces guidance and Codes of Practice for employment, service provision and other matters in relation to the Equality Act 2010.

To illustrate [discrimination on the grounds of sexual orientation](#), the Equality and Human Rights Commission uses the example of a couple who are refused fertility treatment because they are lesbians.

The General Medical Council's '[Good medical practice](#)' (2013) links to a range of other diversity and equality websites can be found on the site.

The [HFEA Diversity Strategy](#) outlines the way we intend to promote diversity and a set of action plans in relation to race, disability, gender, sexual orientation, religion or belief, and age. Centres may wish to refer to this when producing or revising their own diversity strategy.

Annex G – Guidance note 30 (Confidentiality and privacy)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

30. Confidentiality and privacy

Version 6.0

Mandatory requirements

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

31 Register information

- (1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which—
 - (a) immediately before the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008, was contained in the register kept under this section by the Authority, or
 - (b) is obtained by the Authority.
- (2) Subject to subsection (3), information falls within this subsection if it relates to—
 - (a) the provision for any identifiable individual of treatment services other than basic partner treatment services,
 - (b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual,
 - (c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,
 - (d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or
 - (e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a relevant individual.
- (3) Information does not fall within subsection (2) if it is provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZF(1).
- (4) In this section “relevant individual” means an individual who was or may have been born in consequence of—
 - (a) treatment services, other than basic partner treatment services, or

- (b) the procurement or distribution of any sperm (other than partner donated sperm which has not been stored) in the course of providing non-medical fertility services.

33A Disclosure of information

- (1) No person shall disclose any information falling within section 31(2) which the person obtained (whether before or after the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008) in the person's capacity as -
 - (a) a member or employee of the Authority,
 - (b) any person exercising functions of the Authority by virtue of section 8B or 8C of this Act (including a person exercising such functions by virtue of either of those sections as a member of staff or as an employee),
 - (c) any person engaged by the Authority to provide services to the Authority,
 - (d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c),
 - (e) a person to whom a licence applies,
 - (f) a person to whom a third party agreement applies, or
 - (g) a person to whom Directions have been given.
- (2) Subsection (1) does not apply where -
 - (a) the disclosure is made to a person as a member or employee of the Authority or as a person exercising functions of the Authority as mentioned in subsection (1)(b),
 - (b) the disclosure is made to or by a person falling within subsection (1)(c) for the purpose of the provision of services which that person is engaged to provide to the Authority,
 - (c) the disclosure is made by a person mentioned in subsection (1)(d) for the purpose of enabling a person falling within subsection (1)(c) to provide services which that person is engaged to provide to the Authority,
 - (d) the disclosure is made to a person to whom a licence applies for the purpose of that person's functions as such,
 - (e) the disclosure is made to a person to whom a third party agreement applies for the purpose of that person's functions under that agreement,
 - (f) the disclosure is made in pursuance of Directions given by virtue of section 24,
 - (g) the disclosure is made so that no individual can be identified from the information,
 - (h) the disclosure is of information other than identifying donor information and is made with the consent required by section 33B,
 - (i) the disclosure-
 - (i) is made by a person who is satisfied that it is necessary to make the disclosure to avert an imminent danger to the health of an individual ("P"),
 - (ii) is of information falling within section 31(2)(a) which could be disclosed by virtue of paragraph (h) with P's consent or could be disclosed to P by virtue of subsection (5), and
 - (iii) is made in circumstances where it is not reasonably practicable to obtain P's consent.

- (j) the disclosure is of information which has been lawfully made available to the public before the disclosure is made,
 - (k) the disclosure is made in accordance with sections 31ZA to 31ZE,
 - (l) the disclosure is required or authorised to be made –
 - (i) under regulations made under section 33D, or
 - (ii) in relation to any time before the coming into force of the first regulations under that section, under regulations made under section 251 of the National Health Service Act 2006,
 - (m) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) for the purpose of carrying out the Authority's duties under section 8A,
 - (n) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) in pursuance of an order of a court under section 34 or 35,
 - (o) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to the Registrar General in pursuance of a request under section 32,
 - (p) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to any body or person discharging a regulatory function for the purpose of assisting that body or person to carry out that function,
 - (q) the disclosure is made for the purpose of establishing in any proceedings relating to an application for an order under subsection (1) of section 54 of the Human Fertilisation and Embryology Act 2008 whether the condition specified in paragraph (a) or (b) of that subsection is met,
 - (r) the disclosure is made under section 3 of the Access to Health Records Act 1990,
 - (s) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or
 - (t) the disclosure is made necessarily for -
 - (i) the purpose of the investigation of any offence (or suspected offence), or
 - (ii) any purpose preliminary to proceedings, or for the purposes of, or in connection with, any proceedings.
- (3) Subsection (1) does not apply to the disclosure of information in so far as -
- (a) the information identifies a person who, but for sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, and
 - (b) the disclosure is made for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent.
- (4) Paragraph (t) of subsection (2), so far as relating to disclosure for the purpose of the investigation of an offence or suspected offence, or for any purpose preliminary to, or in connection with proceedings, does not apply—
- (a) to disclosure of identifying donor information, or
 - (b) to disclosure, in circumstances in which subsection (1) of section 34 of this Act applies, of information relevant to the determination of the question mentioned in that subsection, made by any person acting in a capacity mentioned in any of paragraphs

(c) to (g) of subsection (1).

- (5) Subsection (1) does not apply to the disclosure to any individual of information which—
- (a) falls within subsection (2) of section 31 of this Act by virtue of any of paragraphs (a) to (e) of that subsection, and
 - (b) relates only to that individual or, in the case of an individual who is treated together with, or gives a notice under section 37 or 44 of the Human Fertilisation and Embryology Act 2008 in respect of, another, only to that individual and that other.
- (6) In subsection (2)—
- (i) in paragraph (p) “regulatory function” has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006, and
 - (ii) in paragraph (t) references to “proceedings” include any formal procedure for dealing with a complaint.
- (7) In this section “identifying donor information” means information enabling a person to be identified as a person whose gametes were used in accordance with consent given under paragraph 5 of Schedule 3 for the purposes of treatment services or non-medical fertility services in consequence of which an identifiable individual was, or may have been, born.

33C Power to provide for additional exceptions from section 33A(1)

- (1) Power to provide for additional exceptions from section 33A(1)
- (2) No exception may be made under this section for -
- (a) disclosure of a kind mentioned in paragraph (a) or (b) of subsection (4) of section 33A, or
 - (b) disclosure in circumstances in which section 32 of this Act applies of information having the tendency mentioned in subsection (2) of that section, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1) of section 33A.

34 Disclosure in interests of justice

- (1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008 falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Authority—
- (a) to disclose whether or not any information relevant to that question is contained in the register kept in pursuance of section 31 of this Act, and
 - (b) if it is, to disclose so much of it as is specified in the order, but such an order may not require the Authority to disclose any information falling within section 31(2) (c) to (e) of this Act.
- (2) The court must not make an order under subsection (1) above unless it is satisfied that the interests of justice require it to do so, taking into account—
- (a) any representations made by any individual who may be affected by the disclosure, and
 - (b) the welfare of the child, if under 18 years old, and of any other person under that age who may be affected by the disclosure.
- (3) If the proceedings before the court are civil proceedings, it—

- (a) may direct that the whole or any part of the proceedings on the application for an order under subsection (2) above shall be heard in camera, and
 - (b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.
- (4) An application for a direction under subsection (3) above shall be heard in camera unless the court otherwise directs.

35 Disclosure in interests of justice: congenital disabilities, etc

- (1) Where for the purpose of instituting proceedings under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of the child, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.
 - (2) Where, for the purposes of any action for damages in Scotland (including any such action which is likely to be brought) in which the damages claimed consist of or include damages or solatium in respect of personal injury (including any disease and any impairment of physical or mental condition), it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of any party to the action or, if the proceedings have not been commenced, the prospective pursuer, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.
- (2A) In subsections (1) and (2) “the relevant statutory provisions” means –
- (a) sections 27 to 29 of this Act, and
 - (b) sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.
- (3) Subsections (2) to (4) of section 34 of this Act apply for the purposes of this section as they apply for the purposes of that.
- (4) After section 4(4) of the Congenital Disabilities (Civil Liability) Act 1976 there is inserted—
- "(4A) In any case where a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, any reference in section 1 of this Act to a parent includes a reference to a person who would be a parent but for sections 27 to 29 of the Human Fertilisation and Embryology Act 1990."

41 Offences

- (5) A person who discloses any information in contravention of section 33A of this Act is guilty of an offence and liable –
 - (a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and
 - (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Licence conditions

T43 The centre must ensure that all information is kept confidential and only disclosed in

circumstances permitted by law.

- T44 The centre must have processes in place to ensure that access to a centre's health data and records is secure at all times; conforms with legislative requirements; and is only available to persons named on a centre's licence or authorised by the Person Responsible. Such processes shall include:
- a. establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records, and the transfer of information
 - b. establishing and maintaining procedures to resolve all data discrepancies
 - c. preventing unauthorised disclosure of information whilst guaranteeing the traceability of gamete, embryo or tissue (cell) donations
 - d. considering and responding to applications for access to confidential records and correctly identifying applicants, and
 - e. receiving, checking and arranging authorised access to confidential data and records.
- T45 Access to registers and data must be restricted to persons authorised by the PR and to the Authority for the purpose of inspection and control measures.

HFEA guidance

Confidentiality

- 30.1** Centres must treat all patients with dignity and respect and must take appropriate measures to maintain their confidentiality.
- 30.2** The centre should ensure that information provided in confidence, including all information relating to donors, patients and children born as a result of treatment, is kept confidential and disclosed only in the circumstances permitted by law. The centre should ensure that patients, their partners, and donors do not have access to any other person's records without first getting that person's consent.
- 30.3** If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.
- 30.4** In relation to the treatment of trans patients and donors, there are additional points on confidentiality that must be taken into consideration. The centre should be aware that under the Data Protection Act 1998, information about a person's gender reassignment or any other information relating to a person's gender history will be classed as 'sensitive personal data' and should not be 'processed'. This includes, among other things, not being shared or disclosed unless certain requirements of the Data Protection Act 1998 have been met.

The centre should take appropriate measures to ensure that they comply with strict prohibitions set out under the Gender Recognition Act 2004 on the disclosure of a patient or a donor who has applied for a GRC, or about the gender history of a person who has a GRC.

Centres may wish to seek legal advice if they are uncertain about the lawful use, sharing or disclosure of the sensitive personal data of transgender patients.

See also

Guidance note 29 – Treating people fairly

Guidance note 30 – Confidentiality and privacy



Breach of confidentiality

30.5 If confidentiality is breached (including disclosure of information in breach of either the HFE Act 1990, the Data Protection Act 1998 or the Gender Recognition Act 2004), the centre should investigate the cause(s) of the breach, take appropriate remedial action, deal with the breach, and notify and submit a full explanation to the HFEA that includes what mitigating actions have been put in place to prevent a similar breach taking place. If it appears that a criminal offence has been committed, the centre should inform the police. Consideration should also be given to whether the breach should be reported to the Information Commissioner.

30.6 The centre should be aware that certain breaches of confidentiality pertaining to a person's gender reassignment or gender history may amount to a criminal offence. For example, the disclosure of certain information in breach of the provisions of section 33A of the HFE Act 1990 and section 22 of the Gender Recognition Act 2004. The centre should consider circumstances where they may need to disclose a person's gender reassignment or gender history (eg, to those within the centre who need to know of a trans patient's previous identity to deliver safe and appropriate care), to determine whether it needs to obtain the person's consent to disclose this information.

See also

Guidance note 27 – Adverse incidents



Access to medical records

30.7 For the purposes of this Code of Practice, a record is defined as information created, received and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium provided they are readily accessible, legible and indelible.

30.8 The centre must establish a documented procedure for controlling access to medical records. This should ensure that arrangements are in place for:

- (a) properly identifying applicants
- (b) promptly considering and responding to applications for access to confidential records
- (c) a designated individual in the centre being responsible for receiving, checking and arranging authorised access to confidential records
- (d) notifying the Information Commissioner in line with the Data Protection Act 1998
- (e) giving all individual donors and recipients who provide information about themselves access to their own individual records of that information and an opportunity to correct it
- (f) ensuring proper procedures are in place to maintain confidentiality when records are stored off site, and
- (g) ensuring that individuals are aware of their rights under the Data Protection Act 1998 to access their own medical records.

NOTE When the centre is part of a larger organisation, the appropriate department of the parent organisation may do some of these procedures, where relevant.

30.9 The centre should have clear security procedures to prevent unauthorised access to records, and take particular care if records are kept outside the licensed premises (eg, when counselling takes place outside the centre). The security procedures should be appropriate to the record keeping system, whether paper-based, electronic or in any other format. Extra scrutiny is recommended if the centre has laboratory equipment that stores patient-identifying information electronically.

30.10 To mitigate the risks of unauthorised people inadvertently gaining access to patient-identifying information through electronic records, the centre should:

- (a) ensure that such information cannot be transferred to portable media-storage devices
- (b) ensure that when hardware is removed from the premises, identifying information has been removed
- (c) consider making it a policy that no data is stored on any third-party device unless there is a process for anonymising or deleting the data
- (d) record and audit potential access to identifying information
- (e) have systems in place to reduce the risks of malicious access to data; these systems should include anti-virus software, firewalls, and network segmentation (including user-/network-level usernames and passwords)
- (f) know what software is installed on centre systems and what it allows
- (g) ensure agreements/contracts with the relevant providers set out expectations.

30.11 If the centre's service providers require access to identifying information to do their job, then the centre must take steps to ensure that any person accessing data is suitable.

30.12 A person whose medical records are held by the centre is normally entitled to receive a copy of their own medical records, so long as they ask in writing (including by electronic means) and pay any fee required. The source of the information and an explanation of any unusual or technical terms should be given.

See also

[Guidance note 4 – Information to be provided prior to consent](#)

[Guidance note 31 – Record keeping and document control](#)



Requests under the Data Protection Act 1998

30.13 The centre should comply promptly with 'subject access requests' made under the Data Protection Act 1998. Usually, such requests will be for copies of medical records. The centre must check the identity of the person making the request and may also request written consent and proof of identity from the partners of applicants if the medical record contains information relating to them. The centre may also levy a fee of between £10 and £50 for copying medical records.

30.14 When proof of identity and payment has been received, the centre has 40 calendar days to respond to the request. The centre should be aware that some requests for information may fall under different information access regimes; they must ensure that they comply within the appropriate timeframes (eg, 20 working days under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004).

30.15 The centre should take into account any other exceptions and modifications to the Data Protection Act 1998 before giving access.

Disclosing non-identifying information: general

30.16 The centre may disclose information that does not identify or could not reasonably be expected to lead to the identification of a person owed a duty of confidentiality. If the centre is unsure whether information it proposes to disclose could identify the person, it should seek independent legal advice.

Disclosure authorised by statute

Interpretation of mandatory requirements 30A



A centre may hold information that could lead to the identification of:

- (a) an individual donor or recipient of gametes or embryos (including mitochondrial donation)
- (b) an individual or couple seeking or receiving treatment services (other than basic partner services), or
- (c) an individual who may have been born as a result of such services or as a result of donated sperm.

The centre may disclose this information only in the specific circumstances set out in the HFE Act 1990 (as amended). The information may, for example, be disclosed:

- (a) to anyone, provided that it is disclosed in such a way that no individual can be identified from it
- (b) to the Authority
- (c) to another licensed centre to enable that centre to carry out its functions under its licence
- (d) to the person to whom the information relates, and to their partner (if they are being treated together, or their partner has served notice of consent to be treated as the legal parent of any resulting child)
- (e) with the consent of each person who could be identified from the information (although disclosure in this case is limited to information other than that from which a donor of gametes could be identified)
- (f) in connection with specific proceedings, including, for example, in relation to the formal complaints procedure, or
- (g) in an emergency, if disclosure is necessary to avert imminent danger to the health of the person to whom the information relates, and it is not reasonably practicable to obtain their consent to disclosure.

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

30.17 If the centre refers a person seeking treatment to another licensed centre, it should provide relevant information in line with good clinical practice. The centre must always supply information relevant to the welfare of the child.



Guidance note 8 – Welfare of the child

Disclosing information to gamete and embryo donors

Interpretation of mandatory requirements 30B



A donor may request information from a centre about the number, sex and birth year of any children born using their gametes or embryos (including mitochondrial donation). If the centre holds that information, it must provide it unless the person responsible considers that special circumstances exist that increase the likelihood of the donor being able to identify any of those children.

Once a person conceived using donor gametes reaches the age of 16, they may ask the Authority to give them certain non-identifying information about the donor and the number, sex and year of birth of any donor-conceived siblings.

Once a person conceived using donor gametes reaches the age of 18, they may also ask the Authority for certain identifying information about the donor, where that information was provided to the centre after the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 came into force.

30.18 The HFEA will seek to inform donors of gametes and embryos that it has received an application by a donor-conceived person for identifying information about them. The HFEA will not give the donor any information about the person making the application.

Disclosing information to recipients of donated gametes and embryos

30.19 The centre may give non-identifying information about the donor to those who receive donor-assisted conception treatment or treatment involving mitochondrial donation and those who have received such treatment in the past.

30.20 The HFEA may also disclose the information that centres may disclose in these circumstances, if that information is contained on its Register.

30.21 The centre should:

- (a) reassure donors and potential donors that they may ask at any time how many children have resulted from their donation
- (b) reassure identifiable donors that attempts will be made to contact them before their identity is disclosed to a donor-conceived person
- (c) encourage identifiable donors to provide up-to-date contact details to help this, and
- (d) respond as fully as possible to patients' requests for non-identifying information about the donor(s) used in their treatment.

Consent to disclose identifying information

Interpretation of mandatory requirements 30C



Patients have the right to decide what identifying information should be disclosed and to whom. Centres should obtain a patient's written consent before disclosing information relating to their

treatment (or providing gametes for a partner's treatment), or storage of their gametes or embryos.

In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or storage. For example, if a patient's partner could be incidentally identified through disclosure of information about a patient's treatment.

If a child born as a result of treatment could be identified, consent must be obtained from the parent(s), unless identification is necessarily incidental to the disclosure of information about the patient's treatment. Once a child born as a result of treatment is considered competent to consent, then their consent (if given) will override the consent of the parent(s).

30.22 Before obtaining consent to disclose information, the centre should give the person enough information for them to make a properly informed decision, including:

- (a) precisely what information is to be disclosed
- (b) the terms on which it is disclosed
- (c) the reasons for disclosure (eg, to keep the person's GP informed about the fertility treatment)
- (d) the implications of disclosure, in particular the fact that, once it is disclosed, the information will be subject no longer to the special provisions of the HFE Act 1990 (as amended) but only to the general law of confidentiality, and
- (e) the categories of people to whom the information is to be disclosed.

30.23 The centre should seek consent to disclosure to the following categories of people:

- (a) the patient's GP or the patient's partner's GP
- (b) other healthcare professionals outside the centre (to enable them to provide the patient or the patient's partner with the best possible medical care)
- (c) auditors or administrative staff outside of the centre (to enable them to perform functions designated to them in connection with the centre's licensable activities), and
- (d) medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).

30.24 The centre should renew consent to disclosure if the nature of the treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used instead of the patient's own, or if the patient moves from unlicensed to licensed fertility treatment).

30.25 The centre should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:

- (a) the precise terms upon which it was disclosed and for which consent has been given, and
- (b) that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.

See also

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

[Guidance note 31 – Record keeping and document control](#)

HFEA consent forms



Other legislation, professional guidelines and information

Legislation

Access to Health Records Act 1990

The Access to Health Records (Northern Ireland) Order 1993

Data Protection Act 1998

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

European Convention for the Protection of Human Rights and Fundamental Freedoms

Equalities Act 2010

Gender Recognition Act 2004

Human Rights Act 1998

Professional guidelines

Care Quality Commission: Code of Practice – confidential personal information (2016)

National Health Service: Code of Practice – confidentiality (2003)

General Medical Council: Confidentiality guidance – protecting information (2009)

Information Commissioner's Office: upholds information rights in the public interest

National Health Service Digital: Code of Practice for health and social care – records management (2016)

Annex H – Guidance note 31 (Record keeping and document control)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

31. Record keeping and document control

Version 4.0

Mandatory requirements

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

12 General conditions

(1) The following shall be conditions of every licence granted under this Act—

...

(b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity),...

...

(d) that proper records shall be maintained in such form as the Authority may specify in Directions,...

...

(g) that the Authority shall be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

(2) Subsection (3) applies to—

(a) every licence under paragraph 1 or 1A of Schedule 2,

(b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application, and

(c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(3) Subsection (3) applies to—

(a) every licence under paragraph 1 or 1A of Schedule 2,

- (b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application, and
- (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

13 Conditions of licences for treatment

- (2) Such information shall be recorded as the Authority may specify in Directions about the following—
 - (a) the persons for whom services are provided in pursuance of the licence,
 - (b) the services provided for them,
 - (c) the persons whose gametes are kept or used for the purposes of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used,
 - (d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence,
 - (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
 - (f) such other matters as the Authority may specify in Directions.
- (3) The records maintained in pursuance of the licence shall include any information recorded in pursuance of subsection (2) above and any consent of a person whose consent is required under Schedule 3 to this Act.
- (4) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.

Schedule 3B - Inspection, entry, search and seizure - Inspection of statutory records

- (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.
- (2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—
 - (a) in a visible and legible form, or
 - (b) in a form from which they can be readily produced in a visible and legible form.
- 3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

Licence conditions

- T34 A document control procedure must be established that records the history of document reviews and ensures that only current versions of documents are in use.
- T37 Proper records must be maintained in such form as the Authority may specify in Directions.
- T38 Records must be legible and indelible and may be hand written or transferred to another validated system, such as a computer or microfilm.
- T39 Such information must be recorded as the Authority may specify in Directions about the

following:

- a. the persons for whom services are provided in pursuance of the licence,
- b. the services provided for them
- c. the persons whose gametes are kept or used for the purpose of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used
- d. any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence
- e. any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo
- f. such information as the Authority may specify in directions as to the persons whose consent is required under schedule to the Human Fertilisation and Embryology Act 1990 (as amended), the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions must be included in the records maintained in pursuance of the licence, and
- g. such other matters as the Authority may specify in Directions.

T40 Information must not be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.

T42 Where gametes or embryos are supplied to a person to whom another licence applies, that person must be provided with such information as the Authority may specify in Directions.

T46 For each patient/donor the centre must maintain a record containing:

- a. patient/donor identification: first name, surname, date of birth, age and sex
- b. how, and by whom, the patient/donor has been reliably identified
- c. the services provided to them
- d. medical history
- e. welfare of the child assessment
- f. consent, including the purpose or purposes for which their gametes or embryos created using their gametes may be used, and any specific instructions for use and/or disposal, and
- g. clinical and laboratory data and the results of any test carried out.

T47 All records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

T48 Patient/donor records required for full traceability must be kept for a minimum of 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority.

Directions

0001 – Gametes and embryos

0003 – Multiple births

0005 – Collecting and recording information for the HFEA

0007 – Consent

0012 – Retention of records

HFEA guidance

Records to keep

31.1 This guidance note does not summarise all the record keeping requirements of a licensed centre. The person responsible should familiarise themselves with these, which are discussed in the following guidance notes:

- 2 – Staff
- 3 – Counselling
- 4 – Information to be provided prior to consent
- 5 – Consent to treatment, storage, donation, and disclosure of information
- 6 – Legal parenthood
- 7 – Multiple births
- 8 – Welfare of the child
- 9 – Preimplantation genetic screening (PGS)
- 11 – Donor recruitment, assessment and screening
- 12 – Egg sharing arrangements
- 15 – Procuring, processing and transporting gametes and embryos
- 16 – Imports and exports
- 17 – Storage of gametes and embryos
- 18 – Witnessing and assuring patient and donor identification
- 19 – Traceability
- 21 – Intra-cytoplasmic sperm injection (ICSI)
- 22 – Research and training
- 23 – The quality management system
- 24 – Third party agreements
- 26 – Equipment and materials
- 27 – Adverse incidents
- 28 – Complaints
- 29 – Treating people fairly
- 30 – Confidentiality and privacy
- 32 – Obligations and reporting requirements of centres
- 33 – Mitochondrial donation

Definitions

31.2 A record is defined as ‘information created or received, and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium providing they are readily accessible, legible and indelible.’

31.3 A documented procedure is defined as ‘a set of written instructions describing the steps in a specific process, including the materials and methods to be used, and the expected end product. This term has the same meaning as standard operating procedures.’

Document control

31.4 The centre should have document control procedures in place to:

- (a) ensure that all documents include:
 - (i) a unique identifier (for instance, the edition, or current revision date or revision number)
 - (ii) page numbers and total number of pages (for example 'page 3 of 10')
 - (iii) authority for their issue, and
 - (iv) author identification
- (b) control all records required to:
 - (i) provide evidence of conforming to legal requirements
 - (ii) operate the quality management system effectively, and
 - (iii) conduct assisted conception processes.

The procedures must cover the identification, collection, indexing, access, storage, maintenance, confidentiality and safe disposal of records.

See also

[Guidance note 23 – The quality management system](#)



- 31.5** A centre that treats trans patients should be aware that other than in a limited number of circumstances, it is unlawful to disclose information about a trans patient's gender reassignment, gender history or application for a Gender Recognition Certificate (GRC). Centres treating trans patients should give consideration to the need or justification for collecting this information, and should have appropriate processes in place to secure that it is only disclosed to those members of the clinical team who need to know to deliver safe and appropriate care or for other lawful reasons. When considering disclosure of information pertaining to trans patients, centres may wish to seek advice from appropriately experienced information law specialists.
- 31.6** Where a trans person, who has previously been a patient, has since taken on a new identity or has obtained a GRC, centres should accurately update medical records to reflect the patient's newly acquired identity. This does not necessarily mean erasing records containing the patient's previous identity, but ensuring appropriate measures are put in place to ensure all records pertaining to future treatment reflect the patient's acquired identity.
- 31.7** When a centre registers a donor with the HFEA, they are required to indicate the donor's gender which must correlate with the gametes being donated (eg, if the donor is donating sperm they must be recorded as a male). However, clinics may add a comment when submitting this information to the HFEA to indicate a trans person's preferred gender, where the donor has consented to disclosure of this information to the HFEA.
- 31.8** When a centre's document control system allows documents to be amended by hand pending their re-issue, the procedures and authority for such amendments should be defined; amendments should be clearly marked, initialled and dated; and a revised document should be re-issued as soon as practicable.

- 31.9** Documents should be reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months.
- 31.10** Access to registers and data must be restricted to people authorised by the person responsible and the HFEA for inspection purposes.

See also

[Guidance note 30 – Confidentiality and privacy](#)



Managing information

- 31.11** The centre should establish documented procedures for managing data and information. These should include:
- (a) accurate recording of information
 - (b) security of data and safeguards against unauthorised modification, addition, deletion, disclosure or transfer of information
 - (c) resolution of data discrepancies
 - (d) maintenance and disaster recovery
 - (e) storage, archiving and retrieval, and
 - (f) secure disposal.
- 31.12** If using off-site storage facilities for archived records, the centre should establish procedures to ensure patient confidentiality is maintained. These should include:
- (a) removal of all patient identifying information that might be visible to staff outside the licensed centre, and
 - (b) ensuring files are properly sealed when they are being transported between the centre and storage facility.

Other legislation, professional guidelines and information

Legislation

[Equality Act 2010](#)

[Gender Recognition Act 2004](#)

Updates to the Code of Practice in October 2017

Strategic delivery	<input checked="" type="checkbox"/> Safe, ethical, effective treatment	<input type="checkbox"/> Consistent outcomes and support	<input type="checkbox"/> Improving standards through intelligence
Details			
Meeting	Authority		
Agenda item	11		
Paper number	HFEA (28/06/2017) 845		
Meeting date	28 June 2017		
Author	Anjeli Kara, Regulatory Policy Manager		
Output			
For information or decision?	For decision		
Recommendation	Agree to the proposed amendments to the Code of Practice. These changes will be introduced in October 2017.		
Resource implications	Within budget		
Implementation date	2 October 2017		
Communication(s)	Code of Practice, Chair's Letter and Clinic Focus article		
Organisational risk	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Medium	<input type="checkbox"/> High
Annexes	Annex A: General Directions 0008 (page 6) Annex B: Guidance note 33 (Mitochondrial donation) (page 13) Annex C: Guidance note 25 (Premises, practices and facilities) (page 31)		

1. Overview

- 1.1.** The Human Fertilisation and Embryology Act 1990 (as amended) (the Act) covers the use and storage of sperm, eggs and embryos for human application, as well as all research involving the use of live human and admixed embryos. One way we help licensed clinics to comply with the Act and relevant legislation is by publishing a Code of Practice. This enables us to meet our statutory duty under the Act to maintain a document that provides guidance on licensed activities to professionals that perform them. Guidance within the Code of Practice also serves as a useful reference for patients, donors, donor-conceived people and researchers.
- 1.2.** We periodically update Code of Practice guidance and other regulatory tools (such as General Directions) to reflect technological and clinical advances in the sector, and provide clarification – typically in April and October. By reviewing the Code of Practice, we aim to ensure that it:
- (a) reflects our current interpretation of the law and regulatory practice
 - (b) is fit for purpose, and
 - (c) makes our regulatory requirements clear, while maintaining regulatory effectiveness.
- 1.3.** This update to the Code of Practice seeks to introduce or update guidance following feedback we have received from both the sector (on a day-to-day operational basis) and in-house from inspectors. The following areas are to be introduced or updated in this update:
- guidance on treating trans patients and donors
 - guidance on embryo research ethics approval, and
 - other minor amendments and corrections (including adding links to useful external information).
- Guidance on treating trans patients and donors, and embryo research ethics approval are formally set out at Authority papers HFEA (28/06/2017) 844 and HFEA (28/06/2017) 843, respectively. They have been noted in this paper to demonstrate what will be included in this update and for completeness.
- 1.4.** The justification for making amendments to the Code of Practice, General Directions and consent forms in this update are set out below. We ask that the Authority considers and agrees to all amendments to Code of Practice guidance and General Directions, so that they may be implemented on 2 October 2017.

2. Treating trans patients and donors

- 2.1.** Authority paper HFEA (28/06/2017) 844 suggests ways we can introduce guidance to clinics on treating trans patients and donors. That paper refers to work we undertook, in response to the increasing number of enquiries we have received from fertility clinics and the public about how they can provide better care for trans patients and donors.
- 2.2.** To briefly recap, while our Code of Practice currently refers to gender reassignment and other protected characteristics under references to the Equality Act 2010, and we remind clinics of their obligation not to discriminate under equalities legislation, we do not have adequate patient information, guidance for the sector, or a way for a trans patient to record their consent.
- 2.3.** To help clinics treat trans patients and donors, we propose introducing Code of Practice guidance on how clinics should care for and treat trans patients. Guidance notes 4 (Information to be provided prior to consent), 5 (Consent to treatment, storage, donation, training and disclosure of information), 6 (Legal parenthood), 11 (Donor recruitment, assessment and screening), 17 (Storage of gametes and embryos), 29 (Treating people fairly), 30 (Confidentiality and privacy) and 31 (Record keeping and document control) will address:
 - General information on treating trans patients and donors
 - Disclosure of information about a patient's gender reassignment (or any other information pertaining to their gender history)
 - Verifying trans patient identity, and
 - Legal parenthood.

Recommendation

- 2.4.** Draft guidance and further information on the abovementioned piece of work can be found at Authority paper HFEA (28/06/2017) 844. The Authority is asked to agree to the proposed changes to the Code of Practice.

3. Guidance for clinics on research ethics approval

- 3.1.** Authority paper HFEA (28/06/2017) 843 sets out options for facilitating embryo research and increasing the availability of embryos. That paper refers to work to clarify the requirements for establishing an independent ethics committee for clinics or laboratories not using the standard research ethics process.
- 3.2.** Before submitting an application for a research licence, applicants are required to acquire independent research ethics committee approval. Through our work with stakeholders and inspectors, we have heard that it can often be problematic to gain ethics approval – particularly for private clinics.
- 3.3.** To help improve the research application process, we propose updating General Directions 0008 to highlight that independent research conducted by research centres can seek ethics approval from the NHS Research Ethics Committee (ie, the committee that provide ethical approval to research involving

NHS patients). It will also clarify that research centres can also seek ethics approval from an independent ethics committee, and set out our expectations on the composition of an independent ethics committee.

Recommendation

- 3.4.** Draft changes to General Directions can be found at Annex A to this paper. The Authority is asked to agree to the proposed changes.

4. Mitochondrial donation

- 4.1.** In December 2016, the Authority took the decision to approve the use of mitochondrial donation in clinical practice in certain, specific, cases. As a result, clinics should only offer mitochondrial donation to patients for whom preimplantation genetic diagnosis (PGD) would be considered inappropriate, or unlikely to succeed.
- 4.2.** While changes were made to the Code of Practice and General Directions in May 2017 to reflect this decision, we propose making very minor corrections to guidance note 33 (Mitochondrial donation) and General Directions 0008 in this update to ensure terminology and phrasing is consistent with other mitochondrial donation materials, provide clarity and avoid confusion. Changes will be made as follows:
- General Directions 0008: Section L19 will see 'A documented rationale of why PGD may be deemed inappropriate and likely to be unsuccessful.' become 'An application should include information that demonstrates why PGD may be deemed inappropriate or likely to be unsuccessful, ensuring that the patient identified for treatment is (or is predicted to be) highly heteroplasmic or homoplasmic for a particular mtDNA mutation in their germ line' (see Annex A), and
 - Guidance note 33 (Mitochondrial donation): Section 33.6 will see '...The centre should only offer MST or PNT to patients for whom PGD is inappropriate and likely to be unsuccessful and who exhibit (or are predicted to exhibit) high levels of germ line heteroplasmy or homoplasmy....' become '...The centre should only offer MST or PNT to patients for whom PGD is inappropriate or likely to be unsuccessful and who exhibit (or are predicted to exhibit) high levels of germ line heteroplasmy or homoplasmy....' (see Annex B).
- 4.3.** Our position on whom should be eligible for mitochondrial donation remains unchanged.

Recommendation

- 4.4.** Draft amendments to guidance and General Directions can be found at Annexes A and B to this paper. The Authority is asked to agree to the

clarification.

5. Medicines management

- 5.1.** To help clinics fulfil their obligations under medicines management, a link to our guide on medicines management – ‘Supplying and dispensing medicines for self-administration’ – will be referenced in guidance note 25 (Premises, practices and facilities) as useful additional information.

Recommendation

- 5.2.** The amendment to guidance note 25 can be found at Annex C to this paper. The Authority is asked to agree to the addition of the abovementioned links.

6. Recommendations and next steps

- 6.1.** The Authority is asked to consider and agree to the recommendations made throughout the paper, subject to Plain Language checks. Where amendments involve consent forms, the Authority is asked to note changes for information.
- 6.2.** All changes will be incorporated in the October 2017 update to the Code of Practice.

Annex A – General Directions 0008

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.



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

Information to be submitted to the Human Fertilisation and Embryology Authority as part of the licensing process

**Ref: 0008
Version: 6**

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 12(1)(g) and 19B(1)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version was issued on:	2 October 2017

General requirement relating to all applications to the Authority

1. Applications to the Authority relating to categories A-M must be made by completing and submitting the relevant on-line application, together with relevant supporting information detailed below, via the 'electronic portal' located on the [Authority's website](#). An application fee (details of current fees payable are available on the Authority's website) must also be submitted.

2. Failure to submit a fully completed application form, pay the application fee or provide all the necessary information set out below will, in normal circumstances, result in the application not being considered until such times as these requirements have been satisfied.
3. Persons Responsible for centres which are licensed by the Authority to carry out licensed activities (treatment, storage, non-medical fertility services or research) must at all times have available the information set out in iv-xiv of paragraph 4 of this Direction and submit this information to the Authority when requested no later than 10 working days after the date of any written request.

Information to be supplied with applications

A. Applications for a new (initial) treatment, storage and non-medical fertility services licence

4. An application for a new licence authorising:
 - (a) activities in the course of providing treatment services; and/or
 - (b) the storage of gametes, embryos or human admixed embryos; or
 - (c) activities in the course of providing non-medical fertility services,
 - (d) must be accompanied by the information specified below:
 - i) where the proposed Person Responsible is not the applicant, a written confirmation from the proposed Person Responsible that the application is made with his or her consent;
 - ii) a current CV of the proposed Person Responsible listing academic and professional qualifications; work experience and registration details with the relevant professional body;
 - iii) a current CV of the proposed Licence Holder listing academic and professional qualifications; work experience and registration details with the relevant professional body;
 - iv) the Person Responsible Entry Programme ("PREP") certificate number confirming satisfactory completion of the PREP by the proposed Person Responsible;
 - v) a floor plan of the premises to be referenced on the licence;
 - vi) a suite of information documents to be provided to patients undergoing treatment at the centre once licensed;
 - vii) a completed self-assessment questionnaire submitted via the electronic portal;
 - viii) a copy of the centre's organisational chart clearly defining accountability and reporting relationships for named individuals;
 - ix) evidence that staff are registered with a professional or statutory body and are appropriately qualified and trained in techniques relevant to their work, or are in a programme of supervised training;
 - x) a copy of the centre's induction and training programme that ensures that staff have adequate knowledge of the scientific and ethical principles, together with the regulatory context, relevant to their work;
 - xi) evidence that a robust quality management system is in place;
 - xii) a statement that all the equipment and processes to be used in activities authorised by a licence, and in other activities carried out in the course of providing treatment services that do not require a licence, have been validated;
 - xiii) a detailed list of the quality indicators, a schedule of the audit programme and the reporting arrangements established for all activities authorised by a licence, and other activities carried out in the course of providing treatment services that do not require a licence; and
 - xiv) a copy of the centre's multiple birth minimisation strategy (where applicable).

B. Applications to renew a treatment, storage or non-medical fertility services licence

5. An application for the renewal of a licence authorising:

- (a) activities in the course of providing treatment services; and/or
- (b) the storage of gametes, embryos or human admixed embryos; or
- (c) activities in the course of providing non-medical fertility services,
- (d) must be accompanied by the information specified below:
 - i) where the Person Responsible is not the applicant, a written confirmation from the Person Responsible that the application is made with his or her consent;
 - ii) a completed self-assessment questionnaire; and
 - iii) a suite of information documents to be provided to patients undergoing treatment at the centre (if different to those submitted with the original or previous renewal application).

C. Applications to vary the activities authorised by a current treatment, storage or non-medical services licence

6. An application to vary the activities authorised by a current licence in the course of providing treatment services or non-medical fertility services must be accompanied by the information specified below:

- (a) copies of information provided to patients relating to the new activity;
- (b) evidence that the process(es) and, where applicable, the equipment used in carrying out the new activity have been validated; and
- (c) a schedule of the quality indicators, and reporting arrangements, established for this activity.

7. An application to vary a licence to allow mitochondrial donation through maternal spindle transfer (MST) or pronuclear transfer (PNT) must be accompanied by the information specified below:

- (a) copies of information provided to patients and donors relating to treatment involving mitochondrial donation and the benefits of participating in follow-up;
- (b) information to demonstrate the competence of the embryologist(s) proposed to conduct the technique(s) being applied for, as follows:
 - i) a CV and references of the embryologist(s), to support their experience and knowledge
 - ii) key performance indicator data relating to the proposed embryologist's/embryologists' experience in carrying out the technique(s) on human eggs or embryos as follows:
 - a. whether they have carried out the techniques in treatment, training or research
 - b. embryo survival rates – must exceed 70%
 - c. blastocyst development rates – which must be no less than 50% of that observed in the control embryos at day five. Where possible, controls should be age-matched to the karyoplast donor
 - d. rate of carryover of mtDNA – should not, on average, exceed 2% and no greater than 10% per embryo
 - iii) any other information that may demonstrate competence (such as their experience of performing micro-manipulation on human or animal (eg, mice) eggs or embryos)
- (c) evidence that the equipment, and process(es) where applicable, used in carrying out the new technique(s) has been validated;
- (d) a schedule of the quality indicators, and reporting arrangements, established for the new treatments; and
- (e) procedures for the follow-up of children born as result of mitochondrial donation, including the arrangements the centre has in place with a mitochondrial disease expert centre.

An application to add or vary the name of the embryologist(s) practising MST or PNT need only include section 7(b) (i-iii).

D. Application to carry out a licensed activity using a 'novel' process

8. Where centres want to carry out a licensed activity using a process that has not been authorised by the Authority, an application must be accompanied by the information specified below:
- (a) copies of information provided to patients relating to the new activity;
 - (b) evidence that the process and, where applicable, the equipment used in carrying out the new activity have been validated; and
 - (c) a schedule of the quality indicators, and reporting arrangements, established for this process.

E. Application for a new (initial) research licence

9. An application for a new licence authorising activities for a research project must be accompanied by the information specified below:
- (a) where the proposed Person Responsible is not the applicant, a written confirmation from the proposed Person Responsible that the application is made with his or her consent;
 - (b) the PR Entry Programme ("PREP") certificate number confirming satisfactory completion of the PREP (for Person Responsible appointed after 1 October 2009);
 - (c) a floor plan of the premises to be specified on the licence;
 - (d) copies of all information provided to patients and/or donors relating to the proposed research project;
 - (e) copies of the consent forms to be used to authorise the use of gametes, embryos or human cells in the research project;
 - (f) evidence of ethics approval of the research project from a properly constituted research ethics committee
- This will normally be a NHS Research Ethics Committee (NHS REC). Research centres outside the NHS may refer projects to a NHS REC or may establish (or seek approval from) an independent ethics committee. The independent ethics committee will be considered to be properly constituted if it meets the standards set out in relevant Health Research Authority guidance; and
- (g) a completed self-assessment questionnaire.
10. For applications for a new licence authorising activities in connection with the derivation from embryos of stem cells that are intended for human application, the following additional information must be submitted with the application:
- (a) evidence that the proposed Person Responsible possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent and has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence; and
 - (b) evidence that the centre has, or is obtaining, a licence from the Human Tissue Authority.

F. Application to renew a research licence

11. An application for the renewal of a licence authorising activities for a research project must be accompanied by the information specified below:
- (a) a completed self-assessment questionnaire;
 - (b) evidence of ethics approval of the research project from a properly constituted research ethics committee;

- (c) copies of all information provided to patients and/or donors relating to the proposed research project (if different to those submitted with the original or previous renewal application); and
- (d) copies of the consent forms to be used to authorise use of gametes, embryos or human cells in the research project (if different to those submitted with the original or previous renewal application).

12. For applications to renew a licence authorising activities in connection with the derivation from embryos of stem cells that are intended for human application, the following additional information must be submitted with the application:

- (a) evidence that the centre has a licence from the Human Tissue Authority.

G. Applications to vary a research licence to vary the purposes for which the research is licensed

13. An application to vary a research licence to vary the purposes for which the current research is licensed must be accompanied by the information specified below:

- (a) evidence of ethics approval of the research project from a properly constituted research ethics committee;
- (b) copies of all information provided to patients and/or donors relating to the proposed research project (if different to those submitted with the original or previous renewal application); and
- (c) copies of the consent forms to be used to authorise use of gametes, embryos or human cells in the research project (if different to those submitted with the original or previous renewal application).

H. Applications to vary a licence to either relocate to new premises or change existing premises

14. An application to vary a licence to either relocate to new premises not authorised by a current licence for the conduct of licensed activities (treatment, storage, research and non-medical fertility services) or to alter premises authorised by a current licence for the conduct of licensed activities (treatment, storage, research and non-medical fertility services) must be accompanied by the information specified below:

- (a) where the Person Responsible is not the applicant, a written confirmation from the Person Responsible that the application is made with his or her consent;
- (b) a floor plan of the premises to be referenced on the licence, and;
- (c) confirmation that any re-commissioned equipment has been tested and validated.

I. Applications to change the Person Responsible or the Licence Holder

15. An application to change the Person Responsible or the Licence Holder of a licence authorising licensed activities (treatment, storage, research and non-medical fertility services) must be accompanied by the information specified below:

- (a) a current CV of the proposed Person Responsible listing academic and professional qualifications; work experience and registration details with the relevant professional body;
- (b) a current CV of the proposed Licence Holder listing academic and professional qualifications; work experience and registration details with the relevant professional body; and
- (c) the PR Entry Programme ("PREP") certificate number confirming satisfactory completion of the PREP (applications for a change of PR only).

J. Applications to authorise preimplantation genetic diagnosis

16. An application to authorise preimplantation genetic diagnosis (PGD) for a condition which has not previously been authorised by the Authority is subject to an application as per paragraph 1.

K. Applications to authorise human leukocyte antigen tissue typing

17. An application to authorise human leukocyte antigen (HLA) tissue typing, in isolation or in conjunction with PGD must be accompanied by the information specified below:
- (a) a copy of a signed letter of support from a clinician responsible for the care of the sibling child providing information on the:
 - i) degree of suffering associated with the disease of the affected sibling,
 - ii) speed of degeneration in progressive disorders,
 - iii) prognosis for the affected sibling in relation to all treatment options available,
 - iv) availability of alternative sources of tissue for the treatment of the affected sibling, now and in the future, and
 - v) availability of effective therapy for the affected sibling now and in the future.

L. Applications to authorise mitochondrial donation for a specific patient

18. Applications for authorisation of mitochondrial donation for a specific patient must be made by completing the relevant application and submitting this to the HFEA.
19. A documented rationale of An application should include information that demonstrates why PGD may be deemed inappropriate and or likely to be unsuccessful, ensuring that the patient identified for treatment is (or is predicted to be) highly heteroplasmic or homoplasmic for a particular mtDNA mutation in their germ line.

M. Applications for Special Directions to export gametes or embryos

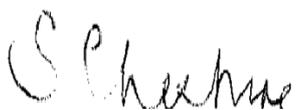
20. An application for a Special Direction to export gametes or embryos must be accompanied by the information specified below:
- (a) a letter from the intended export destination centre/clinic confirming that it is willing to accept the gametes or embryos for the purpose specified in the application form.

Notifying the Authority of information relating to licensed activities

21. Persons Responsible must notify the Authority, through the electronic portal located on the Authority's website, of all processes undertaken in the licensed centre in carrying out a licensed activity.

Additional information to be submitted to the Authority as part of on-going compliance

22. Persons Responsible for centres licensed by the Authority must complete and submit to the Authority the self-assessment questionnaire (SAQ) published on the Authority's website no later than six weeks prior to the date on which the Authority has confirmed it will carry out an inspection visit. Before submitting the SAQ, Persons Responsible must confirm that the information they have provided on that document is true and accurate.
23. Where a member of the Authority's Compliance Department requests the Person Responsible to submit a further SAQ in addition to that required by paragraph 21 above, the Person Responsible must submit this to the Authority no later than 15 working days after the date of the written request.
24. Where a member of the Authority's Compliance Department requests the Person Responsible to submit a further PREP, the Person Responsible must submit this to the Authority no later than 21 working days after the date of the written request.


Sally Cheshire**28 June 2017**

Chair, Human Fertilisation and Embryology Authority

Version control	
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Annex B – Guidance note 33 (Mitochondrial donation)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

33. Mitochondrial donation

Version 3.0

Mandatory requirements

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

In cases where an egg or embryo has been created following mitochondrial donation, the following provisions of the HFE Act 1990 should be read so that they are modified as set out below:

3 Prohibitions in connection with embryos

(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except--

(a) in pursuance of a licence, or

(b) in the case of--

(i) the keeping, without storage, of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo,

in pursuance of a third party agreement.

(1B) No person shall procure or distribute an embryo intended for human application except in pursuance of a licence or a third party agreement.

(2) No person shall place in a woman--

(a) an embryo other than a permitted embryo (as defined by section 3ZA), or

(b) any gametes other than permitted eggs or permitted sperm (as so defined).

(3) A licence cannot authorise--

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal, or

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, ...

(d)

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with [the day on which the process of creating the embryo began], not counting any time during

which the embryo is stored.

3ZA Permitted eggs, permitted sperm and permitted embryos

- (1) This section has effect for the interpretation of section 3(2).
- (2) A permitted egg is one--
 - (a) which has been produced by or extracted from the ovaries of a woman, and
 - (b) whose nuclear or mitochondrial DNA has not been altered.
- (3) Permitted sperm are sperm--
 - (a) which have been produced by or extracted from the testes of a man, and
 - (b) whose nuclear or mitochondrial DNA has not been altered.
- (4) An embryo is a permitted embryo if--
 - (a) it has been created by the fertilisation of a permitted egg by permitted sperm,
 - (b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and
 - (c) no cell has been added to it other than by division of the embryo's own cells.
- (5) Regulations may provide that--
 - (a) an egg can be a permitted egg, or
 - (b) an embryo can be a permitted embryo,

even though the egg or embryo has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.
- (6) In this section--
 - (a) "woman" and "man" include respectively a girl and a boy (from birth), and
 - (b) "prescribed" means prescribed by regulations.]

Modification of section 31ZA: Request for information as to genetic parentage or mitochondrial donors etc,

- (1) A person who has attained the age of 16 ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2) or (2A).
- (2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person ("the donor") other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that—
 - (a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information), or
 - (b) stating whether or not that information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so—
 - (i) the number of those other persons,
 - (ii) the sex of each of them, and
 - (iii) the year of birth of each of them.
- (2A) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person is the applicant's

mitochondrial donor, and if it does show that, giving the applicant the following information contained in the register—

- (a) the screening tests carried out on the mitochondrial donor and information on that donor's personal and family medical history,
 - (b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and
 - (c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person who requests information under this section, but not giving any information which may identify the mitochondrial donor or any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor, by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.
- (3) The Authority shall comply with a request under subsection (2) if—
- (a) the information contained in the register shows that the applicant is a relevant individual, and
 - (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (3A) The Authority must comply with a request under subsection (2A) if—
- (a) the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, and
 - (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (4) Where a request is made under subsection (2)(a) and the applicant has not attained the age of 18 when the applicant gives notice to the Authority under subsection (1), regulations cannot require the Authority to give the applicant any information which identifies the donor.
- (5) Regulations under subsection (2)(a) cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority could not have been required to give information of the kind in question.
- (6) The Authority need not comply with a request made under subsection (2)(b) by any applicant if it considers that special circumstances exist which increase the likelihood that compliance with the request would enable the applicant—
- (a) to identify the donor, in a case where the Authority is not required by regulations under subsection (2)(a) to give the applicant information which identifies the donor, or
 - (b) to identify any person about whom information is given under subsection (2)(b).
- (7) In this section—

“relevant individual” has the same meaning as in section 31;

“the relevant statutory provisions” means sections 27 to 29 of this Act and sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.

(8) In this section and sections 31ZB to 31ZE—

“mitochondrial donor-conceived person” means a person who was or may have been born in consequence of treatment services using—

- (a) an egg which is a permitted egg for the purposes of section 3(2) by virtue of regulations under section 3ZA(5), or
- (b) an embryo which is a permitted embryo for those purposes by virtue of such regulations;

the “mitochondrial donor” in respect of a person who was or may have been born in consequence of treatment services using such a permitted egg or such a permitted embryo is the person whose mitochondrial DNA (but not nuclear DNA) was used to create that egg or embryo.

Modification of section 31ZD: Provision to donor of information about resulting children

- (1) This section applies where a person (“the donor”) has consented under Schedule 3 (whether before or after the coming into force of this section) to—
 - (a) the use of the donor’s gametes, or an embryo the creation of which was brought about using the donor’s gametes, for the purposes of treatment services provided under a licence, or
 - (b) the use of the donor’s gametes for the purposes of non-medical fertility services provided under a licence.
- (2) In subsection (1)—
 - (a) “treatment services” do not include treatment services provided to the donor, or to the donor and another person together, and
 - (b) “non-medical fertility services” do not include any services involving partner-donated sperm.
- (3) The donor may by notice request the appropriate person to give the donor notice stating—
 - (a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,
 - (ab) the number of persons in respect of whom the donor is a mitochondrial donor,
 - (b) the sex of each of those persons, and
 - (c) the year of birth of each of those persons.
- (4) Subject to subsections (5) to (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.
- (5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify the persons falling within paragraphs (a) to (c) of subsection (3).
- (6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the

person responsible and the person responsible—

- (a) has notified the donor that the information concerned is not held, or
 - (b) has failed to comply with the request within a reasonable period.
- (7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible—
- (a) has notified the donor that the information concerned is not held, or
 - (b) has failed to comply with the request within a reasonable period.
- (8) In this section “the appropriate person” means—
- (a) in the case of a donor who consented as described in paragraph (a) of subsection (1)—
 - (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or
 - (ii) the Authority, and
 - (b) in the case of a donor who consented as described in paragraph (b) of subsection (1)—
 - (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or
 - (ii) the Authority.
- (9) In this section “the relevant statutory provisions” has the same meaning as in section 31ZA.

Modification of paragraph 4 of Schedule 3

Variation and withdrawal of consent

- (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.
- (1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “egg A” and “egg B” have the same meanings in this paragraph as in that regulation).
- (1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.
- (2) Subject to sub-paragraphs (3) to (3B), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used—
 - (a) in providing treatment services,
 - (aa) in training persons in embryo biopsy, embryo storage or other embryological

techniques, or

- (b) for the purposes of any project of research.
- (3) Where the terms of any consent to the use of an embryo (“embryo A”) include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).
- (3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “embryo A” and “embryo B” have the same meanings in sub-paragraph (3B) as in that regulation).
- (3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.
- (4) Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.
- (5) Where the terms of any consent to the use of a human admixed embryo (“human admixed embryo A”) include consent to the use of a human admixed embryo or embryo whose creation may be brought about in vitro using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research.

Modification of paragraph 22 of Schedule 3 (paragraphs which apply to mitochondrial donation)

Consent for use of eggs or embryos created following mitochondrial donation

- (A1) For the purposes of this Schedule, neither of the following is to be treated as a person whose gametes were used to create an embryo (“embryo E”)—
 - (a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5), the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;
 - (b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5), the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.
- (3B) For the purposes of this Schedule, in a case where an egg is a permitted egg by virtue of regulations under section 3ZA(5) the egg is not to be treated as the egg of the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

Regulations

Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015

Interpretation

- 2.— (1) In these Regulations “the Act” means the Human Fertilisation and Embryology Act 1990.
- (2) In these Regulations “polar body nuclear DNA” means any nuclear DNA located in a polar

body.

- (3) In these Regulations a reference to the removal of any nuclear DNA (including polar body nuclear DNA) includes a reference to the removal of any material which is necessarily removed along with that DNA, and such material may include any associated organelles.
- (4) For the purposes of these Regulations, the following are to be treated as removed from an egg—
 - (a) any polar body nuclear DNA which is destroyed while still located in the egg; and
 - (b) any material which is necessarily destroyed along with that DNA, and such material may include any associated organelles.
- (5) In these Regulations a reference to the insertion of nuclear DNA includes a reference to the insertion of any material which is necessarily inserted along with that DNA, and such material may include any associated organelles.

Permitted eggs and permitted embryos

Permitted egg

3. An egg (“egg P”) is a permitted egg for the purposes of section 3(2)(b) of the Act if—
 - (a) egg P results from the application of the process specified in regulation 4 to two eggs, each of which—
 - (i) is a permitted egg as defined in section 3ZA(2) of the Act (not an egg which is a permitted egg by virtue of these regulations), and
 - (ii) was extracted from the ovaries of a different woman;
 - (b) that process has been applied to those eggs in the circumstances specified in regulation 5; and
 - (c) there have been no alterations in the nuclear or mitochondrial DNA of egg P since egg P was created by means of the application of that process.

Permitted egg: process

- 4.— (1) The process referred to in regulation 3(a) consists of the following two steps.
 - (2) In step 1—
 - (a) either—
 - (i) all the nuclear DNA of an egg (“egg A”) is removed, or
 - (ii) all the nuclear DNA of egg A other than polar body nuclear DNA is removed; and
 - (b) either—
 - (i) all the nuclear DNA of another egg (“egg B”) is removed, or
 - (ii) all the nuclear DNA of egg B other than polar body nuclear DNA is removed.
 - (3) In step 2 all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

Permitted egg: circumstances

5. The circumstances referred to in regulation 3(b) are that—

- (a) the Authority has issued a determination that—
 - (i) there is a particular risk that any egg extracted from the ovaries of a woman named in the determination may have mitochondrial abnormalities caused by mitochondrial DNA; and
 - (ii) there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease; and
- (b) egg B was extracted from the ovaries of the woman so named.

Permitted embryo

6. An embryo (“embryo P”) is a permitted embryo for the purposes of section 3(2)(a) of the Act if—
- (a) embryo P results from the application of the process specified in regulation 7 to two embryos, each of which—
 - (i) is a permitted embryo as defined in section 3ZA(4) of the Act (not an embryo which is a permitted embryo by virtue of these regulations), and
 - (ii) was created by the fertilisation of a permitted egg as defined in section 3ZA(2) of the Act (not an egg which was a permitted egg by virtue of these regulations) extracted from the ovaries of a different woman;
 - (b) that process has been applied to those embryos in the circumstances specified in regulation 8; and
 - (c) since embryo P was created by means of the application of that process—
 - (i) there have been no alterations in the nuclear or mitochondrial DNA of any cell of embryo P, and
 - (ii) no cell has been added to embryo P other than by the division of embryo P’s own cells.

Permitted embryo: process

- 7.— (1) The process referred to in regulation 6(a) consists of the following two steps.
- (2) In step 1—
- (a) either—
 - (i) all the nuclear DNA of an embryo (“embryo A”) is removed, or
 - (ii) all the nuclear DNA of embryo A other than polar body nuclear DNA is removed; and
 - (b) either—
 - (i) all the nuclear DNA of another embryo (“embryo B”) is removed, or
 - (ii) all the nuclear DNA of embryo B other than polar body nuclear DNA is removed.
- (3) In step 2 all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.

Permitted embryo: circumstances

8. The circumstances referred to in regulation 6(b) are that—

(a) the Authority has issued a determination that—

- (i) there is a particular risk that any embryo which is created by the fertilisation of an egg extracted from the ovaries of a woman named in the determination may have mitochondrial abnormalities caused by mitochondrial DNA; and
- (ii) there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease; and

(b) embryo B was created by the fertilisation of an egg extracted from the ovaries of the woman so named.

Supplemental provision – licences

9. (1) Any reference to a permitted egg in a licence whenever issued does not include an egg which is a permitted egg for the purposes of section 3(2) of the Act by virtue of regulation 3 unless express provision is made in the licence to that effect.
- (2) Any reference to a permitted embryo in a licence whenever issued does not include an embryo which is a permitted embryo for the purposes of section 3(2) of the Act by virtue of regulation 6 unless express provision is made in the licence to that effect.

Licence conditions

- T124 a. No clinic may carry out either the process of pronuclear transfer* (PNT) or maternal spindle transfer* (MST) or part of either process, unless express provision has been made on the clinic's licence permitting it to undertake either or both processes.
- b. Neither PNT nor MST may be carried out under third party, satellite or transport agreements.
- c. No clinic may provide treatment using gametes or embryos which have been created using PNT or MST unless express provision has been made on the clinic's licence permitting the clinic to undertake either or both processes.

*Wherever reference is made in this licence to PNT or MST, or to the process of PNT or MST, it is to be treated as a reference to the process described in Regulation 4 or Regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

- T125 PNT and MST must only be carried out on premises of clinics that are licensed to undertake mitochondrial donation ('MD'). These processes must not be carried out on the premises of a clinic that is operating under a third party, satellite or transport agreement with a clinic that holds a licence to undertake MD.

- T127 a. No alterations may be made to the nuclear or mitochondrial DNA of an egg created by means of the application of MST.
- b. No alterations may be made to the nuclear or mitochondrial DNA of an embryo created by means of the application of PNT, and no cell may be added to an embryo created by means of the application of PNT other than by the division of the embryo's own cells.

- T128 In the case of treatment involving mitochondrial donation, the clinic must ensure that it only carries out the process of PNT or MST for a particular, named patient once the Authority has issued a determination that:
- there is a particular risk that any egg extracted from the ovaries of the named woman, or any embryo created by the fertilisation of an egg extracted from the ovaries of the named woman, may have mitochondrial abnormalities caused by mitochondrial DNA, and
 - there is a significant risk that a person with those abnormalities will have or develop a

serious mitochondrial disease.

T129 Only those embryologists assessed as competent by the Authority to undertake PNT, MST or both, and named on the front of this licence, are permitted to undertake those processes or any part thereof.

Directions

0001 – Gametes and embryo donation

0005 – Collecting and recording information for the HFEA

0006 – Import and export of gametes and embryos

0007 – Consent

0008 – Information to be submitted to the HFEA as part of the licensing process

HFEA guidance

Staff to be involved in mitochondrial donation

- 33.1** A senior clinical geneticist/mitochondrial disease specialist should be involved in deciding whether a particular patient should receive mitochondrial donation treatment.
- 33.2** The centre should ensure that a multidisciplinary team is involved in providing the treatment. The team should include mitochondrial disease specialists, reproductive specialists, embryologists, clinical geneticists, genetic counsellors and molecular geneticists. It should maintain close contact with the primary care physician, the referring clinician, or the mitochondrial disease centre.
- 33.3** Only embryologists who have been assessed as competent by the HFEA and named on the clinic's licence can perform maternal spindle transfer (MST) or pronuclear transfer (PNT) techniques as defined in Regulation 4 and 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015. An application for an assessment of the competence of an embryologist must be submitted to the HFEA and will be considered by a Licence Committee. When submitting an application to the HFEA for a competency assessment, the person responsible (PR) and the relevant embryologist should provide:
- (a) evidence of the embryologist's experience of carrying out MST or PNT in treatment, training or research on human eggs or embryos (eg, embryo survival rates, blastocyst development, and rate of carryover of mitochondria, in line with key performance indicators (KPIs) determined by the HFEA)
 - (b) references to support the embryologist's experience and knowledge, and
 - (c) any other information that may demonstrate competence (such as the embryologist's experience of performing micro-manipulation on human or animal (eg, mice) eggs or embryos).
- 33.4** The PR should submit an application to the HFEA for an assessment of the competence of each embryologist who intends to perform MST or PNT or any part thereof. A PR wishing to make any changes to the authorised embryologists must submit an application to the HFEA for a variation of the clinic's licence, accompanied by the relevant evidence of competency for each proposed embryologist.

Mitochondrial donation for the avoidance of serious mitochondrial disease

Interpretation of mandatory requirements 33A



Maternal spindle transfer (MST) can only be carried out where the Authority has issued a determination that —

- there is a particular risk that any eggs collected from the patient named in the application form may have mitochondrial abnormalities caused by mitochondrial DNA; and
- there is a significant risk that a person with those abnormalities will have, or develop, serious mitochondrial disease.

Pronuclear transfer (PNT) can only be carried out where the Authority has issued a determination that—

- there is a particular risk that any embryos created with eggs collected from the patient named in the application form may have mitochondrial abnormalities caused by mitochondrial DNA; and
- there is a significant risk that a person with those abnormalities will have, or develop, serious mitochondrial disease.

Treatment involving mitochondrial donation can only be carried out by a clinic that is licensed to do so, as evidenced by express provision on the clinic's licence permitting it to undertake either MST, PNT or both.

The process of MST or PNT (as defined in Regulation 4 and 7 of the Human Fertilisation and Embryology Authority (Mitochondrial Donation) Regulations 2015) may only be carried out by embryologists who have been assessed by the HFEA as competent to undertake these processes and who are named on the clinic's licence.

MST or PNT may only be carried out on the premises of a clinic licensed to undertake mitochondrial donation and may not be done on third party premises or the premises of any satellite centre.

Clinics that are not licensed to undertake MST or PNT for treatment purposes may not use eggs or embryos created using these techniques in treatment services.

33.5 The centre should discuss with the patient the likely outcomes of the proposed treatment, the nature and potential risks of the treatment, and any other treatment options that may be suitable, such as preimplantation genetic diagnosis (PGD) or egg donation.

33.6 When deciding if it is appropriate to offer MST or PNT in particular cases, the seriousness of the disease in that case should be discussed between the patient seeking treatment and the clinical team. The level of risk for those seeking treatment and any child that may be born will also be an important factor for the centre to consider, and should be discussed with the patient. The centre should only offer MST or PNT to patients for whom PGD is inappropriate **and or** likely to be unsuccessful and who exhibit (or are predicted to exhibit) high levels of germ line heteroplasmy or homoplasmy. In making this assessment, the centre should take into account:

- the particular mutation involved,
- the inheritance pattern in the family, and
- the likely clinical manifestations of disease and the efficacy of any previous treatments such as PGD.

For an overview of how the Statutory Approvals Committee will assess a case by case application, download 'Mitochondrial donation: explanatory note for Statutory Approvals Committee'.

- 33.7** The centre should consider the following factors before deciding whether it is appropriate to offer MST or PNT in particular cases. Having considered these factors, if a decision is taken to offer MST or PNT, the clinic would need to submit an application for authorisation to the HFEA.

The Authority's assessment of the seriousness of a mitochondrial disease will be made, where possible, based on the most severe symptoms that could be expected for a particular patient's case. When submitting an application to the HFEA, the PR must, wherever possible, provide supporting evidence detailing:

- (a) the patient's medical history
- (b) the patient's family medical history of mitochondrial disease (to include previous cases of PGD treatment or details of affected family members)
- (c) the patient's mutant mitochondrial DNA (mtDNA) load and threshold associated with symptoms of disease (to include details about the level of heteroplasmy or whether the patient is homoplasmic for a mitochondrial mutation)
- (d) scientific literature relevant to the mtDNA mutation or disease, and
- (e) any additional information which the clinician may consider is relevant to the application, such as a statement from a genetic counsellor.

Embryo transfer using embryos following mitochondrial donation

- 33.8** Embryos that have undergone either MST or PNT (or any other technique) should not be transferred with any other embryos that have not undergone the same technique in the same treatment cycle.
- 33.9** A centre should not perform embryo biopsy (such as for the purpose of PGD or preimplantation genetic screening (PGS)) on embryos that have undergone MST or PNT.
- 33.10** A centre should use the same sperm provider for both steps of PNT unless there is a good reason for not doing so (ie, if the mitochondria donor is a close genetic relative of the intended father).

Genetic consultation and counselling

- 33.11** The centre should ensure that people seeking treatment have access to mitochondrial specialists, clinical geneticists, genetic counsellors and, where appropriate, infertility counsellors. Patients who have been referred by one clinic to another for the purposes of mitochondrial donation must be offered specific counselling about mitochondrial donation by the clinic licensed to do mitochondrial donation, regardless of whether the patient has previously been offered counselling by the referring centre.
- 33.12** The centre should work closely with the local genetics/mitochondrial disease centre of those seeking treatment.

Information for those seeking mitochondrial donation

- 33.13** The centre should ensure that people seeking MST or PNT are given appropriate information about the treatment. Where a patient has been referred by one clinic to another for the purposes

of mitochondrial donation, the clinic licensed to provide mitochondrial donation must ensure that it provides the patient with appropriate information including:

- (a) information about the process, procedures and possible risks involved in mitochondrial donation, including the risks for any child that may be born following the mitochondrial donation, and the risks of IVF treatment
- (b) information about prenatal testing following treatment (in these circumstances, the patient should be counselled about the specific additional risks associated with prenatal testing), and
- (c) information about the experience of the centre and embryologist(s) carrying out the techniques.

33.14 The centre should also provide information to those seeking treatment to help them make decisions about their treatment, including:

- (a) genetic and clinical information about the mitochondrial disease
- (b) the possible impact (if known) of the mitochondrial disease on those affected and their families
- (c) the importance of telling any resulting children of the mitochondrial donation treatment
- (d) information about treatment and social support available, and
- (e) information from a relevant patient support group or the testimony of people living with the condition, if those seeking treatment have no direct experience of it themselves.

33.15 If the person seeking treatment has already been given information about the particular mitochondrial disease, for example from a regional mitochondrial disease centre with appropriate expertise, the centre does not need to provide this information again. However, the centre should ensure that the information which has been provided is accurate, sufficiently detailed and that the patient fully understands the information.

33.16 Before providing mitochondrial donation treatment, the centre should ensure that those seeking treatment have had sufficient opportunity to fully consider the possible outcomes and risks of these techniques and their implications.

33.17 The centre should provide information to people seeking mitochondrial donation treatment about the collection and provision of information, specifically:

- (a) information that centres must collect and register with the HFEA about the donors
- (b) what information may be disclosed to people born as a result of the mitochondrial donation and in what circumstances, and
- (c) that person's right to access anonymous information about the mitochondrial donor from the age of 16.

33.18 The centre should give people seeking mitochondrial donation treatment information about the screening of people providing mitochondria. This information should include details about:

- (a) the sensitivity and suitability of the tests, and
- (b) the possibility that a screened provider of mitochondria may be a carrier of a mitochondrial disease or infection.

33.19 The centre should provide information that explains the limitations of procedures and the risks of treatment to anyone seeking mitochondrial donation treatment. The centre should make available appropriate counselling.

See also[Guidance note 3 – Counselling](#)[Guidance note 20 – Donor assisted conception](#)

NOTE Guidance note 20 applies to mitochondrial donation except sections 20.1, 20.2 (d)ii-v) and 20.12.



Importance of informing children of their origins

33.20 The centre should tell people who seek mitochondrial donation treatment that it is best for any resulting child to be told about their origin early in childhood. Centres should refer to guidance set out in guidance note 20 on the importance of informing children of their donor origins.

33.21 Centres should inform patients of the potential risk of mitochondrial disease in future generations and the potential ways to avoid this (eg, that any female born following MST or PNT, should she wish to have children of her own, could have her eggs or early embryos analysed by PGD in order to select for embryos free of abnormal mitochondria).

See also[Guidance note 20 – Donor assisted conception](#)

Eligibility requirements for mitochondrial donors

Mandatory requirements

Licence conditions

T52 Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely:

- a. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg, superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)
- b. the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:
 - HIV 1 and 2: Anti-HIV – 1, 2
 - Hepatitis B: HBsAg and Anti-HBc
 - Hepatitis C: Anti-HCV-Ab

- Syphilis: see (d) below
- c. the centre must devise a system of storage which clearly separates:
 - quarantined/unscreened gametes and embryos
 - gametes and embryos which have tested negative, and
 - gametes and embryos which have tested positive
- d. a validated testing algorithm must be applied to exclude the presence of active infection with *Treponema pallidum*. The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific *Treponema* confirmatory test is non-reactive. The donor whose specimen test reacted on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use
- e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)
- f. This requirement has been removed.
- g. HTLV-1 antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas
- h. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, *T. cruzi*), and
- i. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

T126 Donors of gametes for use in MST and or PNT must be screened for pathogenic mitochondrial DNA mutations, and an assessment of the risk of transmission of any mitochondrial disease in the donor's family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be clearly communicated and explained to the recipient.

Interpretation of mandatory requirements 33B



Sections (a) to (h) of Licence condition T52 on medical and laboratory tests should apply to mitochondrial donors and to men providing sperm used to fertilise eggs of the mitochondrial donor in the process of PNT.

33.22 As well as taking their medical history (in line with T52 and T126), the recruiting centre should take details of previous donations. If a prospective donor cannot give a full and accurate maternal family history, the centre should record this fact and take it into account in deciding whether or not to accept their eggs for treatment.

33.23 Centres should ensure that they keep up to date with relevant literature and professional guidance, such as on refinements to the techniques, to improve their efficacy in treatment.

Centres should also keep up to date with emerging research relevant to mitochondria haplotype matching and consider matching the haplotypes of donors with recipients where possible.

- 33.24** Before accepting a mitochondrial donor, centres should follow the same requirements and guidance as set out in guidance note 11, except guidance 11.2, 11.3, 11.32 g) and j), 11.32 i)-l), 11.36, 11.37, 11.38, 11.39, 11.42, 11.46-11.52.
- 33.25** Guidance on the upper age limits for egg and embryo donors does not apply for mitochondrial donors. There is some evidence to suggest that mitochondria in a woman's eggs accumulate damage over time meaning the eggs of older donors may have reduced mitochondrial function. Age should therefore be taken into consideration when determining the suitability of a woman donating her eggs, in conjunction with an assessment of her reproductive health, such as an assessment of ovarian reserve.
- 33.26** The ten family limit guidance for those providing donor gametes (or embryos created using donated gametes) outlined at 11.46, does not apply to:
- (a) egg donors who have donated their mitochondria only, or
 - (b) sperm donors who have donated for pronuclear transfer where they will not be genetically related to the child.

See also

[Guidance note 11 – Donor recruitment, assessment and screening](#)



Information for prospective mitochondrial donors

- 33.27** Before any consents or samples are obtained from a prospective mitochondrial donor, the recruiting centre should provide information about:
- (a) the screening that will be done and why it is necessary
 - (b) the possibility that the screening may reveal unsuspected conditions (eg, mitochondrial related anomalies or HIV infection) and the practical implications of this
 - (c) the scope and limitations of the genetic testing that will be done and the implications for the mitochondria donor and their family
 - (d) the importance of informing the recruiting centre of any medical information that may come to light after donation and that may have health implications for any woman who received treatment with their mitochondria, or for any child born as a result of such treatment
 - (e) the procedure used to collect gametes, including any discomfort, pain and risk to the mitochondria donor (eg, from the use of superovulatory drugs)
 - (f) the legal parenthood of any child born as a result of their mitochondrial donation
 - (g) what information about the mitochondrial donor must be collected by the centre and held on the HFEA Register
 - (h) that only non-identifying information will be disclosed when the applicant is aged over 16. No identifying information about the donor will be disclosed
 - (i) the possibility that a child born as a result of their mitochondrial donation who is disabled as a result of an inherited condition that the donor knew about, or ought reasonably to have known about, but failed to disclose, may be able to sue the donor for damages, and
 - (j) the ability of the mitochondrial donor to withdraw consent, the procedure for withdrawal of consent for the use of their mitochondria, and the point up until which the donor can withdraw consent.

Informing mitochondrial donors about information available to children born from the treatment

- 33.28** The centre should inform mitochondrial donors that anyone born as a result of their mitochondrial donation will have access to the following non-identifying information provided by them, from the age of 16:
- (a) the screening tests carried out on the mitochondrial donor and information on that donor's personal and family medical history
 - (b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and
 - (c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person born from their donation.

Consent

- 33.29** The centre should obtain written informed consent from patients and their spouse or partner (if relevant), for mitochondrial donation treatment. Where a patient and their partner have been referred by one centre to another for the purposes of mitochondrial donation, the clinic that will be undertaking the mitochondrial donation must obtain consent specific to the treatment involving mitochondrial donation, regardless of what consent the patient and their partner may have provided to the referring centre. This is because the centre doing the mitochondrial treatment will have the necessary experience and expertise in mitochondrial donation and is best placed to provide the relevant information and obtain fully informed consent.
- 33.30** For mitochondrial donors, the centre should obtain the donor's written informed consent to the donation of her eggs or embryos for MST or PNT.
- 33.31** Any prospective women donating their eggs for mitochondrial donation, or men donating sperm for PNT where they will not be genetically related to the child, should be aware that they cannot withdraw or vary their consent once the donated egg or embryo has undergone the process of MST or PNT (ie, all the nuclear material has been moved from one egg or embryo to another).
- 33.32** Centres should follow all other requirements and guidance on consent as outlined in guidance note 11 on donor recruitment, assessment and screening and in guidance note 5 on consent to treatment, storage, donation and disclosure of information.

Import of eggs or embryos which have undergone mitochondrial donation

Interpretation of mandatory requirements 33C

It is not lawful in the UK to provide treatment using gametes or embryos created abroad following the use of pronuclear transfer or maternal spindle transfer. Schedule 1(f) and 3 (i) of General Direction 0006 provides that the purpose of importing gametes or embryos must be to provide treatment services. However, as treatment using gametes or embryos created abroad following the use of pronuclear transfer or maternal spindle transfer is not lawful, it follows that the import of such gametes or embryos should not take place.



See also

[Guidance note 5 – Consent to treatment, storage, donation and disclosure of information](#)

[Guidance note 11 – Donor recruitment, assessment and screening](#)

[Guidance note 16 – Imports and exports](#)

Follow-up arrangements

- 33.33** Centres offering mitochondrial donation should have a documented process setting out how children born from mitochondrial donation will be followed up, where patients have consented to follow-up. These should include long-term medical follow-up of children born as a result. Centres should establish links with mitochondrial disease centres to facilitate follow-up. If the patient is not a UK resident but nevertheless wishes to participate in follow-up, the centre and patient should discuss whether the patient wishes to be followed up at a mitochondrial disease centre based in the UK or a relevant centre overseas, in a location more convenient for the patient.
- 33.34** Centres should explain to patients the benefits of participating in follow-up, both immediate follow-up and long term follow-up.
- 33.35** If a centre becomes aware that a child born following mitochondrial donation has been born with a mitochondrial disease, birth defect, or genetic abnormality, or if there has been some other adverse outcome (including but not limited to failed or no embryo development, miscarriage or premature birth) following treatment involving mitochondrial donation, the centre must regard this as an adverse incident and report this to the HFEA in line with the requirements on adverse incidents set out in guidance note 27. This is to capture information about any abnormalities that may occur as a result of carrying out the MST or PNT treatment, to inform any regulatory or licensing action that the HFEA may wish to take and to inform the scientific sector.

See also

[Guidance note 27 – Adverse incidents](#)

Annex C – Guidance note 25 (Premises, practices and facilities)

NOTE: Updated text is highlighted in red; deletions are highlighted in yellow.

Enclosed in Annex B

Guidance note 25: Premises, practices and facilities (Version 6.0)

25. Premises, practices and facilities

Version 6.0

Mandatory requirements

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

12 General conditions

- (1) The following shall be conditions of every licence granted under this Act –
- (a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried out on only on the premises to which the licence relates and under the supervision of the person responsible, (aa) that any activities to which section 3(1A)(b) or (1B) or 4(1A) applies shall be carried on only on the premises to which the licence relates or on relevant third party premises,...

16 Grant of licence

- (1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.
- (2) The requirements mentioned in subsection (1) above are—
- ...
- (d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities...
- (2) The Authority may revoke a licence otherwise than on application under subsection (1) if—
- ...
- (d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,

- (e) it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence...

Schedule 2 – Activities for which licences may be granted

- 4 (1) a licence under this Schedule can only authorise activities to be carried out on –
 - (a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or
- 4 (1A) applies, on relevant third party premises...
- (2) A licence cannot –
 - ...
 - (d) apply to premises of the person who holds the licence in different places.

Licence conditions

- T1 The activities authorised by the licence must be carried out only on the premises specified in this licence and under the supervision of the person responsible (PR). However, where authorised by a licence, procurement, testing, processing or distribution of gametes or embryos intended for human application can also be carried out on relevant third party premises, provided that such premises, and the activities undertaken there, are covered by the terms of a written third party agreement.
- T2 Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.
- T17 A centre must have suitable facilities to carry out licensed activities, or other activities carried out for the purposes of providing treatment services that do not require a licence.
- T20 In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP_ Annex 1 and Directive 2003/94/EC). It must be demonstrated and documented that the chosen environment achieves the quality and safety required.

NOTE Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.

- T21 If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics, (cytogenetics and molecular genetics) haematology, bacteriology, virology and clinical biochemistry.
- T124
 - a. No clinic may carry out either the process of pronuclear transfer* (PNT) or maternal spindle transfer* (MST) or part of either process, unless express provision has been made on the clinic's licence permitting it to undertake either or both processes.
 - b. Neither PNT nor MST may be carried out under third party, satellite or transport agreements.
 - c. No clinic may provide treatment using gametes or embryos which have been created using PNT or MST unless express provision has been made on the clinic's licence permitting the

clinic to undertake either or both processes.

*Wherever reference is made in this licence to PNT or MST, or to the process of PNT or MST, it is to be treated as a reference to the process described in Regulation 4 or Regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

T125 PNT and MST must only be carried out on premises of clinics licensed to undertake mitochondrial donation ('MD'). These processes must not be carried out on the premises of a clinic that is operating under a third party, satellite or transport agreement with a clinic that holds a licence to undertake MD.

HFEA guidance

Definition of premises

Interpretation of mandatory requirements 25A



A licence can apply only to one premises; if a centre wishes to conduct licensed activities in a building different from the licensed premises, and not subject to a third party agreement, a separate licence will be required.

The HFEA must approve all new premises or changes to existing premises before use.

- 25.1** The HFEA defines premises as the specific area where a centre conducts its business, as identified on a floor plan submitted by the centre to the HFEA.
- 25.2** The centre should provide the HFEA with a floor plan that defines the premises to be licensed, including the purpose of each room.
- 25.3** When setting up or altering premises, the centre should review Health Technical Memoranda and Health Building Notes (published by the Department of Health) in considering the location and the services to be provided. In particular, the centre should consider Health Building Notes on day surgery and outpatient departments.
- 25.4** The centre should ensure it can provide ongoing assurance that its premises are fit for purpose, and evidence of:
 - (a) maintenance of lifts
 - (b) fire safety
 - (c) maintenance of ventilation and heating systems
 - (d) electrical safety
 - (e) medical gas safety.

Detailed guidance on these can be found in the relevant Health Technical Memoranda.

Moving to new premises

- 25.5** Before moving to new premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of the intended move by submitting an application to vary the

licence with information about the new premises. The HFEA will consider the application and information, and may need to inspect the premises.

Changing existing premises

- 25.6** Before planning any changes to the existing premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of any planned changes to the premises by submitting, in advance, an application for a variation of the licence with information on the planned changes.
- 25.7** The HFEA will consider the application and information, and may need to inspect the premises.

Acquiring additional premises

- 25.8** If a centre wishes to conduct licensed activities not subject to a third party agreement in premises other than those specified on the current licence (eg, in a different building), it should contact its inspector for advice and notify the HFEA in writing. The centre should also submit an application for a new licence with information about the additional premises.

Centre facilities

- 25.9** The centre should provide for the privacy, dignity and respect of all prospective and current patients and donors, as well as providing a safe working environment for all staff. Consultation and the exchange of personal information should be carried out in private (ie, cannot be overlooked or overheard by others).
- 25.10** The centre should have facilities for reception, clinical and counselling activity, laboratory work, storage of confidential records, storing gametes and embryos, and staff.
- 25.11** The centre should display a copy of its Certificate of Licence where it can easily be read by current and potential patients and donors.
- 25.12** The centre should have appropriate procedures to ensure premises comply with relevant requirements for safety and air quality, and these procedures should be validated.
- 25.13** The person responsible should assess how many treatment cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skill mix of staff members. Activity should be adjusted according to the findings of the assessment.

Clinical facilities

- 25.14** The centre should ensure that its clinical facilities:
- (a) provide privacy and comfort for those:
 - (i) considering donation and seeking treatment
 - (ii) undergoing examination and treatment, and
 - (iii) producing semen specimens.
 - (b) are equipped with backup and emergency clinical facilities that:

- (i) are equivalent to those provided as standard practice in other medical facilities
- (ii) are appropriate to the degree of risk involved in any planned procedure, and
- (iii) can cope with emergencies known to occur in this clinical field.

Counselling facilities

25.15 The centre should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions.

See also

[Guidance note 3 – Counselling](#)



Laboratory facilities

25.16 The centre's laboratories should comply with current professional guidelines, legislation and regulations.

25.17 Procedures must be evaluated for hazards to laboratory staff, and precautions put in place to minimise potential hazards.

See also

[Guidance note 15 – Procuring, processing and transporting gametes and embryos](#)

[Guidance note 24 – Third party agreements](#)



Staff facilities

25.18 The centre should have staff amenities that are easily accessible and include:

- (a) toilet facilities
- (b) a rest area with basic catering facilities and a supply of drinking water
- (c) a changing area and secure storage for personal belongings, and
- (d) storage for protective clothing.

Infection control

25.19 When developing infection control policies and procedures, centres should consider the Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance.

25.20 Infection control policies should ensure that staff and patients are protected from acquiring infections in the course of providing treatment. In particular, these policies should ensure that:

- (a) there are effective procedures in place for preventing and controlling infections, such as hand decontamination, policies on wearing sterile gloves, dress code, and the safe use and disposal of sharps
- (b) staff are aware of their role in these procedures
- (c) a person is identified as the infection control lead for the centre

- (d) management systems are in place to ensure infection control issues are dealt with.

Management of medicines

25.21 Where controlled drugs are used, centres should be aware of the legal requirements, and have a controlled drugs accountable officer registered with the Care Quality Commission.

25.22 Centres should have policies and procedures in place for:

- (a) storing, disposing of, and managing the wastage of medicines, ensuring medicines can be accurately identified, are within date, and are kept safely (to prevent unauthorised access)
- (b) managing medicine stock, ensuring staff can identify and respond when new stock is needed
- (c) prescribing and dispensing medicines, ensuring only suitably qualified staff prescribe medicines, patients are given information on the risks and side effects, and patients receive appropriate medicines (taking into account factors such as medical history and allergies)
- (d) administering medicines, ensuring only suitably qualified staff do so, and patients who self-administer receive clear written and spoken instructions
- (e) dealing effectively with any emergencies following the administration of medicines by developing appropriate contingency plans.

25.23 Centres should ensure they keep accurate records that clearly set out the medication a patient is receiving.

The surgical pathway

25.24 Before doing an operation, centres should assess the suitability of a patient to have this, including a review of their medical history, allergies and known reactions to medicines.

25.25 The consultant anaesthetist or person administering the sedative should review the patient's notes before an operation. This review should take into account that patients having operations, under either general anaesthetic or sedation, are at risk of compromise to airway, breathing and circulation. There should be an anaesthetic chart in the patient's notes, containing information such as:

- (a) known drug allergies
- (b) previous problems with anaesthetics or sedatives
- (c) airway assessment
- (d) whether the patient is taking any regular medication
- (e) any post-operative instructions (eg, whether the patient will need antibiotics).

25.26 When doing a surgical procedure, centres should ensure that they:

- (a) use a theatre check list
- (b) monitor the patient before inducing the anaesthetic or sedative, and throughout the procedure
- (c) have contingency plans in case problems arise during an operation, such as a severe allergic reaction or major bleeding
- (d) have a discharge policy, ensuring that patients are discharged appropriately and by suitably trained staff.

- 25.27** Centres should keep accurate documentation about the operation undertaken, including the anaesthetic or sedative given, and details of patient monitoring.
- 25.28** Centres should ensure patients receive safe and appropriate post-operative care in line with professional guidelines. Where a general anaesthetic or sedative is used, centres should have a fully equipped recovery area, staffed by recovery staff trained to professional standards. Second recovery areas should provide close and continued supervision of all patients, who should be visible to the nursing staff.
- 25.29** Where recovery areas are not available or not required, centres should consider how they can be sure that the relevant staff and equipment are in place for safe post-operative care.
- 25.30** Centres should ensure that their procedures are suitable for the type of anaesthetic or sedative provided.
- 25.31** Centres should ensure that only an appropriately qualified person provides an anaesthetic.
- 25.32** If an anaesthetic is used at remote sites, centres should have a resuscitation team led by an Advanced Life Support provider. Where this is not the case, the anaesthetists should provide competency-based evidence of their ability to provide both advanced life support and the safe transport of a patient requiring multi-system support.

Safeguarding

- 25.33** Centres are expected to have a policy and procedures for safeguarding those who use their services. These should set out what staff should do if they suspect that a person has been abused, neglected or harmed in any way. The policy and procedure should include:
- a statement of roles and responsibilities, authority and accountability that is specific enough to ensure all staff understand their roles and limitations
 - how to deal with allegations of abuse, including procedures for providing immediate protection in emergency situations, assessing abuse and deciding when intervention is appropriate, and reporting suspicions to the police when necessary
 - what to do if necessary action is not taken
 - a comprehensive list of points of referral, explaining how to access support, advice and protection at all times (including outside normal working hours), with contact addresses and telephone numbers
 - how to record allegations of abuse, any investigations and subsequent action
 - a list of sources of expert advice
 - a full description of channels of inter-agency communication, for example with local authorities, and procedures for decision making
 - a list of all services that might offer victims access to support or redress.
- 25.34** Centres should review procedures annually, or more often to incorporate any lessons learned or changes to legislation.
- 25.35** Centres should provide training for staff on the safeguarding policy and their responsibilities, including:
- awareness that abuse can happen, and the duty to report this
 - recognition of abuse, and responsibilities for reporting this.

- 25.36** If abuse, neglect or harm is suspected, it may be in the best interests of the individual to disclose confidential patient information. The safeguarding policy should set out the principles governing the sharing of information. These principles can be summarised as follows:
- (a) Information should be shared only on a 'need to know' basis, when it is in the best interests of the patient or donor.
 - (b) Confidentiality and secrecy are two different things.
 - (c) The individual should give informed consent to disclosure, but if this is not possible, it may be necessary to disclose personal or sensitive personal information, despite a duty of confidentiality or legislation that would ordinarily prohibit disclosure.
 - (d) It is inappropriate to give assurances of absolute confidentiality in cases where there are concerns about abuse.
 - (e) Exchange or disclosure of personal information should be in line with the Data Protection Act 1998, where this applies.

Other legislation, professional guidelines and information

Legislation

[The Human Medicines Regulations 2012](#)

[The Misuse of Drugs Regulations 2001](#)

Professional guidelines

[Academy of Medical Royal Colleges: Safe sedation practice for healthcare procedures – standards and guidance \(2013\)](#)

[Association of Anaesthetists of Great Britain and Ireland: Checking anaesthetic equipment \(2012\)](#)

[Association of Anaesthetists of Great Britain and Ireland: Controlled drugs in perioperative care \(2006\)](#)

[Association of Anaesthetists of Great Britain and Ireland: Immediate post-anaesthesia recovery \(2013\)](#)

[Association of Anaesthetists of Great Britain and Ireland: Infection control in anaesthesia \(2008\)](#)

[Association of Anaesthetists of Great Britain and Ireland: Pre-operative assessment and patient preparation – the role of the anaesthetist \(2010\)](#)

[Care Quality Commission: Controlled drugs](#)

[Department for Health: Health Building Notes \(2013\)](#)

[Department for Health: Health Technical Memoranda \(2013\)](#)

[Department of Health: No Secrets – guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse \(2000\)](#)

[General Medical Council: Good practice in prescribing and managing medicines and devices \(2013\)](#)

[Information Commissioner's Office: Key definitions of the Data Protection Act](#)

[Nursing and Midwifery Council: Standards for medicine management \(2007\)](#)

[Royal College of Anaesthetists: Guidelines for the provision of anaesthetic services \(2015\)](#)

[Royal College of Radiologists: Standards for the reporting and interpretation of imaging investigations](#)

United Kingdom Accreditation Service: Clinical pathology accreditation

World Health Organisation: Surgical safety checklist and implementation manual (2008)

Clinic Focus articles

Clinic Focus article: Surgical procedures: an evaluation (April 2014)

Other information

Human Fertilisation and Embryology Authority: Medicines management – a whistle-stop guide (2017)