

Information Provision

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

Details:

Meeting	Authority
Agenda item	11
Paper number	HFEA (14/03/18) 875
Meeting date	14 March 2018
Author	Chris Hall, Interim Head of Information

Output:

For information or decision?	For decision
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Recommendation	<p>The Authority is asked to approve:</p> <p>That we formally advise clinics with third party patient record systems that their suppliers should be given six-months' notice of changes to be made to enable data submission to the HFEA;</p> <p>The proposed changes to General Direction 0005;</p> <p>The proposed arrangements for data confirmation.</p>
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Resource implications	N/A
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Implementation date	Summer 2018
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Communication(s)	Chair's letter attaching Direction will be issued in April 2018, within Clinic Focus. Substantial engagement activity with clinics' patient record suppliers is underway.
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Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
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Annexes	<p>Annex 1: General Direction 0005</p> <p>Annex 2: Chair's letter</p>
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1. Background

1.1. At the March 2017 meeting of the Authority we brought early thoughts on our information policy for comment. The areas under review were as follows:

1. The foundations of the Register
2. Register data submission: quality and timeliness
3. Publishing data – Choose a fertility clinic
4. Clinics' websites and marketing
5. Information security
6. Accessing anonymised and identifying HFEA register data for research and understanding
7. Opening the Register

1.2. We explained that to reap the benefits of the investment we have made via the Information for Quality programme we needed to revisit the rules and expectations for data provision (that is the submission of data to the HFEA by clinics) which are currently set out in a mixture of policy, directions and guidance in the Code of Practice, to strike a new information 'bargain' between ourselves and the bodies we regulate. As such, the focus of this paper are areas 1-3 above. Work is underway in the remaining areas through consultation on the Code of Practice; in the newly established intelligence team; and in the Chief Information Officer function.

1.3. By way of reminder, we collect information from licensed clinics:

- because it is required by law, to enable us to provide donors, donor-conceived people and their parents with the information they are entitled to;
- to provide prospective and current patients and donors with sufficient, accessible and up-to-date information to allow them to make informed decisions
- to provide information that enables us to assess compliance of individual clinics against agreed standards
- to provide information that enables us to alert clinics of performance changes
- to obtain information about current practice that is considered by the professional groups and other relevant stakeholders to be useful and beneficial
- to provide identifying information that enables linkage studies about children conceived as a result of licensed treatment
- to enable ethically and scientifically approved data research.

1.4. We have an information submission policy. This paper highlights two principal changes - to General Direction 0005, and arrangements we put in place for clinics to confirm to us the quality of their data before we publish, for example in Choose a fertility clinic.

2. Introduction of the new data submission system

- 2.1.** We are proposing to introduce clinics to the new system at the HFEA conference in March 2018. Soon after we will be providing clinics with access to a Beta version from April 2018 to enable clinics to familiarise themselves with the new system and to receive training – but not submit data to us.
- 2.2.** At present, however, only a minority of clinics (c.30%) use an HFEA system to submit their data to us. Until we have agreed a timetable for those clinics (the majority, c.70%) who rely on third-party patient record systems to submit data to the HFEA we cannot switch to the new data submission system.
- 2.3.** We have already had discussions with the various third party providers. The next stage in that process is to issue the rules of engagement to clinics - in relation to submission timescales (General Direction) and clinics signing off data prior to their publication by us (verification).
- 2.4.** In normal circumstances when we propose changes to the data submission system we allow clinics that use third party patient record system suppliers a period of grace to implement those changes. This has been based on custom and practice rather than as part of an agreed policy. We wish to formalise this and propose a six-month preparation period for those clinics (and their third-party supplier). We will communicate this ‘starting the clock’ process in a Chair’s letter (draft at annex 2).
- 2.5.** We now seek the approval of the Authority, as we prepare to implement the new system. It is important these requirements are in place prior to then.

3. Changes to General Direction 005

- 3.1.** Following the launch of our new submission system we will have a new set of expectations and arrangements relating to good quality and timely data submission by clinics. We want to provide a transparent framework for clinics (and for the HFEA) about those expectations.
- 3.2.** We seek to do this first by the rules of the proposed new General Direction, backed up by modest changes to the Code of Practice in its October 2018 update.
- 3.3.** General Direction 0005 (at annex 1) sets out mandatory requirements for clinics on collecting, recording and submitting information. The main changes to this version of the Direction are:
 - To reflect the changes in the new submission system we no longer refer to ‘forms’. Instead we refer to ‘Information types’ detailed in the data dictionary, the purpose of each information type, and the deadline for submission;

- A reduction in the period allowed of correction of submission errors from 2 months to 4 weeks;
 - Subtle changes in tone with more use of the word “must”
 - A standardisation of submission deadlines so that they are always expressed in weeks
 - We no longer refer to the person responsible signing off a hard copy of their CaFC data before publication as we expect that this will be done electronically via the Clinic Portal
- 3.4.** Code of Practice (guidance note 32) sets out obligations and reporting requirements of centres (along with presenting mandatory requirements from Licence Conditions and the Act) will be amended to reflect the changes in the new submission system - that we no longer refer to ‘forms’; and the process by which PRs will verify their data ahead of publication on CaFC.
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4. Clinic data confirmation

- 4.1.** One of the advantages of the new system we have been promoting is the benefit to clinics in submitting higher quality data, due to higher standards of validation – making it much more difficult to submit erroneous data.
- 4.2.** The new data submission system allows us to streamline what we currently call the pre-publication CaFC verification process. In short, we ask PRs to confirm all errors have been dealt with for the previous year relating to births, and pregnancies and treatments, and that all relevant records have been submitted to the HFEA.
- 4.3.** We have given much thought to a new data confirmation process, to ensure that we increase the quality of data in the system on an ongoing basis, and can release and use this information to deliver a range of new outcomes. Notably, we see our intelligence team delivering its new strategy and enabling patients to have more current data on which to base treatment decisions.
- 4.4.** Alongside this work we believe that a more frequent confirmation process is necessary to support improved patient choice. In the past we have reduced the frequency of the verification process to reduce the burden on clinics. As such, on the surface more frequent data confirmation (at annex 2) may look counter-intuitive.

However, we believe the new system will be much more user-friendly and this will far outweigh any disadvantages relating to the frequency of the proposed arrangements for confirmation. We will discuss the fine detail of the data confirmation proposal with the sector over the summer.

5. Recommendations

5.1. The Authority is asked to approve:

- that we formally advise clinics with third party patient record systems that their suppliers should be given six-months' notice of changes to be made to enable data submission to the HFEA;
- the proposed changes to General Direction 0005; and
- the proposed arrangements for data confirmation.

Annex 1 Directions given under the Human Fertilisation and Embryology Act 1990 (as amended)

Collecting, recording and submitting information

Ref: 0005Version: 5

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 12(1)(d) and 12(1)(g)
These Directions came into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version was issued on:	1 April 2018]

- Centres undertaking any licensed treatments, except for IUI using partner sperm (see 7.), must submit information relating to such activities to the HFEA.
- Centres must submit information via an HFEA approved data submission system. Detailed information on each record type is available within the HFEA's UK ART Data Set Dictionary published on the Clinic Portal:

Information type	Purpose	Submission deadline
Patient registration	To provide identifying information about the female patient having treatment	Before treatment commences.
Partner registration	To provide identifying information about the partner of the patient	Before treatment commences.
Donor registration	To provide identifying, contact, personal information about the donor and why they are donating.	Before first use of donor gametes or embryos or before stimulation to collect eggs from a donor. Pages 3 and 4 of the HFEA Donor Information form must be scanned and attached to the registration record on the HFEA register within 4 weeks of donor registration.
Intended parent registration	To provide identifying information about an intended mother or intended father in surrogacy.	Before first use of intended parent's gametes in treatment.
Surrogate registration	To provide identifying information about a surrogate.	Before the surrogate's treatment commences.
Mitochondrial donor registration	To provide identifying information about the mitochondrial donor. This is required even if the mitochondrial donor is also registered as a patient or egg donor	Before the stimulation to collect eggs from the mitochondrial donor.
Pronuclear only sperm donor registration	To provide identifiable details of a donor whose sperm will only be	2 weeks after sperm is released for use by the clinic, or in the case of

	<p>used in pronuclear transfer mitochondrial donation treatment for fertilisation of the mitochondrial donor's eggs</p> <p>Note: This is not required if the individual is already registered as a sperm donor or is the partner of the woman being treated.</p>	imports, 2 weeks after receipt of the imported sperm
Stimulation	To inform the HFEA when a cycle in which it is intended to collect eggs has started	3 calendar days after the last menstrual period or stimulatory drugs being administered to/taken by a patient with the intention to collect eggs.
Donor insemination treatment	To inform the HFEA when a patient has been inseminated with donor sperm.	2 weeks after the insemination date of the cycle
IVF treatment, and embryo creation and use	To inform the HFEA about the circumstances surrounding egg collection, embryo creation and use (ie, transfer, storage, donation, discard).	2 weeks after the treatment cycle date. Treatment cycle date is the latest of egg collection or collection abandonment date, mixing date, embryo transfer date or embryo storage date.
Frozen embryos	To inform the HFEA of the thawing and use of embryos (i.e. whether they have been used in treatment, stored, donated or discarded).	2 weeks after the thaw date.
Early pregnancy outcome	To inform the HFEA of the early outcome of a treatment	8 weeks after the treatment cycle date.
Pregnancy outcome	To inform the HFEA of the outcome of any early outcome recording 'fetal pulsation seen'	52 weeks after insemination or embryo transfer date.
Mitochondrial donation treatment	To inform the HFEA of a treatment cycle involving mitochondrial donation	To be submitted using a paper* form 2 weeks after the treatment cycle completion date
Embryo and gamete movement – in	To inform the HFEA about the number of embryos, eggs and ampoules, straws or vials of donor sperm transferred from another UK centre or imported from outside the UK.	On the day of receipt for embryos, eggs transferred from another UK centre or imported from outside the UK. 1 week after receipt of ampoules, straws or vials of donor sperm transferred from another UK centre or imported from outside the UK.
Embryo and gamete movement – out	To inform the HFEA of the number of embryos, eggs and ampoules, straws or vials of donor sperm removed from storage at a centre and the	When embryos, eggs and ampoules, straws or vials of donor sperm are removed from storage and transferred to another UK centre or

reason for the removal

exported outside the UK.

* All paper forms submitted should be sent by recorded delivery and addressed to the HFEA's Register Information Team.

1. Where an error is identified, centres must correct the error within 4 weeks.
2. All amendments to data previously submitted by clinic staff to the Authority must be done via an HFEA approved data submission system.
3. The registration record must be updated to record any patient, partner, or donor variation to consent given to disclose register information for research purposes within 2 weeks of the change being made. The consent for disclosure of information related to a child born because of treatment must be notified to the HFEA via within 2 weeks of the decision where it is different to the consent provided by the patient and if appropriate partner. This can be done via the submission of a Consent Variation form available from both the HFEA website and the Clinic Portal.
4. Where a licensed centre marks data as deleted, clearly stated reasons why must be provided.

Other submissions

1. All licensed centres undertaking Intra Uterine Insemination (IUI) with partner sperm must submit an annual return to the Authority no later than 28 February in each calendar year. The annual return must be submitted via the Clinic Portal.
2. All licensed centres undertaking maternal spindle transfer and/or pronuclear transfer must complete and submit to the Authority a copy of the 'Mitochondrial donation follow-up information sheet', available via the HFEA website and Clinic Portal no later than 29 October each year. Licensed centres holding these records must be able to produce copies of those records upon request from an HFEA member or employee.
3. To enable a previously anonymous donor to register as identifiable on the HFEA Register a donor re-registration (also known as a B form) must be submitted. B forms are available on the Clinic Portal and HFEA website.
4. Before centre data is published on Choose a Fertility Clinic (CaFC), the Person Responsible (PR) must satisfy themselves that the data to be published is accurate and confirmed. A PR sign-off sheet for each CaFC publication available within the Clinic Portal and must be submitted by the published confirmation deadline.
5. Persons Responsible must ensure that, before they sign off their data electronically via the Clinic Portal, they are satisfied that:
 - the number of treatment cycles (both generic IVF and DI) completed within the reporting period is 100% accurate;
 - all early outcome relating to cycles in a) above and all outcome data relating to clinical pregnancies in a) above has been submitted to the Authority and have been filled in accurately; and
 - all registration data relating to persons whose gametes are used in treatment in (a) above has been accurately submitted to the Authority.

Sally Cheshire CBE

Chair, Human Fertilisation and Embryology Authority

Annex 2 Chair's letter (draft)

XX/04/2018 - CH (18) X

01 April 2018

Ref CH (18) XX

Dear colleague,

Update to General Direction 0005

I am writing to inform you that General Direction 0005 setting out the mandatory requirements for clinics on collecting, recording and submitting data to the HFEA Register of information has been amended.

The changes are made to support the implementation of our new data submission system. The changes reflect changes to submission timescales and clinic confirmation and sign-off of data prior to publication by us.

The main changes to the Direction are:

- To reflect the changes in our new data submission requirements we no longer refer to 'forms'. Instead we refer to 'Information types' detailed in the data dictionary, the purpose of each information type, and the deadline for submission;
- A reduction in the period allowed of correction of submission errors from 2 months to 4 weeks;
- A standardisation of submission deadlines so that they are with a sole exception always expressed in weeks;
- Subtle changes in tone with more use of the word "must"
- Simplification of some submission requirements to, for example, "before treatment", "before use of donor gametes or embryos"
- We no longer refer to the person responsible signing off a hard copy of their CaFC data before publication as we expect that this will be done electronically via the Clinic Portal.

General Direction 0005 (Version 5) will come into force later this year with the implementation of the new data submission system. You will be informed in advance.

Update of third-party patient record systems used to submit data to the HFEA Register

A key strand in implementing the new system is that all clinics can continue to submit Register data to us in accordance with the new Direction (General Direction 0005 version 5).

Clinics submitting treatment information to the HFEA system directly will move over to the new HFEA system (later in the year). An increasing number of clinics now submit treatment information to us via third-party patient record systems. Providers of those systems now need to make changes such that the benefits are available to all clinics as soon as possible. It is also necessary to minimise disruption to related activity, such as your and our monitoring of your performance, fee billing and so on).

Our usual practice is to allow clinics that use third party patient record systems sufficient notice for their system suppliers to implement proposed changes. We have been in regular contact with most suppliers alerting them to the changes.

We now require clinics with those third-party patient record systems that their suppliers must be given six-months' notice commencing xx/xx/2018 to give them time to make the necessary changes to enable your continued data submission to the HFEA.

We will work closely with suppliers but it is necessary for them to make the necessary changes to ensure compatibility with the HFEA's new data submission system by the end of the six-month preparation period. In the event that changes have not been such that the system is ready for submissions, it will be necessary for you to use an alternative compatible system or the HFEA's own data submission system (PRISM direct-entry) to submit Register data as required by Direction 0005 (Version 5).