

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY POLICY ON COLLECTION, CONFIRMATION AND PUBLICATION OF REGISTER DATA

Policy Version: 2.0

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Doc name: Policy on Collection, Confirmation and
Publication of Register Data

Release date:

1.0 POLICY STATEMENT/INTENTIONS

- 1.1 This document sets out the Authority's policy on:
 - 1.1.1 the methods and timescales for collection of data which the Authority is required to maintain in a Register in accordance with Section 31 of the Human Fertilisation and Embryology Act 1990 (as amended) ('Register Data');
 - 1.1.2 the process by which licensed clinics are required to confirm the accuracy and authenticity of the Register Data that they provide to the Authority; and
 - 1.1.3 the arrangements for publication of extracts of Register Data on the 'Choose a Fertility Clinic' pages of the Authority's website.
- 1.2 This policy replaces all previous policies relating to these matters.
- 1.3 This policy is to be read in conjunction with Direction 0005 on Collecting and Recording Information for the Human Fertilisation and Embryology Authority, the Authority's Code of Practice, and Authority's Compliance and Enforcement Policy.

2.0 COMMENCEMENT

- 2.1 This policy will be effective as from 1 October 2009.

3.0 INTRODUCTION

- 3.1 Under the Human Fertilisation and Embryology Act 1990 (as amended), the Authority has a statutory duty to:
 - 3.1.1 provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment or to those who may wish to do so;
 - 3.1.2 promote compliance with the Act and the Authority's Code of Practice; and
 - 3.1.3 maintain a register of information relating to:
 - 3.1.3.1 the provision for any identifiable individual of treatment services other than basic partner treatment services;
 - 3.1.3.2 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;

TRIM reference: 2009/05463

Version: 2.0

Doc name: Policy on Collection, Confirmation and
Publication of Register Data

Release date:

- 3.1.3.3 the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman;
 - 3.1.3.4 the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services;
 - 3.1.3.5 the use of an embryo taken from any identifiable woman; or
 - 3.1.3.6 information which shows that an individual was or may have been born as a result of treatment services (other than basic partner treatment services) or the procurement or distribution of sperm (other than partner-donated sperm which has not been stored) in the course of providing non-medical fertility services.
- 3.2 As the UK Competent Authority, the HFEA is required under the EU Tissues and Cell Directive (Directive 2004/23/EC) to compile summary statistics of Intra Uterine Insemination ('IUI') and Gamete Intra-Fallopian Transfer ('GIFT') treatments using partner sperm. This information is published on a calendar year basis.
- 3.3 The Authority publishes extracts of Register Data in the form of 'Choose a Fertility Clinic' pages on its website (<http://www.hfea.gov.uk/fertilityclinics>), which is updated on a quarterly basis in January, April, July and October.
- 3.4 From October 2009, the published data will cover a three-year period.
- 3.5 These data extracts now generate considerable interest from the sector, and are the subject of greater media and public scrutiny than before. The Authority therefore considers it important to state clearly the procedures and timelines that it expects to be followed in respect of the collection, confirmation and publication of Register Data.

4.0 PROCEDURES

4.1 ROLES AND RESPONSIBILITIES

- 4.1.1 The Authority's Information Team shall be responsible for:
 - 4.1.1.1 notifying clinics of the deadlines for submission of data, sign off and publication of Register Data;

TRIM reference: 2009/05463

Version: 2.0

Doc name: Policy on Collection, Confirmation and Publication of Register Data

Release date:

- 4.1.1.2 timely publication of each 'Choose a Fertility Clinic' guide;
 - 4.1.1.3 ensuring that all clinics are aware of the process for signing off and publication of Register Data;
 - 4.1.1.4 ensuring that each clinic has access to all the necessary reports and information required to enable it to confirm the accuracy of the Register Data provided to the Authority;
 - 4.1.1.5 ensuring that all reports are cleared/validated before the data is signed off, or published as confirmed;
 - 4.1.1.6 dealing with queries raised by clinics in relation to their register data and information to be published in the clinics' 'Choose a Fertility Clinic' entry;
 - 4.1.1.7 ensuring that data published in the 'Choose a Fertility Clinic' section of the HFEA website is properly identified as confirmed or unconfirmed; and
 - 4.1.1.8 ensuring that appropriate caveats are published in the 'Choose a Fertility Clinic' section of the HFEA website where clinics have only been open for part of the three-year period for which data is published, where clinics have closed and reopened, or where two or more clinics have merged.
- 4.1.2 The Person Responsible for each licensed clinic shall be responsible for:
- 4.1.2.1 submission of relevant data in accordance with the proper means and timelines specified in Direction 0005 on Collecting and Recording Information for the Human Fertilisation and Embryology Authority;
 - 4.1.2.2 confirming the accuracy of the information submitted to the HFEA; and
 - 4.1.2.3 upon notification from the Authority of errors or omissions relating to a clinic's data, promptly ensuring that those errors or omissions are rectified.

4.2 COLLECTION OF REGISTER DATA

- 4.2.1 The Authority requires all licensed clinics undertaking IVF, Donor Insemination, Egg Retrieval for Storage, or Donation to create, store and submit records relating to Register Data to the Authority, through the Electronic Data Interchange ('EDI') system.

TRIM reference: 2009/05463

Version: 2.0

Doc name: Policy on Collection, Confirmation and Publication of Register Data

Release date:

- 4.2.2 The Authority requires all licensed clinics undertaking IUI or GIFT with partner sperm to submit an annual return to the Authority no later than 28 February in each calendar year. The annual return must be in the form set out in Direction 0005 on Collecting and Recording Information for the Human Fertilisation and Embryology Authority.
- 4.2.3 The Authority requires all licensed clinics to submit Register Data on the following forms:

Type of Form	Purpose of Form
Patient registration	To provide details of the patient receiving fertility treatment.
Partner registration	To provide details of the partner of the patient receiving fertility treatment.
Donor information	<p>To provide identifiable details of a donor and the reasons why they are donating.</p> <p>Licensed centres must use Donor Information for D v.2009 to record information relating to donors and ensure that sections 1-20 are completed for each donor.</p> <p>Patients providing gametes for a surrogacy arrangement must be registered as donors, therefore Donor Information forms must be completed for them.</p>
Donor re-registration (also known as a B form)	This form enables a previously anonymous donor to register as identifiable on the HFEA register.
Intention to treat	To inform the HFEA when a cycle in which eggs are to be collected has started.
IVF treatment & embryo creation and use	To inform the HFEA about the circumstances surrounding egg collection, embryo creation and /or transfer.

TRIM reference: 2009/05463

Version: 2.0

Doc name: Policy on Collection, Confirmation and Publication of Register Data

Release date:

Donor insemination treatment	To inform the HFEA when a patient has been inseminated with donor sperm.
Early pregnancy outcome	To inform the HFEA of the early outcome of a treatment.
Pregnancy outcome	To inform the HFEA of the outcome of any early outcome recording 'fetal pulsation seen'.
Donor Sperm procurement	To inform the HFEA about the quantity of sperm donated by each donor.
Embryo & gamete movement – in	To inform the HFEA about the number of embryos, eggs and ampoules, straws or vials of sperm transferred from another UK centre or imported from outside the UK.
Embryo & gamete movement – out	To inform the HFEA about the number of embryos, eggs and ampoules, straws or vials of sperm removed from storage at the centre; the reason for the removal; the centre code or the country of destination to which transferred or exported.

4.2.4 The Authority requires all licensed clinics to submit Register Data on the appropriate forms within the following timescales:

Category of Information	Timescale for Records to be submitted to the Authority no later than:
Patient registration details	5 working days after the patient has confirmed intention to undergo treatment
Partner registration details	5 working days after the patient has confirmed intention to undergo treatment
Intention to treat	3 calendar days after last menstrual period or stimulatory drugs being administered to/taken by a patient with the intention to perform IVF treatment.

TRIM reference: 2009/05463

Version: 2.0

Doc name: Policy on Collection, Confirmation and Publication of Register Data

Release date:

Donor information	5 working days after confirmation of sperm being released for use by the clinic, the harvesting of oocytes or in the case of imports, receipt of the imported eggs, sperm or embryos
IVF treatment & embryo creation and use	5 working days after the treatment cycle completion date
Donor insemination treatment	5 working days after the last insemination of the cycle
Early pregnancy outcome	8 weeks after the treatment cycle completion date
Pregnancy outcome	8 weeks after the predicted outcome date

- 4.2.5 The Authority requires the staff of licensed clinics to fill in the appropriate forms according to the guidance issued by the Authority. This guidance is available on the Authority's website at <http://www.hfea.gov.uk/2505.html>.
- 4.2.6 Where licensed clinics wish to amend the data that they have previously supplied to the Authority, they will be required to submit a correcting form. This will be the same as the original form supplied to the Authority, but clearly marked as a correcting form, and referencing the number of the original form that is to be corrected.
- 4.2.7 Where a licensed clinic has submitted duplicate forms, a deletion request should be made to the Authority via the EDI system clearly referencing the form to be deleted and stating the reasons for the request.
- 4.2.8 The forms received by the Authority from licensed clinics through the EDI system will be held in database tables on the Authority's computer servers. The date of receipt of the form will be recorded as the 'Envelope Receipt date'. Each form will be given a unique reference number.
- 4.2.9 Upon receipt of the forms by the HFEA, the Authority's servers will process them against a series of validation rules, to assess whether the forms are filled in correctly and whether all required information on the forms is supplied. The forms are also cross-referenced to ensure all other expected forms have also been submitted to the Authority (e.g. when an early outcome form is

received the system checks that the relevant treatment and patient registration forms are on the system).

- 4.2.10 The Authority's validation process does not assess the veracity of the information supplied by licensed clinics, and does not check the data supplied by licensed clinics against the medical records held by them.
- 4.2.11 The data received by the Authority from these forms submitted by licensed clinics will be used to produce a number of reports, including:
 - 4.2.11.1 the 'Validation Error Report', which identifies any inconsistencies or omissions on forms submitted. The Validation Error Report is updated daily and highlights what information or amendments are required.
 - 4.2.11.2 other reports which identify any information gaps or queries that may affect a clinic's statistics for the 'Choose a Fertility Clinic' entry ('verification reports').

4.3 CONFIRMATION OF REGISTER DATA FOR THE 'CHOOSE A FERTILITY CLINIC' SECTION OF THE AUTHORITY'S WEBSITE

- 4.3.1 8 weeks prior to the sign-off deadline, the Authority's Information Team will contact the Person Responsible of each licensed clinic, setting out the deadlines for submission of data to the Authority, sign-off, and publication of Register Data on the Authority's website.
- 4.3.4 The letter will also inform Persons Responsible when the verification reports for that clinic's data will be available, and will inform the Person Responsible of the requirements set out in paragraphs 4.3.7, 4.3.8 and 4.6.4.
- 4.3.5 8 weeks prior to the sign-off deadline, the Authority will make available to clinics a set of verification reports. The purpose of these reports is to identify any missing or erroneous forms or highlight any information the Authority considers necessary to complete the confirmation process.
- 4.3.6 8 weeks prior to the sign-off deadline, the Authority will also supply the licensed clinics with spreadsheets of raw data. The raw data details every treatment form for a specified 12-month period

and identifies which of those cycles have been included in the 'Choose a Fertility Clinic' entry.

- 4.3.7 If a licensed clinic cannot access the verification reports on the EDI system, it is the Person Responsible's responsibility to contact the Information team and inform them of this fact as soon as possible. Upon notification, the Information Team will find an alternative method to supply the reports.
- 4.3.8 2 weeks prior to the sign-off deadline, a Person Responsible should ensure that:
 - 4.3.8.1 all verification reports relating to his clinic have been cleared or confirmed;
 - 4.3.8.2 the raw data is reviewed against their clinical records to identify any discrepancies not identified by the verification reports (e.g. verification reports have been cleared but the licensed clinic still does not agree with the 'Choose a Fertility Clinic' draft entry);
 - 4.3.8.3 any outstanding forms have been submitted to the Authority; and
 - 4.3.8.4 the Information Team is informed no later than 1 week prior to sign-off if there are any concerns about the data, (the HFEA cannot guarantee to resolve any queries raised later than this before publication).
- 4.3.9 Any data or forms provided to the Authority after the deadline for submission of data notified to the licensed clinics will not be reflected in the 'Choose a Fertility Clinic' entry.
- 4.3.10 Where there remain unresolved discrepancies between data held by the Authority and that held by the licensed clinics or where there are outstanding items missing or unconfirmed on verification reports after the deadline for submission of data, that clinic's 'Choose a Fertility Clinic' entry will be published as unconfirmed.
- 4.3.11 When a Person Responsible is satisfied with accuracy of the data for their licensed clinic they must sign-off this data. To do this the Person Responsible must sign and date a hard copy of their summary data and return it to the HFEA no later than 5pm on the date notified to the clinics (the 'sign-off deadline'). The draft entry can be returned by post, fax or by email with a scanned pdf file.

4.3.12 Where the Information team has not received the signed hard copy of the draft 'Choose a Fertility Clinic' entry from a Person Responsible by the sign-off deadline, the data for that licensed clinic data will be published as unconfirmed.

4.3.13 After midnight on the date notified to the clinics as the deadline for submission of data, the draft entry for each licensed clinic will be frozen, and any subsequent submission of data via the EDI system by a licensed clinic will not be registered in the draft entry.

4.4 PUBLICATION OF EXTRACTS FROM REGISTER DATA ON 'CHOOSE A FERTILITY CLINIC' SECTION OF THE AUTHORITY'S WEBSITE

4.4.1 The data that is published on the 'Choose a Fertility Clinic' section of the Authority's website will be accompanied by the following caveat:

'This data is supplied to the HFEA by individual clinics who are responsible for confirming the accuracy of the information supplied by them. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as amendments are notified to us by clinics, or issues with the data are identified through our quality management systems.'

4.4.2 Alternative caveats may be necessary under the conditions identified in sections 4.1.1.7 and 4.1.1.8.

4.4.3 The following data will not be published in the 'Choose a Fertility Clinic' part of the Authority's website:

4.4.3.1 treatment cycles in which both fresh and frozen embryos were transferred in the same cycle;

4.4.3.2 any mixed IVF and GIFT cycle.

4.4.4 The information listed at 4.4.3 will not be published because there would be ambiguity as to which treatment type the outcome should be attributed to.

4.4.5 Confirmed and unconfirmed data will be clearly distinguished on the 'Choose a Fertility Clinic' part of the Authority's website.

4.5 DIRECTIONS

- 4.5.1 This policy should be read in conjunction with Direction 0005 on Collecting and Recording Information for the Human Fertilisation and Embryology Authority.

4.6 FAILURE TO COMPLETE THE CONFIRMATION PROCESS AND TO CLEAR ERROR REPORTS

- 4.6.1 The Authority will only publish and update data on the 'Choose a Fertility Clinic' part of its website at fixed quarterly intervals.
- 4.6.2 The Authority will require Persons Responsible who have not confirmed the data for their centre by the original sign off date, to confirm such data by the next sign-off date. Failure to do so may be brought to the attention of the Authority's Licence Committee.
- 4.6.3 The Authority considers that data which has been signed-off by a Person Responsible is suitable for publication as 'confirmed data'. Upon publication, such data may be used and relied on by potential patients to make decisions about their treatment. Therefore, the Authority stresses that Persons Responsible should not sign off the data for their licensed clinic unless and until they are satisfied as to the accuracy of the data that they have provided.
- 4.6.4 In particular, the Authority requires Persons Responsible to ensure that, before they sign-off their data, they are satisfied that:
 - 4.6.4.1 the number of treatment cycles completed within the reporting period is 100% accurate;
 - 4.6.4.2 all early outcome forms and all outcome forms have been submitted to the Authority, and have been filled in accurately; and
 - 4.6.4.3 all registration forms relating to patients undergoing treatment have been submitted to the Authority and have been filled in accurately.
- 4.6.5 Where the Authority becomes aware that a licensed clinic has made amendments to its data after that data has already been signed-off by the Person Responsible for the clinic, and those amendments relate to issues that the Person Responsible should reasonably have been aware of, or addressed, before signing-off

the data, the matter will be brought to the attention of the Authority's Licence Committee.

4.6.6 Where the confirmation process in respect of any data has not been completed by the deadline (whether or not this is because of delays on the part of the licensed clinic or by the Authority), the data will be published as 'unconfirmed data'.

4.6.7 The Authority requires Persons Responsible to ensure that the error reports made available by the Authority are reviewed by their licensed clinics on a weekly basis. This is in order to prevent a build up of unresolved data issues, which may affect the quality of the data held by the Authority in its statutory Register.

5.0 REVIEW

5.1 This policy will be reviewed every 3 years.

5.2 The date of the next review is scheduled for September 2012.

Control sheet

Document control

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Version	Changes	Drafted/Updated by:	Release date
1.0	First draft	David Gomez	17/09/08
2.0	Revised to accommodate launch of updated Choose a Fertility Clinic, publication of 3 years' data, and implementation of new directions	Richard Martin	09/09/09

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