

10 January 2014

Open Consultation Response: Nuffield Council on Bioethics: The linking and use of biological and health data

In response to the consultation on the linking and use of biological and health data, the following information is submitted to assist the Nuffield Council on Bioethics. Our submission includes:

- The role of the HFEA and its legislative framework;
- How the sharing of our data facilitates research; and
- How we are seeking to improve the collection of health data and information

1. The role of the HFEA and its legislative framework

Legislation

The HFEA is required by Section 31 of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended) to maintain a Register of Information which records, amongst other things details of regulated assisted reproductive treatments and the use and storage of gametes and embryos. However, the majority of data fields outlined are determined by HFEA policy rather than the legislation itself. The forms we require clinics to complete can be found on our website at: <http://www.hfea.gov.uk/fertility-clinic-forms.html>

There are statutory limits to what information the HFEA can disclose and to whom. The legislation provides very strong protection of patient, donor and offspring confidentiality (stronger still than normal medical confidentiality). Any (even inadvertent or indirect) disclosure of an individual's information that is contained on our Register may constitute a criminal offence. Therefore, in response to question 1 (Do biomedical data have special significance?) the data held by the HFEA has special confidentiality provisions which apply to it.

This data has the potential to be used for linkage in research to many other datasets, however the strict confidentiality provisions surrounding data relating to IVF treatment means that specific systems are required for use of this data in research.

Finally, the HFEA also have a statutory duty to provide information to patients and the public about fertility treatment and licensed clinics and therefore serves a role as an information provider.

Role as information provider to the public

In 2009 the HFEA launched a new and improved interface for patients to access data (primarily success rate data regarding IVF and other fertility treatments) relating to individual HFEA licenced centres, called *Choose a Fertility Clinic*: <http://guide.hfea.gov.uk/guide/AdvancedSearch.aspx>

The Choose a Fertility clinic search engine aims to provide:

- More meaningful data and more guidance on how to use it;
- A better search facility; and
- More information about treatments and services offered

We also provide many other routes for patients, public and researchers to access information e.g. a fertility treatment: trends and figures report, a *One at a time* website, and a donor statistics reports:

- http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2011_-_Annual_Register_Report.pdf
- <http://www.oneatitime.org.uk/>
- <http://www.hfea.gov.uk/3302.html>

2. How the sharing of our data facilitates research

The HFEA does not conduct any published research as an organisation. However we do facilitate research via two main routes:

Research using anonymised data - Research that aims to only interrogate the HFEA Register and not link subjects contained in our Register to other datasets (for example to explore long term health outcomes of fertility treatments for women and their children), does not need to have access to patient identifying information. **The HFEA publishes an anonymised extract from the register on its website and this can be readily accessed by researchers.** This is an incredibly rich source of approximately 20 years' worth of data and can be viewed at: <http://www.hfea.gov.uk/5874.html>

This research can answer important questions, like which factors (patient, treatment type, technique used) influence treatment outcomes, or which indicators might suggest that a patient should have only one or two embryos transferred during treatment.

Research using patient-identifying information - The statutory provisions now contained in the HF&E Act 1990 (as amended), and in regulations covering the disclosure of Register data for research purposes, set out for the first time that under strict conditions identifying information about fertility patients can be made available to research. This requires a specific consent regime.

The HFEA convenes a Register Research Panel to give thorough scrutiny to any applications for access to patient-identifying information for research purposes, and must ensure that appropriate safeguards are in place before agreeing to any application. Details of research that is currently being conducted can be found at: <http://www.hfea.gov.uk/5968.html>

A recent example of a successful linkage project investigated whether children born after assisted reproductive treatment (ART), such as in vitro fertilisation

(IVF), have a higher risk of developing cancer than other children. The researchers also aimed to assess whether different types of infertility or different fertility treatments might be associated with different types of childhood cancer. The findings showed no evidence of an increased risk of cancer:
<http://www.nejm.org/doi/full/10.1056/NEJMoa1301675>

3. **How is the HFEA seeking to improve the collection of health data and information?**

Given the particular complexities relating to data held by the HFEA, the organisation understands that there is a need to ensure that information collection is governed by rigorous regulatory mechanisms and a framework that is sensitive to scientific and ethical issues.

In recognition of this the HFEA is embarking on a substantial programme of work that we are calling *Information for Quality*. This aims to transform the way we collect and use information.

Its starting point is a review of the information we collect from licensed clinics taking into account the uses to which it is put, enabling the creation of a *data dictionary* a published document that sets out the data held by the HFEA (both historical and current), the definition of each item including the frequency of collection and the veracity of each.

Clinics spend a substantial amount of time submitting their data to the HFEA. As well as reviewing the quantity of information collected and submitted we are also reviewing the *process* by which data is submitted to the HFEA with a view to streamlining further.

This is expected to improve the quality of the information we hold and reduce the cost of its submission. We are reviewing the way we publish information, for example choose a fertility clinic, and seeking to maximise the information we hold by publishing a wider range of reports and encouraging the use of linkage studies. As such we are in the early stages of discussion with the Health and Social Care Information Centre to explore how we can enhance this aspect of our work drawing on wider understanding of health datasets and from best practice.

We also use the website to promote transparency and enable us to be held to account for the decisions and actions we take.