

The UK Human Fertilisation and Embryology Authority (HFEA): Experience with ART in the UK

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Introduction

One of the key differentiating factors between the Human Fertilisation and Embryology Authority (HFEA) in the UK and similar authorities in other countries is that the UK alone requires all treatment cycles of IVF, or any procedure whereby gametes or embryos are manipulated, stored and/or used for treatments or research, to be reported to the authority along with details of both procedures and outcomes. In the UK, clinics are required by law to record and submit clinical data on all such treatments and they can lose their license if they fail to comply with this policy. Therefore, this legal requirement attaches a greater degree of accuracy to this database compared to others such as SART in the USA and FIVNAT in France. As such, the HFEA dataset provides a perfect opportunity to test key hypotheses related to clinical preferences and outcomes following procedures of assisted conception.

Established in August of 1991, 13 years after the birth of Louise Brown, the first IVF conception of Professor Robert Edwards and the late Mr. Patrick Steptoe, the HFEA maintains one of the world's largest IVF datasets as it oversees activities in accordance with the 1990 Human Fertilisation and Embryology Act (Her Majesty's Stationary Office, 1990, c. 37). As a non-departmental, government body the HFEA regulates and inspects all clinical facilities providing IVF, donor gamete or donor embryo services, or provisioning the cryostorage of sperm, eggs or embryos. Its main purpose is to safeguard the interests of patients or donors, children, embryos, gametes, doctors, scientists, the wider public, and future generations (HFEA 2003).

The principal tasks of this authority are to license and monitor all UK clinics that provide in vitro fertilisation (IVF), donor gametes (insemination and egg or embryo donation), and the storage of human gametes and embryos. In an additional role, the HFEA reviews individual patient records in light of the provision of treatment services, and advises the Secretary of State on important matters of policy.

According to published literature (HFEA Literature 2003), the HFEA's statutory functions include:

- Producing the *HFEA Code of Practice* which provides guidelines to clinics about the proper conduct of HFEA-licensed activities;
- Maintaining a formal register of information about donors, treatments and children born from those treatments;
- Providing relevant advice and information to patients, donors and clinics; and
- Regularly reviewing information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFEA Act 1990.

How the HFEA collects treatment data

Licensed clinics are required to complete several forms of consent for each patient, which then are sent to the HFEA where they are held in confidence and reviewed periodically to guide policy in making changes to medical practice. These forms require at various stages the commitment of doctors, nurses, embryologists and the patients themselves. Doctors oversee the process to ensure accurate information is recorded in a timely fashion. Embryologists record data at the time of egg collection and transfer, and patients themselves report their own results of the pregnancy test(s), complications, birth event(s) and any abnormalities.

Once the information is received by the HFEA, data are entered in a master database and analysed. Under no circumstances is identifying information disseminated to the public.

In addition to the number of HFEA forms that are completed by patients and hospital carers, patients' IVF and obstetric histories are also recorded, along with number of prior treatment attempts per specified clinic. Reasons for infertility are indicated on each of the forms as: male-factor, female-factor or idiopathic.

Storage of Gametes and Embryos

Patients must indicate from the outset the duration they wish their samples to be stored. In instances where samples are to be stored for more than 5 years, a designated HFEA form must be signed by a qualified medical practitioner. In addition, most clinics require a preconceptual agreement that lists choices for disposition of their sperm, eggs and/or embryos in the event of death or mental incapacitation of the putative mother or biological father. Sperm, eggs and/or embryos may be allowed to perish or else continue in storage for an indicated purpose that must be stated in advance. Patients can withdraw their consent at any time, also, provided their samples have not already been used.

Gamete and embryo details are recorded on the HFEA Treatment and Embryo Creation and Use Form. This form indicates which patients are using whose samples for their treatment, as would be the case with a donor for another patient's treatment, or in a surrogacy arrangement. Patients and/or donors must consent to and provide details of the reasons for egg collection to create embryos and indicate whether this is for contemporaneous treatments or use at a later date, and whether embryos are to be stored cryogenically. If some embryos are to be donated for research purposes, then patients must state so prominently on this form. In addition, total number of previous IVF pregnancies attempted is recorded along with the resultant number of live births. Duration of infertility is recorded along with the duration of treatment. Number of eggs retrieved and the number of those mixed, fertilised, used, stored, thawed, and/or transported are likewise indicated on this form.

The date of egg collection (day/month/year) is recorded along with, where applicable, the method of hormone stimulation (e.g. anti-oestrogens, gonadotrophins, or another type). If no eggs were collected, the reason is stated from a choice of contraindications in light of risk of Ovarian Hyperstimulation Syndrome (OHSS), inability to retrieve eggs, or another reason. When eggs are collected, the number retrieved are recorded and their fates determined by the patient. Possible embryo fates include: storing for later use, discarding, using a certain amount in fresh cycle IVF and donating some or all to research facilities.

As sperm, egg freezing and embryo freezing are becoming increasingly popular techniques in assisted conception more forms are required to ensure each treatment is documented. When gametes or embryos are to be stored, patients must complete either the Form of Consent to Storage and Use of Eggs and Embryos, or the Form for Consent to Storage and Use of Sperm and Embryos. On each of these, patients indicate their consent to donate their eggs or sperm for the purpose of treating themselves (with or without a named partner), treating any others, and/or donating gametes or embryos for research purposes.

In the case of gamete donors, a Donor Information Form is completed for the HFEA which lists the donor's: name(s), date and place of birth, sex, height and weight, ethnic group, eye colour, hair colour, skin colour, religion, occupation, interests, the date the gametes were first used or supplied for use in treatment, any donations to other centres, any children of their own, and a brief narrative of one's self to pass to any child born as a result of their help, as well as to their legal parents.

When it is decided to undergo a treatment cycle of IVF, the type of treatment is indicated (e.g. fresh/frozen, stimulated/unstimulated, IVF or IVF with ICSI, etc.). Then the date of embryo transfer (day/month/year) is recorded along with any consequent outcomes of no pregnancy, biochemical pregnancy only, miscarriage, ectopic pregnancy, heterotopic pregnancy, molar pregnancy and foetal heartbeat confirmed. If embryos are not transferred in a given treatment cycle, the reasons are recorded.

In addition to the requested data, patients may state particular conditions as to use of their gametes or embryos. The normal maximal allowable storage time for gametes (eggs and sperm) is 5 years and 10 years for embryos. Storage of gametes or embryos for durations of more than 5 or 10 years, respectively, requires medical consent. If no other indications are given, samples are thawed and discarded.

Outcomes

Outcomes are recorded on the HFEA Pregnancy Outcome Form and include: number of gestational sacs detected by foetal heart pulsation, the age of gestation in weeks, and whether a treatment cycle and pregnancy resulted in a live birth surviving through 27 completed days post-delivery. Miscarriages, terminations, embryo reductions, still births and/or neonatal deaths are also recorded, along with their cause(s) if known. In the event of a live birth, plurality is listed along with weight of each child in grams. The sex (male/female) of each baby is indicated along with their place of birth and county of registration, if known. The delivery day (day/month/year), method of delivery, NHS number, and any congenital abnormalities also are recorded.

How the clinics and HFEA collect outcome data

Many units operate a satellite system whereby smaller district general hospitals (DGHs) refer patients into a tertiary centre for treatments such as IVF with or without ICSI. Under such circumstances, a patient may initially present to a larger clinic but receive their treatments in a smaller clinic closer to home. However, satellite centres are the responsibility of the licensed centre, and it is the responsibility of the latter to ensure that all forms are complete accurately and in a timely fashion.

Advantages and Limitations of the HFEA Database

It goes without saying that the construction and maintenance of a complex database such as described above is not without limitations as well as advantages. The primary advantage is that, because all births from assisted conception are included, long-term follow-up studies are possible on subsets of the data. A secondary advantage is that data reliability and completeness tend to bolster public confidence in policies and reports directed toward patients as well as practitioners. A third and vitally important advantage is that members of the public who wish to avail themselves of infertility treatment are able to compare clinic success rates from a totally independent source. Lastly, the data lend themselves to a variety of research endeavours.

Amongst the most obvious limitations of the present system in the UK is that the number of forms required for each patient constitutes a bureaucracy, notwithstanding the fact that without the forms the database could not exist. Further, the need to fill out the forms in every instance is time consuming and financially costly which certainly is factored into the overall cost of each treatment cycle. Third, the creation

of comparative results in tabular form allows the public to “cherry pick” to attend one clinic or another based entirely on numerical success rates (positive or negative) rather than making a choice based on the quality of medical care. Finally, the promulgation of national policies that regulate reproduction should be based on sound science, but the implementation of these policies may abrogate the patient’s right to choose her therapy in the manner that she feels most appropriate. This is particularly evident in terms of the numbers of embryos transferred per cycle.

The policies of HFEA are unique to that body and to the United Kingdom. They do not copy nor act in concert with other regulatory bodies in different countries - the principle ones being SART in the United States and FIVNAT in France. Interested readers are free to consult the HFEA website as well as the respective websites of SART and FIVNAT for further details which are in the public domain.

Quality Management in Assisted Reproduction

Reproductive medicine is among the fields in which the introduction of quality management has made great strides. Certainly, this has been true of European IVF centres and the UK in particular. In the past, a series of specific quality management systems for various industries came into existence worldwide such as the Good Production Practice (WHO directive, 1964), which was developed for the pharmaceutical and food industries and the European Community Pharmaceutical Directive which was established for the clinical and research settings (European Community Pharmaceutical Directive, 1965).

In June 2004, the Oxford Fertility Unit, Nuffield Department of Obstetrics and Gynaecology, University of Oxford, became the first University-based fertility centre in the United Kingdom to achieve certification of ISO 9001:2000. Use of the International Standard Organisation (ISO 9001 manual series: 2000) manuals became globally widespread during the 1980s and created regulations for quality management systems with the standards series 9001 through 9004. The ISO 9001 standard is applicable for manufacturing and complicated service enterprises including hospitals and fertility units. Certification of this quality assurance standard ISO 9001 is given when assessment of clinical, nursing and laboratory procedures has been made. Patient care, facilities and customer satisfaction are evaluated by this organisation. The implementation of ISO 9001 guarantees quality and standardises management systems to provide quality service to all patients, employees and associates working within the centre.

Conclusions

As the HFEA dataset is comprehensive it serves as an excellent model for other countries, particularly where clinics are not absolutely required by law or policy to report treatment and outcome data for IVF. Eliminating underreporting of treatments and outcomes in countries beyond the UK can be expected to lead to a more accurate indication of healthy baby rates within and between populations that differ in age and treatment histories. The ISO 9001 standard will guarantee a high standard of treatment provision and patient satisfaction in existing and emerging fertility clinics around the world.

References

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