Regulatory reform: data-sharing

Introduction

1. The Human Fertilisation and Embryology Act 1990 (as amended) (the Act) sets out a range of conditions that govern the use of fertility data in both treatment and research.

2. Those restrictions are typically tighter than for most other medical records, reflecting in large part the sensitivity surrounding assisted reproduction treatment when the Act was drawn up. While fertility treatment is now more common and more talked about, we should not assume that all patients would be relaxed about a general loosening of the confidentiality requirements.

3. We do not have evidence as to whether sharing fertility treatment information in wider health records could add to burdens for patients who may perceive their treatment to carry a stigma, or add to burdens for patients who are concerned that views around their fertility treatment could negatively affect the other (non-fertility related) healthcare that they might receive.

4. It therefore follows that although the issues set out in this paper can appear technical, there is a need to seek an appropriate balance between the wishes of some patients and the benefits to treatment and research as a whole

The sharing of patient data in a medical setting

The current situation

5. The Act requires that fertility patients' treatment details are kept confidential from their other medical treatment data. This is in marked contrast to most other examples of wider medial practice in the NHS at least, where patient information is shared for the purposes of individual care without seeking the patient's consent. This enables the NHS to improve the individual's care, speed up diagnosis, and function more safely and smoothly as well as providing important centralised records for research or commissioning.

6. However, under the Act the disclosure of information about an individual's fertility treatment, within the normal bounds of medical confidentiality, could result in identifying information about their partner, or child born from treatment, being disclosed to other healthcare professionals without their consent.

Issues

7. **The difficulty of sharing fertility treatment details within other clinical settings makes joined-up patient care more difficult.** The restrictions in the Act on fertility clinics sharing records data with other healthcare providers can have a directly negative effect (or risk such an effect) on patient care. Two examples illustrate the issue. First, Ovarian Hyperstimulation Syndrome (OHSS) is a potentially serious side effect which some patients develop in reaction to the drug treatment necessary for IVF which is why the HFEA requires licensed clinics to report all 'severe' and 'critical' cases of OHSS to us. The confidentiality provisions of the Act, mean that fertility clinics have to rely on building relationships and data sharing agreements with their local hospitals in order to get a clear picture of the number of OHSS cases amongst their patients. However, not all patients with OHSS will attend a local hospital that has a data sharing agreement with their clinic. Second and more generally, if health professionals do not know a

patient is/has gone through fertility treatment with access to their medical notes, patients may not receive the right ongoing medical support, nor the right number of scans and check-ups, risking babies being born too early, or patients experiencing untreated severe anxiety during and after pregnancy. For patients whose treatment was unsuccessful, their GP would not have been informed of the outcome, so no follow-up or support will be offered.

Options for change

8. **The difficulty of sharing fertility treatment details within other clinical settings makes joined-up patient care more difficult.** The Act could be updated to require automatic records sharing from clinics to the NHS central records systems, to support more joined up and safer patient care at hospitals and GPs. Analogous provision would also need to be made for patients receiving medical treatment wholly from private providers.

The sharing of patient data in a research setting

The current situation

9. The Act and HFE (Disclosure of information for research purposes) regulations 2010 prevent the HFEA from sharing register data with researchers where it would identify gamete or embryo donors, patients and their partners undergoing treatment with donated gametes or embryos, and donor-conceived offspring.

Issues

10. **Exempting donor information on the register from research use.** Under the Act, only HFEA register information about gamete or embryo donors, patients and their partners undergoing treatment with donated gametes or embryos, and donor-conceived offspring that has been completely anonymised, can be shared with researchers. This means that various other kinds of important research that could benefit single patients and same-sex couples, as well as all others who use donated gametes (and obviously donors and donor-conceived people themselves) are entirely prevented from happening by these legal restrictions. Given the removal of donor anonymity in 2005, which is effective from 2023, and the growth of genetic testing websites, the concerns around donation are arguably less than when the regulations were first drawn up.

Options for change

11. **Exempting donor information on register from research use**. The changes described above suggests that the risks are reducing while the potential benefits of research are increasing. This lead us to the recommendation that the Act should be amended to allow register information from the donors of gametes and embryos to be shared for all kinds of research, beyond anonymised research.

Incentivising the use of HFEA Register data in research

The current situation

12. The Act and HFE (disclosure of information for research purposes) regulations 2010 allow the HFEA to charge research applicants a fee to cover the cost to the HFEA of the collation and disclosure of information from the register. The fee is based on a charge of £500 per day, to a maximum chargeable cap of ten working days, at £5,000 for the disclosure of identifiable/depersonalised data. We are currently unable to charge at all for preparing anonymised data sets.

Issue

13. **The charging regime is insufficient to drive the proactive use of the HFEA Register data**. The current limit of £5,000 is frequently insufficient to cover HFEA's staff time costs alone for the time it takes to prepare data for researchers, which often goes beyond ten working days. Preparing (currently non-chargeable) anonymised data sets can take a comparable amount of work to prepare as with the (chargeable) identifiable/depersonalised datasets. And since some such requests may come through the Register Research Panel process, depending on a comparable amount of work may go into reviewing and approving anonymised datasets.

    This means that the HFEA struggles to responded to researchers requests or has to do so out of pocket. It also means that the HFEA cannot proactively engage with the research community, which may in itself act as a brake on much needed research.

    Raising the fee charged might appear counter-productive, but researchers tell us that the maximum £,5000 is much lower than typical costs for obtaining comparable types of research data obtained from other sources, and that in addition those data holders are usually not limited to staff time cost-recovery costs only. Those higher costs are usually funded from the grant application itself.

Option for change

14. **The charging regime is insufficient to drive the proactive use of the HFEA Register data**. The Act should be amended such that HFEA should be able to charge full cost recovery to researchers for access to our register data regardless of how identifiable it may be, at a rate set by the Authority. Rates should not be set and specified by the Act's regulations but should develop over time alongside the charges relating to comparable data sets.