

The HFEA Information Strategic Framework

Becoming a recognised source of authoritative information, a focused regulator and a joined-up policy maker

HFEA, October 2008

1. Overview

1.1 This document maps out the ambitions we have for the HFEA as an information provider. It lists the many initiatives we have recently taken to improve how we collect data from the fertility sector (in its widest possible sense), record and analyse it, and in turn use it to provide authoritative, targeted information back to all those with an interest in what we do.

1.2 We have a statutory duty to provide information to patients, the general public, clinics and the Government (section 8 of the HFE Act 1990). This recognises that we are uniquely placed to use our expertise in the regulation of fertility services in order to help others make informed decisions: People who are considering the use of fertility services, clinics that need to understand regulatory and best practice requirements and policy makers who are addressing hard to predict consequences of technological progress.

1.3 Section 31 and 33 of the HFE Act deal in more detail with the major repository of information we have set up: the register. The register contains information about regulated fertility treatments, donation and the use of embryos. Those conceived through donation have limited access rights to information about their donor – the end of donor anonymity in 2005 has expanded these significantly.

1.4 The end of donor anonymity is just one of the drivers for change that has focussed our minds more acutely on the value and centrality of our information. Some other drivers (for example rising expectations by the public and the HFE Bill currently going through Parliament) are discussed in more detail in this document. The amount of information you can find on the internet about health related topics, and about healthcare and its providers has increased exponentially over recent years. This means there is more, not less, need for authoritative, reliable, impartial information provided from us.

1.5 We are also not acting in isolation. For example the Department of Health, the National Institute for Health and Clinical Excellence and the NHS itself have all launched information quality initiatives that aim to enable service users and providers to access reliable, personalised information in order to aid decision making. Despite there being much room for improvement and thus a renewed emphasis on our handling of information, it is also worth mentioning that in some respect the HFEA has been at the forefront of developments in health information: Ever since its inception, the HFEA has published clinic by clinic results – a move which is now widely repeated across various health sectors.

1.6 Although this document focuses on our role as a provider of information, it is important to emphasise that better information management is not just about providing more tailored information to our external stakeholders, it is also about everything else we do as a regulator and policy maker. Information is the most

important asset for evidence based policy making and for risk based regulation. We will see the benefit of better information management not just in the way we deal with public requests for our information, but also in how well we are able to join up our various functions, focussing our regulatory powers where it matters and allowing policy making to benefit from our regulatory experience.

2. Principles

2.1 We have defined our general purpose and principles. These are also relevant to this information strategic framework and will inform how we act as an information provider.

Purpose

We are the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. We set standards for, and issue licences to, centres. We provide authoritative information for the public, in particular for people seeking treatment, donor conceived people and donors. We determine the policy framework for fertility issues, which are sometimes ethically and clinically complex.

Principles

1. We treat people and their information with sensitivity, respect and confidentiality.
2. We observe the highest standards of integrity and professionalism in putting into effect the law as it governs our sector.
3. We consult widely - listening to and learning from those with an interest in what we do.
4. We keep abreast of scientific and clinical advances.
5. We exercise our functions consistently, proportionately, openly and fairly.

Principles of information provision

2.2 Applying these broader principles to the role of the HFEA as an information provider leads to the following commitments:

- We want to be the recognised source of accurate, independent and tailored information on the fertility sector.

- We will simplify our data collection and will remove duplication wherever possible.
- We will comply with all statutory requirements, in particular our duty to maintain the security of confidential and sensitive information.
- We are committed to understanding the diverse and changing information needs of our various stakeholders and aim to address them in a flexible, responsive and timely way.
- We will provide information in order to:
 - enable patients, donors, and donor conceived individuals to make appropriate decisions
 - continuously improve clinical practice and patient care
 - support research of high quality
 - create and maintain confidence in the effective regulation of the fertility sector

3. Drivers for change

The HFE Bill

3.1 The HFE Bill currently going through Parliament widens our existing statutory obligations. Donor conceived people will be able to access non-identifying information about their donor when they reach 16, and identifying information once they are 18 years old. They can also get in touch with their donor-conceived genetic siblings, with mutual consent. Donors are entitled to learn of the number, sex and year of birth of children born from their donation.

3.2 The Bill will also for the first time make it clear that the information contained in our register (which dates back to 1991) is a valuable research tool and should be used as such.

Programme 2010

3.3 We are currently conducting a major improvement programme, called Programme 2010. In addition to gaining a better understanding of what our public and users want and to respond to that, the Programme aims to:

- implement all the changes required by the HFE Bill – expected to become law in 2009;
- review and where possible streamline all our structures, processes and procedures;
- ensure compliance with wider government initiatives and legislation (Better Regulation agenda, Regulatory Enforcement and Sanctions Bill, Information Governance Assurance Programme); and
- improve our performance as a regulator.

3.4 As part of Programme 2010, numerous projects have been set up reviewing current practice and aiming to improve performance of the HFEA as a regulator. Many projects are directly concerned with our role as an information provider. These projects are listed throughout this document in order to set out how we aim to achieve our vision as an information provider.

Rising expectations

3.5 The HFE Bill, once it has become law (expected for October 2009) is not the only factor that drives change in the way we deal with information. All those with an interest in what we do have increased expectations about how we should behave as an information provider.

Patients and those considering treatment

3.6 Fertility patients and those deciding whether to start treatment are in particular need of reliable, authoritative and independent information. Unwanted childlessness is distressing, and patients can be vulnerable to exaggerated expectations and commercial pressures. It is not our role to tell patients what to do, but we believe firmly that patients can only make the right decisions for themselves, their families and partners, if they have all the relevant information provided to them, in the format they find most useful. This includes information about clinical outcomes, costs, social and emotional impacts of infertility and its treatment, and regulatory requirements. We also aim to help patients find other trustworthy sources of information and support.

The general public

3.7 The field of fertility medicine and embryo research is often controversial and always fast moving. Strong, and often contradictory, views are frequently expressed in the media, in the political arena and by those who are personally affected. The UK settled for a legislative approach where permissiveness (clinicians and researchers can do more things than in other countries) was combined with regulatory force (through setting up a statutory regulator, the HFEA). In fact, our duty to provide accurate and independent information to anyone with an interest in what we do or regulate, is part of this: transparency about what goes on in the world of fertility is a prerequisite for public confidence in regulation.

3.8 The 'public' does of course not consist of homogenous groups with identical interests. We deal with many different interest groups, campaigners, Parliamentarians, journalists and professional bodies and consider their interest in our information legitimate and a corporate priority.

Anyone involved in donation

3.9 Those who have been conceived through donation, and those who have given or received donated embryos or gametes, are reliant on our register information in a particularly intimate and personal way. Public attitudes about donation and about the importance of knowing one's origins have slowly changed over the years. This was reflected in the law when donor anonymity came to an end in 2005. We are aware that the number of applications to access register information will grow and that each applicant deserves to be treated with the highest possible degree of accuracy, sensitivity and care. We are also fully committed to protecting the confidentiality of personal information as a prerequisite to maintaining public trust in our register.

Fertility practitioners and licensed clinics

3.10 Those working in a clinic that is regulated by us are most heavily burdened by our requests for information. Most of the information collected from centres about treatment cycles, embryos, or the use of donated gametes is required by the law. Clinicians are clearly interested in providing the same information only once, and in the ease and clarity of this process. They also have a rightful expectation that all the information they contribute to our Register is put to the best possible use, and that it is analysed and published in order to improve practice in the sector.

Researchers

3.11 We hold a unique data set which is of interest to researchers both inside and outside the medical field. New legislation will entitle them to access register data, in exceptional circumstances even where this identifies those who received fertility treatment without their consent. This access right will be more clearly defined in regulations which the Department of Health will consult on late in 2009.

3.12 We are aware that the confidentiality of those whose information is held on the register and the expectations of those wishing to use this information to increase our knowledge of the safety and implications of fertility treatments need to be finely balanced. Another question of balance is that the HFEA is obliged, under better regulation principles, to minimise the amount of data it collects from those it regulates, despite this information being of interest to researchers. We are committed to being a responsive and accommodating partner to those who wish to use register information for high quality research, whilst maintaining the confidentiality requirements imposed by law and bearing in mind the need for minimising the burden of data collection on the sector.

Government

3.13 The HFEA has a duty to advise the Secretary of State of developments in the field of fertility science. Regularly, this takes place through informal contact with other Government departments or regulators. At times, Government formally asks us for advice. For example this was the case when we conducted a policy review on behalf of the Government on whether sex selection should be allowed for non-medical reasons. We report to the Government on how well we respond to requests for information.

4. Information held by the HFEA

4.1 Our different roles as a regulator, a policy maker and the owner of a register incorporate a variety of ways in which data is collected in the first instance and then turned into useful information. The following describes the main sources of information we own.

Register information

4.2 Proportionally the biggest share of data we collect is register information. Every time a patient starts regulated treatment, or gametes or embryos are stored, a form is filled in and sent to us. There is a statutory obligation on clinics to provide this data and on us to collect it.

4.3 Since 2007 this process no longer involves manual form filling and checking, but is done electronically, through the Electronic Data Interchange (EDI). EDI also has a wide range of verifying and checking processes built into its architecture. This guarantees to a large extent that incomplete or logically incoherent forms cannot be returned to us. EDI has made the process of data submission and analysis much easier, but there is still room for improvement.

Review of register data collection and EDI V2

A 'stock take' of all the register information that is collected is currently taking place (as part of a wider information audit in Programme 2010). This is to assess statutory compliance (are we collecting all the information we are obliged to collect). However, given changes to our data set were only introduced in 2007, no fundamental changes to the data currently collected by us are expected to take place this year.

A wider, more fundamental review of our data collection more generally will take place from autumn 2009 onwards, after the review on fees has been completed.

Implementation of the HFE Bill will require clinics to submit new information about patients consenting to their data being disclosed to researchers. This will take place from October 2009.

Later this year, a new more user friendly version of the system for data collection, Electronic Data Interchange, (EDI V2) will be introduced. The user experience has been trialled with clinics and has led to improvements and a reduction of duplication.

4.4 Register information is used to establish the level of fees clinics need to pay to the HFEA. More importantly, it is used to establish how well IVF and other fertility treatments 'work', both at a national and at a clinic level. This information is published every year and is often referred to as 'success rates'. However, the information contained in the register is much richer than this term suggests. The HFEA has moved to publishing a 'long term data analysis' on its website, which sets out long term trends in the UK fertility sector.

4.5 The wealth of information contained in the register needs to be put to better use for patients, clinics and researchers. There are plans under way to extend the analysis and publication of our national dataset to allow all those with an interest to benefit from the insights that can be derived from it. The substantial ongoing work around 'outcome data' will be discussed in more detail below.

Regulation as knowledge generation

4.6 We also collect and collate significant amounts of information through our regulatory function. Inspectors assemble compliance information about clinics before, during and after inspection visits. Clinics are obliged to tell us of incidents or 'near misses' (where patients or gametes and embryos were inadvertently put at risk of harm). We are obliged to keep a register of such incidents. We are also contacted by patients with comments or complaints about clinics, and where this is appropriate, incidents and complaints are investigated further. All this regulatory activity needs to be regarded as knowledge generation, which must be used to help us and the sector to make informed decisions and to improve practice.

4.7 Feeding into these regulatory processes is the information generated through operational audit. Its role is to check the quality and completeness of reporting of treatment information by clinics. Varying degrees of compliance are used to judge the level of risk inspectors expect to address at individual clinics. A further contributor of knowledge in the regulatory field is our legal team, who deal with clinic non-compliance in its widest sense and enable Licence Committees to make informed decisions about individual clinics.

Review of inspection and licensing

We aim to streamline licensing and inspection processes and to put the information required and generated by inspectors and licence committees at the core of business planning and regulatory processes. We are reforming our committee structure and the way we handle licensing.

The Code of Practice is also undergoing a fundamental review – which will be consulted on during the winter 2008/09 – and the aim is to join up inspection protocols and Code of Practice guidance more than has been the case in the past.

New licensing and inspection protocols and the improved 8th edition of the Code of Practice will go live in October 2009.

Policy, research and engagement with the HFEA's various publics

4.8 Our policy function also generates significant amounts of information, through research, consultations, surveys, horizon scanning and the commissioning of expert advice. We are uniquely placed to bring together the perspectives and knowledge of a wide range of parties – in turn these parties, ranging from patients and clinics, to other regulators or interest groups, need to be enabled to access our information in order to aid more coherent policy development and increased trust in our regulatory oversight.

The policy process – a review

We aim to develop a more coherent and joined-up approach to policy making at the HFEA. As part of this review, a more consistent approach to research, horizon scanning and consultation, all of which generate rich information, will be developed. The work will conclude in April 2009.

4.9 Our communication team also collects information about the sector and everyone with an interest in it. Through public events, regular surveys, and wider engagement with the media and stakeholders, we learn of what all relevant parties think about the fertility sector, but also – importantly – about ourselves. Patient users of our website can sign up to join a patient panel. We involve these volunteers in regular surveys about issues of concern, in order to incorporate the patients' perspective at an early stage in policy and regulatory processes. We understand that we need to become smarter at gathering and analysing information about the various groups that together make up our 'public' and need to get better at tailoring our information provision to the diverse needs of all those with an interest in what we do.

5. Information provision

5.1 We provide information for a wide range of users and in a variety of formats. The following section lists how information about fertility is accessed by all those who have an interest in fertility related issues. It also gives an overview of what we do to improve our information service.

Public enquiries

5.2 We handle around 1500 requests for information from the public per month. The majority of these are straightforward requests for printed patient information or come from callers who can simply be pointed towards the relevant information on our website, but some of them are more complex and require the input from members of staff from the communications, policy, regulation or legal teams. Around 80 Parliamentary Questions and 140 Freedom of Information Requests are also handled by us per year.

5.3 We cannot answer clinical questions and cannot advise patients on what they should do in individual circumstances, but clearly, many patients look towards us as an authoritative source of information when they make crucial decisions in sometimes difficult circumstances. Currently there is no overarching system for analysing or cross referencing enquiries that are handled by different parts of the organisation.

Customer Relationship Management, CRM

The HFEA has recently developed a customer relationship management system that, amongst other objectives, aims to increase the consistency and effectiveness of handling public enquiries.

Implementation of the system will also help us to better analyse of the types of information that are requested from us and will in turn enable more joined up responses to issues as they arise in the sector.

Website

5.4 The www.hfea.gov.uk website is one of the main ways in which those interested in what we do access our information. The website receives just under half a million visits per year, about one fifth of those visits are to the separate 'find a clinic' website tool, which enables patients to view statistical and other background information about individual centres. The pages that are the most frequently viewed are those that contain information tailored towards patients, with the 'for clinics' pages a long way down the list. 70% of the website users are patients or prospective patients. They spend on average 4 minutes on the site.

5.5 Apart from information mostly aimed at patients, the website also addresses a wide range of other issues: it presents policy reviews, lists regulatory information about clinics (inspection and licence committee reports for example) and describes the HFEA works as a regulator and policy maker. Increasingly, the HFEA also aims to put 'softer' information about fertility issues on its website, for example about the emotional impact of infertility and its treatment. To this end it publishes accounts of individual patients who have offered their stories for publication. The website also signposts users to other sources of useful information and support.

Review of the website

We are currently working to improve our website, concerning both its content and architecture. We know that, increasingly, patients and the public will use the web to access the information they require and that we therefore need to prioritise this channel of communication.

During November and December the current website will be tested for usability and user expectations. Recommendations will then be factored into devising a revised site, due to go live in April 2009. New content for the site will be developed throughout 2009 (for example a new way of presenting outcome data and performance of clinics, see below).

Outcome data

5.6 One of the main questions patients ask of our data is what their chance of having a baby after fertility treatment will be. Chances vary according to obstetric and medical history and age of the patient. We publish 'outcome data' for various age groups, and also on a clinic by clinic basis.

5.7 Patients tell us (through the patient panel) that live birth rates are the most important piece of information they want when making decisions about treatment options (followed by costs). However, there is widespread discontent amongst clinicians with the way we present live births rates. The information is often turned into 'league tables', creating the impression that variations in live birth rates reflect different levels of quality between clinics. This is contested by clinics, claiming that the data published does not take account of case mix or socio-economic factors. More importantly, the numbers of treatment cycles on which live birth rates are based are often not high enough to render meaningful small variations between clinics or years. This is why some clinics and experts have suggested that our way of publishing live birth rates is misleading.

Review of outcome data and performance measurement

Through engaging with those who contribute and use our outcome and performance data, we are currently developing options for better representation of outcomes and performance variation. In the autumn and winter of 2008/9, these options will be further discussed with all relevant stakeholders and user tested.

The aims of this work are:

- to find a better way of using the whole national dataset (which contains the complete number of treatment cycles and can therefore most reliably be analysed according to varying factors, for example medical history of the patient or previous IVF attempts)
- to develop a more meaningful way of publishing outcome data (i.e. live birth rates) that takes account of statistical margins of uncertainty
- and to find a more holistic way of describing a clinic's performance and its quality of care, i.e. not only focussing on outcome data, but including regulatory compliance information, patient views and so on.

Authority decisions are expected in the spring of 2009, when the results of this work and the improvement of the website can usefully be synchronised.

Opening the register, OTR

5.8 Under current legislation, 18 year old donor conceived individuals can access information from the register about their donor. The register was set up in 1991, so the first donor conceived people will soon be old enough to access the register for this information. The HFE Bill will extend these access rights to 16 year old donor individuals, donor conceived genetic siblings and donors. Until 2005, donors remained anonymous, but pre-2005 donors can retrospectively make themselves identifiable, if they wish.

5.9 Even where donation remains anonymous, donors can be told of the number and gender of their children. Recipient parents are currently also given non-identifying information about their donor, like profession or interests; this is not a statutory right and might be reviewed as OTR access policies are being developed (see below).

5.10 So far, we only receive a handful of register requests per month. But with the coming of age of donor-conceived offspring and the extension of access rights through the HFE Bill, we need to be prepared for a significant increase in applications to the register.

5.11 Dealing with this very personal information and handling contact with people who are very intimately affected by our policies requires a whole new set of considerations and a great deal of sensitivity. We are aware of our responsibility towards the donor conceived and their families on the one hand and donors on the other, and want to learn from best practice in other countries and sectors.

Developing an OTR policy

We are currently developing a long-term policy on accessing information from our register. This is partly a response to the new access rights granted by the HFE Bill, but also an acknowledgement that organisationally we still have some thinking and planning to do in order to be fully prepared for the coming of age of the first generation of donor conceived people contained in the register.

An Authority Working Group has been set up to discuss and resolve a range of issues contained in this policy area. It is expected that the Authority will make policy decisions early in 2009, with a view to having the policy implemented in time for the HFE Bill commencement date of 1 October 2009.

Use of register data for research

5.12 The HFE Bill will for the first time establish a statutory right of access to information held in our register. This however, without lifting the very strict confidentiality requirements imposed by the HFE Act itself. We welcome this move and want to work closely with the research community to enable maximum learning and insight from our register data, without increasing the regulatory/ data collection burden for fertility clinics.

5.13 Already, researchers have at times asked us for access to register data, but up until now, only statistical, not identifiable, information could be shared. So far, these very few requests have been dealt with by a sub-committee of the Authority. No charges were raised.

5.14 Given the Bill changes, we anticipate a significant increase in such research requests and are working closely with the Department of Health, the Patient Information Advisory Group (PIAG) and other relevant parties to develop workable and responsive policies and processes.

Register access for research policy

In light of the anticipated commencement of the HFE Bill in the autumn of 2009, we are currently developing policies and processes to enable researchers' access to register information. The policy needs to address issues such as data sharing and handling, data security and sharing of research findings. The HFE Bill also allows us to raise fees in order to cover the cost of the service that is

provided to researchers – how this power should be used is another question that needs to be resolved. We have set up an expert advisory group in order to help with this policy development.

The Department of Health will consult on regulations that set out more of the framework for governing research access to the register during the winter of 2008/09. We will also seek the views of the wider research community before a decision is taken by the Authority in the spring of 2009.

6. Information use within the HFEA

6.1 This paper expresses our commitment to place the information we collect, use and provide more consciously in the centre of our corporate development and business planning. At present, our dataset is not being fully utilised, analysed and interpreted, both for us, but also for our various stakeholders.

6.2 Weak information management systems mean that even simple queries, to which we are obliged to respond quickly, can trigger more work than they would generate if strong information management processes were in place.

6.3 This framework provides evidence that much is being done to turn the HFEA into a more intelligent and effective user of its data and information. We are implementing a customer relationship management system, we are reviewing our publication of register information, and we are working with clinicians, patients, researchers and interest groups to become a flexible and responsive information provider. Other initiatives have not been discussed in detail, but will also significantly contribute to an improved knowledge management environment, for example the introduction of a unique identifier for patients and their records, or our continued commitment to simplify and standardise our data collection. We are aware that knowledge management behaviours need to be embedded in all our activities, ensuring that knowledge is shared across the organisation and with external stakeholders.

6.4 Thinking more consciously and in a more sustained way about the information we hold as a valuable asset will not only improve our performance as an information provider, but will also turn us into a better policy maker and regulator. Evidence based policy making and risk-focussed regulation relies heavily on the intelligent use of all available information. With the completion of Programme 2010 and all the information-relevant projects outlined in this paper, we confidently expect to be in a position to respond to the rising expectations our public have about the HFEA as an information provider.