

HFEA: Innovation in regulation

February 2017

Introduction

The UK has a strong tradition of innovation in the field of assisted reproduction and research involving human embryos. The first 'test-tube' baby, Louise Brown, was born in the UK in 1978. And we, the world's first regulator of IVF and other assisted reproduction services, were established in law in 1991.

Many leading edge developments have followed, right up to the present day when in 2015 – following extensive public dialogue led by us – the UK Parliament made lawful for the first time in the world treatments which could avoid the inheritance of serious mitochondrial diseases. Following this historic decision, we convened further expert panel reviews into the safety and efficacy of the techniques and in December 2016 we approved their cautious use in treatment. That same year we licensed the Francis Crick Institute in London to undertake research involving the new gene editing techniques CRISPR-Cas9 in human embryos for the first time in the world outside of China.

These ground-breaking developments have happened because of regulation not in spite of it. The Human Fertilisation and Embryology Acts 1990 and 2008 and the HFEA have provided a stable, yet flexible, framework in which UK bio-science and clinical expertise have been able to flourish. Scientists and clinicians have been able to go about their work free of the 'culture wars' that have hampered such activity in the USA or the regulatory free-for-all of much of the Far East.

This document sets out the actions that we are taking to ensure that the UK remains a jurisdiction where such innovation can continue to flourish, where clinical practice and ethical research can continue to develop and where the public continue to be reassured that nothing is done without expert oversight.

To help us to set out what we will do in the future to support innovation, we consulted with stakeholders in 2016 seeking views on our approach. We received 18 responses to our invitation. On the whole, stakeholders were supportive and provided useful challenge and feedback. A summary of the responses and how we have responded to comments is included in the annex to this plan.

Our innovation and regulation plan

Our approach to innovation and regulation is framed by wider Government policy on productivity and science.

This Government is committed to doing all that it can to unlock productivity and make Britain the best place in the world to start and grow a business. In July 2015 the Government's productivity plan *Fixing the foundations: creating a more prosperous nation* was launched, setting out the Government's strategy for productivity growth.

The productivity plan required departments 'to work with regulators to publish innovation plans ... These will set out how legislation and enforcement frameworks could adapt to emerging technologies and disruptive business models'. The aim of innovation plans is to ensure the UK regulatory framework is working effectively to support innovation and that regulators are using innovation to deliver their own work more effectively and to reduce burdens on business.

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On science, in December 2014 the last Government published *Our plan for growth: science and innovation*, setting out the Government's aim to be the best place in the world for science and business. The regulatory framework to support research and innovation is a key enabler in that plan.

Productivity and science are also key components of the Government's recent Green Paper *Building our Industrial Strategy* published in January 2017.

As the UK regulator of assisted reproduction services and research involving human embryos, we need to respond to the policy demands of productivity and science without undermining the statutory duties set by Parliament. We believe that we are agile in balancing a wide range of interests – medical, social, ethical and legal, as well as those relating to science and economic growth. We were subject to a major review of our activities in 2011/12; and our triennial review took place in 2016. Both reviews affirm the vital role we play in balancing the interests of science and society and both recognise the role we play in fostering innovation.

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That said, we are not complacent. This is our assessment of innovation and regulation. We consulted on our initial plan in spring 2016 and this plan reflects the results of that consultation. However, we see the plan as live and as such welcome feedback at any time.

Like many other regulatory bodies, we must, so far as is relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed). Regulation is not necessarily burdensome as long as it is effective. Ineffective regulation can be burdensome and stifle innovation. As such, we are committed to being an effective regulator.

The assisted reproduction sector is thriving in the UK. The value of the sector to UK GDP is estimated to be in the region of £600 million a year. Unusually for medicine in the UK, the majority of services – some 60% – are provided by the private sector, with the NHS providing the remaining 40%. In setting policies, we need to ensure that innovation can take place in both the public and private sectors, and that patients are protected wherever they receive treatment.

This document is framed by the three challenges set to Government departments by the Chief Executive of the Better Regulation Executive in July 2015:

1. How legislation and enforcement frameworks could adapt to new technologies and disruptive business models to encourage growth.
2. An assessment of how new technology is likely to shape the sectors being regulated.
3. Actions for how regulators could better utilise new technologies to generate efficiency savings and reduce burdens on business.

Challenge 1: How legislation and enforcement frameworks could adapt to new technologies and disruptive business models to encourage growth

As noted earlier, we were established in 1991 as an executive, non-departmental public body, the first statutory body of our type in the world. By law, anyone wishing to provide assisted reproduction services or undertake research involving human embryos in the UK can only do so under a licence from us.

The Human Fertilisation and Embryology (HFE) Act 1990 (the Act) was the first legislation of its kind in the world, yet it has stood the test of time remarkably well. The legislation was revised in 2008 but many of its key elements remained broadly unchanged.

The Act requires us to:

- license and monitor clinics carrying out in vitro fertilisation (IVF) and donor insemination
- license and monitor establishments undertaking human embryo research
- maintain a register of licences held by clinics, research establishments and storage centres
- maintain a register of all treatments
- regulate storage of gametes (eggs and sperm) and embryos
- implement the requirements of the European Union Tissue and Cells Directive (EUTCD) to relicence IVF clinics and to license intrauterine insemination (IUI), gamete intrafallopian transfer (GIFT) and other services.

The Act sets the framework in which fertility services and embryo research can be provided. In view of the controversial nature of this aspect of clinical practice and research, the Act sets out many of the key policy principles which Parliament thought were most important, governing, for example, the centrality of consent to the treatment process, the use to which research involving human embryos can be put, the types of inherited conditions for which embryo testing is permissible and so on. This level of detail in the primary legislation means that there are inevitably constraints on innovation. Those constraints are, in effect, the bargain between science and society which Parliament has decided is appropriate in this area of medicine.

The Act also sets out the basic enforcement framework which licensed clinics and research establishments have to follow. Again, this acts as a constraint in that we do not have a free hand to decide how to regulate.

However, the Act also requires us to publish a Code of Practice which allows us to set out the detailed regulatory requirements. We update the Code of Practice periodically, with the approval of the Secretary of State.

The combination of high level principles in the Act and detailed requirements in the Code of Practice has provided the regulatory system with the flexibility it needs to respond to most changes in clinical practice and science over time.

The remainder of this section considers the ways in which we enable innovation within the legislative and enforcement framework.

Scientific 'breakthrough' innovation

The UK has a world-leading record in breakthrough innovation in the field of assisted reproduction and embryo research. Two recent examples illustrate that statement.

The first involves mitochondrial donation, which became legal in the UK in 2015. The technique was developed in Newcastle and in the USA and allows the donation of healthy mitochondria from a donor egg or embryo to a woman whose mitochondria carries a serious inherited disease. Such diseases are often fatal or life limiting and until now there were no treatment options available that allowed such women to have a genetically related child.

The HFE Act 2008 was purposively amended to allow the possibility of regulations to allow such treatments, and after our extensive consideration on the safety and efficacy of these treatments and a consultation with the public about the acceptability of the proposed treatments, Parliament approved a change in the law – a world first.

The second involves the use of the new powerful genome editing technique CRISPR Cas9 in research. In February 2016, we approved the use of this technique in a research project at the Francis Crick Institute in London. This was the first time that these techniques have been approved in a regulated environment and the first time the techniques have been authorised anywhere in the world outside of China.

In both these examples it is clear that the fact that the UK has robust regulation enabled, rather than inhibited, the introduction of such ground breaking innovation.

Research innovation

As noted above, research on human embryos has been a central component of the UK regulated landscape since the passing of the Act in 1990. The Act sets out strict conditions under which such research can take place, providing reassurance to the public, some of whom hold principled moral objections to any such research. It is easy to underestimate the success of the regulatory system in promoting research innovation in such a contested area of medicine.

Our new strategy 2017-20 commits us to helping to foster a more active research culture in our sector, which we believe will ultimately lead to better treatment outcomes.

Clinical innovation

There have been a number of significant clinical innovations in the UK over the 25 years of regulation. These continue to this day. We have an established process for considering such innovations – or novel processes – which enables a robust yet relatively quick assessment of the safety and efficacy of any new process.

Embryo testing, by either pre-implantation genetic diagnosis (PGD) or pre-implantation genetic screening (PGS) has developed rapidly in the UK, particularly in recent years with the introduction of new testing technologies. Embryo testing involves the testing of an embryo in vitro to assess whether it carries a

genetic defect that would lead to a serious inherited condition, like cystic fibrosis. If successful, a child will be born free from the condition.

The procedure is licensed by us and can only be used where the inherited condition is serious. To date, we have licensed PGD for around 400 serious conditions, providing new treatments options for many families. Developments in testing technology is only likely to increase the number of conditions available for treatment and in the last business year alone, we have licensed about 50 new conditions, many of them very rare. The licensing process is both rigorous and relatively quick, offering reassurance to the public and reducing the time that anxious patients have to wait for new treatment options.

New entrants and granting new licences

The IVF sector in the UK is thriving. Over the last five years, we have licensed approximately 20 new entrants. We adopt a flexible approach, recognising that start-up costs can be prohibitive. We provide a named 'point of contact' to make it easier for new entrants to engage with what can be quite complex regulatory requirements. And the process is reasonably smooth yet appropriately rigorous; from the point of receiving the licence application to granting a licence can be as little as 60 working days. The cost of the licence is also only £500.

For bio-science start-ups and market entrants, the UK regulatory framework can be highly complex and, depending on the products involved, can involve several regulatory bodies. In such cases it is vital that the different regulatory bodies work together to provide consistent advice and rules.

The Cell Therapy Catapult, which is focused on the development of the UK cell therapy industry, has led the creation of a regulatory advice 'one-stop shop' for the development of regenerative medicines with just that aim. The service provides a single point of access to the four relevant regulatory bodies: the Medicines and Healthcare products Regulatory Authority (MHRA), Health Research Authority (HRA), Human Tissue Authority (HTA) and ourselves. This will go a long way to removing one of the most significant roadblocks to the development of the industry in the UK.

Ongoing regulation

The law requires that all licensed centres are subject to an inspection by us at an interval not exceeding two years. We work hard to ensure that the preparation required by licensed centres in advance of inspections, and the inspection itself, are proportionate and reasonable.

- We provide an overview of the findings and feedback from inspection in a report to Authority each year. Similarly, we report on the extent to which we meet the requirements of the 'Regulators' Code'.
- All reports of inspections and the licensing decisions taken as a consequence of them are published on our website. We will be exploring whether we can do more to promote examples of good practice observed at clinics so that others can learn from this and improve their services.
- We balance consistency and certainty of judgments with an evolving set of expectations. We do so partly to ensure inspections add value and keep things fresh and partly to respond to changing expectations (internally and externally driven); for example, fit with our strategy evolution, new obligations and so on.
- In 2013, by agreement with the Care Quality Commission (CQC), we enabled licensed clinics to 'de-register' with the CQC by absorbing some responsibilities (medicines' management) within our framework.
- We fit the inspection regime to developments in the sector where possible and in doing so we will not preclude adapting to new, disruptive business models. For example, we have seen an increasing trend toward consolidation and 'groups' of clinics in the UK. We have responded by developing a group-wide approach to regulation which is being rolled out alongside the inspection schedule. In practice this

means formulating a regulatory plan with the members of the group (where, say, there is a common quality management system across the group of clinics) so that inspection findings identified in one group member (positive or negative) can be taken into account at the inspection in the next member.

- Our view, and it is one we believe is shared by well-run licensed clinics, is that strong and consistent regulation makes good business sense – and brings a lighter touch regulation for businesses which are most compliant.

Challenge 2: An assessment of how new technology is likely to shape the sectors being regulated

Developments in new technology are one of the key drivers in the field of assisted reproduction and embryo research. Some of those developments offer the prospect of new clinical and research advances – like the new testing technology referred to earlier which is leading to more accurate and cheaper identification of inherited conditions that might be treated by testing embryos in vitro.

Other developments offer promise, but the evidence of effectiveness is, as yet, inconclusive – like time lapse imaging which, it is claimed, allows for more accurate identification of the best embryo to put back into the womb. Still other so-called ‘treatment add ons’ lack any peer reviewed evidence base.

We have developed a range of mechanisms and responses for identifying, assessing and approving such new technologies in the sector we regulate. Such mechanisms are vital in a highly competitive and often commercial field, where patients can be confused by the claims and counter-claims of the merits of a particular technology. In our new strategy for 2017-20, we aim to encourage an enquiring culture and responsible innovation in clinics, leading to more scientific and clinical research.

Horizon scanning

We established a horizon scanning function as early as 2004 to identify issues that could have an impact on the field of assisted reproduction or embryo research. Issues are identified from journal articles, conference attendance and contact with experts, such as our Horizon Scanning Panel, an international group that meets annually.

By identifying issues early, we are aware of potential licence applications and can prepare, if necessary, a policy or position. The horizon scanning process is an annual cycle that feeds into our business planning and consideration of ethical issues and standards.

Evaluating safety and efficacy

As a means of evaluating safety and effectiveness of such technologies, we have a Scientific and Clinical Advances Advisory Committee (SCAAC) which advises our board (the Authority) on scientific and clinical developments, including research, in the field.

If a clinic wishes to carry out a licensed activity using a new process (that the Authority has not authorised) then the clinic would need to apply to us for authorisation. The procedure for considering whether or not a novel process should be added to the list involves scrutiny by SCAAC, who in turn advise our Statutory Approvals Committee (SAC), who make the final decision as to whether the process should be allowed in licensed clinics.

We have worked closely with other partners in the regulatory system to ensure that overlaps and duplication do not act as an impediment to innovation. The ‘one-stop shop’ for regenerative medicine referenced earlier is now established.

In addition, we have worked closely with the MHRA to introduce proportionate arrangements governing the use of the ‘media’ in which embryos are cultured. Clinics historically manufactured such media in-

house, with commercially produced products following on more recently. Together with the MHRA, our joint application of a proportionate regime requiring CE marking of such products has contributed to higher standards of safety and efficacy.

Regulatory responses to new technology in the clinic

As noted earlier, we have an established process for considering clinical innovation – or novel processes – which enables a robust yet relatively quick assessment of the safety and efficacy of any new process.

Where a particular piece of technology falls within the scope of licensed activity, we can use this process to evaluate the proposed innovations. We recently worked with a clinic and the MHRA to enable a specific technology to be introduced carefully and safely.

Increasingly, licensed clinics are investing in new technologies like that to better track patients and their gametes. New electronic witnessing systems reduce human error and provide greater assurance that a particular embryo and a particular patient are linked.

Witnessing has long formed a key part of our inspection regime and we have adapted that regime to take account of the evidence that these new electronic systems provide. This has greatly simplified the auditing of records, reducing the time spent on this aspect of the inspection for both our inspectors and clinic staff.

Informing patients

We play an important role in providing clear evidence-based information to patients and the public, through a range of platforms, principally our website but also literature, leaflets, workshops and new forms of social media.

As part of a substantial piece of work to review our information systems, our Information for Quality (IfQ) programme will be providing more, and clearer, information about new technologies to enable patients to make more informed treatment decisions; and to ensure that people with fertility problems can explore a greater range of options available to them.

Challenge 3: Actions for how regulators could better utilise new technologies to generate efficiency savings and reduce burdens on business

New information systems are vital if we are to continue to reduce our costs and the costs of regulation.

Better information for patients and those we regulate

By law, licensed clinics are required to submit a large amount of information to us relating to all licensed treatments on a near real-time basis. With around 80 licensed clinics providing approximately 60,000 treatment cycles per year, that is a substantial servicing burden.

We know that our system for doing so is outmoded, clunky, non-interactive, requires specialist expertise established over time and, as a consequence, is burdensome.

In 2014 we embarked on a major transformation programme, Information for Quality (IfQ), with the aim of making a radical improvement to our information systems. IfQ encompasses:

- An improved facility for clinics to interact with us by redesigning our 'Clinic Portal' (used by clinics to submit treatment data to us) and combining it with data submission functionality that is currently provided in a separate system we use called Electronic Data Interchange (EDI).

- New standards of data accuracy through a revised dataset and data dictionary¹, which will be approved by the Standardisation Committee for Care Information (SCCI).
- A new database of treatments to allow for easier analysis to drive clinical improvements. This involves revising our current database (known as the Register) and migrating the historical data contained within it to the new database.
- An improved method of presenting information to patients to enable more informed treatment choices – through the redesign of our website and Choose a Fertility Clinic (CaFC) search function.
- The redesign of our main internal systems and supporting IT processes.

Building a more sustainable IT infrastructure

IfQ has been developed to meet the strict new technology rules for all public bodies enforced by the Government Digital Service (GDS). Its digital service standards encompass factors such as:

- putting user needs at the heart of development
- building the service using agile, iterative and user-centred methods
- making all new source code open and reusable and publishing it under appropriate licences
- using open standards and common government platforms where available, and
- creating a service that is simple and intuitive enough that users succeed first time.

The GDS has approved our proposals and the test and review period (known as ‘beta’) is now coming to a close. Our new Clinic Portal was launched in January 2017, our website is due to go live later in the spring and the new treatment submission system will be available in early summer 2017.

The way we structure our web applications is ‘tightly coupled’ (highly dependent) on our Register. To enable IfQ’s goals we will move to ‘loosely coupled’ systems – known as service orientated architecture. This will improve the way our IT systems work.

Encouraging new market entrants

Many licensed clinics deploy ‘third party’ patient administration systems, from which a subset of the information required by us is drawn. We recognise the third-party market is evolving but still undeveloped.

In developing IfQ, we came under pressure from stakeholders to develop an all-encompassing patient administration system and make it available to providers. This was also an argument that some stakeholders made in the consultation. We disagree. This is not a core skill for us; others in the marketplace are better placed to do so and it is not a regulator’s job and to do so could potentially stifle innovation. We think the merits of our approach can be seen by the presence of at least one new market entrant providing a new service to a range of clinics.

¹ A data dictionary is a set of information describing the contents, format, and structure of a database and the relationship between its elements.

Improving clinic performance through better information

Already, much of the performance information that forms a basis of our inspection assessments is available to clinics through an online portal. This allows licensed centres to see key outcome level information, such as success rate, multiple birth and self-assessment performance.

Over the last 25 years we have built up a vast amount of information about fertility treatments in the UK. We hold this information on our Register, the world's largest national dataset about assisted reproduction treatments, including those related to treatments using donated eggs, sperm and embryos.

In 2008, we supported change to our legislation to enable the Register to be opened up for use in high quality research. We aim to be a good research partner to those with a legitimate interest in our Register, while also respecting the highly sensitive and confidential data we hold. Our Register Research Panel (RRP) was set up in 2010 to approve applications from external researchers for access to patients' identifying information in undertaking linkage studies. Several studies have been published or are underway, including:

- mortality and general health in children born after IVF, UCL (approved 2012)
- development and validation of statistical models to predict pregnancy outcomes following in vitro fertilisation (IVF) treatment, University of Aberdeen (approved 2013)
- the effect of maternal age, embryo cryopreservation and culture on perinatal outcomes and child health, University of Manchester (approved 2013)
- investigating the impact of culture media on IVF treatment and child health outcomes: a national culture media questionnaire and HFEA Register data linkage study, University of Manchester (approved 2015).

In addition, numerous other studies using our data have been published. For example, in 2015, this included:

- live birth rate associated with repeat in vitro fertilisation treatment cycles²
- treatment cycles factors affecting embryo viability and uterine receptivity.³

Taken together, such research is improving clinical knowledge, providing better information for patients, and may drive further innovation in future. We are ambitious to use this information to provide more insights and to foster improvement and our new strategy 2017-20 will ensure that we are sufficiently resourced to exploit these opportunities in the future.

Using better IT to reduce our costs and the costs of regulation

The provision of enhanced technology is also essential for the delivery of our services. By enhancing our own systems, we can reduce our operating costs, and simplify the data submission process that clinics' experience, reducing the time taken by clinics to transact with us.

Our corporate infrastructure includes services such as email, voicemail, remote access, servers and personal computers, without which we cannot function efficiently, even for relative short time periods. The ongoing provision of these services requires robust and dependable infrastructure that is highly resilient yet also able to flex with corporate need.

We will achieve this by:

² Smith A, Tilling K, Nelson S, Lawlor D. Live birth rate associated with repeat in vitro fertilization cycles. *Journal of American Medical Association*. 2015;314(24):2654-2662.

³ Roberts S, Hann M, Brison D. Factors affecting embryo viability and uterine receptivity: Insights from an analysis of the UK registry data. *Reproductive Biomedicine Online*. 2015;0,0.

- the use of 'off the shelf' solutions for productivity software
- selecting secure and resilient technologies that enhance information management, security and governance
- the use of standardised, well supported 'cloud' technologies where appropriate
- replacing the user IT estate with a common hardware platform
- simplifying the management and administration of our systems
- reducing the complexity so that support services can be provided more easily.

Better value for the public

For a budget of approximately £5 million per year, we achieve much. Our public subsidy has reduced by over 40% since 2010, such that only £1million of our budget now comes from the Government.

In addition, we are responding to a drive by Government (across healthcare and other industries) to maximise the potential for exporting our expertise, raising standards overseas and raising revenue for the UK. As such we are exploring with Healthcare UK how we can best provide a service to international partners, for example by providing assistance in establishing a regulatory regime in countries without one.

Summary

Our plan for innovation and regulation responds to the three challenges set out to Government departments by the Chief Executive of the Better Regulation Executive in July 2015.

1. How legislation and enforcement frameworks could adapt to new technologies and disruptive business models to encourage growth

Innovation, development and growth in the assisted reproduction sector have happened because of regulation not in spite of it. We and the Human Fertilisation and Embryology Acts 1990 and 2008 have provided a stable, yet flexible, framework in which UK bio-science and clinical expertise have been able to flourish. The combination of high level principles in the Act and detailed requirements in the Code of Practice have provided the regulatory system with the flexibility it needs to respond to most changes in clinical practice and science over time.

2. An assessment of how new technology is likely to shape the sectors being regulated

We have well-established mechanisms to respond to emergent technology, in its widest sense, including an annual horizon scanning process and expert advice from our Scientific and Clinical Advances Advisory Committee. We have a track record of both being aware of developments and, where appropriate, reacting and responding to these such that the regulatory framework is both adaptable and robust.

3. Actions for how regulators could better utilise new technologies to generate efficiency savings and reduce burdens on business

We have an ambitious programme of change supported by new technology to generate efficiency savings and reduce burdens on business. This programme, known as Information for Quality, will be completed this year.

Where this document commits to future or intended actions we will use our existing business planning mechanism to ensure that actions are captured, monitored and reported to the Authority.

Annex: Innovation and regulation plan consultation feedback

Our draft innovation and regulation plan was published as a consultation draft in April 2016. We invited responses to be submitted by 6 June 2016 – an eight-week consultation period. We promoted the consultation using a variety of mechanisms including our regular monthly communication to stakeholders, prominent positioning on our website and repeated tweets on Twitter. A total of 18 responses were received.

The questions on which we sought views were:

1. Do you agree the HFEA has a role to play in promoting innovation?

Two thirds of respondents agreed that we have a role to play in promoting innovation. Comments included that we can do so by sensitive and sensible regulation and to some extent ‘driving the sector forward.’

One respondent noted that both in promoting and regulating research with wide-ranging impacts, we, with our partner bodies (such as the HTA and the MHRA), have an important coordinating role to play. Conversely, one respondent noted that as an independent regulator and body at arm’s length of the Government, we should not be encouraged to become involved in commercial activities, which could be viewed as converting a medical need to the commercialisation and commodification of the human embryo.

2. From what you have experienced of the HFEA and read here does it do enough to promote innovation? If not we would be pleased to hear your suggestions for improvement.

On the whole, respondents considered that we could do some more or a lot more to promote innovation, with only a small minority suggesting we do enough. In particular, respondents want us to do more in conducting studies or encouraging studies in relation to the efficacy of new clinical procedures or the introduction of new technology.

As part of our newly-developed website (due to be launched in spring 2017), we will be providing more and clearer information about new technologies to enable patients to make more informed treatment decisions; and to ensure that people with fertility problems can explore a greater range of options available to them.

Other respondents noted that we do not promote good practice from a specific clinic or what a clinic does well for ‘fear of apparent bias’. Inspection reports do comment on notable or good practice although this is not promoted as such. This is an area worthy of additional exploration.

3. Do you think the HFEA understands potential scientific and technological developments?

The majority of respondents think we fully or partially understand potential scientific and technological developments. One respondent noted that whilst we ourselves do not necessarily possess the full range of necessary expertise, we engage well with expert advisors to access this knowledge and expertise.

Another respondent acknowledged that in such a contested area of medicine, it is important that the voice of experts is seen alongside the wider public interest. The fact that members of the Authority include both lay representation and others involved in the fertility sector was therefore seen as a strength, particularly when scientific and technological advances are giving rise to ever more complex issues.

4. Do you think the HFEA has the mechanisms in place to use potential scientific and technological developments to generate efficiency savings and reduce burdens on business?

Most respondents did not know, with only two respondents indicating that we do. One respondent indicated that it was a mistake not to introduce a generic reporting system for clinics. We disagree.