

Human Fertilisation and Embryology Authority

A Hampton Implementation Review Report

December 2009

Human Fertilisation and Embryology Authority

This review is one of a series of reviews of regulatory bodies focusing on the assessment of regulatory performance against the Hampton principles and Macrory characteristics of effective inspection and enforcement. It was carried out by a review team drawn from the Better Regulation Executive, Companies House and Natural England, in April 2009.

Further information about the reviews can be found at:

<http://www.berr.gov.uk/whatwedo/bre/inspection-enforcement/implementingprinciples/reviewing-regulators/page44054.html>

EXECUTIVE SUMMARY AND CONCLUSIONS

Key findings from the review:

The Human Fertilisation and Embryology Authority (HFEA) demonstrates good compliance with the principles contained in the Hampton report in some areas of its business, notably in relation to its advice and guidance and the data requests it makes of stakeholders. There is room for improvement in other areas, such as the consideration of risk in its decision making and more effective use of the existing sanctions regime.

The HFEA has a comprehensive change programme underway, which is due to be fully implemented by 2010. If successful, this programme will set in place a number of mechanisms and tools which will improve the HFEA's compliance with the Hampton principles.

The Review took place in April 2009, and its findings reflect a "snapshot" of its work at that point in time. HFEA's work on the change programme and other initiatives has continued in the meantime, but the Review Team is not in a position to comment on the outcomes of work carried out since that date.

Key findings

- The HFEA has effective mechanisms in place to undertake consultation with stakeholders. It has its finger firmly on the pulse of stakeholder views and scientific advances, and has built a very good two-way communications network. This has contributed to regulatory frameworks in the fields of multiple births and Stem Cell Research which stakeholders believe to be proportionate and effective.
- The Code of Practice is a comprehensive guidance product and compliance tool which has been developed in consultation with users. The HFEA has adopted a process of continuous improvement with the Code of Practice and has recently reviewed, redesigned and improved its usability. In particular, the Code of Practice now distinguishes clearly and distinctly between legal requirements and best practice.
- HFEA staff are well regarded by fertility clinic and research stakeholders – the support given by the

Inspectors to clinicians who are licence holders is worthy of special mention. This support is highly valued by licence holders.

- Legislative change is a catalyst for organisational change in some areas and HFEA is considering through its Change Programme how to make changes to better incorporate Hampton principles into processes.
- The HFEA has carried out a minimum data set review – this type of review is considered best practice and in line with Hampton principles.
- The HFEA demonstrates transparency by making its inspection reports available online, together with minutes of meetings of the Licence Committee which discuss these reports.

Main issues for follow-up identified during the review:

The key follow-up issues identified are:

- The Review Team welcomes the work the HFEA is doing to redevelop its risk tool and believes that the successful implementation of this tool should be an immediate and key priority.
- In this context, the criteria governing licensing decisions following inspections are currently neither well-defined nor transparent. This has the potential to lead to a lack of consistency in decision making.
- As a result of the governance arrangements set out in the HFE Act, the process of applying sanctions can be long-winded. Decisions must be made by the “Licence Committee” and, unlike other regulators, HFEA’s inspectors are unable to take immediate action themselves when they identify a serious breach. Therefore, for the end-user or patient, decisions to impose a sanction may lack the pace and responsiveness required to provide protection.
- Whilst planned visits have merit the HFEA could better utilise risk-based, targeted, unannounced inspections to test compliance.
- The HFEA does not utilise the full range of its sanctions, in part because its existing

sanctioning options appear to the Review Team not to be flexible enough to handle different levels of non-compliance. In view of this, the HFEA should consider whether civil sanctions under the Regulatory Enforcement and Sanctions Act would provide greater flexibility.

- While the HFEA Inspectorate has a strong advice and guidance relationship with those organisations it regulates, as with any regulator there is always a danger that, if left unmonitored, this relationship could drift and lead stakeholders to question the regulator's independence, objectivity and consistency. The Review Team would encourage the HFEA to remain vigilant to ensure it maintains an appropriate degree of 'distance' between itself and its regulatory community.
- In order to achieve better compliance with the Hampton Principles, the HFEA is relying heavily on the successful implementation of its Change Programme. However, there are a number of risks to the successful delivery and implementation of this programme and the Review Team was not presented with compelling evidence to suggest that HFEA has a robust strategy in place to ensure that the programme achieves its stated benefits.
- Whilst the HFEA is focused (rightly) on the clinical risk to patients and children born as a result of treatment and on the protection of the embryo, the Review Team believe that it should work to develop more of a strategic awareness of the sector that it regulates. The Review Team consider that, at present, elements of the organisation see adherence to process as success (or compliance) in itself. There is a need to also measure outcomes when assessing a low risk licence holder/clinic. For example - asking the question "what is the rate of significant errors in fertilisation in that clinic compared with the national rate?" as opposed to "does the inspection of this clinic indicate they have adhered to witnessing procedures?"

INTRODUCTION

Introductory background information about the regulator such as the rationale for establishing it:

The Human Fertilisation and Embryology Authority (HFEA) is a statutory body reporting to the Secretary of State for Health. It was established in August 1991 under the Human Fertilisation and Embryology Act 1990. Its primary remit is to licence and monitor UK clinics that offer in-vitro fertilisation (IVF) and donor insemination (DI) treatments, and all UK based research into human embryos. It also regulates the storage of eggs, sperm and embryos.

The first statutory body of its type in the world, the HFEA's creation reflected public and professional interest in the potential future of human embryo research and assisted reproduction treatment. The recommendation for such a regulatory body had come from the 1984 report of the [Committee of Inquiry into Human Fertilisation and Embryology \(the Warnock Report\)](#).

The legislation establishing the regulator:

The HFEA was established under the Human Fertilisation and Embryology Act 1990, which also sets out its statutory objectives. The Act was amended in 2001 to allow the use of embryos in stem cell research. HFEA has also taken on additional responsibilities as a result of the EU Tissues and Cells Directive (2004/23/EC).

The regulator's statutory remit or objectives:

HFEA has a number of statutory functions, based on two specific roles: firstly, the licensing and regulation of clinics and research establishments providing treatment, storage and research; and secondly, the maintenance and publication of information about donor treatment and assisted conception. The current statutory functions are:

- To license and monitor clinics that carry out in vitro fertilisation (IVF) and donor insemination (DI);
- To license and monitor establishments undertaking human embryo research;
- To maintain a register of licences held by clinics, research establishments and storage centres;
- To regulate the storage of gametes (i.e. eggs and sperm) and embryos;
- To implement the requirements of the European Union Tissue and Cells Directive (EUTCD) to

re-licence IVF clinics and to license Intrauterine Insemination (IUI), Gamete Intrafallopian Transfer (GIFT) and other services new to regulation;

- To investigate and keep a register of serious adverse incidents and reactions;
- To produce and maintain a [Code of Practice](#) which gives guidelines to clinics and research establishments about the proper conduct of HFEA licensed activities;
- To maintain a formal register of information about donors, fertility treatments and children born as a result of those treatments;
- To publicise the HFEA's role and provide relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients, including servicing the statutory right of access to register information;
- To review information about human embryos and developments in research involving human embryos, and the provision of treatment services and activities governed by [the HFE Act](#);
- To monitor any subsequent developments in this area and, where appropriate, advise the Secretary of State for Health on developments in these fields.

HFEA's licensing responsibilities include:

- To issue treatment, storage and research licences to centres;
- To define and promote good clinical practice and high ethical standards;
- To ensure clinics comply with the requirements of the 1990 HFE Act and the EUTCD;
- To renew licences – treatment and storage licences can be issued for up to five years and research licences for a maximum of three years.

The regulator's budget:

HFEA's total expenditure in 2007-08 was £7.9 million. Its net expenditure was £2.6 million, financed largely through grant-in-aid received from the Department of Health (DH) of £2.5 million. It received income totalling £5.2 million from fees charged to clinics (e.g. for licences, renewals, variations) and had capital funding of £250k.

Number of staff

In the financial year 2007-08, the agency employed an

(including breakdown of policy and frontline staff):

average of 90 staff. It is based at 21 Bloomsbury Street, London.

Governance

The HFEA Authority is chaired by Professor Lisa Jardine and has 22 members. Under the 1990 Act, the Chair, Deputy Chair and at least half of the membership must be laypersons, in order to ensure objectivity – i.e. neither doctors, nor scientists involved in human embryology research or the provision of infertility treatment.

The role of the Authority is to determine HFEA policies and to make decisions on each treatment and research licence application. It meets nine times per year and is supported by a number of committees composed from its membership. Minutes and papers from both Authority and committee meetings are published on the HFEA website.

The Authority's executive provides support, information and recommendations for the Authority to make its policy and licensing decisions.

The sectors and number of businesses regulated either directly or indirectly:

HFEA licenses clinics and research establishments carrying out IVF, other assisted conception procedures and human embryo research. This is a growing sector, not just in the UK but also globally, and the regulatory framework has evolved accordingly to take account of technological developments (e.g. use of hybrids), Government policy (e.g. availability of IVF treatment on the NHS and legalisation of stem cell research), as well as emerging ethical issues (e.g. women from poor countries selling their eggs, same-sex couples, anonymity for donors).

Infertility Treatment

As January 2009, there were 117 HFEA-licensed treatment clinics in the UK (up from 85 in 2006), of which 90 state they see NHS patients. There are 45 NHS-licensed centres and 80 privately licensed centres. The number of licensed clinics has grown recently due to the fact that, following the implementation of the EUTCD in July 2007, HFEA has taken on responsibility for regulating clinics offering treatments such as Intra Uterine Insemination (IUI) using husband's or partner's sperm and Gamete Intra Fallopian Transfer (GIFT) – this accounts for 33 clinics.

Based on 2006 figures, around a quarter of the clinics in the UK are based in London and the spread across the rest of the country is fairly even at around 5-7 clinics per region.

In the UK an estimated one in seven couples has difficulties conceiving. In 2006, 34,855 patients were undergoing IVF treatment and there were 10,242 successful births giving rise to 12,596 babies. The trend here is upwards – the figures for 2004 were 30,861 patients, with 8,251 births giving rise to 10,242 babies. The trend for donor insemination (DI), however, is down. In 2006, there were 2,106 patients, compared to 6,893 in 2004 and 455 successful births (489 babies) compared to 707 births (749 babies). Around 1.4% of all births and 1.7% of all babies born in the UK are the result of IVF and DI. Around a third of all patients are in London and, again, the spread across other UK regions is fairly even, at around 7-9% of the total number.

The National Institute for Health and Clinical Excellence (NICE) produced guidelines in 2004 recommending that the NHS fund three cycles of IVF treatment per couple, where the woman is aged 23-39, based on estimates that around 50% of women would conceive after three cycles. The Secretary of State for Health agreed that NHS Trusts should fund one cycle and, based on 2005 figures, 90% of trusts do so. The overall cost to the NHS of IVF treatment is £28 million, with each individual treatment costing £3,000. However, the NHS funds only 25% of treatments in the UK; most people undergoing treatment do so privately at a cost of around £4,500.

Embryology Research

The UK is an acknowledged world leader in embryology research. The HFEA website lists 27 current research projects, conducted mainly in universities, hospitals, charities, research institutions or commercial organisations. Under the HFE Act, any research must relate to one or more of the following purposes:

- To promote advances in the treatment of infertility;
- To increase knowledge about the causes of congenital diseases;
- To increase knowledge about the causes of

- miscarriage;
- To enhance knowledge in the development of more effective contraception;
- Detection of genetic or chromosomal abnormalities before implantation;
- To increase knowledge about the development of embryos;
- To increase knowledge about serious disease; or
- To enable any such knowledge to be applied in developing treatment for serious disease.

The HFEA looks to undertake extensive horizon scanning work using scientific expertise from the UK and abroad to enable it to gain early warning of new scientific and clinical developments which may impact on assisted reproduction or embryo research. This allows the HFEA to consider the legal, ethical and scientific implications of any new technique that scientists or clinicians may wish to use in HFEA-licensed research. This allows the Authority to be prepared with information in order to make a decision on the potential licensing of techniques.

Broadly speaking, research projects are either aimed at improving infertility treatment (i.e. to improve the chances of fertilisation and conception, for example through better storage techniques) or stem cell research (i.e. using cells to conduct research into therapies to combat diseases such as diabetes, Alzheimer's or Parkinson's).

THE HAMPTON VISION

Both the Hampton and Macrory reports are concerned with effective regulation – achieving regulatory outcomes in a way that minimises the burdens imposed on business. Key to this is the notion that regulators should be risk-based and proportionate in their decision-making, transparent and accountable for their actions and should recognise their role in encouraging economic progress.

Any findings relevant to whether the regulator is risk-based:

The HFEA recognises the importance of having a risk-based approach to compliance and enforcement and licensing decision-making. At a micro level, there is some evidence that HFEA bases licensing and inspection decisions on a risk-based approach. In particular, decisions on periods of licence renewal for individual fertility clinics are based on inspectors' assessments of the level of compliance, and the corresponding risk of future non-compliance.

However, the Review Team found that a consistent risk-based approach across the organisation is lacking at present. HFEA acknowledges this situation. Its previous risk assessment tool was abandoned as it was considered unfit for purpose and the regulator is currently in the process of redesigning a risk tool. The Review Team welcomes this, looks forward to seeing progress towards implementation of the new framework and notes the importance of ensuring staff have a common understanding of how it should be applied in practical terms.

Any findings relevant to whether the regulator is transparent and accountable:

The Review Team saw some evidence of good practice in relation to transparency. In particular, the HFEA publishes each clinic's inspection reports on its website, together with minutes of the Authority Licence Committee which makes the final decisions on licence renewals for fertility clinics. The agenda, papers and minutes of Authority and other committee meetings are also made available on the HFEA's website.

Furthermore, the HFEA publishes information on the performance of clinics (e.g. numbers of successful conceptions and multiple birth rates). This enables prospective patients to make an informed choice when deciding on where and from whom they wish to receive treatment.

The Authority makes licence and licence renewal decisions which require highly scientific knowledge and clinical expertise in a field where medical advancements are rapid. There is, therefore, a need for the Authority to be informed by experts in the field when considering licence applications and renewals.

However, there is a perception among some stakeholders who spoke to the Review Team that the Authority's independence and accountability may be compromised because members of the Authority have business interests in the IVF treatment industry. The Review Team was presented with no firm evidence of this and notes that the HFEA has strict rules in place regarding conflicts of interest of Authority members; indeed, over half the membership are lay members, including the chair and deputy chairs and have no business interests in the IVF industry. That said, in view of stakeholders' perceptions, there may be more that the HFEA can do, through communication, to demonstrate the integrity of its decision making.

Any findings relevant to whether the regulator encourages economic progress:

The IVF sector is growing. This could be as a result of increasing knowledge and expertise in IVF practice but also because it is a profitable industry. The primary focus of the HFEA is on ensuring that couples with fertility problems are able to conceive safely and in an ethically proper manner, rather than on encouraging the economic viability and competitiveness of the sector. However, in its regulatory activities, the HFEA does take account of its impact on fertility clinics, for example by keeping the burdens placed on them during inspections to a minimum and by ensuring that the guidance contained in the Code of Practice is clear.

Similarly, the regulatory framework designed and operated by the HFEA for stem cell research has been praised by stakeholders as facilitating scientific progress, while ensuring that proper ethical safeguards are in place.

DESIGN OF REGULATIONS

Hampton principles

All regulations should be written so that they are easily understood, easily implemented, and easily enforced, and all parties should be consulted when they are being drafted.

When new policies are being developed, explicit consideration should be given to how they can be enforced using existing systems and data to minimise the administrative burden imposed.

Key findings on
Design of
Regulations:

- The HFEA plays a central role in the development of policy and regulation in the areas of fertility treatment and embryology research. This is a fast moving area, as the technology develops, with its consequent ethical issues which need to be taken into account in policy making.
- Through effective stakeholder consultation and horizon scanning, the HFEA has been well placed to develop regulatory frameworks, particularly in relation to multiple births and stem cell research.
- Due to the pace of clinical developments, innovations and improvements in techniques in this sector, the HFEA policy team is necessarily reactive and tends to be strongly informed by the business sector and scientific community on where policy change and development should focus. Through this approach, it is effective in establishing and embedding policy change and buy-in from the industry it regulates.
- In addition, it has developed good networks to enable it to undertake informal stakeholder consultation, in particular with clinics, central government policy makers, licence centre panels, patient groups and other peer/pressure groups.
- The HFEA has successfully influenced regulations coming from Europe, in particular, ensuring proportionate regulatory requirements for air quality and partner treatments.

- As part of the change programme, HFEA has recently employed an economist, which has improved its analysis of impacts on the business/sector, in terms of costs and benefits, of the policies it has developed. The review team welcomes this development and believes this capability could add to ongoing robust assessment of the impacts throughout the policy-making cycle.

Background information such as the regulator's role in developing regulations:

The original legislation of 1990 was UK based, but this is an area in which the EU is now involved. Through the 2007 EUTCD, the HFEA is the national competent authority for the UK. The UK legislation was updated in 2001 to permit embryonic stem cell research into common diseases, and again in 2008 to prohibit sex selection for social reasons, permit various forms of embryo testing under licence and permit research on human-animal hybrids. The amended Human Fertilisation and Embryology Act 2008 took effect from October 2009.

The Authority also implemented changes to its regulatory procedures to take account of recommendations made by Professor Brian Toft in his 2004 report. This was triggered following four adverse events at Leeds Teaching Hospitals NHS Trust, including incorrect identification of sperm samples which led to mixed race twins being born to a Caucasian couple and the discarding of a couple's embryos without their consent.

Any examples of significant good regulatory practice:

Regulation of Stem Cell Research - When research on human-animal hybrids was first proposed, HFEA recognised the scientific value of the research, and was minded to give its approval. However, there was a considerable political and public knee-jerk reaction that such research should be banned. The HFEA approach, therefore, was to launch a large scale public consultation which on the one hand delayed the research by a year, but, on the other, ensured that a full debate took place and that the time was taken to get the regulatory framework right, creating the right balance between facilitating scientific progress and the serious ethical issues involved.

The 2007 multiple births policy implementation is a good example of a sound approach to policy development. HFEA consulted effectively, prepared a

good quality impact assessment, and ran a targeted communication plan with stakeholders to ensure that all parties understood the rationale behind the policy decision.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principles:

The HFEA demonstrates good practice in most aspects of its work on design of regulations. It has a good track record in relation to formal and informal stakeholder consultation and to using horizon scanning of scientific developments, in order to shape the regulatory frameworks for which it is responsible. As noted above, the Review Team believes that the employment of an economist is a welcome step in relation to a more robust approach to measuring the impacts of policy proposals. The HFEA should continue to develop this approach through embedding use of impact assessment more thoroughly in its policy work.

ADVICE AND GUIDANCE

Hampton principle

Regulators should provide authoritative, accessible advice easily and cheaply.

Key findings on Advice and Guidance:

- The HFEA has a good communication network. It utilises the internet effectively to communicate to regulated centres and other stakeholders.
- The HFEA are well plugged into stakeholder groups both formally and informally, for example through a network of meetings and focus groups, e-letters, centres user-guide, conferences, and their Code of Practice (COP).
- The Code of Practice is a clear and comprehensive guide for licence holders on how to comply with regulations.
- The HFEA is continuously improving and re-designing its Code of Practice. Recent improvements are the separation of mandatory and best practice activities. The Review Team saw this constant drive for improvement as a positive indicator of HFEA's efforts to give clear and consistent guidance to the regulated sector.
- Clinician stakeholders appreciate the allocation of a specific point of contact for each licence holder (an inspector). The Inspectorate is available to provide detailed advice and guidance to each clinic on aspects of the Code of Practice. A similar support mechanism is in place for research licensees.
- Evidence was seen that the inspection visits also provide an opportunity for informal advice and guidance to be given directly to clinics.
- The HFEA has an e-alert system to inform licence holders of patterns of adverse incidents and provide guidance as to how to mitigate against the risk of such incidents re-occurring in the future.

The Review Team commends this approach.

- The HFEA Inspectorate's strong advice and guidance relationship with stakeholders is good practice. However, such relationships carry the inherent risk that stakeholders may call into question the independence, objectivity and consistency of the regulator, where relationships are perceived as being too close. Whilst we saw no evidence that relationships were too close during the Review, we believe that the HFEA needs to remain vigilant in order to guard against this risk.

Background information such as the means by which the regulator provides advice and guidance:

Under the Human Fertilisation and Embryology Act, 1990, the HFEA is required to give guidance to licensed centres about 'the proper conduct of activities carried out in pursuance of a licence'. This guidance is contained in the HFEA Code of Practice, which at the time of the review was in its 7th edition.

New edition of the Code

The 8th edition of the Code was published in July 2009, to take account of changes introduced by the amended HFE Act. The Code came into effect on 1 October 2009. The Authority took account of feedback from users of previous editions to improve the content, style and structure of the Code, in particular by:

- Distinguishing clearly between mandatory requirements and best practice guidance;
- Removing the duplication which existed between legislation, standards, licence conditions and HFEA guidance;
- Reducing complexity and improving the navigation of the Code; and
- Putting the guidance into plain English.

Website and Other Media

The HFEA website looks to be a useful source of information and guidance can be easily located. There is a helpful 'Choose a fertility clinic' function. In addition, there are clear signposts on the front page to information for patients, donors and clinic staff and other professionals respectively. Finally, there are FAQs attached to many of the areas of guidance on the website.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

This is an area of strength for the HFEA, and there is good compliance with Hampton, for the reasons given above.

DATA REQUESTS

Hampton principle

Businesses should not have to give unnecessary information or give the same piece of information twice.

Key findings on Data Requests:

- For patients and the general public to have confidence in this industry and for research results to hold credibility there is a reasonable requirement by HFEA for a high standard of record-keeping among those it regulates.
- Generally, and with some exceptions, the HFEA collects only the data which is needed for the effective functioning of the regulatory framework. It has recently completed a review of the “minimum data set”.
- The licence application form appears to have been primarily created for clinic applicants and is less well tailored for research licences. There appears to be a ‘one size fits all’ approach. For research applicants there is little guidance on how to complete an application form. HFEA might like to consider reviewing the licence form so that it becomes easier for research applicants to complete.
- The Review Team believes that the HFEA needs to exercise caution to ensure that it does not, in specific areas, collect data over and above that which supports its core business and ability to assess compliance. For example, there is no legal requirement to collect ‘intention to treat’ information from clinics. The HFEA contends, however, that this information is useful when presenting to patients the overall success of clinics’ practices.
- Research stakeholders are required to re-submit data they have already provided to the HFEA when they provide updates on the progress of their

research projects, as part of their licensing requirements. The HFEA recognises that there is potential to make better use of the data supplied by licence holders for research and analysis but this needs to be balanced against overburdening business with extraneous data requests.

- The HFEA needs to ensure that the reasons and justifications for data collection are well understood by the Authority and the sectors it regulates.

Background information such as the data required by the regulator; the means by which business can return data, etc:

HFEA makes a number of data requests of licence-holders in relation to licence applications and activities undertaken as part of their licensed work. Under the HFE Act, activities requiring a licence are:

- Bringing about the creation of an embryo in vitro either for treatment or research;
- Keeping or using an embryo either for treatment or research;
- Storing any gametes;
- Using donated sperm or donated eggs in the course of providing treatment services for any woman;
- Treatment involving the use of fresh partner gametes;
- Non Medical Fertility Services.

Any examples of significant good regulatory practice:

HFEA has made good steps to implement the use of e-forms and interactive online applications. Through the EDI system HFEA pre-populates subsequent forms to prevent repetitive provision of the same data.

The regulator has recently carried out a review to establish the minimum data set required.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

The HFEA has gone to some length to ensure that the data it requests from stakeholders is necessary for the smooth running of the regulatory framework. It would appear, however, that more thought could be given to ensuring that researchers are not overburdened by being asked to supply information more than once. Additionally, the HFEA should consider what communication may be necessary to improve stakeholder awareness of the use to which submitted data is put.

INSPECTIONS

Hampton principle

No inspection should take place without a reason.

Key findings on Inspections:

- HFEA inspections of fertility centres are well organised – clinics are, in the main, notified clearly in advance of the areas that will be covered and given a timetable. Inspectors have a structured approach to the day and provide clear feedback, including on breaches and how to remedy them.
- However, the HFEA could make more use of unannounced inspections. Stakeholders have indicated that unannounced inspections reduce the burden of preparing for visits. Unannounced visits can give a more accurate snapshot of compliance levels and can be used to validate the effectiveness of the risk tool and self-reporting regime.
- The Review Team welcomes HFEA's intention to implement a new risk tool in order to aid the assessment of risk of non-compliance by clinics and to enable inspections to focus on high risk areas.
- Some centres have multiple licences, for treatment and storage, as well as for research. Usually these do not have the same renewal dates, which necessitate multiple inspection visits. While HFEA endeavours to ensure that multiple licences' renewal dates converge, it could consider whether it is possible to reduce the burden on licence holders further by widening the scope for combined inspection visits.
- It appears that, while the Inspectorate carries out inspections and, on the evidence uncovered at those inspections, makes recommendations to the Licence Committee, the Inspectorate has little autonomy devolved by the Licence Committee to make assessments and risk-based decisions about

maintaining compliance.¹

- HFEA has agreed a new compliance cycle which will lead to a reduction in the overall numbers of routine inspections and make interim inspections shorter and more focused. The Review Team welcomes this commitment, in view of comments received from HFEA stakeholders that interim inspections (required by law to be carried out at no more than 2 year intervals) have tended to be no less burdensome than a licence renewal inspection.

Any relevant background information such as the number of inspections and the number of businesses inspected; the regulator's risk model etc

HFEA inspects all licensed fertility centres in the UK. After an inspection, a report is produced which goes to the HFEA Licence Committee. These reports, and the minutes of the Licence Committee at which they were discussed, are then published on the Authority website.

Inspection reports set out the quality of service provided by HFEA-licensed clinics to patients and donors, including: information provided to patients and to the HFEA; clinical and laboratory processes; clinic staff competence; the clinic premises and equipment; and how well the centre is organised.

Any examples of significant good regulatory practice:

The HFEA is currently working to combine its process of auditing clinics' record-keeping with its inspection regime.

The HFEA publish their inspection reports online for ease of access making them freely available for public scrutiny.

The HFEA's team of inspectors are generally well-regarded in the industry as professionals who understand the industry and research projects.

Review findings:
The extent to which the review team believes the regulator is acting in line with the Hampton principle:

The inspection regime appears to be moving in the right direction in relation to the Hampton principles. There is evidence that the Executive is driving the implementation of Hampton principles into compliance and inspection processes; for example, ensuring interim inspections target areas of risk rather than repeat the full Renewal of Licence inspection which is

¹ This reflected a legal requirement at the time of the review.

a fuller audit of adherence to procedures within the Code of Practice. If the new risk framework is successfully introduced, this would bring the HFEA into full compliance with Hampton in this area.

For there to be real evidence that the HFEA has wholly embraced these principles, stakeholders involved in the compliance cycle need to feel them in operation. It is vital that the Authority is seen to embrace the Hampton principles for the benefit of the wider industry and the Review Team would like to see the Authority more actively driving Hampton principles from strategy into operational delivery.

SANCTIONS

Hampton & Macrory principles

The few businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions.

Regulators should be transparent in the way in which they apply and determine administrative penalties.

Regulators should avoid perverse incentives that might influence the choice of sanctioning response.

Regulators should follow up enforcement actions where appropriate.

Key findings on Sanctions:

- The process of applying sanctions appears long-winded. By law, licensing decisions must be made by the Licence Committee and, unlike many other regulators, HFEA's inspectors cannot take immediate action themselves when they identify a serious breach. Therefore, for the end-user or patient, decisions to impose a sanction may lack the pace and responsiveness required to provide protection.
- There appears to be a reluctance to utilise the full spectrum of sanctions for fear of negative impact on availability of treatment. For example, staff reported to the Review Team a reluctance to recommend that the licence of a clinic in a remote area be suspended for fear that patients would have to travel further afield to receive treatment.
- The HFEA's enforcement and compliance policy is not a clear guide for the regulated sector on the approach of the regulator to the application of sanctions. The focus of the policy appears to be more concerned with internal processes, rather than promoting a transparent approach by setting out what action can be expected as a result of breaches of the legislation/Code of Practice. In this context there is a perception among stakeholders that the Review Team spoke to that the HFEA is not consistent in its approach to administering

sanctions and fostering compliance among clinics.

- The Licence Committees currently makes all licence decisions, which, as noted above, can have the effect of slowing down the process. There are early signs of cultural change as consideration is being given to allowing the Executive to convene a Licence Panel² where low risk/routine licence decisions can be made. However, the Authority will still decide which licence decisions can be delegated to the Executive's Licence Panel. The Review Team supports this initiative and hopes that the opportunity will be taken to maximise the possibilities for streamlining decision-making.
- As the Executive's change programme 2010 embeds objective judgement tools; business processes and decision trees, the Authority should begin to have the confidence to genuinely relinquish routine and low risk decisions to the Executive.

Background information such as a summary of sanctions available to the regulator and any data on sanctions imposed by the regulator:

The HFEA's sanctions are limited by law to:

- Varying licences / adding conditions to a licence;
- Suspending a licence;
- Revoking a licence.

The decision to impose any sanction must be made by the Licence Committee. The Executive makes recommendations to the Authority's Licence Committees.

There have been occasional instances of licences being suspended and very few instances of a clinic or research centre's licence being revoked. The most commonly deployed sanction is for the Licence Committee to amend the conditions attached to granting a licence. It is currently rare that a licensee is issued with additional conditions and licensees can apply to have conditions removed.

Review findings:
The extent to which

The existing sanctioning regime set out in legislation is arguably unsatisfactory, in terms of allowing the HFEA

² A new Panel is now in operation, since October 2009.

the review team believes the regulator is acting in line with the Hampton principles and Macrory characteristics:

to deal with breaches of the law in a proportionate manner.

On the relatively rare occasions when breaches occur with serious repercussions for individual patients, the HFEA takes a number of factors into account when deciding whether to take enforcement action. The HFEA will, for instance, take the need for ongoing access to treatment into account when considering the position of a specific clinic. The Review Team's opinion was that the regulator should ensure that this factor did not hold too much weight when assessing the merits of using sanctions.

The HFEA's risk-assessments and sanctions decision-making processes need to strike the right and proportionate balance between the protecting the public interest and ensuring services remain available locally for those who rely on access. The Review Team would encourage the HFEA to have the confidence to use the full range of sanctions at its disposal in cases where these are necessary and proportionate.

The HFEA has an aspiration to adopt the civil sanctions under the Regulatory Enforcement and Sanctions Act. The Review Team believes that this could enable the HFEA to improve compliance within the regulated sector, providing it demonstrates a willingness to take proportionate action when breaches occur.

There is a perception among stakeholders that HFEA lacks a consistency of approach to breaches of the Act. The Review Team was presented with no firm evidence of this and notes that the HFEA has a Compliance and Enforcement Policy. In view of stakeholders' perceptions, the Review Team are concerned that the demonstration effect of the current sanctioning system may not be being fully maximised. There may be more that the HFEA can do, through communication of its Compliance and Enforcement Policy, to demonstrate the consistency of its approach to breaches of the Act.

FOCUS ON OUTCOMES

Hampton principle

Regulators should measure outcomes and not just outputs.

- Key findings on Focus on Outcomes:
- The HFEA does not see an increase in success rates of IVF treatment as being a measure of successful regulation of the industry.
 - The HFEA's support of patients is greatly appreciated by this group. The Authority's expertise and credibility adds to the ethical debates around the use of human embryos.
 - Given the prescriptive nature of the legislation, and as a consequence the Code of Practice, there is a tendency to rely on process as an indicator of success rather than outcomes to measure compliance. For example, the organisation's Key Performance Indicators focus on activities (e.g. numbers of inspections) rather than outcomes. It is recommended that the regulator increases its objective measurement of how the sector's compliance will be improved as a result of their activities; thus enabling them to hone their activities, selecting to carry out only those activities which have a measured positive impact. This will encourage continuous improvement.

Background information such as the regulator's key objectives:

The HFEA is currently carrying out a significant change programme. Planned changes could significantly improve the Compliance and Enforcement functions of the regulator. For example, a Risk Assessment tool will guide compliance and inspection activities, the Inspectorate plans to launch a self-assessment and inspection workbook for licence holders to complete and the Authority is showing the first 'green shoots' of devolving decision-making to the Inspectorate teams via the Executive Licensing Panel.

The HFEA's legislative framework is about enhancing public confidence in the fertility and embryology research sectors. Its remit is broader than just licensing IVF clinics and research centres which use

human embryos – the HFEA also provides information and support to patients of infertility clinics and acts as a conduit for ethical discussion around medical advancements and the use of human embryos.

For example, if a clinic reports to the regulator that they have breached an element of the Code of Practice, the regulator may send out an e-alert to all clinics with suggested best practice to avoid a similar event elsewhere. This practice in itself is commended by the Review Team. However, the regulator does not then measure or analyse the success of this e-alert system in fostering compliance with the same element of the Code of Practice. How effective are e-alerts at changing behaviour or reducing the risk of a similar breach occurring in another licensed centre? The regulator is unaware whether this activity actually improves compliance. There is the possibility to feed the subject of e-alerts into the risk assessment process and the Review Team believe that information gathered through the inspection regime could be used to assess compliance with the areas of the Code of Practice which have been the subject of e-alerts.

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

The HFEA has some room for improvement in this area. The Review Team acknowledges the work of the Change Programme to address some aspects of its Enforcement and Compliance activities. However, more could be done in terms of business planning to demonstrate how the HFEA's regulatory performance is contributing towards, for example, better and safer fertility treatments and facilitating scientific progress through stem cell research helping develop new therapies.

**Appendix 1:
Review team
membership**

Sarah Escott leads delivery of Natural England's statutory wildlife management and licensing which includes designing service processes and commissioning guidance to meet requirements of new or changing legislation and principles of Hampton.

Poppy Saunders works at the Better Regulation Executive. Her role involves parliamentary liaison and providing a whole of Government picture on programmes such as the Administrative Burden Reduction Programme. Prior to this Poppy was Head of Investigation at the Security Industry Authority, a national regulator.

Peter Tong works at Companies House, an agency of BIS, in Cardiff as Head of IT Strategy & Architecture. The role entails recommending, costing and mapping out technical options and investments over the long term.

Prior to joining the Civil Service in 2004 he worked in the retail financial services sector for 16 years in a number of IT related posts.

Better Regulation Executive
Department for Business, Innovation and Skills
3rd Floor
1 Victoria Street
London SW1H 0ET

Website: www.berr.gov.uk/bre

URN: 09/1542

© Crown copyright 2009

The text in this document may be reproduced free of charge in any format or media without requiring specific permission. This is subject to material not being used in a derogatory manner or in a misleading context. The source of the material must be acknowledged as Crown copyright and the title of the document must be included when being reproduced as part of another publication or service.