



## Focus on improvement

Report on licensed clinics' performance  
**April 2006 - March 2007**

August 2008

# Contents

1. Executive summary		3
2. Introduction		4
3. Inspection findings		5-11
3.1 What clinics did well		5-6
3.2 What was not causing concern		6
3.3 What clinics need to improve		6-7
3.4 What we found and why it matters		7-11
4. Delivering Improvement in Practice		12-13
4.1 Enforcement action taken and compliance		12
4.2 Renewal of licence		12-13
4.3 Interim inspections		13
5. Changes since Driving Improvement		14
6. Adverse incidents and Alerts		15-17
7. Patient satisfaction		18-22
7.1 Patients' views		18-20
7.2 Complaints		20-22
8. Conclusion		23
<b>Appendices:</b>		
Methodology	Appendix A	24
Categorisation of inspection reports	Appendix B	25
Detail of the content of categories	Appendix C	26-30
How we license and inspect clinics	Appendix D	31

## 1. Executive summary

This report provides a second overview of standards in the UK's licensed fertility clinics, based on an analysis of the Human Fertilisation and Embryology Authority's (HFEA) inspection reports, patients' views about clinics, including their complaints, and incidents. It highlights information for staff in clinics against which they can measure their own performance with the aim of continuing to drive improvement across the fertility sector. The report does not look at research licences, an overview of which can be found at <http://www.hfea.gov.uk/en/372.html>, titled 'Human Embryo Research in the UK'.

Clinics providing IVF treatment broadly met the standards expected of them by the HFEA and provided a good service for patients. They generally responded well when improvement was needed, often carrying out changes before the inspectors had left the clinic. Most conditions and recommendations made in 2005-06 had been complied with by the time of clinics' subsequent inspections.

Patient surveys showed a high level of satisfaction with the treatment provided by clinics and HFEA received a relatively low number of complaints.

However, there were some areas where managers should focus on improvement, including five where there were relatively large numbers of issues both in 2005-06 and 2006-07.

These were:

- Laboratory Processes and Practice
- Equipment Safety, Servicing and Maintenance
- Information for Patients and Donors
- Clinical Practice
- Consent

The HFEA used a variety of regulatory interventions and other developmental tools throughout the year to drive forward improvement in practice. For example, in response to concerns about laboratory procedures, HFEA issued two Alerts relating to witnessing (see page 17), developed new directions and provided an audit tool for Persons Responsible (PRs) to use when checking laboratory protocols.

## 2. Introduction

The HFEA was set up in August 1991 to help protect the interests of patients undergoing *in vitro* fertilisation treatment (IVF) and donor insemination (DI), through licensing and the regular inspection of fertility clinics.

The HFEA was the first statutory body in the world to regulate human embryo research and fertility treatment. It was established by the Human Fertilisation and Embryology Act 1990 (HFE Act), which is currently being reviewed by Parliament. All clinics carrying out IVF and DI treatment (and, from July 2007, other types of fertility treatment including intrauterine insemination), must be licensed by the HFEA.

This report analyses the quality of services provided by the 87 clinics that were licensed by the HFEA between 1 April 2006 – 31 March 2007.

The report is based on:

- the inspections of 60 of those clinics;
- a survey of patient questionnaire responses for all clinics;
- an overview of all the complaints and incidents reported to the HFEA during that period.

The purpose of this report is to promote learning and improvement in the fertility sector. It will also contribute to an ongoing process of quality assurance of regulatory processes within the HFEA.

The inspection process is a core activity of the HFEA and is a legal requirement. Licensed clinics are fully inspected when the licence is due for renewal, usually every three or five years. During 2006-07, most clinics where the licence was not due for renewal received an interim inspection, unless a licence committee considered this unnecessary because the clinic was low risk and complied well with requirements.

Each renewal and interim inspection is documented in a report written by HFEA inspectors. The final version of these reports is presented to a HFEA licence committee and is publicly available through the HFEA website. The information in the report comprises the key evidence on which a licence committee judges whether to grant or renew a licence and, if so, whether additional conditions or other restrictions should be placed on that licence. A more detailed explanation of how the HFEA inspects and licenses clinics can be found in Appendix D.

No individual clinics have been named in this report. The reports analysed are those arising from inspections carried out during the business year 2006-07, which do not include every clinic. Details of each clinic and their latest report can be found on the HFEA website at [www.hfea.gov.uk](http://www.hfea.gov.uk)

## 3. Inspection findings

This section focuses upon issues raised by inspectors in their reports. There are many examples of good practice noted in the reports. These are the categories of service provision where there were no or few issues recorded. A full list of areas covered during inspections can be found at Appendix B.



Inspectors were generally satisfied with their findings at most clinics in respect of many of these areas of service provision. However, it is important to note that reports of **interim** inspections may reflect a particular focus of the inspection process at that time. Similarly, although **renewal** inspections are comprehensive, they do not necessarily include every area of potential non-compliance. There were 31 renewal and 29 interim inspections included in the analysis.

### 3.1 What clinics did well

Inspectors now comment on areas of firm compliance in reports. This section records positive aspects of a clinic's treatment services. Common themes and innovation by individual clinics highlighted include:

#### Management

- The quality of multi-disciplinary meetings and dissemination of information about the meetings
- Appointment of a Quality Manager and/or participation in a recognized quality management system
- Stable staff; close working relationships
- Fertility-specific questionnaires collated for every 50 responses and report produced
- Weekly educational meetings for all staff

#### Patient experience

- Free counselling, either for one session or as many as required
- Walk-in services
- Existence of a Patient Panel or Patient Support Group
- Patient letters detailing treatment in case of need for such information in an emergency
- Separate waiting room for patients attending with children
- Free complementary therapy

#### Clinical and scientific practice

- Computer-based laboratory facility monitoring system
- Monthly nursing bulletin
- Daily diary of patient progress
- Passport identification of donors and overseas clients

- Mini incubators used for embryo culture to lessen the risk of cross infection between patients' samples where the clinic treats some viral positive patients

### 3.2 What was not causing concern

No issues were raised in 17 categories in the inspection reports analysed:

- Business planning
- Clinical governance
- Payment of treatment fees to HFEA
- Choice of treatments
- Donor selection
- Egg sharing
- Protection of the child
- Assessment of patients
- Safe handling
- Pre-implantation genetic diagnosis/pre-implantation genetic screening (PGD/PGS)
- Recruitment and retention of staff
- Risk management
- Contingency arrangements
- Patient feedback and satisfaction
- Suitable premises
- Information management

### 3.3 What clinics need to improve

Improvements could be made in 21 categories raised in the inspection reports:

#### Management

- Leadership and management
- Organisation of the clinic
- Resource management
- Confidentiality including safe storage of records
- Information to the HFEA
- Staff competence

#### Patient experience

- Welfare of the Child arrangements
- Privacy and dignity of patients
- Complaint handling
- Counselling facilities and services
- Information for patients and donors
- Consent

#### Clinical and scientific practice

- Incident management
- Storage facilities for embryos and gametes
- Safe equipment
- Prevention of incidents and accidents
- Protocols
- Record keeping
- Procedures in practice

- Laboratory process and practice
- Clinical practice

### 3.4 What we found and why it matters

The range of categories where concerns were raised by inspectors are discussed in more detail below, in descending order of frequency.

#### Laboratory procedures and practice

Laboratory procedures are a critical component of good quality treatment. It is particularly important that laboratory staff follow strict procedures for witnessing the transfer of sperm, eggs and embryos between equipment and patients in order to minimise any risk of errors in identity. The HFEA has issued two Alerts, (see Page 17), on witnessing in the period.



Laboratory processes featured in 14 incidents/near misses in the period, and witnessing featured in 23 incidents/near misses.

More issues were reported in this category than any other. This is likely to be linked to the increased rigour with which inspectors scrutinise laboratory practice.

The breaches included: issues related to witnessing such as discrepancies in documentation on witnessing, double witnessing not always recorded, and some procedures not being witnessed. Lack of a third reference marker for identification purposes was also an issue.

#### Information for patients and donors

Good information is central to high standards of treatment. Patients need full and appropriate information if they are to be able to assess the treatment options available to them and to give informed consent to their chosen option.

Problems with the standards of information given to patients are not just apparent from clinic inspections. Lack of information or the way that information is communicated is a frequent source of complaints from patients to HFEA. Complaints are further discussed elsewhere in the report.

This category had a relatively high number of issues of non-compliance.

#### Clinical practice

The single greatest risk of IVF – for both mother and child – is a multiple birth. Clinics are required to record information on the number of embryos transferred in order to enable the HFEA to check that the practice of three embryo transfer was only carried out in defined, limited circumstances.

The non-compliance included: a level of mixed IVF (in vitro fertilisation)/ICSI (intra-cytoplasmic sperm injection) cycles which was higher than guidance (clinics must not mix ICSI/IVF treatment in more than 2% of the cycles carried out in a year. This is to enable follow up studies of offspring); and issues relating to three embryo transfers.

### **Safe equipment, servicing and maintenance**

Equipment safety is important not just for the safety of treatment being given at the time, both for patients and staff, but also in ensuring the safety of material kept for patients in the long term. This is particularly important for those patients, such as patients undergoing chemotherapy treatment, who could not replace the gametes and embryos in storage.

Some of the problems in this category concerned the failure of clinics to fit dewars (the tanks in which frozen embryos and gametes are stored) with low-level nitrogen alarms and to have these connected to an auto-dialler system for warning staff at any hour that the nitrogen levels are dropping. If this happens and prompt corrective action is not taken, there is a high risk that the stored gametes or embryos may be damaged. There have been serious incidents in the past where equipment failure has led to loss of stored material.

This category had the fourth highest number of issues.

### **Consent**

As with other medical procedures, patients must consent to IVF treatment before receiving it. But these patients not only have the complication of making decisions about what should happen at the time of the treatment, but also what should happen in the future. For example, decisions will need to be made about what should happen to any embryos created and not used, or sperm or eggs to be stored.

Patients need sufficient information to be able to make decisions and give consent. When the appropriate forms are not completed properly, or the issues are misunderstood, this can give rise to unintended consequences and great distress.

The breaches included: gametes or embryos in store or used after the consented period.

### **Complaint handling**

Good implementation of a robust complaint policy will help minimise the distress of patients who have concerns about the treatment and care that they have received. If a complaint is not well handled by a clinic, the patient may choose to complain to the HFEA.

### **Organisation of the clinic**

Clinics must have agreements with their satellite or transport units and communication between sites should be robust if patients are to receive seamless care from all units.

In 2005-06, there were no issues in relation to organisation. However, in 2006-07 there were five, including lack of written agreements with satellite or transport units.

## Resource management

Resourcing issues commonly include out-of-hours arrangements, particularly concerning the availability of staff for witnessing purposes.

## Confidentiality (including safe storage of patients' records)

The maintenance of high standards of confidentiality by providers of fertility services is governed by stringent statutory requirements. Concerns here included patients' notes being left unsupervised in public areas of a clinic.

## Privacy and dignity

Privacy and dignity issues usually relate to poor environmental standards in the facilities provided by clinics for male partners and donors to produce sperm.

## Procedures in practice

Administrative procedures within, or associated with, laboratories or procedures associated with storage vessels, are everyday activities within all clinics. They included tasks such as the topping up of dewars, audit of stored material and emergency procedures.

The breach involved the reimbursement of a donor not being in line with current requirements.

## Information to the HFEA Registry

The HFEA relies on information provided by clinics to ensure accurate data is held on treatment cycles and their outcomes. The data should be reported within a specified time and in a consistent and reliable manner.

The breaches included: issues relating to the reporting of treatment cycles to the HFEA.

## Protocols

Clinics must ensure the safety and quality of techniques and consistency of practice by having protocols or standard operating procedures (SOPs). These ensure that agreed methods for carrying out each activity are followed by all staff.

Standard guidelines for IVF procedures are issued by professional bodies such as the Royal College of Obstetricians and Gynaecologists (RCOG) and the Association of Clinical Embryologists (ACE) and the HFEA gives guidance through its Code of Practice and Chair's letters. These should be adapted to the particular circumstances of each clinic, and are vital in the induction and training of new staff.

Most protocol issues are included within the category to which they pertain. However, there are sometimes issues related to lack of version control or other administrative processes.

## Leadership and management

Good leadership and management are essential to the smooth and effective running of any organisation. Those responsible for managing IVF clinics (Persons Responsible) have specific obligations under the legislation in addition to their professional and managerial duties. HFEA provides a distance learning pack (the PR entry programme, PREP) for PRs to ensure that they are aware of their responsibilities.

## Adverse incident management

Adverse incidents are not always reported to the HFEA and this was evidenced in two reports when inspectors became aware of unreported incidents as a result of a clinic's inspection. There can be some confusion over what constitutes an incident despite an explicit description from the 6<sup>th</sup> and subsequent editions of the Code of Practice.

*Adverse incidents are defined as any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed clinic. (6<sup>th</sup> edition Code of Practice sec 2.24)*

## Welfare of the child arrangements

The legislation governing fertility requires clinics to take into account the welfare of any child who may result from treatment, and of any other child who may be affected by the birth, before treating a woman (section 13(5) HFE Act 1990).

Welfare of the child arrangements caused a number of issues to be recorded in the last analysis of inspection reports. However, the number of concerns in this category has reduced considerably, possibly because the guidance issued by HFEA changed in November 2005 to focus on risk factors that could lead to serious harm to a child.

## Prevention of incidents and accidents

Clinics need to be aware of lack of security or improvements necessary in relation to safety so as to take appropriate steps to prevent incidents and accidents.

## Staff competence, qualifications, training and continuing professional development

Continuing professional development (CPD) is essential for professionals within clinics. Many professions have specific requirements to which members must adhere. The qualifications and training of personnel should be documented and updated as necessary. Training and development needs should be appraised regularly so that clinics are aware of CPD requirements.

## Counselling facilities and services

Given the emotional difficulties faced by many patients receiving fertility treatment, it is important that clinics provide ready access to good quality counselling about the treatments and options on offer to them. This is reflected in the law, where section 13(6) of the HFE Act 1990 requires clinics to provide a suitable opportunity for counselling to women and men being treated about the implications of their treatment before it begins.

## **Storage facilities for embryos and gametes**

The storage facilities for embryos and gametes are carefully controlled so that the risk of any adverse incident is minimised. The storage facilities must be adequate to meet this need.

## 4. Delivering improvement in practice

The HFEA has a range of powers to encourage clinics to improve their practice. These improvements are initiated both through the inspectors themselves and through the work of the licence committee.

Much of the improvement comes as an immediate result of the ongoing partnership between HFEA staff and the people working in clinics. Clinic staff ring HFEA inspectors for advice or guidance in particular situations and prompt notice is usually taken of inspectors' recommendations both during an inspection and on an ongoing basis.



For more serious matters, inspectors make recommendations in their reports to a licence committee regarding the actions that should be taken to secure improvement where needed. These can include advice on the length of licence to be granted at renewal, with a maximum of five years set down in the legislation.

HFEA licence committees have the power to impose conditions on a clinic licence to enforce compliance. Ultimately, a licence committee has the sanction of suspending or revoking a licence.

### 4.1 Enforcement action taken and compliance

In 2005-06, licence committees imposed eight additional conditions. Seven of these had been met by the time of the inspections recorded in the reports analysed for this document. The majority of recommendations had also been complied with.

In 2006-07, licence committees varied the conditions attached to the licence of two clinics. The additional conditions concerned:

- Safe equipment
- Information for the HFEA Registry (treatment records)

### 4.2 Renewal of licences

During the reporting period:

- Fifteen clinics had their licence renewed for five years
- One clinic had its licence renewed for four years and three months to coincide with a research licence
- Ten clinics had their licence renewed for three years

Some clinics had each of the following:

- Renewal for three years, condition added
- Renewal for one year, condition added
- Renewal for one year at clinic's request
- Renewal for one year (clinic moving)
- Licence to be reviewed following further analysis

It should be noted that 25 clinics were not inspected in 2006-07, in most cases because a licence committee (1 March 2006) agreed that inspection could be waived for some low risk clinics.

### **4.3 Interim inspections**

The licences of 28 clinics continued unchanged and there was one proposal to vary the licence of one clinic.

## 5. Changes since 2005-06 (Driving Improvement Report)

Comparison between the analysis of 2005-06 (“Driving Improvement report”) and this analysis of 2006-07 demonstrated five categories with consistently high numbers of issues in both years.

The categories are:

- Laboratory processes and practice
- Safe equipment, servicing and maintenance
- Information for patient and donors
- Clinical practice
- Consent

A total of 78 reports were analysed in 2005-06 and 60 reports in 2006-07. If the total issues within each category is adjusted for the smaller number of reports analysed in 2006-07, the following categories had markedly **fewer** issues than in 2005-06:

- Leadership and management
- Welfare of the Child
- Staff competence
- Counselling facilities and services

As is described in Appendix A, issues relating to protocols were not analysed in the same way in both years. This means that there is some distortion which results in the number of issues per category for 2006-07 (other than protocols) being **higher** than they would have been if the methodology had been the same in both years.

## 6. Adverse incidents and alerts

Clinics are expected to record any adverse incidents that occur and report these to HFEA within 24 hours. The information is used to help individual clinics improve patient care and the safety of gametes and embryos through the production and distribution of Alerts.

The purpose of Alert notices is to share with clinics:

- information on any adverse incident or near miss
- what led to its occurrence
- the associated or root causes identified from investigation
- the actions that can be taken to minimise the chance of recurrence

All Alerts are anonymised to protect patient and clinic confidentiality.

It is the duty of the Person Responsible in each clinic to review every Alert as soon as it is issued and disseminate the information amongst their team. This is monitored at inspections to ensure widespread awareness of the contents of the Alert. It is expected that clinics will discuss Alerts in team meetings to ensure good practice in use of equipment or detail of procedures.

It is the responsibility of all clinics to put processes into place to manage the risks to patients and staff. When an incident is reported, the HFEA works constructively with the clinics to support their programme of remedial action.

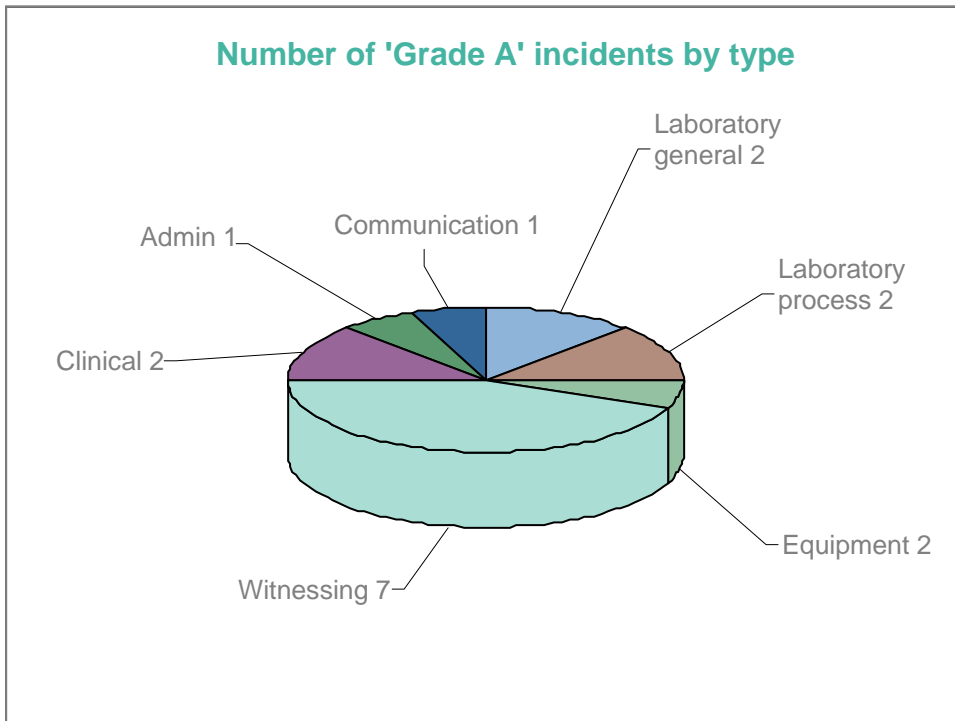
### Incidents and Alerts 2006-07

Between 1 April 2006 and 31 March 2007, more than 48,000 treatment cycles were provided for over 36,000 patients. During this period, 173 incidents were notified to HFEA. Although comparisons are difficult, in 2006, around 14,800,000 in-patient treatment episodes were provided by the NHS and 1,172,465 adverse incidents were reported to the National Patient Safety Agency (NPSA).

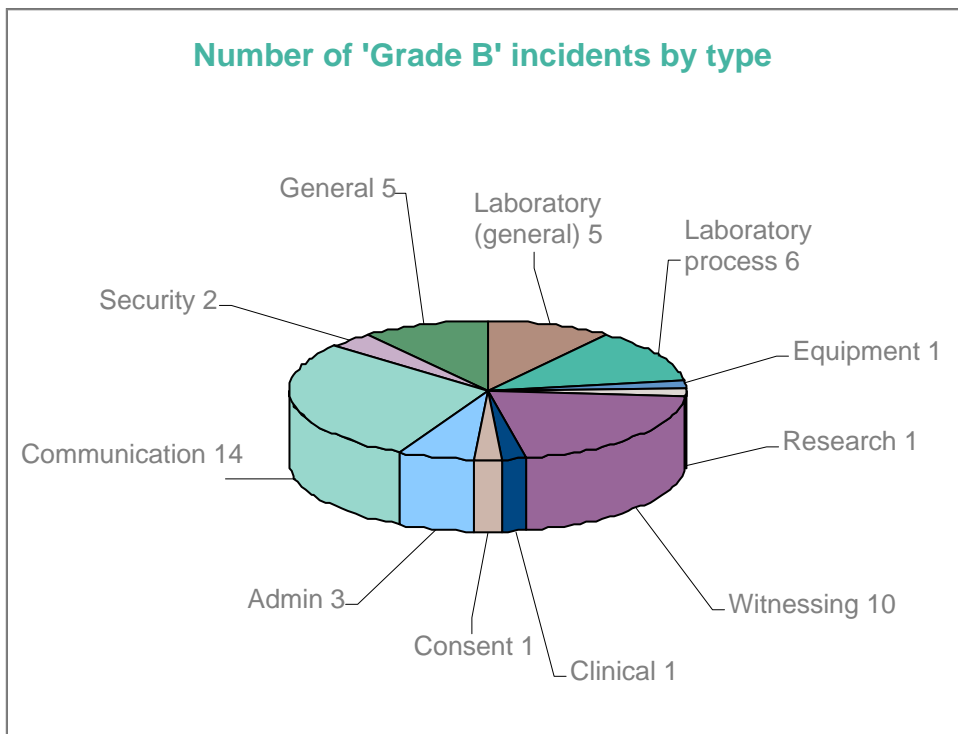
Incidents are graded A, B or C according to the likelihood of a recurrence, and the severity of the potential outcome(s) by a multi-disciplinary team which usually includes the inspector for the clinic.

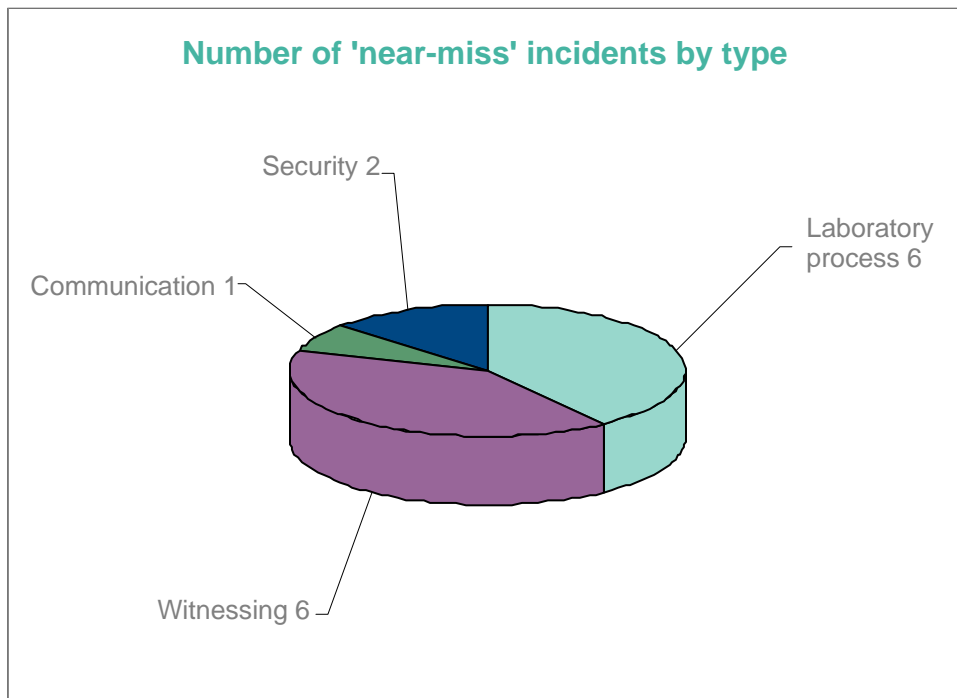
Category	April '06 – Mar '07
A	17
B	49
C	92
Near Miss	15
Total	173

**Figure 1: Table to show the number of incidents reported to HFEA between April 2006 and March 2007.**



**NOTE: Some incidents fall into more than one category:** for the purposes of numbers we only add the incident to the category we consider is the main issue.





During 2006-07, three Alerts were issued, representing the learnings from many incidents:

- one detailed the risks associated with transferring samples between clinics, nationally and internationally, and the need for clinics to strengthen their risk-control measures in this area.
- two Alerts were issued to help staff at clinics address the risks associated with witnessing the correct identification of gametes and embryos.
- HFEA also issued new directions to PRs to follow regarding witnessing and developed an audit tool for them to use when checking the suitability of laboratory protocols, in order to help secure improvement.

## 7. Patient satisfaction

HFEA has several means by which to gauge patient satisfaction with the service provided by licensed clinics:

- patient complaints
- interviews with patients during inspections
- responses to questionnaires and
- the patients' panel, Fertility Views

### 7.1 Patients' views

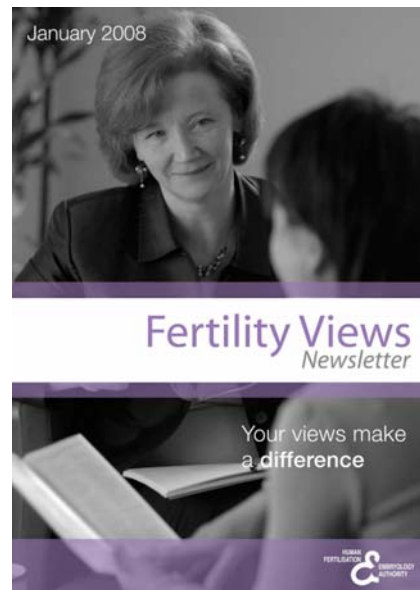
From July 2004 onwards, the HFEA has been using questionnaires to gather feedback from patients about their experiences of care at the regulated IVF clinics.

Patient satisfaction questionnaires are completed in one of two ways:

- on paper, returned as part of the inspection process
- online via the HFEA website

Prior to each interim or renewal inspection, each clinic is asked to distribute 100 questionnaires to recent patients randomly. Clinics may request additional copies of the questionnaire if needed. An online version is also available on the HFEA website. The data collected not only illustrates the patient's perspective of the clinic and the quality of its service but also allows for the comparison between clinics.

The HFEA also runs an online patients panel 'Fertility Views' which gathers patient views on a range of issues approximately twice a year. There were approximately 900 panel members in 2006-07.



### Responses to questionnaires (2006-07)

Around 11,500 paper questionnaires were distributed during the period of which approximately 2,735 were returned, a response rate of around **24%**.

This compares with a response rate of **11%** in the previous year. Additionally, there has been a significant increase in the number of responses completed online via the HFEA website.

### Respondent/Patient views

Analysis of patient questionnaires indicates a high level of overall satisfaction with services provided by licensed clinics.

The patient questionnaires look at six key aspects of the service provided asking a range of questions that are brought together to provide an overall assessment of each area.

An overall national satisfaction level for each area has been calculated for this report.

The six areas are:

### Clinic and staff

This looks at six areas including overall cleanliness, adequacy of the waiting area, privacy, and respect and dignity. There was an overall **78%** approval rating for this area of the service provided by clinics during the period.

### Provision of information

Two questions were asked relating to satisfaction with the information received (both verbal and written) and the time allowed for questions from the patient. Across all clinics, there was a **96.7%** approval for the information provided by these clinics.

### Provision of counselling

Awareness and provision of counselling services was rated at **87.3%** across all clinics.

### Consent and treatment

Satisfaction on consent and treatment was rated at **90.2%** across all clinics.

Issues covered by this included:

- explanation of the consent forms before signing
- provision of time to consider treatment options; and
- maintaining contact whilst the clinic stores gametes on behalf of the patient

### Drugs

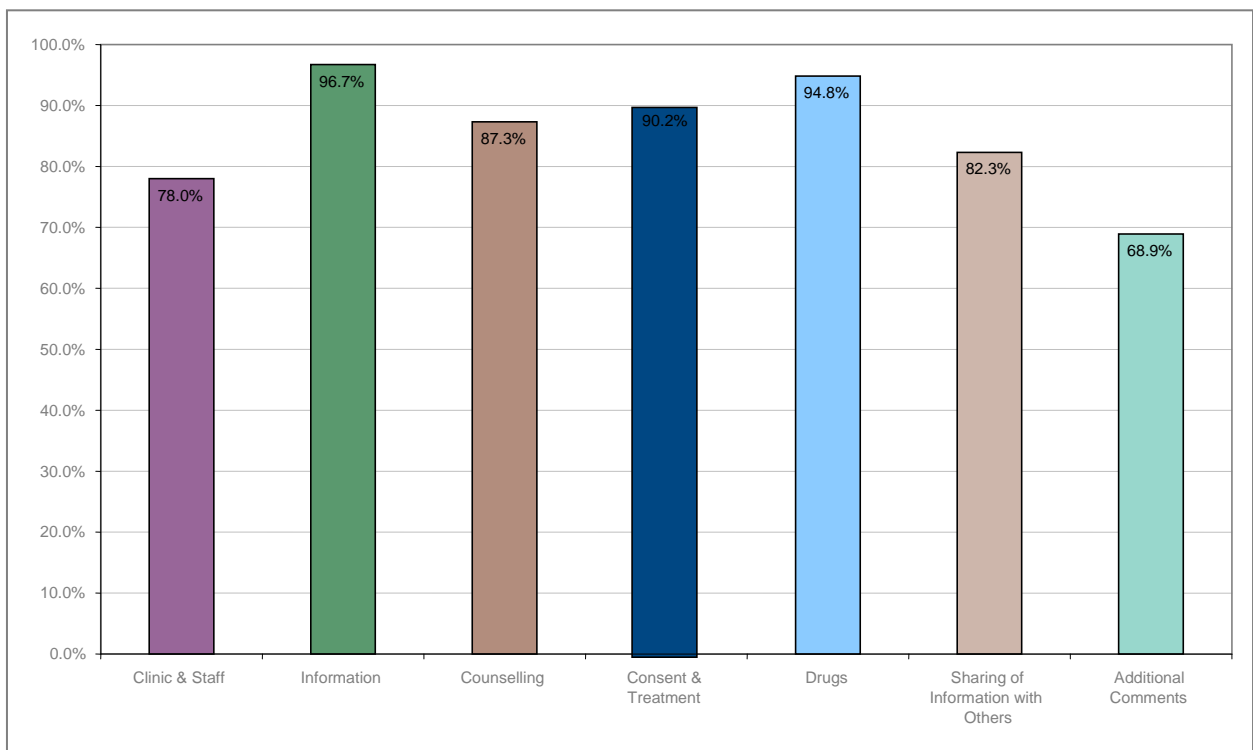
Issues relating to drugs provided by the clinics were given a **94.8%** approval rating. Explanation of the purpose of the drugs provision and emergency contact details were evaluated for this factor.

### Sharing information with others

The explanation provided by the clinics of who is legally allowed to know about a patient's treatment and contact information satisfied **82.3%** of respondents.

### Additional comments

Additional (positive) comments were observed in **68.9%** of the responses. This is significant after assessment by balancing with the negative comments and indicates a mostly positive view of the clinics providing fertility treatment.



**Figure 2a – Approval Ratings across all clinics by 2006 – 07 questionnaire responses**

## 7.2 Complaints

Clinics are expected to have their own procedures for dealing with complaints and inspectors check that these are followed and operate satisfactorily. Where these have not resulted in a satisfactory outcome for patients, or have not been handled well by clinic staff, they can result in complaints to HFEA.

The HFEA's scope for dealing with complaints is limited. We can only investigate complaints if they relate to a potential breach of the terms of the licence or of the legislation, or indicate circumstances which we would classify as a serious adverse incident, triggering our duty to investigate. We often receive complaints about other matters, for example, cost and charges, which we have no powers to pursue. Patients can also be disappointed that, as a regulator, we have no remit to act as an advocate in disputes between clinics and patients.

The recurrent themes of the few complaints received do, however, match closely the issues raised by patients in general feedback to HFEA, in particular concerns about the quality and timeliness of information and about the emotional support received.

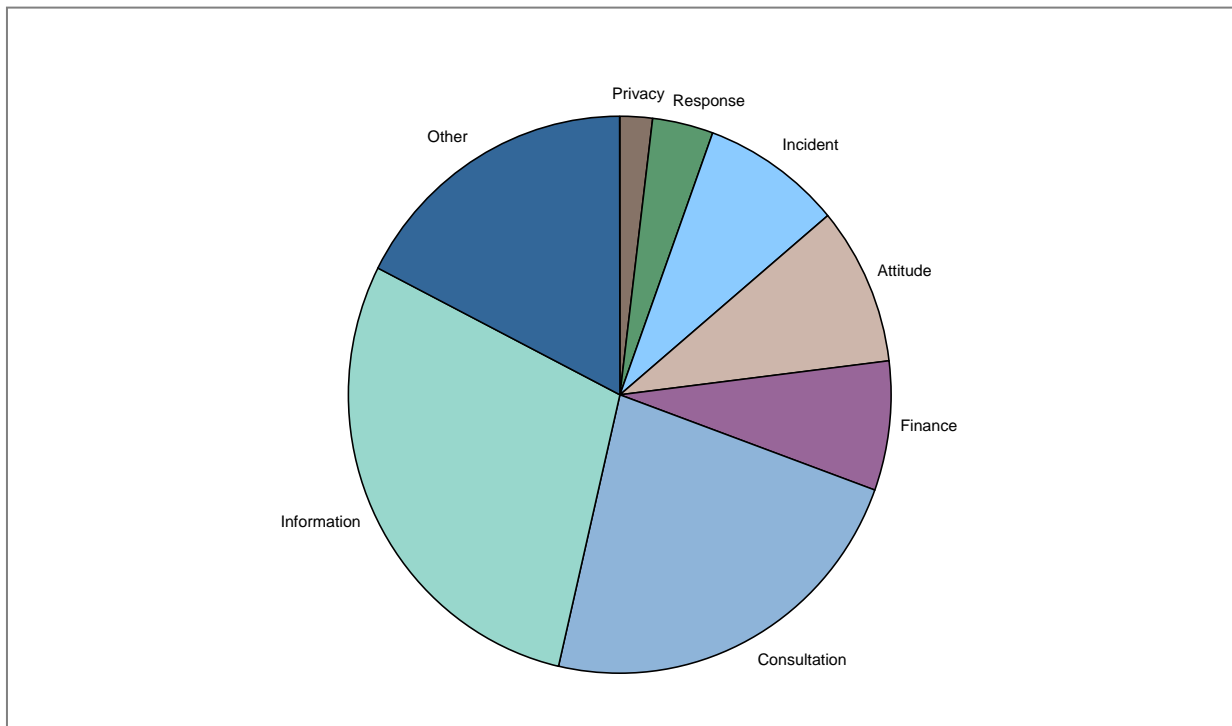
### Complaints in 2006-07

Between 1 April 2006 and 31 March 2007, HFEA received **141** new complaints involving **34** clinics. Most complaints were handled well by clinics.

There were no complaints received from patients about **47** licensed clinics. The number of complaints received by the HFEA about clinics generally remains low in relation to the volume of treatment cycles – over 40,000 treatment cycles are undertaken each year.

### What kinds of complaints did we receive?

Complaints are often complex, covering several issues. The chart below shows the categories of complaints in the proportion received.



**Figure 2b - Complaints by Category (April 2006 – March 2007)**

The areas of most concern to patients are information and consultation. During the past year there has been an increase in the number of complaints involving information. Patients typically complain about too much or too little information, or about its lack of clarity.

Many complaints are well handled by clinics. Some complaints are an ongoing source of distress both for patients and clinic staff. Whilst issues around information provided by clinics are the most frequent type of complaint at the moment, patients often say to the HFEA that it is the way information is given to them that has exacerbated their distress.

There are a few clinics that need to improve their management of complaints. Very often if a complaint is dealt with straight away and in a sympathetic manner by clinic staff the complainant will be satisfied and will not formalise their complaint, nor will they be inclined to approach the HFEA.

Rushed consultation and a lack of understanding or empathy and failing to listen to patients is a common complaint about consultations with clinicians. Complaints also arise because of differences in diagnosis when patients change to another clinic.

The overriding message that comes out of reading complaint letters is that empathy and time are needed at all stages of treatment and particularly when giving bad news. For many clinicians and their team members this is a fundamental part of their approach to giving quality care to their patients. For other clinicians it can sometimes seem like an optional extra which is not always a core value of the team.

Complaints about finance include disputes about the type of treatment patients thought they were buying and its associated costs, compared to what they were subsequently charged for.

**HFEA is currently amending its Code of Practice to provide guidance to Persons Responsible on producing individual costed treatment plans for patients before they start their treatment. These plans will detail what the treatment involves and the cost of each element of the treatment.**

This would ensure those patients are better informed about the full range of costs they are likely to incur and therefore feel less of a need to complain subsequently.

Interestingly, complaints about privacy and dignity do not appear to be an issue in the smaller and medium size clinics and point to an area of concern that larger clinics need to be aware of and address.

## 8. Conclusion

HFEA found a high level of patient satisfaction overall with the services provided by licensed clinics during 2006-07. We received a relatively low number of complaints, although more than the previous year, relating to fewer than half of the clinics. Most of the complaints related to information provided (or not provided) to patients and the way in which their consultation was handled by clinicians.

Few adverse incidents relative to the number of treatments carried out were reported, most concerning laboratory practice and processes. Useful learning was shared from these through HFEA Alerts.

Generally clinics complied well with the requirements of legislation and guidance and were prompt to make improvements when concerns were raised by inspectors. Little regulatory action was thought necessary by licence committees.

### Methodology

Some clinics were inspected twice in the period. In these cases only one report of the clinic has been included in the analysis.

Every item recorded on the reports as a breach of the HFE Act, condition or direction, or non-compliance with the Code of Practice, Chair's letter or recommendation was identified as one item. Breaches and issues of non-compliance were each counted as one item.

All the data was put into an excel spreadsheet and 10% of the data was quality assured with a member of the Regulation team.

The analysis included 60 reports (the final population). The final population has been deemed to be a sufficiently large proportion of the entire population to make it appropriate to draw inferences that can be applied to all clinics.

In 2005-06, issues relating to protocols were analysed on the basis of no more than one protocol issue per clinic. In 2006-07, the recording of protocol issues had been refined by inspectors and it was thus possible to allocate protocol issues to the relevant category e.g. a protocol issue relating to Welfare of the Child procedures has been classified under Welfare of the Child.

There were some protocol issues in 2006-07 which were of a general nature e.g. lack of version control on documents and these have been allocated to the protocol category. If protocols are compared on a like for like basis (breaches, non-compliance and recommendations) the results are:

Protocols			
2006 – 07		2005 - 06	
Number of Issues	% of 60 reports	Number of Issues	% of 78 reports
24	40	38	49

Minutes of the licence committees were analysed to ensure that the outcome of the inspections can be referred to in this report.

### Categorisation of inspection reports

#### Organisation

- Leadership and management
- Organisation of the clinic
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

#### Quality of service

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18 years)

#### Premises and equipment

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/accidents

#### Information

- Information management
- Information for patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

#### Laboratory and clinical practice

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS (Pre-implantation genetic diagnosis/pre-implantation genetic screening)
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

### Detail of the content of categories

(including issues noted as “recommendations” by inspectors – the recommendations have not been used in the analysis of inspection findings)

#### Consent

The issues included:

- Protocols and procedures
- Consent missing from records
- Storage out of consent period
- IUI out of consent period
- Ownership of sample produced at home

#### Counselling facilities and services

The issues included:

- Difficult access to appointments with the counsellor
- Lack of counsellor’s qualifications
- Isolation of the counsellor
- Need for audit of provision of counselling
- Provision of independent advice
- Consent from patients for counsellors to discuss their treatment with the team
- Low uptake
- Lack of counsellors name on patient information
- Need for back-up counsellor or support

#### Clinical practice

The issues included:

- Lack of documented nursing policies
- Three embryo transfer including lack of documented reasons

#### Complaint handling

The issues included:

- Lack of information for patients of a contact number for the HFEA
- Inadequate complaint handling procedures or documentation
- Non-display of complaints procedure in waiting rooms
- Inadequate complaint log

#### Confidentiality (including safe storage of patients’ records)

The issues included:

- Patient notes being left unsupervised in public areas of clinic
- Insecure storage
- Need for interpreter to sign confidentiality agreement
- Lack of separate theatre log

#### Incident management

The issues included:

- Lack of awareness of what constitutes an incident
- Incidents not reported to the HFEA

## Information management

The issues included:

- Poor system of notification of arrival of patients
- Review needed of information management
- Need for back-up of information on treatment service provided

Note: Information management comprises general issues related to how clinics process and use information and is different from the specific issues of information which clinics provide to the HFEA and information for patients.

## Information for patients and donors

The issues included:

- Non compliance with the Chair's letter (03) 06 that all men who have made provision for posthumous conception should be contacted by the clinic and informed of the additional consent required under the Human Fertilisation and Embryology Act 1990 (HF & E Act), (Deceased Fathers' Act) 2003
- Revision of documents
- Success rates
- SEED review (the Sperm, Egg and Embryo Donation review)
- Lack of information for donors, including removal of donor anonymity  
Need for review of leaflets/booklets
- Chair's letter (06) 01

## Information to the HFEA Registry and updates

The issues included:

- Late reporting of information to the HFEA
- Inconsistent patient format adopted in feedback to HFEA
- Audit results
- Quality of forms completed
- DI success rates

## Laboratory procedures and practice

The issues included:

- Inadequate witnessing, not contemporaneous or not double witnessed
- Non-separated samples
- More than one unprocessed sample at a time on the workstation
- Unscreened samples in store
- Absence of three unique identifiers for patients and their gametes
- Mouth pipetting
- Protocol review

## Leadership and management

The issues included:

- Not seeking to gain consent from HFEA for a potential change of nominal licensee
- Non-display of the clinic's licence/not up to date version
- Individuals not included on licence
- Lack of meetings, or minutes, or agendas, or poor circulation
- Communication within the team
- Resource discussion to be held with Trust

## Organisation of the clinic

The issues included:

- Lack of agreements with satellite/transport clinics
- Lack of or an inaccurate organisation chart
- Service level agreement problems
- Communication issues with satellite clinics

## Patient feedback and satisfaction

The issues included:

- Development of a patient questionnaire

## Prevention of incidents and accidents

The issues included:

- Unauthorised access to premises and records
- Open doors or security between areas
- Sign needed warning of danger of liquid nitrogen
- Lack of awareness of the staff of HFEA alerts
- Lack of awareness of clinic staff of emergency contact numbers
- Position of tanks
- Protocol needed for action when oxygen alarm activated
- Need to monitor potential for unauthorised entry
- Cryostore to be locked when not in use

## Privacy and dignity

The issues included:

- The inadequacy or lack of a dedicated sperm production room
- Privacy needed for phlebotomy procedures

## Procedures in practice

The issues included:

- Confirmation of patient identity
- Reimbursement of donors
- Update of paperwork
- Need for audit of tanks
- Dewar top up not to be undertaken alone
- Documentation of nitrogen levels
- Improvement in audit process
- Review of laboratory protocols
- Review of status of stored material
- Emergency procedures

## Protocols

The issues included:

- Lack of protocols
- Protocols not submitted
- Lack of version control

## Record keeping

The issues included:

- Need to update database when material moved
- Need for audit of records

- Paperwork discrepancies

Note: there is some overlap of this category with information management, but record keeping specifically relates to the recording or audit of records.

### Resource management

The issues included:

- Staffing levels
- Out of hours number manning, or rota or response
- Need for permanent administration staff
- Working hours
- Consideration of compensation for working weekends

### Risk management

The issues included:

- Resuscitation equipment in theatre
- Dewar alarm response
- Out of hours telephone calls
- Witnessing steps
- Absence of spare dewar
- Unscreened samples in long term store
- Samples in store without alarm
- Storage of donor sperm
- Seeking consent at time of embryo transfer

### Safe equipment, servicing and maintenance

The issues included:

- Failure of clinics to fit dewars with alarms and for the alarms to be connected to an auto-dialler as specified in Chair's Letter CH (04) 03
- Need for protocol
- Need to analyse trends in sub-optimal equipment
- Laminar flow cabinet needed
- Low oxygen alarm to be tested
- Need for a calibration log of oxygen monitor
- Need for pulse oximeter
- Storage tanks to be secured and alarmed
- Inadequately maintained or replaced equipment
- Need to check emergency trolley
- Provision of a fridge for dedicated use
- Lack of back up power supply
- Lack of spare dewars
- Lack of maintenance contracts

### Staff competence, qualifications, training and continuing professional development (CPD)

The issues included:

- Lack of qualifications
- Lack of access to training or induction
- Need for participation in a quality management system
- Need for update of basic life support
- Absence of written records of training activities undertaken or competencies

- Lack of review of CPD
- Training to be formalised
- Lack of appraisal by staff with competency in fertility treatment

### **Storage facilities for embryos and gametes**

The issues included:

- Need for spare vessels

### **Suitable premises**

The issues included:

- Location of equipment
- Need for improvement of premises
- Air quality or testing
- Entrance needs signage

### **Welfare of the Child arrangements**

The issues included:

- Need for protocol to be amended
- Gaps in audit
- The need for re-assessment of patients

### How we license and inspect clinics

The law, (HF & E Act 1990), says that any clinic in the UK that carries out IVF treatment must be licensed by the HFEA. This is in order to ensure that patients have the security of knowing that they will receive safe treatment from competent practitioners and that the creation and use of embryos is appropriately controlled.

Licences are issued or renewed following an inspection; they usually last for three to five years, although shorter licences may be issued when the HFEA has concerns about how the service is being run.

Inspections are carried out by teams of in-house inspectors employed by the Authority, together with external advisers who are experts from the field, as required. Clinics are usually given good notice of inspections but some visits are unannounced. Inspectors may be on site in a clinic for a few hours or up to two days, depending upon the scale and complexity of the services provided and the extent of any problems found.

The findings of each inspection are reported to a licence committee once the person responsible (PR) for the IVF clinic has had an opportunity to comment on the report. These reports are published on the HFEA website.

Licence committees are drawn from members of the Authority, who are appointed by the Government for a renewable term of three years, either for their expertise in the field or their lay interest. Each committee consists of between three and five members and is chaired by a lay person. Licences are issued with a standard set of conditions that apply to all or most clinics. If particular standards are not being met, licence committees have the power to propose additional conditions or to propose to revoke a licence, if they have more serious concerns.

Where members are worried about the safety of patients, gametes or embryos, and/or if they think a criminal offence may have been committed, licence committees can suspend a licence with immediate effect, for up to three months, whilst further investigations are carried out and significant improvements made.