

# **Driving Improvement**

**Lessons from the UK's fertility sector  
2005-06**

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## EXECUTIVE SUMMARY

This report provides an assessment of the standards in the UK's fertility sector based on an analysis of the Human Fertilisation & Embryology Authority's inspections, patient complaints about clinics and incidents reported to the HFEA between 1 April 05 and 31 March 06. One of the HFEA's key role as regulator is to bring this information together so that clinics can learn from each other's experiences and to drive improvement across the fertility treatment sector as a whole.

In general clinics providing IVF treatment broadly meet the standards expected by the HFEA and provide a good service for patients. Where improvement is necessary, most clinics respond to requests and use advice well, although a few persistently cause concern and are slow to comply with requirements.

However there are some clear areas where improvement is required across the sector.

The greatest need for improvement by clinics is in the **provision of information to patients**. Information should be clear, accurate, comprehensive and up to date. Patients should be given time to absorb the information and the opportunity to explore fully its implications.

Good information is linked to **counselling** and **consent**. Too many patients do not receive access to suitable counselling services. This means patients are not getting the opportunity to talk through their options thoroughly to help build an understanding of their treatment.

If patients do not receive comprehensive information or an opportunity to explore their options fully then their ability to give informed consent for their treatment is compromised. This can have serious implications both during their treatment and in the future. Weaknesses in these areas are also seen through patient complaints with **information**, **attitude** and **consultation** the three main causes of concern.

Clinics also need to improve their practice across a variety of other areas including **equipment safety**, **protocols**, **clinical practice** and **record keeping**.

A few clinics show systemic problems related to poor **leadership and control** across a range of their operation. These centres having a disproportionate amount of the problems found across the UK's IVF sector.

The HFEA has used a variety of regulatory interventions throughout the year to drive forward improvements in clinic practice. These have included **licence conditions**, **reductions in licence length** and a proposed **revocation of licence**.

The HFEA has also introduced a new **assessment and professional development** process for people who hold the **Person Responsible** role in clinics. This should tackle the systemic problems of those clinics with poor leadership and help strengthen the standards of management and operation across the UK's fertility sector as a whole.

## INTRODUCTION

The Human Fertilisation and Embryology Authority (HFEA) was set up in August 1991 to help protect the interests of patients undergoing IVF and donor insemination (DI) through regulation and regular inspections of fertility clinics.

The HFEA was the first statutory body in the world to regulate human embryo research and fertility treatment and was established by Parliament through the Human Fertilisation and Embryology Act 1990 (HFE Act). All clinics carrying out IVF and DI must be licensed by the HFEA. Details of the licensing process can be found in Appendix A. This law, related legislation and associated guidance in the HFEA's Code of Practice set out the standards expected for safe and appropriate behaviour in the UK's clinics.

This report is based on the results of seventy eight (78) inspections that were reported to licence committees between 1 April 2005 and 31 March 2006. During this period most fertility clinics were inspected annually for licensing or monitoring purposes. The report also brings together an analysis of incidents reported by clinics to the HFEA and the complaints that the HFEA had reported to it. The HFEA now also has a predictive tool, known as the risk matrix, which was introduced in 2006 to enhance the targeting of inspections. The risk matrix looks at a wider range of factors to help us prioritise those clinics which are most likely to need an inspection – while this analysis looks at the results of inspections.

The report reviewed the issues raised by inspectors in their reports and weighted them to give a 'compliance score'. This score was calculated by assessing whether the issues raised involved breaches of the legislation (scored -3) or the Code of Practice (scored -2) or were other forms of poor practice (scored -1). Detail of the methodology of this analysis can be found Appendix A.

The report highlights how well fertility clinics met the standards expected of them, and areas where improvement is needed. The report includes a review of the complaints received from patients during that period and analyses the incidents reported by clinics in order to contribute to learning and improvement in the sector.

The aim of this report is to present an overall picture of current performance in the UK fertility sector, to highlight areas of best practice that can be shared across the fertility sector and to focus on those areas where clinics need to make most efforts to show good practice and improvement.

No individual clinics have been named in this report as it is designed to provide an overall picture of the UK's fertility sector rather than being a 'naming and shaming' exercise. Details of individual clinic practice can be found in the inspection reports for each centre but details of complaints and incidents cannot be disclosed to protect patient confidentiality.

# INSPECTIONS OF CLINICS

## How well did clinics perform?

Overall, the fertility sector performed well at meeting the standards it was expected to meet. Eighty per cent (80%) of fertility clinics met 79% of the standards set. However, there was a wide variation in performance between individual clinics, with five having a 'clean sheet' of no issues, the remainder having weighted improvement scores ranging between one and 31. We subsequently looked in detail at those clinics which had particularly low compliance scores to see if there were particular factors in those clinics which had multiple issues.

This table shows the breakdown of compliance scores across the areas of clinic practice assessed in HFEA Inspections:

<b>CATEGORY</b>	<b>Total Compliance score</b>
Information for Patients	-62
Safe Equipment	-55
Protocols	-53
Consent	-51
Laboratory procedures	-43
Counselling	-39
Record Keeping	-36
Staff Competence	-32
Welfare of the Child	-32
Clinical Practice	-29
Leadership	-25
Prevention Incidents	-17
Incident Management	-17
Confidentiality	-15
Complaint Handling	-13
Risk Management	-12
Information to HFEA	-11
Resource Management	-10
Suitable Premises	-9
Procedures in Practice	-8
Privacy and Dignity	-5
Information Management	-5
Organisation of Centre	-4
Live Birth Rates	-4
Patient Feedback	-3
Assessment of Patients	-3
Storage Facilities	-3
Business Planning	-2
Clinical Governance	-2
Donor Selection	-1
Safe Handling	-1
Contingency	-1

## What did clinics do well?

Many aspects of care were well-provided by the clinics. Inspectors found few issues relating to the following areas of treatment, care or management in the 78 clinics inspected:

### **Patient Skills**

- Assessment of patients
- Choice of treatments
- Confidentiality
- Complaint handling
- Privacy and dignity
- Protection of children

### **Treatment & techniques**

- Donor selection
- Egg sharing
- Live birth rates
- Pre-implantation genetic diagnosis/screening (PGD/PGS)

### **Centre management**

- Business planning
- Clinical governance
- Risk management
- Safe handling
- Information management
- Premises
- Payment of statutory fees
- Staff recruitment and retention
- Storage facilities

## **What did clinics need to improve?**

Clinics were poorer at meeting standards about the following areas:

### **Patient skills**

- Information for patients
- Counselling
- Consent

### **Treatment & Techniques**

- Clinical practice
- Equipment safety
- Laboratory procedures
- Welfare of the child assessment

### **Centre Management**

- Leadership
- Staff competence
- Protocols
- Incident management
- Record keeping

## **Specific areas of concern**

The areas that clinics were worst at meeting are discussed in more detail below.

### **Information for patients**

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 proper consent to their chosen option.

Problems with the standards of information given to patients are not just apparent from clinic inspections. Lack of information is a frequent source of complaints from patients to HFEA. These are further discussed later in the report.

Nearly half (47%) the clinics had problems meeting the standards expected for patient information. Some of the issues were minor, others more serious. Four clinics had failed to comply with a requirement to notify men who had stored sperm of a change in the law regarding consent for posthumous use. Other clinics were failing to record what information had been given to the patient or to keep track of which version of documents was in use.

### **Counselling**

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 is started.

Inspectors found two breaches of the Act, seven of the Code of Practice and nineteen other practice issues concerned with counselling.

The problems with counselling fell into three categories:

- the counsellor's qualifications and isolation
- lack of patient awareness of, and access to, counselling provision
- the quality of service and facilities

## Consent

As with other medical procedures, patients must consent to fertility 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, as the case of Natalie Evans illustrates. In the period under review, there were eight breaches of the law and eleven breaches of the Code of Practice related to consent.

## Equipment safety

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 chemotherapy patients – who could not replace the material in storage.

Most 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 material will be damaged. There have been serious incidents in the past where equipment failure has led to serious loss of stored material.

Eighteen clinics had failed to comply with this requirement, or were unlikely to do so, by the deadline of 30 June 2005. The financial implications of the requirement were a worry for some clinics, but good notice had been given of its introduction and the costs had been evaluated against the benefits for patients of safeguarding often irreplaceable embryos.

Another area of concern for inspectors was the failure of two clinics to fit an atmospheric oxygen alarm in the room where dewars were stored, and of another to have a faulty oxygen monitor. Falling oxygen levels are linked to rising nitrogen levels and pose extremely serious risks to staff safety in the event of such incidents.

## **Protocols**

Clinics must have protocols or standard operating procedures (SOPs) to ensure that agreed methods for carrying out each activity are followed by all staff which, in turn, should ensure the safety and quality of techniques and consistency of practice.

At nearly half the clinics (49%), inspectors found inadequate or non-existent protocols for clinical, laboratory or management processes. However, this does not necessarily mean that staff were not following appropriate procedures, even without up-to-date documentation.

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 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.

## **Laboratory procedures & witnessing**

It is 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.

Most of the issues picked up on inspection in this area concerned weaknesses in witnessing. Whilst 76% of clinics met the standard, some had a problem with staff resources, particularly at weekends, when only one person was on duty and an independent witness of procedures was not available.

## **Record keeping**

Good record keeping is fundamental to ensuring clinical governance, patient safety and high quality provision of care. It is essential to record accurately the identity of stored gametes and embryos and the length of time for which storage is lawfully permitted. It is a major concern for patients if embryos or gametes cannot be found or are allowed to perish prematurely.

Poor record keeping or failure to audit stored material was an issue for 28% of clinics.

## **Welfare of the child**

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).

Despite this being a contentious issue for some clinics, 82% of them met the standards. The HFEA has since revised its guidance after widespread consultation to focus on the likelihood of serious harm to any child born from fertility treatment. There should be little or no reason for non-compliance in future.

## **Leadership and management**

Good leadership and management are essential to the smooth and effective running of any organisation. Persons Responsible for managing fertility clinics (PRs) have specific obligations under the legislation in addition to their professional and managerial duties. A few PRs were found not to have given sufficient attention to these and were failing to ensure suitable practice. Some clinics failed to maintain and display an up to date licence.

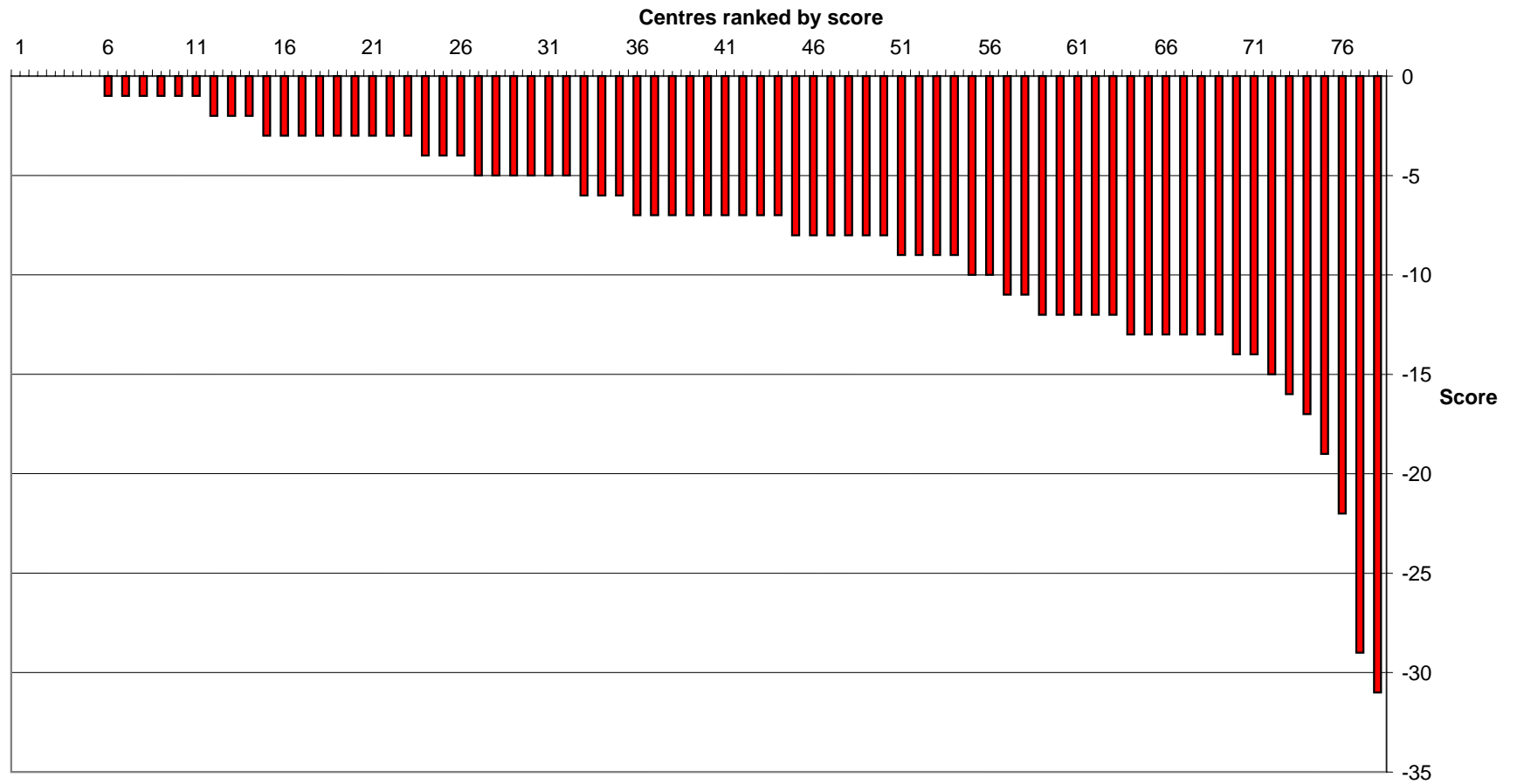
## **Clinical practice**

The single biggest risk of IVF – for both mother and child – is through multiple births. The main concern in this area was the failure of some clinicians to record when they had transferred three embryos into a patient.

Clinics are required to record information on the number of embryos transferred in order to be able to check that the practice of three embryo transfer was only carried out in defined, limited circumstances.

Figure 1

### Compliance score for UK fertility clinics



## **Clinics with multiple issues**

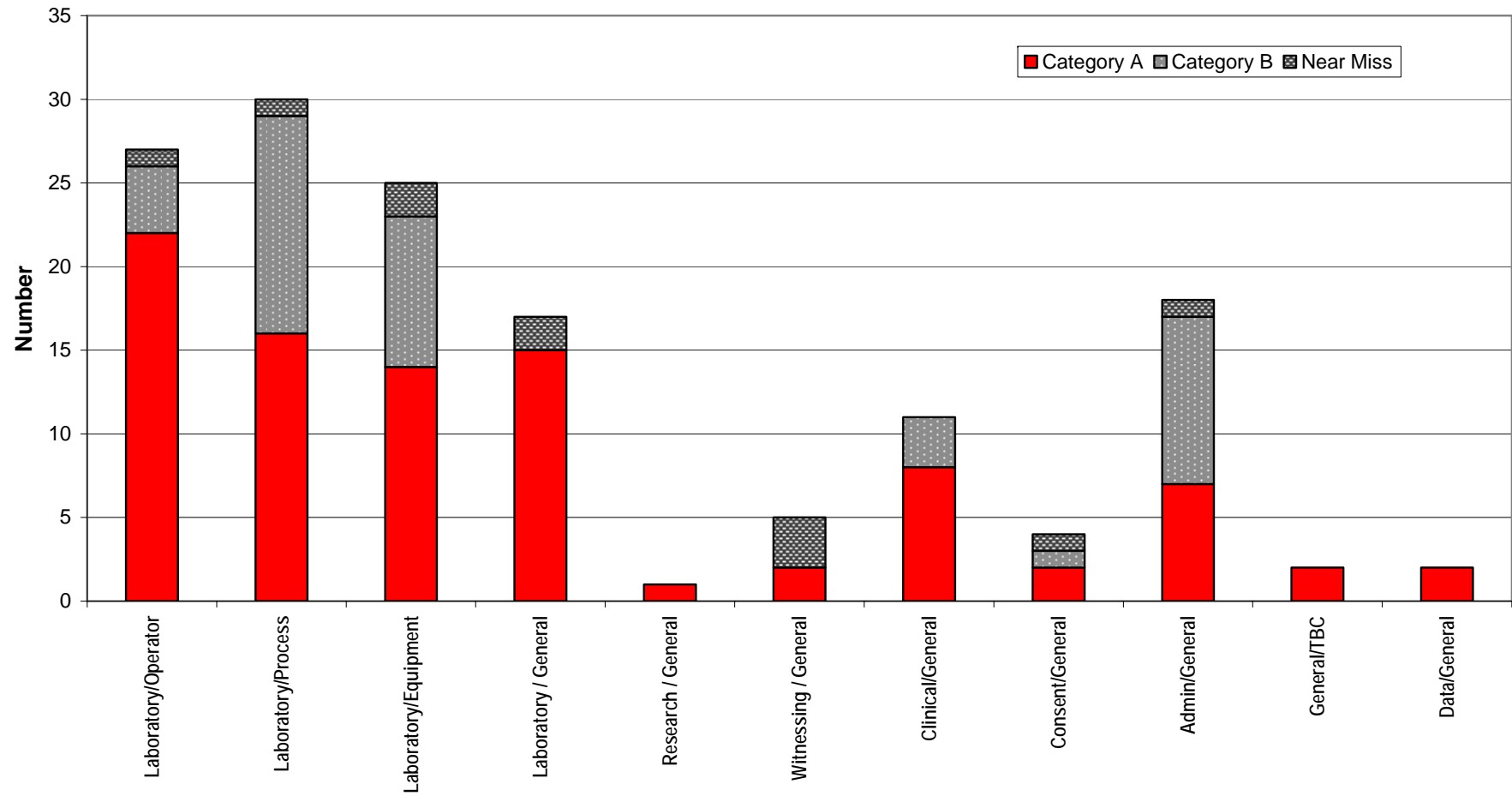
Nearly a quarter of the poor performance identified by inspectors took place in just six clinics (see *Figure 1*). Together these clinics accounted for 23% of the total compliance score for all the 78 clinics reviewed. These clinics had compliance scores of -15 or lower, with two of these clinics having compliance scores of around -30.

These clinics demonstrated the systemic problems caused by poor leadership and control. The key issues identified in these clinics were:

- Leadership and management – e.g. where the Person Responsible at a centre does not devote sufficient time to the management of the centre to ensure effective scrutiny
- Protocols
- Laboratory process and practice
- Staff competence, qualifications, training and continuous professional development (CPD)

Figure 2

Number of Incidents 2005-06 categorised by type



# ADVERSE INCIDENTS AND ALERTS

## Introduction

Clinics are expected to record any adverse incidents that occur and to report these to HFEA within 24 hours. The information is used to help individual clinics improve patient care and staff safety and to inform a wider analysis of risk to patients, gametes and embryos and/or staff.

If an incident raises a significant issue or if patterns of incidents point to a particular area of concern then the HFEA will analyse the issue and issue a clinic incident alert. This is anonymised to protect the confidentiality of patients and clinics. This alert is issued to all clinics so they can all learn the lessons of those incidents and minimise the risk of mistakes being repeated. The HFEA Alert system, introduced in June 2003, is the first system of its kind in the world of assisted reproductive treatment.

Alerts provide information on:

- What led to these occurring
- The associated or root causes identified from investigation
- Actions that should be taken to minimise the risk of reoccurrence

Alerts are classified on a three-point scale

- **A** – major or serious consequences for patient, embryo, gamete or staff safety and service quality
- **B** – minor consequences for patient, embryo, gamete or staff safety or service quality
- **Near miss** – events or activities with the potential for either of the above (A or B)

Inspectors monitor how reliable clinics are at reporting incidents and how well the Person Responsible uses alerts to ensure good practice. Under-reporting of adverse incidents is a problem in some clinics and a barrier to improving the safety of patients, gametes and embryos.

## Incidents and alerts 2005-06

Between April 2005 and March 2006, 140 incidents and near-misses were reported to HFEA. These were categorised according to severity as follows:

Grade	Severity
A	91
B	38
Near Miss	11
Total	140

A breakdown of incidents by type is shown in Figure 2.

Over three-quarters of these adverse incidents occurred in the laboratory. Gametes and embryos are subject to most manipulation in this often busy environment. Inevitably those parts of treatment that occur outside the body have most external intervention and so are more vulnerable to equipment and human error.

Incidents typically include loss of embryos or gametes through dropping dishes or tripping when holding them or accidental disposal. Equipment failure can compromise the viability of embryos.

Nine clinics received additional inspections to investigate incidents. We have collaborated with other regulators where possible and appropriate, including the Medicines and Healthcare Products Regulatory Authority (MHRA) Healthcare Commission and Health and Safety Executive. Such investigations are designed to be supportive but the HFEA will take swift action if urgent improvement by a clinic is required.

During 2005/06, four Alerts were issued, representing the learning from many incidents. They concerned:

- Managing and communicating the risks of ovarian hyper-stimulation syndrome (OHSS)
- Better handling of pipettes to reduce the risk of losing embryos during transfer
- Standards of equipment purchased and used in laboratories
- The assessment and management of risks to the power supply to critical electrical equipment

## PATIENT 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, they can result in complaints to HFEA.

The HFEA's scope for dealing with complaints is relatively limited. We can only investigate complaints if they relate to the terms of the licence or a potential breach of the legislation. We often receive complaints about other matters, for example costs and charges, which we have no powers to pursue. Patients are also disappointed that, as a regulator, we have no remit to act as an advocate in disputes between clinics and patients.

### Complaints 2005-06

The number of complaints HFEA receives is low in relation to the volume of treatments carried out. Overall, the low volume of complaints, the views expressed in patient questionnaires received during inspections and the findings of the patient panel, **Fertility Views** all indicate a high level of satisfaction with services provided by licensed clinics.

Many clinics handle complaints well, but some do not and complaints can be a source of great distress for patients if not properly dealt with.

Between April 05 and March 06, the HFEA received 66 complaints about 35 licensed clinics. This represented an overall increase of 22% on the previous year. Unlike incidents, which mostly occur in the laboratory, it is the consulting room that gives rise to most complaints.

The areas of most concern to patients were:

- Information – including too much or too little information, or its lack of clarity. Information about the cost of treatment
- Attitude - including lack of understanding and respect and lack of empathy from clinicians.
- Consultations – including rushed or poor patient consultation or insufficient discussion about treatment options.

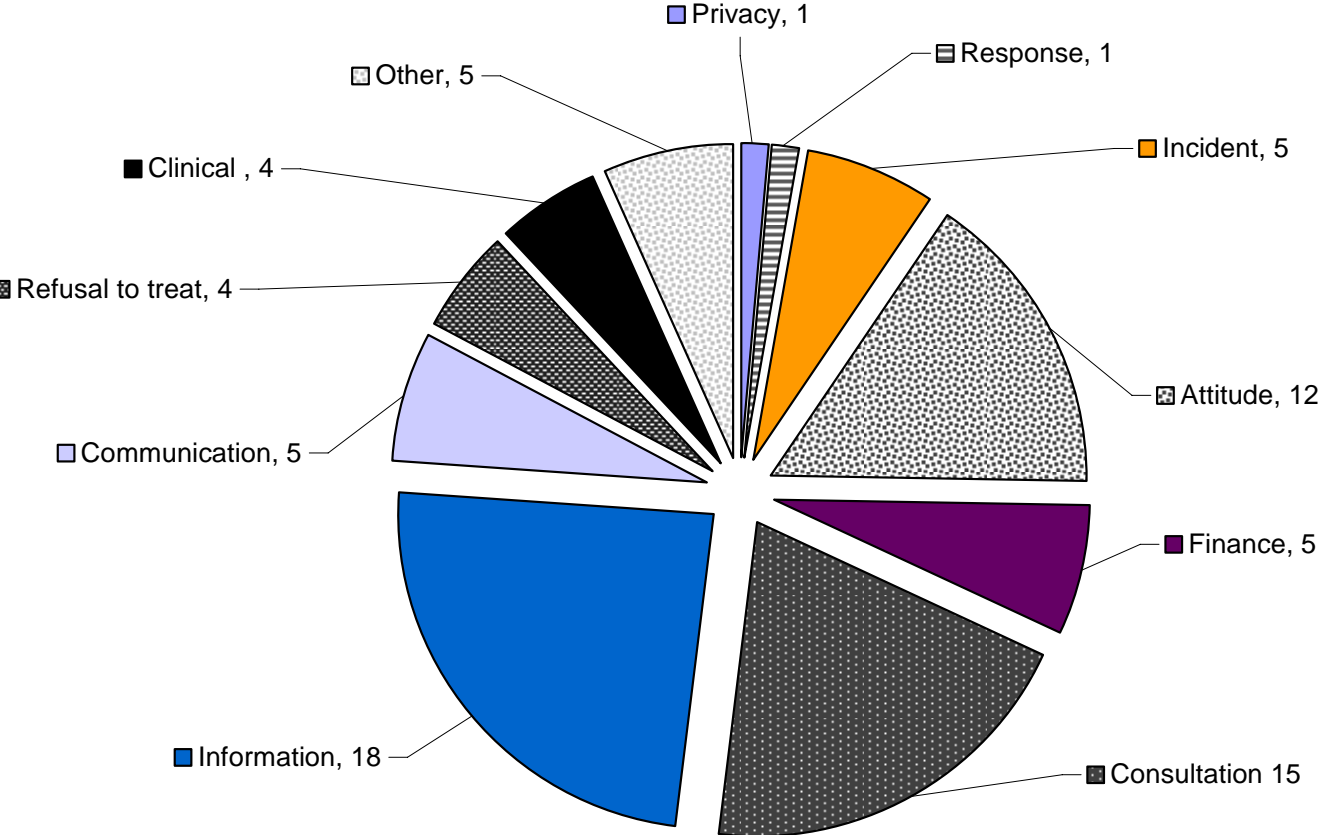
Other issues of concern included

- Poor clinical practice
- Finance - including disputes about the type of treatment patients thought they were buying and its associated costs, or the inability to obtain NHS funding
- Refusal to treat - the past year has seen an increase in complaints about refusal to treat (for example, same sex couples).

The full breakdown showing the number of complaints for each category is shown in Figure 3.

Figure 3

Complaints by category (Apr 05 - Mar 06)



## Lessons for clinics

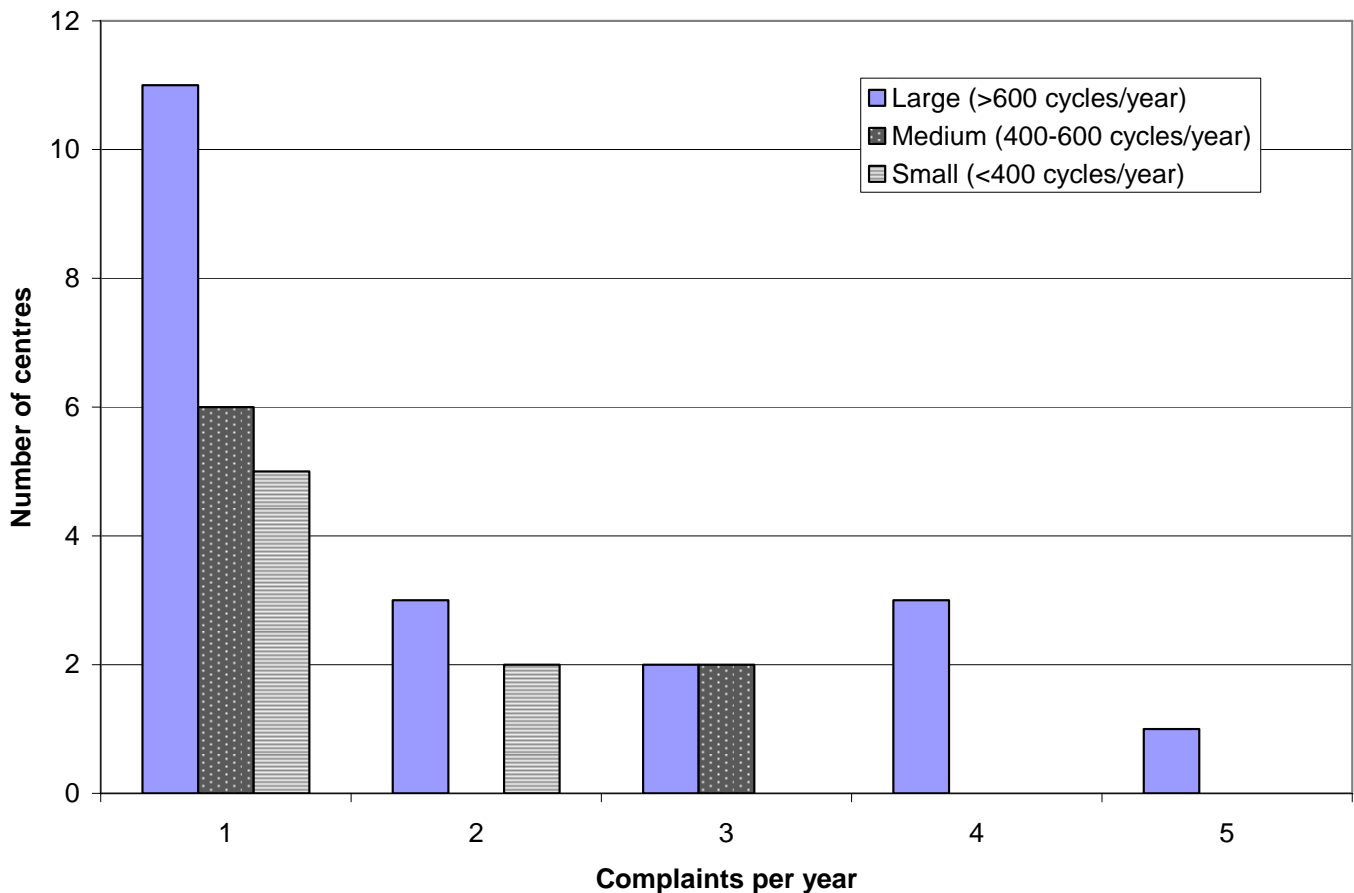
The most frequent type of complaint received concerned information provided by clinics. Communicating information that is painful to hear requires great skill. Often it was the way in which information was conveyed that exacerbated distress.

The overriding message that comes out of receiving letters of complaint is that empathy and time are needed at all stages of treatment, particularly when it is not successful. For many clinics, this is a fundamental part of their approach to providing quality care. For others, it can sometimes seem an optional extra, rather than a core value of the team.

Clarity over the cost of treatment – though not a matter within the HFEA's powers – is a major area of concern in patient complaints. Clinics need to be much more forthcoming and explicit about the expected cost of the treatment the patient is planning.

Figure 4

### Number of complaints by centre size



## **PATIENT FEEDBACK: FERTILITY VIEWS**

Another valuable source of information is through Fertility Views – the HFEA’s online patient consultation panel. Fertility Views comprises more than 700 people who have had, or are considering fertility treatment. The Fertility Views panel provide their views on a range of aspects relating to fertility treatment through a series of questionnaires.

In the last year, areas considered by Fertility Views panel include:

- How many embryos to transfer in treatment
- Availability of donor eggs and sperm for treatment
- Satisfaction with clinics
- Treatment costs
- Access to the HFEA Guide to Infertility
- Donating eggs, sperm and embryos for research

Patients also raised a number of issues of their own. Their key concerns centred on:

- cost of treatment
- access to NHS funding
- length of waiting times

Full details of the issues considered in the last year can be found in the Fertility Views newsletters on the ‘For Patients’ section of the HFEA website.

## **DELIVERING IMPROVEMENT IN PRACTICE**

The HFEA has a range of powers to encourage clinics to improve their practice which are delivered 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 will ring HFEA inspectors for advice or guidance in particular situations and prompt notice is usual taken of inspectors recommendations both during an inspection and on an ongoing basis.

For more serious matters, Inspectors make recommendations in their reports to 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, or, more unusually, the operation of the current licence following an interim inspection.

HFEA licence committees have the power to impose conditions on a clinic licence to make them improve. Ultimately a licence committee has the sanction of demanding a new person takes responsibility for clinic management or even taking away a clinic's licence if it is felt this is the only option to secure standards of patient care

In 2005-06, as in previous years, by far the majority of clinics respond positively to any concerns raised by inspectors and licence committees. Often they take swift action to remedy deficiencies: typically Inspectors found that 20-30% of the issues raised on inspection had been dealt with by the time reports had been presented to committee.

### **Enforcement action taken and compliance**

In previous years, licence committees had imposed 32 additional conditions on clinics. Twenty-six of these had been met by the time of these inspections. Of the six conditions not met, two related to one centre.

Between April 2005 and March 2006, licence committees imposed a new condition on each of the six clinics with the lowest compliance scores. The additional conditions concerned:

- Consent
- Laboratory processes and practice
- Clinical practice
- Suitable premises
- Management

Ten clinics had the renewal of their licence restricted, with licence periods from as little as six months to two years. Three of these clinics had previously had their licence suspended and one was subject of other regulatory activity. The licence committee proposed to revoke the licence of another clinic where it had not reached the stage of renewal.

Clinics where licence restrictions have been made receive additional inspections, as well as advice and information from inspectors, to follow-up their findings and ensure that improvements are made. HFEA staff also contribute to training events arranged by professional bodies and the Authority holds conferences each year to help inform ongoing professional development in the sector.

### **Improving clinic management**

Poor management was identified as a root cause of systemic problems in those clinics which caused the greatest concern. This shows the importance of the statutory position of 'Person Responsible' (PR) in ensuring a strong and effective management culture throughout a clinic.

In 2006 the HFEA has taken a number of measures to strengthen and support the role of PRs in UK clinics.

Firstly, we have developed a learning and professional development programme for those people coming forward to become PRs. This interactive programme is designed to enable prospective PRs to understand fully the extent of their legal duties and to improve their management skills by introducing quality management systems into their clinic.

Completion of this programme is followed by a more rigorous procedure for assessing the suitability of candidates applying to be PRs and the approval of their licence.

## **APPENDICES**

### **APPENDIX A**

#### **How we license and inspect clinics**

The law 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 for the IVF clinic (PR) 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 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.

## APPENDIX B

### Report methodology

Approximately 100 inspection reports and their associated Licence Committee minutes were read. Of these 33 were excluded for reasons including the following:

- Some centres had reports that were considered by Licence Committee more than once or additional reports on the same centre were written within the year. In both these instances the first report has been included in the analysis, but not later reports or re-considered reports
- Items related to representations
- Reports related to licence variations

Having read the reports every issue was scored with breaches of the Act or failure to comply with a condition scoring “3”, breaches of the Code of Practice or failure to comply with a recommendation “2” and minor issues “1”; thus the higher the weighted score, the more issues or problems that were found. A separate note was made of breaches that had been addressed or partially addressed by the time the report was presented to Licence Committee, although this did not affect the score.

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

In summer 2006 the HFEA’s inspection team had just moved to a new system of categorisation of issues found during inspections. This analysis uses the new categorisation so as to facilitate consistency in comparison for analysis in the future. Whilst every effort has been made to ensure that issues were accurately allocated to the appropriate category, there is the possibility of a small number of errors.

The analysis included 78 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 centres.

Minutes of the Licence Committees were analysed to ensure that the outcome of the inspections can be referred to in this report. How the issues were categorised is shown in the table on page 5.

