

**Independent review of the
circumstances surrounding
four adverse events that
occurred in the Reproductive
Medicine Units at The Leeds
Teaching Hospitals NHS
Trust, West Yorkshire.**

Professor Brian Toft

Executive Summary

Background

1. On 12 July 2002 I was commissioned by Sir Liam Donaldson, the Chief Medical Officer, to investigate the circumstances surrounding four adverse events that had occurred in the Reproductive Medicine Units ('centres') at The Leeds Teaching Hospitals NHS Trust, West Yorkshire. Two expert assessors were also appointed to assist me in the review. This report sets out the conclusions that I have reached and my recommendations as to how such events might be prevented in the future.
2. Assisted conception treatment in the United Kingdom is regulated by the Human Fertilisation and Embryology Act 1990 (HFE Act) and the Human Fertilisation and Embryology Authority (HFEA) was set up under the Act to licence such treatment. Our review of the four adverse incidents therefore included the HFEA's regulation and inspection processes in place at the time of the adverse events as they related to the centres in Leeds.
3. **It is therefore very important to bear in mind that the discussion in this report about both the regulatory regime and the events at Leeds relates to a period prior to July 2002.** The analysis includes some discussion of the HFEA's early development solely to put in context the later progress of the Authority's culture, processes and procedures.
4. The starting point for the Review Panel, the HFEA and the Trust is that patient safety is paramount. As a result, since July 2002 when we started our work, the HFEA and the Trust have started to put in place the necessary processes to support the recommendations made by the Review Panel. We believe that both the HFEA and the Trust have since made significant progress.
5. One issue of considerable importance to the Review Panel is the need to ensure that details are not divulged in this report that might lead to the identification of the patients concerned. This arises both from the general requirement to keep all patient information confidential and the

particularly robust provisions in the HFE Act to do so for patients receiving assisted conception treatment. However, so onerous are the confidentiality provisions in the Act that we have made recommendations about the need for change in appropriate circumstances – see chapter 3. Another factor is that an injunction remains in force in respect of one of the incidents, preventing identification of the families involved.

The HFEA

6. Since its inception in 1990 there has been a rapid expansion in the number of centres inspected and licensed by the HFEA. However, the Authority's budget has, until recently, remained relatively unchanged. The need for continued financial saving has affected the Authority's approach to its statutory duties, including a change in 1999 to what we consider to be a less robust approach to inspections. This involved more focused inspections on centres that were considered a greater risk. While the modified inspection regime had the desired effect on the HFEA's costs it has not been as effective as originally envisaged.
7. A number of additional issues concerning the HFEA are also discussed in this report. We have concluded that the culture of the HFEA has developed in a way that appears to make it difficult for some licence committees to censure centres using the regulatory tools available. We also found that the way in which the confidentiality provisions of the HFE Act have been interpreted over the years has inadvertently led to the development from a 'culture of confidentiality' to a 'culture of secrecy' within the Authority. This has had a prejudicial effect on the ability of the HFEA to execute its duties in an open and effective way.
8. We have identified a number of potential vulnerabilities in the arrangements used to select and train members of the Authority, inspector co-ordinators and external specialist inspectors as well as in the processes in place to assess the performance of inspector co-ordinators and external specialist inspectors.
9. We also found weaknesses in the HFEA's risk management, administrative, and document archiving systems and believe that the practices and procedures used in the licensing and inspection of centres is not as robust as it could be. For example, the guidance to centres provided by the HFEA Code of Practice does not make a clear distinction between legal compliance and advice on good practice.

10. Communications between the HFEA, the public, assisted conception treatment centres and the professional bodies, whose members provide such treatments, also need to be improved.
11. We found that the current arrangements for the Department of Health's oversight of the HFEA did not always detect the potential vulnerabilities to which the HFEA is exposed.
12. However, we do recognise that all these issues are part of the overall development of the HFEA in an evolving area of risk management. The Authority is already addressing the concerns that have been identified and we believe that substantial progress has been made.

The Leeds Reproductive Medicine Units

13. Although the two reproductive medicine centres at Leeds are on separate sites, they both have common management arrangements. The intention is to provide the services offered by these centres on one larger site although at the time of writing this report this had not taken place.
14. We heard evidence that while the facilities provided at the two sites were not optimal, this was expected to be resolved with the merger of the centres. This view was shared by the HFEA which, while recognising that conditions were not ideal, did not judge the facilities to be unsafe. As a result, formal conditions were not imposed on renewal licences requiring improvements to the facilities, even though the person in charge of one of the centres had asked them to do so.
15. Additionally, while both centres contribute substantial income to the Trust's revenue we were concerned to find that neither centre had representation on its management board.

Adverse events

16. The Review Panel investigated four adverse events at The Leeds Teaching Hospitals NHS Trust: two involving the incorrect identification of sperm samples; one involving the loss of embryos following a failure to check liquid nitrogen in a cryogenic freezer; and one involving the disposal of embryos following an administrative failure. We concluded that these adverse events were caused through a mixture of inadvertent human error and systems failure.

17. In the first incident involving the incorrect identification of sperm samples, mixed race twins were born to a Caucasian couple. In this case we concluded that it was impossible to say with certainty at what point in the process the misidentification of sperm had occurred. However, a number of weaknesses were found in the practices and protocols used in the embryology laboratory and these are set out in detail in the report, together with recommendations to avoid similar incidents in the future.
18. In the second incident involving the incorrect identification of sperm samples, the error was identified and the embryos were not used. In this case the embryologist concerned was at a loss to explain how the error might have occurred. However, we were told that, due to a combination of circumstances, there was a shortage of staff at the time and as a consequence the embryologist concerned had a very heavy workload.
19. In addition, an informal double checking procedure that had been brought into use had been temporarily suspended on this occasion due to the pressure of work. The error was identified however when a member of staff became available and a double check was carried out. Again, detailed observations and recommendations have been made to try to prevent further similar incidents.
20. In the adverse event that led to a patient's eggs being compromised following the failure of the cryopreservation process, the embryologist stated that she had simply forgotten to check the level of the liquid nitrogen before starting the freezing process. In this case a number of potential vulnerabilities were identified in the centre's induction training process and these are the subject of a number of recommendations.
21. The adverse event that led to the embryos of a couple being discarded without their consent occurred because the letter they sent to the centre authorising the continued cryostorage of their embryos had not been filed with their medical notes. We found that this was the result of a combination of scattered document storage facilities, an uncoordinated archiving system for medical records plus staff shortages and pressure of work at the centre and recommendations have been made accordingly.

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Introduction

1. The Leeds Teaching Hospitals NHS Trust (the Trust) in West Yorkshire operates two separate assisted conception services centres (the centres) under licences granted by the Human Fertilisation and Embryology Authority (HFEA). One centre is located in the General Infirmary at Leeds (LGI) and the other at St. James's University Hospital (SJH).
2. Following successful assisted conception treatment (ACT) at LGI, twins were born to a Caucasian couple Mr and Mrs A. Shortly after the birth, the parents became concerned that the children possessed physical features that did not match their own genetic background. Subsequent genetic testing revealed that while Mrs A was the children's biological mother Mr A was not their biological father.
3. During preliminary investigations into the circumstances surrounding the assisted conception treatment received by Mr and Mrs A, the Department of Health (DH) learned that there had been three other occasions when inadvertent adverse events had occurred at LGI. One incident involved the wrong sperm being injected into the eggs of a second woman patient at LGI. Another event took place at SJH when six surplus frozen embryos, which were being stored for a couple were accidentally discarded without the couple's permission. Finally, there was a failure of the cryopreservation freezing system at LGI that had compromised the survival of seven embryos belonging to another couple.
4. As all centres in the United Kingdom are licensed and inspected by the HFEA, questions were raised about the regulatory inspection regime's apparent failure to detect the lack of suitable protocols and procedures that might have prevented these adverse incidents from occurring.

Terms of reference

5. As a result of the events noted above I was commissioned by Sir Liam Donaldson, Chief Medical Officer for England, to hold an Independent Review with a remit to:

‘Case A - Investigate the circumstances leading up to the fertilisation and implantation of embryos fertilised during the intracytoplasmic sperm injection procedure using sperm belonging to someone other than the husband.’

‘Case B - Investigate the circumstances leading to the wrong sperm being used to inseminate 11 eggs.’

‘Case C - Identify the circumstances which led to the destruction of six embryos contrary to the patients’ wishes.’

‘Case D - Identify the circumstances that led to the failure of the cryopreservation freezing process thus compromising seven embryos undergoing that procedure.’

‘Advise on the areas of vulnerability identified in the ACT procedures on the removal, storage, use and destruction of sperm, eggs and embryos and to make recommendations as to the way these might be eliminated or reduced to As Low As Reasonably Practicable (ALARP).’

‘Investigate the HFEA’s process of regulation and inspection in relation to the centres and to advise on any vulnerabilities and how they could be reduced.’

‘Report to the CMO as soon as possible.’

Acknowledgements

6. Subsequently, two Assessors, clinical experts who are highly regarded in their respective fields, were appointed to assist this Independent Review. These were:

Dr Ceinwen Gearon, Director of Embryology, The Lister Hospital, London.

Mr Kevin Artley, Consultant Obstetrician and Gynaecologist and Medical Director, Burton Centre for Reproductive Medicine, Queen’s Hospital, Burton on Trent.

7. I would like to express my most sincere thanks to Dr Gearon and Mr Artley for the assistance and support provided during this Review. However, the conclusions expressed in this report are my own and therefore any errors are solely my responsibility.
8. Prior to commencing the formal hearing, each member of the Review Panel visited the centres at LGI and SJH in order to gain first hand knowledge of the physical characteristics of the premises and to be taken through the different sequences of actions that were believed to have taken place. I would like to thank all those concerned for their assistance during the visits made by members of the Review Panel for they were very useful and helped to increase our understanding of the evidence that was presented.
9. I should also like to thank all the staff at the Trust who gave evidence to the Review Panel for the forthright answers they gave in response to the questions put to them. From our first contact with the Trust the staff have at all times been open and cooperated fully with the Review Panel. Additionally, as issues have come to the attention of the Review Panel, possible recommendations have been discussed so that they could be addressed by the two centres as early as possible.
10. On the other hand, the HFEA, in the first instance, did not provide the level of cooperation to be expected in a Review of this nature and that led to delays in the work of the Review Panel. However, following a change in the administration of the HFEA a more constructive working relationship was established. As with the two centres, where issues have been identified during the course of the Review, possible recommendations have been discussed so that they could be addressed by the HFEA at the earliest possible moment.
11. I would also like to thank the following for their assistance:
12. Veronica English, British Medical Association; Philip Gifford, Heath and Safety Executive; Flora Goldhill, Department of Health and former Chief Executive of the HFEA; Dr Michael Murphy, National Blood Service; Geraldine Scruton and Martin Absolom, Dental Practice Board; Daniel Greaves, Better Regulation Task Force; Professor Bridget Hutter and Henry Rothstein, London School of Economics; Mr Ken Smart, Civil Aviation Authority Accident Investigation Branch; Professor Robert W. Shaw, Derby City General Hospital; Dr Robert Turner, HM Treasury; Ian Weston, Civil Aviation Authority; Chrys Hadjiantonis, Civil Aviation Authority; Catherine Savage, Health Professions Council; Dr Graham Groom, Association of Clinical Scientist, Dr Karen Turner,

Association of Clinical Embryologists; Angela Barron, The Chartered Institute of Personnel and Development; and Barbara Hassan, Samantha Savage and Michael Evans, Department of Health.

Context

13. It is important to recognise that our investigation and the findings of this report relate solely to the situation that existed prior to the commencement of this review in July 2002. The HFEA has during the course of the review already started to put in place processes which support the recommendations made by the Review Panel as set out in Chapter 8.
14. An organisation's culture, processes and procedures take time to develop. Thus, an overview of some of the HFEA's early development has been included within this report solely in order to set the scene for what followed.

Witnesses

15. Of the witnesses invited to give evidence to the Review Panel only two replied that they were '*not minded to attend*'¹ in person. These were Dame Ruth Deech (Chairman of the HFEA 1994-2002) and Ms Suzanne McCarthy (Chief Executive of the HFEA 1996-2000). They both referred the panel to the written information available from the HFEA and offered to consider whether they could give a written reply to any questions that the panel thought only they could answer. However the panel concluded that under the circumstances such an approach was not feasible.

Sources of information

16. This report draws upon a number of sources of information, written and oral statements of the witnesses who appeared before the Review Panel, confidential clinical papers, confidential expert reports, confidential internal letters, HFEA licence committee minutes, HFEA summary inspection reports and other documents that are publicly available. The sources are referenced at the end of each chapter.

References

1. *Dame Ruth Deech and Ms Suzanne McCarthy, personal communication.*

Human Fertilisation and Embryology Act 1990

- 1.1 It would be difficult to discuss our findings or recommendations without first setting out some of the background to the relevant legislation. This chapter provides a brief commentary on the Human Fertilisation and Embryology Act 1990 and the Authority set up under the Act to monitor and regulate assisted conception treatment and research in the UK. It also discusses the development of some of the treatments available in UK centres.
- 1.2 Following a period of extensive public consultation in November 1990, Parliament passed the Human Fertilisation and Embryology Act (HFE Act)¹ and in doing so put in place a legislative framework designed to regulate the activities of all organisations in the United Kingdom that wished to undertake *in vitro* (in glass) fertilisation techniques (IVF) or other treatments involving the use of donor sperm, including research. The legislation also provided for the creation of the world's first statutory body of its kind, the Human Fertilisation and Embryology Authority (referred to as the HFEA). Thus for the first time an area in the field of medicine would be controlled by an independent statutory authority as opposed to self or voluntary regulation.
- 1.3 The duties of the HFEA include advising the Secretary of State for Health on matters appertaining to human fertilisation when requested to do so, the licensing and inspection of all centres in the UK and the maintenance of a Code of Practice² (COP) that provides centres with guidance on how they should carry out their licensed activities.
- 1.4 Under the provisions of section 25 of the HFE Act all centres are expected to follow the standards set out in the COP. These include the professional, legal and ethical standards which provide the basis for the HFEA's monitoring work. If a breach of the Code occurs it will be referred to a Licence Committee (LC) where the circumstances surrounding the breach will be considered. Section 25 effectively requires a licence committee to take into account compliance with the Code when deciding whether or not to vary, revoke or place conditions on a centre's licence.

- 1.5 The development of the HFEA, its policies, operational activities and the specific HFEA inspections that relate to the adverse incidents referred to in our terms of reference will be discussed in later chapters.

Patient Confidentiality

- 1.6 The work of the HFEA and that of centres is subject to the confidentiality provisions contained in section 33 of the HFE Act. In addition, for Case A, an injunction remains in force protecting the identity of the families involved. As a result, where the Review Panel considered that revealing a particular item of information might possibly lead to the identification of the patients concerned then that data has either been left out of this report or anonymised so that those involved cannot be identified.
- 1.7 However, while it is recognised that it is absolutely necessary to ensure that patient confidentiality is maintained at all times the interpretation of the provisions of section 33 of the HFE Act has on occasions impeded the progress and transparency of this review. A number of these difficulties will be discussed in Chapter 3.

Person Responsible

- 1.8 In order to ensure that each centre is appropriately administered, section 17 of the HFE Act makes provision for the nomination of an individual at each centre whose function is to ensure compliance with the conditions of the licence granted by the HFEA. This nominee is known as the Person Responsible (PR).

Nominal Licensee

- 1.9 Typically, the individual nominated as the PR for a centre will also be the person who is the Licensee. However, such an arrangement is not compulsory and the HFE Act makes provision for an individual other than the PR to be nominated as the Licensee. This latter arrangement has a number of advantages and these will be discussed later.

In Vitro Fertilisation

- 1.10 Louise Brown, born in 1978, was the first child born in the world as a result of the use of IVF techniques. Her birth dramatically expanded the options available to couples unable to conceive naturally and as a result a number of centres in the UK started to offer this treatment.
- 1.11 The attractiveness of IVF treatments to patients can be observed by the fact that in 1990 a total of 64 licenced centres treated almost 10,000 patients, resulting in the birth of 1,443 children. However, by 2000 the number of centres had increased to 105. 29,698 patients were treated and this resulted in the birth of 8,489 babies.

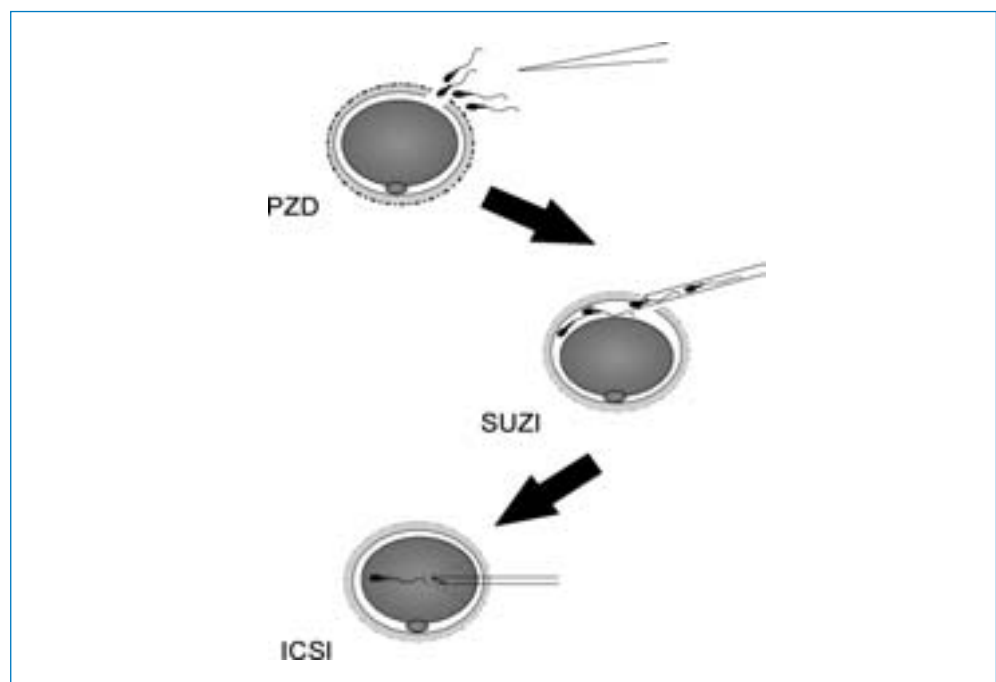
IVF treatments

- 1.12 The staff who provide IVF treatments for patients are doctors, nurses and embryologists. Doctors and nurses are involved in all the procedures where physical contact is made with the patients, such as in the collection of eggs and their replacement following IVF treatment.
- 1.13 Embryologists on the other hand undertake the necessary scientific techniques on the eggs and sperm once they have been obtained. A point to note however is that while the doctor and nurse have to be state registered before they are allowed to practise, embryologists working solely in the private sector do not and this is an issue that will be considered briefly in Chapter 7.
- 1.14 Not only has the number of people undergoing assisted conception treatment increased but also the type of treatments available to them has expanded. The use of routine IVF techniques to treat severe male factor infertility (that is men who have extremely low numbers of spermatozoa or whose spermatozoa do not function normally) was found to be less successful than its use in the treatment of other forms of infertility. As a result, microsurgical fertilisation techniques that utilise a mechanical system of achieving fertilisation were developed in order to improve the chance of success for couples where the male partner suffered severe subfertility.
- 1.15 Essentially three types of micromanipulation procedures have been used in clinical assisted conception programmes (Figure 1). The first procedure to be developed involved the creation of an artificial gap in the zona pellucida (the shell of the egg), either by manually dissecting a hole using needles or by using a chemical agent to burn a hole in the zona. This type of procedure was described as Partial Zona Dissection (PZD)

or Zona Drilling. Once the zona was breached, the eggs were then inseminated as for routine IVF by mixing the eggs with sperm in a dish. The second technique was a more invasive procedure that totally bypassed the zona by depositing spermatozoa directly into the space beneath the zona. This technique was termed Subzonal Insemination (SUZI). The use of SUZI meant that the number of spermatozoa required to achieve fertilisation was dramatically reduced with usually between three and twenty spermatozoa being injected into each egg. The third and final development involved the direct injection of a single spermatozoon into the body of the egg. This technique, intracytoplasmic sperm injection (ICSI), required only a single spermatozoon per egg.

- 1.16 In 1992, Palermo and his colleagues in Brussels reported the first human pregnancies as a result of ICSI. This was rapidly followed by a succession of reports indicating that ICSI was an appropriate and successful technique for the treatment of male factor infertility and that the results that could be obtained were comparable to routine IVF with the use of normal spermatozoa and superior to the results that could be achieved using SUZI. Thus, ICSI has become a routine form of treatment for male factor infertility. It should be noted that in the UK before embryologists are permitted to undertake ICSI procedures they have to be approved by the HFEA. This will be discussed briefly in Chapter 6.

Figure 1: Development of micromanipulation techniques for assisted fertilisation



ICSI procedures

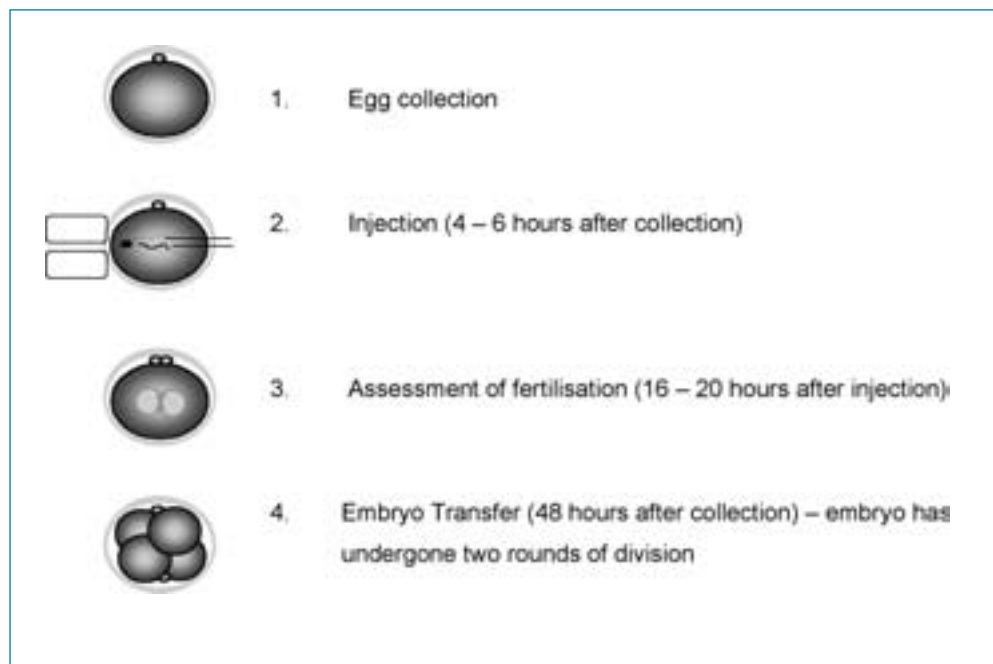
- 1.17 In order to conceive a child using the ICSI method the female partner is administered drugs that will stimulate her ovaries so as to encourage more than one of the fluid-filled cysts that contain eggs, known as follicles, to grow. Once the size and number of follicles are deemed to be satisfactory a simple surgical procedure is used to aspirate their contents. An embryologist then assesses the contents using a Dissecting Microscope (Plate 1) and removes and washes any eggs found. When all the follicles have been aspirated, the eggs are placed in a culture dish. These dishes are labelled in such a way as to clearly identify the patient (Plate 2). One or two hours later, in order to identify eggs suitable for ICSI the two layers of cells surrounding the eggs are removed using an enzymatic digestion technique.
- 1.18 On the day of his female partner's egg retrieval the male partner is taken to a Sperm Production Room where he produces a semen sample *via* masturbation. The sample is produced into a sterile non-toxic container that is sealed with a lid and clearly labelled with the woman's name. The container is then placed and sealed in an envelope that displays details identifying the man and his partner on the outside (Plate 3). The envelope containing the semen sample is then taken to the Sperm Treatment Laboratory so that the sample can be prepared for use in the ICSI procedure. This process will be explained in more detail when discussing the circumstances surrounding Cases A and B.

ICSI laboratory procedure

- 1.19 When a patient's eggs are at the correct stage of development and her partner's sperm has been prepared, the eggs undergo the ICSI procedure, typically four to six hours after they are collected.
- 1.20 The ICSI procedure is carried out on a high-powered microscope using commercially available microtools (Plate 4). At the end of the procedure the injected eggs are returned to an incubator and maintained in an environment of 5% carbon dioxide in air at 37°C (Plate 5).
- 1.21 It is important that the eggs and sperm and the resulting embryos are kept at 37°C in an appropriate culture environment at every point in the procedure. Thus, much of the equipment used in the IVF laboratory is warmed to ensure that there is little variation in temperature. Furthermore, in order to identify material from different couples, every container in which the eggs, sperm or resulting embryos are stored

should be clearly labelled with identifying information related to a particular couple. All centres that provide the ICSI service have to provide information on itself and the proposed ICSI practitioner to the HFEA. The practitioner as noted earlier also has to be approved by the HFEA. A simple illustration of the creation of a human embryo using the ICSI procedure can be observed in Figure 2 below.

Figure 2: Creation of a human embryo via ICSI



Transfer of embryos

1.22 Providing there are viable embryos as a result of the ICSI procedure then the embryos will be transferred to the patient two days after the ICSI procedure.

Cryopreservation of embryos

1.23 If, after the embryo transfer procedure has been completed, there are any viable embryos of adequate quality left then patients may give their consent for their embryos to be frozen (Plate 6), in the first instance, for up to five years. Once frozen the patient's embryos may, under certain circumstances, be held in a centre's cryopreservation storage unit (Plate 7) for up to a statutory maximum of 5 years or longer providing certain conditions are met.

- 1.24 However, should the cryopreservation process become disrupted or fail for some reason then the viability of the embryos undergoing the procedure may be compromised. This will be discussed in Case D.
- 1.25 It should also be noted that a centre may not store embryos if the patient and her partner have not provided written consent. Nor may embryos be stored for longer than the period for which consent has been given or after the maximum period laid down in the legislation. This is because the HFE Act provides that storage may only be carried out with effective consent (section 12 of and schedule 3 to the HFE Act) and in accordance with the time periods set out in the legislation. Failure to observe these conditions will always constitute a breach of licence conditions.
- 1.26 Furthermore, the COP requires that an annual review be conducted by all centres to ensure that their records are consistent with the actual genetic material in storage. Another purpose of the review is to ascertain the purpose and duration of storage and identify any action that might be required with regard to any of the embryos that are held. Thus, centres should be fully aware of their responsibility with regard to consent forms and expiry dates as will be discussed in Case C.

Discarding of embryos

- 1.27 The HFE Act requires cryopreserved embryos to be discarded when the period for which consent has been given has expired (paragraph 2(2)(a) of schedule 3 to the HFE Act) or when they have been stored for the maximum period permitted by the legislation (section 14(1)(c) of the HFE Act). However, as discussed in respect of Case C, circumstances can unintentionally lead to the destruction of embryos where the necessary consent remains in force and the statutory storage period has not been exceeded.

Background to the adverse incidents

- 1.28 Reason³, Turner and Pidgeon⁴, Toft and Reynolds⁵ and others have comprehensively argued that the precursor conditions required for the creation of an adverse event may lay cloaked in the social and technical fabric of an organisation for many years before an untoward incident occurs. Similarly, an organisation's culture, i.e. the commonly accepted way of behaving within any given organisational settings, does not spring

into existence overnight as an established phenomenon. It takes time for the complex sets of individual and collective perceptions to develop and coalesce into a system of commonly shared values (Johnson).⁶

- 1.29 Therefore the actions that individuals take within an organisation are determined by the understanding that they have of any particular situation. People try to make sense of their organisational settings and then act in the belief that the assumptions that they have made are facts (Weick):⁷ *It is therefore imperative to understand the organisational setting in which the adverse incident[s] took place*⁸.
- 1.30 The different organisational contexts in which the adverse events noted above took place will be described in the following chapters.

Observations

- 1.31 Since the birth of Louise Brown in 1978 the number of techniques available to treat couples who want children but are subject to infertility problems have increased. Similarly, the number of patients wanting to avail themselves of such services have also rapidly increased. To meet this patient-led demand for assisted conception treatment both private practice and the NHS responded by, in the first instance, increasing the skills in the centres that already existed and second by providing additional centres to deliver IVF services. This in turn increased the advisory and regulatory workload of the HFEA.
- 1.32 IVF techniques have brought happiness for numerous couples over the past 20 years or so. However, when an adverse event takes place it can have a devastating effect upon all those involved. It is therefore crucial that society learns from such incidents and so far as it is possible attempts to make sure they do not recur. This report is a first step in that process.

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Voluntary Regulation of Human *in vitro* Fertilisation

Warnock Committee

- 2.1 The ability of clinicians and scientists to assist women to conceive children has raised and continues to raise many difficult questions, including those concerning ethical, religious and practical issues. It was for such reasons that in 1982 the British Government established a *Committee of Inquiry on Human Fertilisation and Embryology* chaired by Dame Mary, later Baroness, Warnock. The focus of the *Warnock Committee* was to determine what policies should be adopted for infertility treatment and embryo research.
- 2.2 The regulation of human activities by the State has a number of functions one of which is to seek to control the behaviour of individuals and groups of people in a particular sphere of endeavour.^{1, 2} Thus when the Warnock Committee published its findings in 1984 it was perhaps not surprising given the level of public concern regarding assisted reproduction that one of its main recommendations was that a Statutory Licensing Authority (SLA) should be established by the Government with the power to control and monitor all work involving human *in vitro* fertilisation. This was a revolutionary concept as the medical profession in England, Scotland and Wales had been a self-regulated body ever since Parliament passed the Medical Act 1858 and established the General Medical Council (GMC).

Voluntary Licensing Authority for Human *in vitro* Fertilisation and Embryology

- 2.3 Recognising the difficulty and time delay that would inevitably be involved in the creation of a statutory body such as that envisaged by the Warnock Committee, the Medical Research Council (MRC) and Royal College of Obstetricians and Gynaecologists (RCOG) founded the *Voluntary Licensing Authority for Human in vitro Fertilisation and Embryology* (VLA) in March 1985 under the Chairmanship of Dame Mary Donaldson. The newly created VLA consisted of people drawn

from both the scientific and medical professions but was balanced by the inclusion of lay people. Thus, for the first time a body other than the GMC would seek to regulate research and the clinical treatment of patients in a field of medicine.

2.4 It should however be borne in mind that the newly created VLA:

‘...was housed within an office at the MRC Headquarters in Park Crescent, which was already overcrowded; when the chairman needed to work at the Authority’s office, it was on a borrowed chair and at the corner of a desk.’³

2.5 The organisational structure of the VLA comprised of Members who carried out the licence inspections and issued licences to centres as appropriate and a secretariat who assisted Members with the administration of the VLA.

2.6 Originally it had been assumed that the VLA would only be in existence for eighteen months to two years and its funding had been agreed on that basis. Therefore, when both the MRC and RCOG had resourcing problems it fell to Parliament in December 1988 to vote the VLA the sum of £45,000 as an additional contribution to its running costs. Thus, while there were problems surrounding the adequate funding of the VLA it nevertheless continued to carry out the task of regulating centres.

2.7 Besides its licensing and inspection roles, the VLA was also concerned to foster good relations and create two-way communication between itself and the centres that it licensed. To that end the VLA held an annual conference for centres where speakers would address topics of interest and attendees could make informal contact with members of the VLA.

VLA Code of Practice

2.8 One of the first tasks of the VLA was to marshal the work that had already been carried out by various expert committees concerned with reproductive medicine and to draw up a COP. The implementation of the Code was one of the conditions required of a centre before a licence to carry out work in the field of reproductive medicine would be granted.

VLA licence application procedure

2.9 All potential centres had to make a written application to the VLA that described the particulars of the treatment services or research that they wished to undertake or were already providing. If a centre was already engaged in providing assisted conception treatment or undertaking research, then the details of all such treatments or research activities, the associated patient documentation and all the protocols used in the provision of those services had to be submitted for evaluation by the VLA. The *curricula vitae* of all senior members of staff also had to be forwarded to the VLA for scrutiny.

VLA inspection visits

2.10 Once the necessary documentation had been received and processed, the VLA would then arrange a visit to the proposed candidate organisation. If the candidate centre was applying to be licensed for the first time, then typically the VLA inspection visit would take place three to six months after the application for a licence. This delay was to give the candidate organisation time to ensure that all its protocols, procedures and operational practices were in place and working. The inspection team would comprise of not less than three Members of the VLA and include a clinician, scientist and one or more lay members. Typically, the clinician would chair the meeting and a member of the VLA secretariat would be present to take notes.

2.11 Each VLA inspection visit followed the same pattern. The visit would commence with a private meeting of the VLA inspection team members during which they would discuss the documentation provided by the centre concerned and identify any issues that required a thorough examination. It should be noted that VLA inspection teams at this time were '*...provided with a check list of routine issues which they needed to cover.*'⁴

2.12 Following the preliminary meeting in private, the inspection team then held discussions with the clinical director and senior staff of the centre. After this the inspection team would make a tour of the clinical and laboratory facilities before having a final meeting in private to discuss their findings and recommendations. Prior to leaving the centre the VLA inspection team would inform the clinical director of their conclusions.

VLA licence committee meetings

2.13 The VLA licence committee (LC) sat on a regular basis, usually meeting once every two months. At these meetings the various inspection teams' findings would be discussed, decisions made whether or not to approve the granting of licences to the candidate organisations and other matters raised of relevance to the VLA.

Interim Licensing Authority for Human *in vitro* Fertilisation and Embryology

2.14 In April 1989 after the Government had committed itself to introduce legislation that would bring into existence a statutory body, such as that recommended by the Warnock Committee, the VLA decided to emphasise the temporary nature of its existence by changing the name of the organisation to that of the *Interim Licensing Authority for Human in vitro Fertilisation and Embryology* (ILA). The ILA however was to remain in existence for a further two years until on 31 July 1991 it finally relinquished its responsibilities for regulating centres to the HFEA.

2.15 However, it should be noted that the Lord Chancellor when introducing the HFE Bill to the House of Lords in December 1989 stated:

*'Although the new authority will in no sense be a direct descendant of the ILA, and will in its membership and functions be a different organisation in that it will have broader power and function, I am sure it will find it useful to draw on that body's experience when it assumes its full powers...'*⁵

2.16 Indeed, the ILA operated in parallel with the nascent HFEA for approximately nine months prior to the change from voluntary to statutory regulation so that relevant skills and experiences could be transferred to the new body. However, while the majority of the members appointed to the HFEA by the Secretary of State in 1991 were new, six of those members had previously been members of the ILA. In addition two members of the ILA secretariat were also transferred in to the new SLA. Therefore, as envisaged by the Lord Chancellor, the new HFEA was able to call upon their skills and experience to help them clarify ILA policy and strategy issues and hence, in as far as it was possible, smooth the transition from a voluntary to a statutory regulatory framework.

Self-regulation

2.17 Historically the state has sanctioned the self-regulation of professions, such as medicine or the law, where a period of prolonged training is required by a practitioner in order to obtain the high degree of specialised knowledge and skills necessary to undertake such work. Usually the application of such training will also require expert judgement to be exercised when it is used in practice. Hence because of the specialised nature of the knowledge to be applied and the degree of expertise required by a practitioner to use it in differing contexts it is argued:

‘...that self-regulation is the only appropriate form of control because only the experts themselves can regulate its practice... Only those within the professional group understand the unique nature of the problems and decision making in their own area of work, and only they can apply effective remedies.’⁶

2.18 However, where it is suspected that a clinician’s performance may not be meeting the required standard, in order for effective remedies to be put in place the problems that are being experienced have to be publicly articulated by his or her peers. There are difficulties with attempting to engage in such behaviour as Rosenthal points out:

‘Until 1985, the official position on collegial criticisms was straightforward. ‘The [GMC] also regards as capable of amounting to serious professional misconduct... [the] deprecation by a doctor of the professional skill, knowledge, qualifications or services of another doctor or doctors.’⁷

2.19 Therefore, criticising a fellow doctor was actively discouraged by the medical profession’s self-regulatory body, although in recent years the (GMC) guidelines regarding a doctor criticising another has changed to allow ‘honest comment’ upon a colleague’s capabilities.⁸ Nevertheless, while there has been a change in the position of the GMC regarding doctors criticising each other, such an edict may well have had little effect on the behaviour of many doctors, including some of those still practising. For example Allsop and Mulcahy argue, ‘The culture of colleague [doctors] relationships has tended to be protective and fraternal rather than to safeguard the quality of care of patients.’⁹

2.20 Likewise, Walshe observes:

All the evidence suggests that most clinicians are reluctant to report matters to the GMC or UKCC (United Kingdom Central Council for Nursing, Midwifery, and Health Visiting) and as a result these regulatory bodies see only a fraction of the true volume of clinical performance or behaviour problems.’¹⁰

2.21 The evidence thus suggests that in general clinicians can be disinclined to criticise their peers publicly and this will be discussed later in the context of the HFEA.

Observations

2.22 As the purpose of the VLA was unique, there was no organisational or regulatory model to be copied. Consequently the VLA was shaped by the experience of those first distinguished pioneers who for the most part came from medical and scientific backgrounds and possessed little or no experience in the design and development of regulatory bodies.

2.23 Moreover, because the VLA had no powers of enforcement, in general the VLA had to persuade centres to submit to its jurisdiction. Since it had a limited ability to apply sanctions to centres that did not comply with its guidelines, it relied to some extent upon the centres co-operating. Consequently there would have been little or no urgency for those who carried out the licensing and inspections of centres to become skilled in regulatory issues or the law, and, in the event, training in such matters does not appear to have been carried out.

2.24 Furthermore, the funding received by the VLA from its inception does not seem to have been the optimum for the range of activities that they were attempting to realize. As a result, it could be argued that all those associated with the VLA/ILA developed the expectation that in carrying out its functions they would have to manage its affairs with limited resources.

2.25 As noted earlier, it had been the intention of the Government that the newly created SLA should not be a *‘direct descendent of the ILA’*. However, Hood *et al.* in their research on regulatory regimes note that many institutionalists maintain:

‘...that policy and administrative routines tend to be heavily influenced by their historical point of origin, with inertia leading to persistence of original form...’¹¹

- 2.26 Indeed, in the search to facilitate the transition from a voluntary to a statutory organisation numerous administrative procedures and several of the people who had been members of the VLA/ILA were transferred to the new HFEA. Gunning and English observed that the new HFEA's '*...inspection process, arrangements, papers and format are essentially the same as the ILA system...*'¹²
- 2.27 Thus, in summary, the evidence suggests that while the new HFEA had been given a greater range of functions and powers, an essentially similar operational approach and culture to that of the VLA/ILA was introduced to the new Authority. There is also evidence to suggest that clinicians may be disinclined to criticise their colleagues publicly. The effect created by these two aspects will be discussed in Chapter 7.

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Statutory Licensing Authority

The Human Fertilisation and Embryology Authority's role

3.1 The HFEA was established by Parliament as an independent body at arm's length from Government to consider issues relating to reproductive medicine and regulate related treatment and research. Essentially, the HFEA has two broad and potentially conflicting functions: one regulatory, and one advisory. Its primary regulatory responsibilities include the regulation, licensing and monitoring of centres, both NHS and private, that undertake reproductive medicine treatments and/or research plus the maintenance of a COP. The HFEA's advisory function is to consider sensitive ethical issues regarding human-assisted conception and to advise the Secretary of State on such matters when requested.

HFEA structure

3.2 The corporate body of the HFEA consists of the Authority supported by the Executive. The Authority is directly accountable to the Secretary of State for ensuring that the provisions of the HFE Act are complied with.

3.3 The Authority consists of a chairman and deputy chairman who along with a number of other individuals are appointed by the Secretary of State for Health on a part-time basis. They meet as required. This group of people includes laypersons, clinicians and individuals regarded as being experts in the provision of assisted conception services, the law and ethics. Schedule 1 to the HFE Act however expressly forbids the Secretary of State from appointing as chairman or deputy chairman individuals who have professional interests in the work that the HFEA regulates. Put in simple terms, both the chairman and deputy chairman must be lay Members of the Authority in that they may not be someone who is medically qualified or have been involved in any of the activities governed by schedule 1 to the HFE Act. Schedule 1 also requires that while at least one third of the total membership must have a certain professional interest in the work that the Authority oversees, the majority of the Authority's Members must be lay people.

- 3.4 The HFE Act does not however specify the maximum number of Members that can be appointed to the Authority, but apart from a short period recently, it has not comprised of more than 21 people. In practice this has meant that nine Members of the Authority have had a professional interest in assisted conception and 12 Members, including the chairman and deputy chairman, have been lay. The legislation also directs that the views of the Authority and the discharge of its duties shall be informed by both men and women.
- 3.5 Appointments to the Authority are made in the first instance for three years – the maximum permitted by the HFE Act. Ministers also make reappointments to the Authority but in accordance with guidelines issued by the Commissioner for Public Appointments. The selection and reappointment of Members of the Authority by the Department of Health (DH) will be briefly discussed in Chapter 4.
- 3.6 The Executive comprises of mainly full-time employees who are led by a Chief Executive appointed by the Authority. The role of the Executive is to support the Authority in carrying out its statutory duties by providing administrative and operational support, i.e. implement the policy decisions of the Authority. Prior to the official establishment of the HFEA as a statutory organisation, civil servants on secondment from the DH were employed to create the new Executive body. As noted in Chapter 2 two members of the VLA/ILA secretariat were also appointed to serve in the ranks of the new Executive.
- 3.7 Similar to the way in which a member of the VLA/ILA secretariat went out on each inspection to provide the inspection team with administrative support, so the HFEA Executive provides each inspection team with a person called an inspector co-ordinator. However, unlike the members of the VLA/ILA secretariat who acted purely as administrators at inspections, an inspector co-ordinator has a much wider role to play. The inspector co-ordinator not only provides advice to the centres to which they are allocated on how to comply with the HFE Act but is also part of the inspection team that seeks to confirm that those same centres are complying with the HFE Act. Thus inspector co-ordinators, like the Members of the Authority, play a dual role and this will be discussed later.

Oversight of the HFEA

- 3.8 As noted earlier Parliament passed the HFE Act in November 1990 and, on 1 August 1991, the HFEA began to carry out its statutory duties as an executive Non-Departmental Public Body (NDPB). However, while the HFEA is a corporate body created by an Act of Parliament it is still subject to review under guidance issued by the Cabinet Office and within such arrangements is accountable to the Secretary of State for Health.
- 3.9 The HFEA is required to report annually to the Secretary of State for Health on the performance of its functions. To that end the HFEA's Chairman attends an annual review meeting with the Minister. An Annual Report and financial statement is produced by the Authority, which, after approval by the Secretary of State, is laid before Parliament. In addition, the HFEA's Chief Executive and other members of the executive staff hold annual accountability review meetings with senior civil servants from the DH.
- 3.10 In practice, the Clinical Quality, Ethics and Genetics Division of the DH acts as the HFEA's sponsor. The function of the sponsoring department is to agree the HFEA's business and corporate plans which includes accountability for the HFEA's activities, the arrangements for agreeing strategic plans, financial planning, personnel management and the publishing of its annual report and accounts. In addition, the HFEA invites a representative of the DH to attend its monthly meetings as an observer and the HFEA Executive has informal daily contact with officers at the DH.
- 3.11 The HFEA is also required to operate in accordance with a Management Statement which is a document agreed between the DH as the sponsoring department and the HFEA. The main purposes of the Management Statement are to record the aims of the HFEA, its objectives and relationship with the sponsoring department.
- 3.12 It is also Government policy that all NDPBs such as the HFEA should be subject to a comprehensive review every five years. The purposes of a Quinquennial Review (QQR) includes reconsidering the functions of the HFEA, the extent to which it continues to meet its aims and objectives, including the duties laid down in the HFE Act, evaluate the HFEA's performance in terms of value for money and to report with recommendations. To date two QQRs have been undertaken, the first reporting in July 1996¹ and the second in October 2000.² In addition,

an independent external study was commissioned by the DH to review the HFEA's organisational development in between the two QQRs.³ However, these arrangements appear to have missed some of the HFEA's potential vulnerabilities that are discussed in this report. Similarly, James noted in his report to the HFEA on corporate governance that:

*'... the deficiencies which have come to light in... aspects of the licensing process were not detected, either through the annual or quinquennial review process.'*⁴

3.13 Likewise, Chantrey Vellacott notes:

*'... the problems experienced by the HFEA have not always been transparent to the DH and the Secretary of State for Health.'*⁵

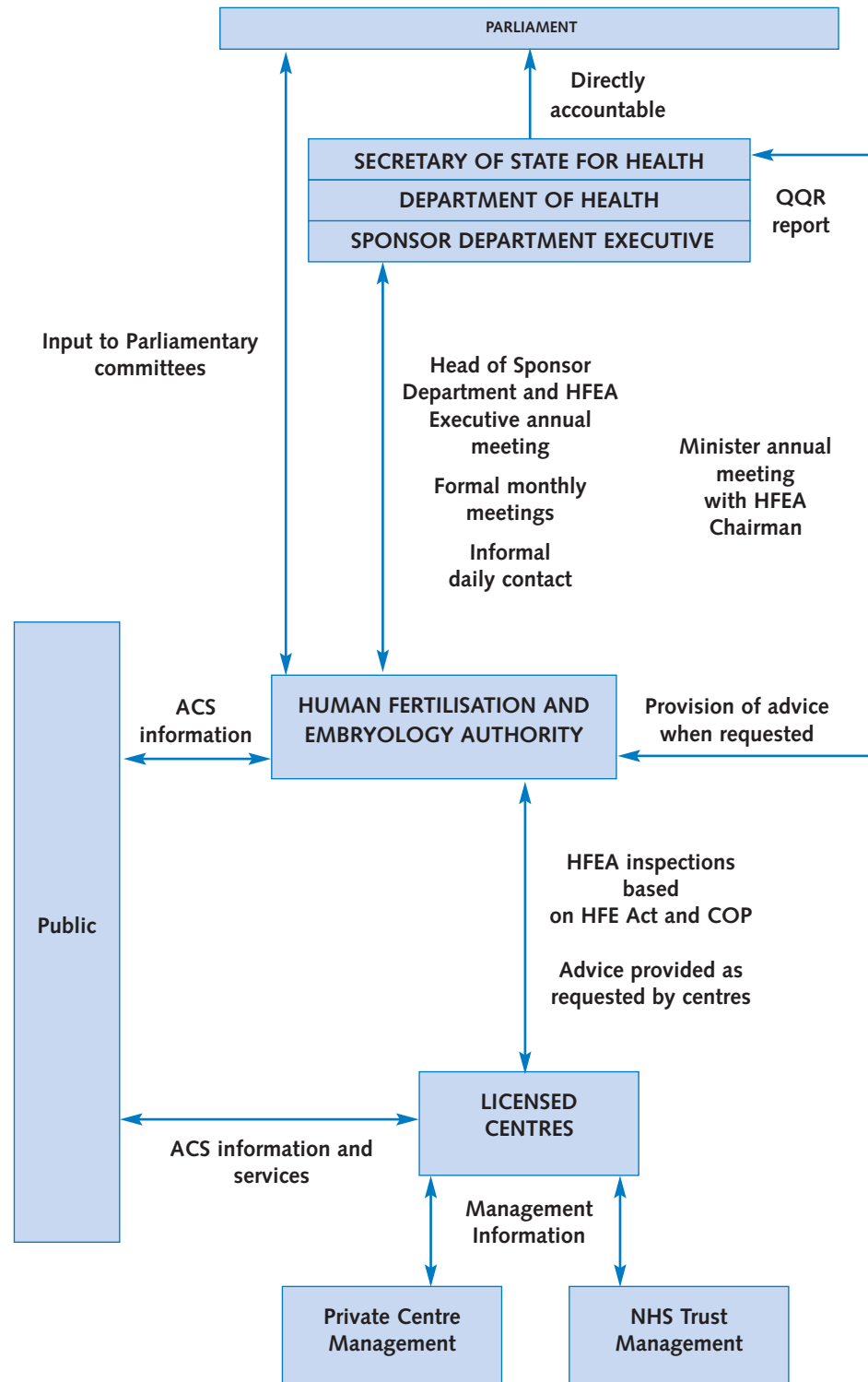
3.14 While neither author articulates the reasons why deficiencies in the inspection and licensing process were not identified by the QQRs, it should be noted that it was senior civil servants from the DH that conducted the two QQRs undertaken to date. And, although the 2000 QQR team did have a specialist in Quality Assurance (QA) systems as part of the inspection team, that particular team member's experience was in providing QA systems to the medical devices industry - not to centres engaged in reproductive medicine. Thus, there was no one involved in either QQR inspection team with any significant current practical experience or academic qualifications in the work carried out in the field of assisted conception services. But in this context it should be noted that QQRs are aimed at establishing in general terms whether the body continues to provide an effective service and one that is still required. Their remit does not usually include the detailed examination of the body's processes and this, perhaps, could be considered to be a gap in the accountability process.

3.15 Furthermore, as will be discussed later, the HFEA does not provide an explicit detailed model against which a centre can be evaluated for compliance with the HFE Act and COP. Rather it is the judgement of those tasked with inspecting centres to determine whether a centre is compliant with the widely written provisions of the legislation and Code. Hence the Review Teams would have had no explicit model against which they could objectively assess the thoroughness of the HFEA compliance process used during their inspection of centres.

HFEA operational and accountability framework

3.16 The HFEA operational and accountability framework is illustrated in Figure 3 below:

Figure 3: HFEA Operational and Accountability Framework Overview



- 3.17 As can be observed in Figure 3 the Authority, through the Secretary of State for Health, is accountable to Parliament which has the overarching responsibility for ensuring that certain activities in the UK concerned with reproductive medicine are subject to the most appropriate controls. Operationally the HFEA provides input to Parliamentary committees when requested. The Authority is also accountable to the Secretary of State for Health (SofS) who, as mentioned above, is directly accountable to Parliament for ensuring that the appropriate arrangements are in place to give effect to the requirements of the HFE Act and subsequent secondary legislation such as the *HFEA (Licence Committee and Appeals) Regulations 1991*.⁶ The operational role of the Authority is to provide advice when the SofS requests it as well as to regulate and monitor assisted conception services in accordance with the HFE Act and its requirements as set out in the COP. Additionally, as noted above, the HFEA is also subject to QQRs, which are arranged by the sponsor department.
- 3.18 The HFEA Executive on the other hand is accountable to both the Authority whom they serve and to a limited extent, such as in the role of accounting officer, to their sponsor department at the DH. The HFEA Executive accountability reviews are conducted through annual meetings with the Head of the sponsoring division in the Department and formal monthly meetings. There is also informal daily contact with officers of the sponsor department. However, despite the level of contact provided by the current accountability processes, weaknesses in the HFEA's operations were not identified until relatively recently (that is, to the date of commencement of this review in July 2002).

Provision of information

- 3.19 Besides its operational advisory and regulatory roles, the HFEA, like the centres themselves, provides information to the public on a range of issues relating to the provision of assisted conception services (ACS) and treatment. The HFEA does not have staff dedicated to the provision of information. Rather, as inspector co-ordinator 3 (IC 3) reported:

*'...anybody within the regulatory team or policy team would be available to give people advice, if needed.'*⁷

- 3.20 This policy assumes that regardless of who responds to a particular question the answer provided would be the same. However, as will be discussed later the members of the Regulatory and Policy Teams within the HFEA were not provided with any formal training in the law and

thus their ability to respond consistently and authoritatively to questions related to the HFE Act may have been compromised. Indeed, a member of the Review Panel noted that there had been several occasions when asking for advice on issues related to the HFE Act or COP where the same question had been put to various people at the HFEA and different answers had been given.

- 3.21 Centres providing assisted conception services are accountable to the HFEA for their compliance with the HFE Act and Code. A centre's level of compliance is determined by a visual inspection of their facilities and the documentation they produce to support their services. However, because the HFEA does not possess the personnel necessary to inspect centres they employ part-time external specialist inspectors (ESIs) to carry out the clinical, scientific and social inspection work for them. But because some of these Inspectors also work at assisted conception centres, as do some of the Authority Members, they in turn are also subject to the HFEA's regulatory regime. This particular aspect of the operational framework will be considered again in Chapter 6.
- 3.22 It should be noted however that the majority of the HFEA's contact is generally with the PR at each licensed centre. The HFEA appears to have little or no contact with the senior management of either NHS Trusts or private hospitals within which centres are located despite the HFEA sending a letter to the PRs of centres in January 2001 encouraging such contact and outlining the advantages (see Chapter 7). Thus, in general the senior management of NHS Trusts or private hospitals only receive information regarding the management and resourcing of centres from the centres themselves and perhaps little if any about issues that may be of concern to the HFEA. This lack of communication, which applied between the HFEA and the Management Board of the Leeds Teaching Hospitals NHS Trust, will be reviewed later.

HFEA Code of Practice

- 3.23 In order to assist centres to comply with the legislation Section 25 (1) of the HFE Act stipulates that:

'The Authority shall maintain a Code of Practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the function of the Person Responsible...'

3.24 Section 25 (3) goes on to state:

'The code may also give guidance about the use of any technique involving the placing of sperm and eggs in a woman.'

3.25 Thus, the content of the COP is the responsibility of the Authority and it has wide-ranging powers over the nature of the guidance that it may contain. A licence committee Member (LCM 1) stated that while it is the Policy Team of the Executive that carries out the actual drafting of the COP:

*'The Code [of Practice] is based on decisions of policy made by the full Authority and then is translated into what would be practicable in guidance to the centres. When it has been drafted we would usually get a legal opinion on the wording as well as to make sure it complies with the Act and that it is an appropriate way to expect compliance from clinics.'*⁸

3.26 However, typically the Codes that have been developed over the years (the fifth edition was published in March 2001) appear for the most part simply to restate the HFE Act. For example, in both the fourth and fifth editions of the COP paragraph 2.1 states: *'The Person Responsible **must** ensure that proper equipment and suitable practices are used'* (emphasis in the original). The terms *'proper equipment'* and *'suitable practices'* are however taken straight from section 17(b) and (d) of the HFE Act but there is no guidance in the Code as to how these particular requirements of the HFE Act might be determined.

3.27 Annex F of the fifth edition of the Code does note that:

'There are a number of professional guidelines from other organisations that are particularly relevant to the provision of licensable activities in licensed centres.'

3.28 However, the Code only provides an indicative list of the professional bodies and the titles of the guidelines that are relevant and it is therefore left to the PR at a centre to decide which guidelines to follow.

3.29 Furthermore the Code, following the HFE Act, has numerous references to subjective evaluation criteria using phrases like *'suitable practices'*, *'proper equipment'* and *'good laboratory practices'*. Thus it is perhaps not surprising that the Person Responsible at the Leeds General Infirmary centre, when discussing the HFEA guidance on the production of good

laboratory practices, remarked that:

*'I do not think that the Code of Practice is detailed enough to be able to help people develop [suitable practices]. If you look at the tissue banking Code of Practice...it states clearly what you need to do, the need for protocols, the need for standard operating procedures and the sorts of people who should be involved in producing those.'*⁹

3.30 LCM 2 when discussing Case A observed that:

*'There is nothing, unfortunately, at this time, and still not, either in ACE [Association of Clinical Embryologists] guidelines, nor in our Code of Practice to suggest there was a correlation between mistakes and the size of the facility. There is no criterion as to what is a suitable size...'*¹⁰

3.31 While LCM 1 stated:

*'...there has never been any set criteria or parameters for what laboratory facilities should be available, so we have never had anything to judge appropriate facilities against. It has always been a matter of the scientific inspector, because it is obviously the inspector whose information we rely on in these cases, making judgements of the facilities that are there, the equipment that is there...'*¹¹

3.32 Other evidence to support the assertion that there are weaknesses in the Code is to be found in the views of the review team who undertook the second QQR where they observed *'...a lack of transparency in the Code of Practice.'*¹² For example, there is no clear distinction within the Code regarding *'...the relationship between legal requirements, guidance on compliance and advice on good practice.'*¹³

Difficulties created by section 33 of the HFE Act

3.33 Of all the problems experienced by the HFEA, centres and patients alike during the first few years one of the more difficult was that caused by the confidentiality provisions in section 33 of the HFE Act. Initially the confidentiality provisions were drawn so tightly that even a patient could not consent to information about their treatment being given to anyone, including health professionals, if they were not directly involved in their treatment, with a breach of this provision being a criminal offence

punishable with up to two years in prison, a fine or both. Clearly such a situation had never been intended when the HFE Act was drawn up and in 1992 the *Human Fertilisation and Embryology (Disclosure of Information) Act* was passed which removed the anomaly¹⁴.

- 3.34 However, even after the passing of the *Disclosure of Information Act* the penalties described above can still be meted out for disclosing, even if unintended, information that breaches the confidentiality provisions of the HFE Act. Thus it is perhaps hardly surprising that Flora Goldhill,¹⁵ the first Chief Executive of HFEA, has remarked that the provisions of section 33 of the HFE Act created within the HFEA organisation a ‘culture of confidentiality’ with respect to safeguarding information about individual patients and children born as the result of assisted conception treatment.
- 3.35 That culture of confidentiality, which arose as a result of the HFE Act, has continued to the time of this review and appears to have grown in its intensity. Indeed, the draconian way in which the provisions of the HFE Act are sometimes interpreted by the individuals to whom they apply have, on occasions, hindered the progress of the Review Panel’s deliberations. For example, the author of this report could not review any document that contained patient identification data, for to have done so, without being a licensed person or an employee of the Authority, would have resulted in a breach of the HFE Act. Thus time had to be spent making sure that documents containing patient identification data had been anonymised before the author could read them. However, it should be noted by the readers of this report that my advisors Dr Gearon and Mr Artley have seen all the relevant confidential medical documentation and this report is based upon our joint deliberations.
- 3.36 Moreover, as noted below, the HFEA witnesses appeared to be anxious when responding to the Review Panel’s questions in case they inadvertently provided information that later might be interpreted as having led to the identification of a patient, thereby laying them open to a criminal prosecution. Indeed, the Executive were so concerned about such a situation arising that they sought legal advice about the confidentiality provisions of the HFE Act so as to provide some guidance to their staff regarding what information they might reveal to the Review Panel (see Appendix). This was because section 33(2)(b) of the HFE Act forbids any person who has been a member or employee of the HFEA to disclose any information obtained ‘...in circumstances requiring it to be held in confidence.’

3.37 The difficulty that can be created by the confidentiality provisions of the HFE Act is demonstrated by an event that occurred during the taking of evidence from witnesses employed in the Executive. The solicitor (S1) engaged to provide legal advice to three of the four inspector co-ordinator witnesses was adamant that members of the Review Panel must not refer to the adverse incidents noted in Chapter 1 by their alphabetical case letter when addressing the witnesses. S1 stating:

*'So if any of you [members of the Review Panel] say, this is about case A, B or C, you could be putting them [HFEA employees] in jeopardy...they cannot be seen to answer questions even if it relates to Case A rather than the name of the person for fear of identification.'*¹⁶

3.38 S1 was clearly correct in seeking to ensure that her clients were not compromised by the actions of the Review Panel, but not being able to refer to the incident concerned placed severe restrictions on what questions the Review Panel could ask since the questions were context dependent. Furthermore, legal advice subsequently sought by the Review Panel in relation to this particular issue was contrary to the view held by S1. However, both sources of advice to the Review Panel were based upon their individual interpretation of section 33(2)(b) of the HFE Act and which view of the law should prevail could only be decided by being tested in a court of law. Given that there were other sources from which the same information could be derived, albeit more time consuming, seeking a view from the court was felt to be inappropriate.

3.39 In relation to the difficulties created by section 33, it should also be noted that the *HFEA Tenth Report and Accounts, 2001* were qualified by the Comptroller and Auditor of the National Audit Office because the confidentiality provisions of section 33 of the HFE Act prevented the audit team from accessing information that they required.

3.40 Additionally, in the report produced by Chantrey Vellacott the legal restrictions created by section 33 were identified as being responsible for compelling the HFEA to dispense with the services of the organisation that had been responsible for maintaining the VLA/ILA Database Register and the need to bring all information technology services in-house.

3.41 The Chantrey Vellacott report also conclude that as a result of the legal limitations imposed on the HFEA under current legislation that:

*'...the HFEA's Data Register will...always have to be developed and maintained in-house at whatever the cost, even if such a development is more inefficient or costly than alternative external solutions.'*¹⁷

3.42 While the second QQR team came to the view that:

*'...where IT [Information Technology] systems could be improved through the use of external experts and in cases where relevant research in the field covered by the HFE Act is being hampered, we believe that the DH and the HFEA, should explore the possibility of reviewing the present law and/or its interpretation without compromising patient confidentiality.'*¹⁸

Observations

- 3.43 The HFEA is supervised by the DH at two levels: ministerial and executive. The former is carried out formally on an annual and five-yearly review basis, the latter through informal daily contact, formal monthly and annual meetings with the sponsor department. However, these arrangements do not appear to have identified all the potential vulnerabilities within the HFEA as discussed in this report.
- 3.44 The composition of the QQR inspection teams have not included any members who have had any significant current academic and practical experience in the field of ACS and this may have inadvertently led to potential vulnerabilities in the HFEA inspection and licensing regime being overlooked.
- 3.45 The provision of information by the HFEA in relation to the HFE Act and Code of Practice may not always be consistent and this could lead to confusion on the part of centres and the public.
- 3.46 The HFEA COP does not appear to have provided centres with sufficiently detailed unambiguous guidance on how they should interpret and implement the HFE Act.
- 3.47 It is clearly important that the identity of those seeking ACS, and their children, should be safeguarded properly. However, the present provisions in the HFE Act appear to go well beyond what is necessary to achieve that aim. The confidentiality provisions of section 33 of the HFE Act are onerous and act as a device to prevent those who have a legitimate reason for accessing the data that the HFEA possesses from

doing so. It is also a barrier that prevents the HFEA from being more transparent about its working practices and prevents them, in the case of information technology, from seeking the best value that is available. This is in contravention of Government policy.¹⁹

References

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2. (October, 2000) *Second Quinquennial Review of the Human Fertilisation and Embryology Authority Report to UK Health Ministers.*
3. Ginnings, P. (November, 1997) *Human Fertilisation and Embryology Authority Study of Organisational Development Final Report.* Confidential document.
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6. *Human Fertilisation and Embryology Authority (Licence committees and Appeals) Regulations 1991, No. 1889.*
7. IC 3, transcript, p.117.
8. LCM 1, transcript, p.17.
9. PR, LGI, transcript, p.146.
10. LCM 2, transcript, p.8.
11. LCM 1, transcript, p. 49.
12. *Second Quinquennial Review*, paragraph 5.34.5.
13. *Second Quinquennial Review*, paragraph 5.61.1.
14. Gunning, J. and V. English, p.136.

15. Flora Goldhill, personal communication.
16. S1, transcript, p.82.
17. Vellacott, C, p.44, op cit.
18. *Second Quinquennial Review*, paragraph 7.9.
19. Prime Minister and the Minister for the Cabinet Office by Command of Her Majesty (March 1999), *Modernising Government*, Cm 4310.

Human Fertilisation and Embryology Authority recruitment, training and development

Authority Member recruitment

- 4.1 Initially, because reproductive medicine and its regulation was in its infancy, the first potential Members of the Authority were identified by the DH informally approaching professional bodies such as the Royal College of Obstetricians and Gynaecologists and soliciting recommendations. Subsequently, those who had been nominated were approached and invited to become Members of the Authority. However, over the years the number of people interested in obtaining assisted conception treatments has increased, as has the number of those practising reproductive medicine. The work of the Authority has grown considerably and consequently so has the burden on its Members. Expectations have also changed about the transparency of appointments to public bodies, leading in the 1990s to the establishment of a Commissioner for Public Appointments. For these reasons the requirements on Members and the recruitment procedures have changed.
- 4.2 Vacancies for a seat on the Authority are advertised widely in the press and elsewhere. All appointments are made in accordance with the guidance issued by the Commissioner for Public Appointments and advice is sought from the Chairman and the Chief Executive of HFEA about the particular skills needed on the Authority prior to each appointment exercise.
- 4.3 As discussed in Chapter 3 appointments to the Authority are made in the first instance for three years. However, there are no explicit limits in the legislation as to the number of times a Member may be reappointed. Thus, there have been occasions when Members have been reappointed to the Authority several times. And, while continuity of personnel in an organisation is often advantageous, there will be occasions when this is not the case. This will be discussed in Chapter 7.
- 4.4 The Chairman assesses the performance of the Authority's Members on an annual basis and a Member may only be reappointed if, during their term of office, they have performed their duties satisfactorily.

Authority Member role

4.5 While a nominal job description is used by the DH for the purposes of advertising for potential Members of the Authority, there are no job descriptions that define the specific skills and experience required by a particular vacancy. Thus, new Members to the Authority are often selected for a vacant seat on the basis of the Authority's current need to respond to forthcoming medical, scientific or ethical issues rather than with trying to ensure that the Authority consists of the individuals necessary to form a balanced and effective regulatory body. This will be discussed in Chapter 5.

Authority Member induction training

4.6 Once appointed, more recent practice has been that a new Authority Member is sent an induction pack by the HFEA. The pack contains papers that include information on how the Authority is structured, its committees, history, strategy and business plan. Information regarding inspection, licensing and other relevant issues such as the HFE Act is provided at a one-day induction meeting.

4.7 However, while initial enquiries by the Review Panel suggested that new Members of the Authority did not receive any training in the law, solicitor S2 brought to the Panel's attention a document entitled *Licensing: The Legal Framework Operational Handbook* that was produced for the use of Members by the HFEA's legal advisors in March 2000. This document is not listed on the induction pack letter and how widely it has been distributed is not known at this time. It is therefore possible that some Members of the Authority may not have received a copy.

4.8 The Review Panel's understanding is however that Authority Members appointed more recently up to the time of writing this report have not received any induction training on the principles of regulation and the inspection of centres.

Authority Member continuing professional development

4.9 From 1998 onwards Members of the Authority have organised an informal one-day retreat where the Members brief each other on current and impending topics within their field of expertise. Members have also received *ad hoc* training on issues such as the Human Rights Act 1998 and legal aspects of the work that the HFEA carries out. There has,

however, never been any formal programme of continuing professional development (CPD) for Authority Members on any aspect of their work for the Authority.

Recruitment of inspector co-ordinators

- 4.10 As noted earlier, initially the HFEA Executive was formed from individuals seconded from the civil service along with two members of the VLA/ILA secretariat who were transferred in to the new HFEA. However, within a short period of time vacancies were, as they are at the time of writing this report, advertised in the press and elsewhere. Applicants come from a wide range of backgrounds including secondment from the civil service.
- 4.11 However, the Review Panel have been informed that recruiting and retaining of inspector co-ordinators (ICs) has become a perennial problem for the HFEA.

Inspector co-ordinators' role

- 4.12 The job description of an inspector co-ordinator provided by the HFEA senior management and relevant at the time of the adverse events noted in Chapter 1 was as follows:

'To act as the Authority's prime contact with a portfolio of licensed treatment and research centres falling within the [HFE] Act with special emphasis on maintenance of standards in accordance with the [HFE] Act and Code of Practice, the inspection of centres, the consideration of and granting of licences and the investigation of complaints against licensed centres.'

- 4.13 Thus, it can be argued, for an inspector co-ordinator completely to fulfil their role as described above it is clear that they must be able to recognise all the appropriate scientific, clinical and social standards applicable to the HFE Act and the COP for each of the activities concerned with the provision of ACS. An inspector co-ordinator must also be physically present when each of the external specialist inspectors carries out their inspection in order to ascertain if both the centre and the inspectors are maintaining the required standard for that particular area of expertise.

- 4.14 However, when asked what they perceived their role to be none of the inspector co-ordinators interviewed appeared to recognise that they were supposed to have responsibility for the maintenance of standards implied in the job description quoted above.
- 4.15 Each inspector co-ordinator appeared to believe that their role in terms of inspections was limited to chairing or co-ordinating the inspection, producing a report and presenting it to a licence committee rather than having responsibility for ensuring the accuracy of its technical content. For example, IC 1 stated that:

*'The [external specialist] inspectors were there to provide the expert input to the inspection team. As an inspector co-ordinator I was there to take that information and put that in the report...'*¹

- 4.16 While IC 2 said,

*'I would believe what the [external specialist] inspectors found.'*²

- 4.17 IC 4 reported that:

*'If I did not understand it [the technical details of an area of specialist expertise], which in fairness was quite often...I would ask the [external specialist] inspector would they please write me a section for the report...I need your knowledge of this particular area.'*³

- 4.18 Similarly, with regard to the maintenance of licensing standards all the inspector co-ordinators interviewed stated that it was only the members of a licence committee's view that counted when the granting, renewal, variation or revocation of a Licence was being discussed. Indeed, the HFE Act only permits Members of the Authority to sit on licence committees. As IC 4 put it, if there was a difference of opinion between the inspection team that had visited a particular centre and the licence committee considering the licence application and the committee decided not to take their advice then: *'The inspection team had no grounds for appeal.'*⁴

4.19 ESI 1 noted that there had been occasions:

*'...when I felt very strongly that it was unwise of them [the licence committee] to have ignored recommendations [criticisms made in a centre's inspection report by the external specialist inspectors].'*⁵

4.20 The views expressed above by the inspector co-ordinators, while not consistent with their job description, are entirely in agreement with the guidance provided by the HFEA for external specialist inspectors in the *Manual for Inspectors* where it is stated that:

*'If no HFEA Member is present at an inspection, the inspector co-ordinator will chair the inspection. He/she is responsible for ensuring the inspection report is properly prepared and may ask an inspector to write a particular section. The inspector co-ordinator will present the report to the licence committee.'*⁶

4.21 ESI 1 however was of the opinion:

*'I would have said it would have been undesirable for an inspector co-ordinator...to chair a full inspection.'*⁷

4.22 The characteristics of a full inspection will be discussed in Chapter 6.

4.23 The written guidance for external specialist inspectors regarding the role of inspector co-ordinators also states that:

*'He/she [the inspector co-ordinator] will also follow up any specific condition and recommendations agreed by the licence committee. These are attached to the centre's licence when it is issued.'*⁸

4.24 However, the job description for inspector co-ordinators given above makes no mention of this requirement to follow up actions. While LCM 1 was of the opinion that the Executive had a diarised system for undertaking this task⁹ IC 4 stated that the HFEA did not have a formal system for tracking the implementation of recommendations or conditions and that inspector co-ordinators *'...would pick them up in the paper work,'*¹⁰ i.e. at the time the documentation for a centre's inspection was being prepared by the inspector co-ordinator concerned.

Inspector co-ordinator induction training

- 4.25 The inspector co-ordinators who gave evidence to the Review Panel regarding the inspections that had taken place before and after the adverse events noted in Chapter 1 stated that prior to being employed by HFEA they had no practical experience of working in a centre undertaking ACS. Furthermore, while all the inspector co-ordinators interviewed had some related experience, for example, having worked for another regulatory body or possessed a doctorate in a scientific discipline associated with assisted conception, none had any comprehensive knowledge or qualifications relating to the clinical, scientific, social or regulatory aspects of the work undertaken in centres carrying out assisted conception or related research. Nor did they have any prior knowledge or experience in the principles of regulation or inspection techniques to be used in centres.
- 4.26 However, all the inspector co-ordinators interviewed reported that upon commencing their employment with the HFEA they did not receive any formal induction training into any aspect of their work. Nor were they provided with a work placement in a centre providing ACS so that they could gain first-hand experience of how centres actually operate in practice.
- 4.27 Generally a new inspector co-ordinator would ‘shadow’ an inspector co-ordinator already in post, attend the inspection of a number of centres with them, read the HFE Act, COP and other documents relating to the work they were about to undertake, i.e. engage in on the job learning. Furthermore, there was no formal test of their ability to undertake the work of an inspector co-ordinator but, providing there were no complaints about their work, they were deemed to be competent and left to get on with the job. IC 4, who had some previous experience in another field of health regulation, also informed the Review Panel that:

‘As you know from your inquiries the Authority always had quite a massive turnover of staff [inspector co-ordinators]. At the time I arrived they were in particularly bad straits...I went on a couple [of inspections] – two before I actually joined them [HFEA] – as an observer; I did another couple [of inspections] and then I was on my own, the first one I did I chaired.’¹¹

- 4.28 In addition, although the inspector co-ordinators interviewed said they could readily seek advice from colleagues or other senior staff if required, no formal management arrangements were put in place to supervise them or have the quality of their work assessed on a regular basis.

Inspector co-ordinator continuing professional development

- 4.29 With regard to continuing professional development the inspector co-ordinators interviewed appear to have different experiences. IC 1 stated:

*'I did not go on a course at the very beginning, there were a number of courses that were carried out during my time there.'*¹²

- 4.30 IC 2, when asked if she had received any continuing professional development, replied¹³ that she could not recall any particular courses that she had attended. IC 3 had attended a course provided by the Industrial Society while IC 4 when questioned about how she would have replied if asked about her knowledge regarding the most appropriate standards to be used in an embryology laboratory said:

*'I would not have had a clue, nor would I have done when I left. Well better than a clue, but not any depth of knowledge...I always would have relied, as I did in inspections, on the scientific inspectors.'*¹⁴

Recruitment of external specialist inspectors

- 4.31 As noted in Chapter 3 a pool of fee-paid specialist inspectors was formed soon after the Authority came into existence to aid the HFEA in its regulatory work. This was because the HFEA's resource base was insufficient to undertake all the statutory inspections required.
- 4.32 The initial selection of such inspectors was undertaken by the Authority taking soundings from the various professional bodies as to who might be suitable to undertake the part-time task of inspecting centres. These individuals were then approached and appointments made with the approval of the Members of the Authority on the basis of their *curricula vitae*. The last recruitment drive made in this way was in 1996 and, as far as can be ascertained, most of the specialist inspectors appointed at that time are still in post. In the intervening period additional inspectors have been appointed on an *ad hoc* basis using the same format.

External specialist inspector role

4.33 The role of each specialist inspector is to determine with regard to their specialist knowledge whether or not a centre is providing ACS in accordance with the details in its application form, the HFE Act and COP. Furthermore, they determine whether a centre has complied with any additional licence conditions imposed by a licence committee or adopted any recommendations that a committee may have made following the centre's last inspection. A specialist inspector is also tasked with engaging the centre's staff in a dialogue so as to promote an exchange of information on best practice.

External specialist inspector induction training

4.34 Since at least 1996 specialist inspectors should have been given a copy of the *Manual for Inspectors*, which contains information about their work and received a one-day induction training course where the HFE Act and COP were discussed. Following this they commenced their duties.

External specialist inspector continuing professional development

4.35 The HFEA has provided a day's training each year following the reintroduction of revised inspection protocols in 2000. But the review panel's understanding¹⁵ is that apart from their induction training, specialist inspectors have not been provided with any other formal training by the HFEA for their role until just recently, although they are invited to attend the HFEA's annual conference. However, they have never received any formal training in the law, inspection techniques or the regulatory issues related to their field of expertise. Nor have specialist inspectors ever been formally examined to ascertain their understanding of any of the aspects of the work they carry out for the HFEA.

4.36 It is interesting to note that Alyson Leslie, when the Interim Director of Regulation at the HFEA, reported that:

*'...the quality of expert [ESI] input is also variable. The way that this has been managed in the past is simply by restricting the numbers of inspections attended by people who were deemed to be weak in inspection.'*¹⁶

4.37 Similarly, ESI 2 also held reservations with regard to the competence of some external specialist inspectors used by the HFEA, stating that:

‘...although they [ESIs] may have had good scientific and academic backgrounds in laboratory work they really were not experienced in what was required in day-to-day IVF laboratory [work].’¹⁷

Observations

- 4.38 The following observations, and those in other chapters, should be considered in the light of the recognition that during the past decade or so the understanding of risk and its management has developed at a remarkable pace. Thus what practices may have been acceptable in the early 1990s would not necessarily be acceptable now. It is in this context that the HFEA’s development of risk management needs to be considered.
- 4.39 There appears to be some confusion as to whether new Members of the Authority have received all the documents that they should have following their appointment in recent years up to the time of this review.
- 4.40 Although many of those joining the Authority as Members have no or little knowledge of the processes used in the provision of ACS, the law or regulatory and inspection processes no formal programme of structured training to address those issues had been implemented.
- 4.41 Similarly, those engaged by the Executive as inspector co-ordinators did not receive any formal training in the provision of ACS, the law or regulatory and inspection processes. Nor did they necessarily have any direct experience of the work carried out in centres, which must have some effect on their ability to understand the context in which the HFE Act and Code of Practice were being applied.
- 4.42 The inspector co-ordinators’ job description does not appear to match their understanding of the functions that they are to perform nor that of the external specialist inspectors with whom they work. There also appears to be differences of view between inspector co-ordinators as to what administrative systems are in place within the HFEA and the way in which their work is to be carried out.

- 4.43 Furthermore, inspector co-ordinators are not formally examined on the knowledge and skills they require as an inspector nor are they supervised or formally assessed as to their proficiency. Additionally, inspector co-ordinators do not have a formal programme of continuing professional development to complete.
- 4.44 The high turnover of inspector co-ordinators at the HFEA has led to at least one newly recruited inspector not receiving the training that such a post requires.
- 4.45 Members of the Authority and inspector co-ordinators are selected following a formal assessment of their *curriculum vitae* and an interview. External specialist inspectors are, on the other hand and at the time of this review, still selected solely on the basis of their *curricula vitae* which could lead to inappropriate appointments being made.
- 4.46 While external specialist inspectors did receive some formal training upon appointment and a small amount of *ad hoc* training over the years, no structured continuing professional development has been put in place to ensure that their knowledge and skills are regularly updated. Additionally, external specialist inspectors, like inspector co-ordinators, are not formally tested on their work-related knowledge and skills nor are they regularly assessed on their competency to undertake the work of an external specialist inspector.
- 4.47 Although the Members of a licence committee are not present at the inspection of a centre there have been occasions when licence committees have decided not to follow the recommendations made by the inspection team.
- 4.48 There is evidence to suggest that the competence of some specialist inspectors is questionable in terms of their work for the HFEA.

References

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2. IC2, transcript, p.63.
3. IC4, transcript 2, p.36.
4. IC4, transcript 2, p.39.

5. ESI 1, transcript, p.33.
6. (March, 1996) *HFEA Manual for Inspectors*, section 4, p.2.
7. ESI 1, p.8.
8. (March, 1996) *HFEA Manual for Inspectors*, section 4, p.2.
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11. IC4, transcript 2, p.6.
12. IC1, transcript, p.7.
13. IC2, transcript, p.51.
14. IC4, transcript 2, p.7.
15. ESI 2, transcript, p.62.
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17. ESI 2, transcript, p.68.

Chapter 5

Human Fertilisation and Embryology Authority licence applications

- 5.1 Under the provisions of section 11(1) of the HFE Act the Authority may grant three types of licence to centres; these are for the storage of embryos and gametes (eggs and sperm); the provision of assisted conception treatment services; and for the purposes of research. A centre may be granted more than one type of licence.

Licence inspections

- 5.2 Section 9 of the HFE Act contains provisions for the premises to be inspected prior to a centre being granted a licence. However, Members of the licence committee are not required to carry out the inspection themselves (section 9(11) of the HFE Act). The scope of inspections is wide ranging and includes record keeping (section 13), conditions for the storage and disposal of licensed material (section 14), and the suitability of staff, equipment and working practices (section 17). Following the granting of a licence or licences to a centre the frequency of inspection at any particular centre is once per year except where a licence committee '*...considers an inspection in that year unnecessary*' (sections 9 and 10).
- 5.3 Initially all centres which possessed a licence or licences were inspected annually and upon meeting the requirements of the HFE Act and COP were issued one-year licences. These inspections, to be discussed in Chapter 6, are known as full inspections because the external specialist inspectors who form the inspection team cover all the major aspects of the work undertaken at a centre, i.e. clinical, scientific and social.

Budgets

- 5.4 Cost savings were particularly important as the letter to the HFEA following the annual HFEA Executive Accountability Review with the Department of Health 1997-98 set out:

‘...cumulative savings of 2-3% per annum were being required in the public sector generally by Ministers.’¹

5.5 However, as noted in Chapter 1, ACS have expanded at a rapid rate since the inception of IVF techniques but as pointed out in a letter to the Department of Health from the HFEA following the 2001-02 annual review *‘...the budget of the HFEA has remained unchanged for most of the life of the Authority.’²*

5.6 Similarly, the Chairman of the HFEA, Suzi Leather, when giving evidence to House of Commons Science and Technology Committee (HCSTC) remarked that:

‘Coming to it from new [the HFEA], when I first heard what the budget was [on average for the HFEA £1.4 million pounds sterling], I thought they had got the decimal point in the wrong place because if you consider the enormity of the task in front of it [the HFEA] many members of the public, looking at how other regulatory organisations are funded, would be surprised that it was funded on that sort of budget.’³

5.7 Furthermore, Professor Lovell-Badge of the National Institute for Medical Research, in a memorandum submitted to the HCSTC on the subject of the HFEA’s budget also observed that:

‘It is clearly not sufficient money for the HFEA to be doing all they would want to do, and probably should be doing, to both regulate and inform the public, etc, about their business.’ (HC 791, Ev.11)⁴

5.8 Evidence to support the contention that the HFEA had previously been under-funded came during the writing of this report. In a response to the House of Commons Science and Technology Committee report *Developments in Human Genetics and Reproduction*, and a detailed business case from the HFEA, the Government announced in November 2002 that it would increase the HFEA’s funding to £5.5 million per annum.

Change to the licence inspection regime

5.9 On 23 February 1995, following an internal review of HFEA’s licensing procedures, the Authority, in an effort to improve the efficiency of

inspections, notified their external specialist inspectors by letter that in future inspections would become more focused. The inspection team's size and make-up would now depend upon a centre's activities, '*...licensing history, and the outcomes of the HFEA's regular monitoring process.*'⁵

- 5.10 Another driver for the HFEA to improve its efficiency came from the Terms of Reference of the first five-yearly QQR where there was a requirement that the QQR team should consider ways and means for streamlining the HFEA's procedures '*in line with the Government's deregulation initiatives.*'⁶ Furthermore during the QQR process, centres had questioned the need for a full annual inspection particularly where HFEA reports and IVF success rates had been satisfactory for a number of years.
- 5.11 In addition, the first QQR held the view that as the HFEA had developed it had acquired significant in-house skills and experience in carrying out inspections and, as a result, the five inspector co-ordinators employed at that time formed a professional inspectorate. With such expertise available, the Review reasoned that the HFEA should be able to move from the then annual inspection with a full team of inspectors to a more flexible and cost effective regime where the full complement of inspectors would not be required at all inspections. It was however recognised that the modified inspection system would have to be flexible and retain the ability to mount full inspections at centres when required. Thus, endorsed by the first QQR and later by the Ginnings Report⁷ the HFEA developed and then commenced the implementation of the new inspection regime in 1999.
- 5.12 In summary, the revised licence system consisted, as before, of a full inspection for all organisations making their first application for a licence to provide ACS and, if successful, being granted a one-year licence. However, in the modified licence regime after three years of experience a licence committee would evaluate the centre's performance and compliance history. If this were deemed to be satisfactory and providing the centre under consideration passed a full licence renewal inspection then that centre would be granted a three-year as opposed to a one-year licence. Inspector co-ordinator 4 remarked that when a licence committee awards a licence for longer than one year to a centre it is because that centre is considered '*...to be a gold standard unit*'⁸ The idea was that the HFEA should target its limited resources at the centres that appeared to need the most help to comply with the legislation and COP.
- 5.13 Once a centre has been granted a three-year licence, instead of having a

full inspection each year during the next two years of its licence period, interim inspections are carried out. An interim inspection can take two forms; either an inspector co-ordinator can visit the centre unaccompanied and look at a particular aspect of the centre's procedures, for example, carry out an examination of their clinical records. Or he or she can attend the centre as chairman of an inspection team. This will usually comprise one external specialist inspector who will carry out an inspection that is focused on a particular element of the centre's activities such as laboratory services. In both cases the full inspection team is not required and this minimises the resources that both the HFEA and the centre concerned has to use in order to comply with the legislation.

Centre activity and licensing index

- 5.14 In an attempt to provide consistency in the application of the new inspection regime, in June 1999 the HFEA introduced a Centre Activity and Licensing Index (CALI) that it had devised. The CALI formula was designed to take account of a variety of risk factors including the number of treatment cycles, the complexity of activities and any previous conditions imposed by a licence committee on a centre. The score derived from the CALI calculation then formed part of a risk assessment process to decide whether or not a centre should be awarded a three-year licence or continue to be subjected to full inspections each year. If a centre is granted a three-year licence the licence committee concerned will also decide what the focus of the following year's interim inspection will be.
- 5.15 The principle of using a CALI score to determine the appropriate inspecting regime of a centre was reinforced in the second QQR when the Review recommended that:

*'Where through a combination of achievement of a history of acceptable compliance as indicated by the CALI score...and the Authority's own 'intelligence', a clinic is deemed to be operating to the satisfaction of the Authority's licence committees and no significant changes in, for example, facilities, staffing, practices, and protocols have taken place, instead of an annual visit the Authority could invite the clinic(s) in question to complete a questionnaire.'*⁹

- 5.16 Similarly, the DH Internal Audit report on corporate governance within

the HFEA recommended that due to the number of inspections that the HFEA was required to complete each year a risk assessment of all centres should be undertaken as a matter of urgency. Once centres had been ranked in order of risk the report suggested that:

*'It may be appropriate for low risk weighted clinics [centres] to be visited only once every three years, and the more risky ones visited more often, with the highest risk clinics being visited at least annually or more often if deemed necessary. Risk self-assessment questionnaires (based on best practice models) could be produced for use by clinics in between visits...'*¹⁰

- 5.17 Thus the DH Internal Audit report, both QQRs and the Ginnings report endorsed the HFEA's view that they should seek to reduce the amount of physical surveillance where a licence committee deemed that the level of risk at a particular centre was felt to warrant such treatment. Consequently, as noted above, 1999 saw the start of licence inspections designed to ascertain which centres, because of their activity and licensing index profile, should be granted a licence for three years instead of one.

Limits to the centre activity and licensing index

- 5.18 It should be recognised however that there are a number of difficulties with trying to calculate the risk of any organisation failing.¹¹ For example, Enron, the energy trader, was perceived to be a successful company until it filed for Chapter 11 bankruptcy protection on 2 December 2001 and a number of allegations of financial impropriety were subsequently made.¹² Similarly, the private Hampshire Clinic in Basingstoke that provided assisted conception services to the public had passed numerous HFEA inspections satisfactorily. It was found later however that an embryologist at the centre had deceived women undergoing fertility treatment into believing frozen embryos had been thawed and implanted into their wombs when they had not.¹³
- 5.19 In a similar vein, during a review of inspection reports held by the HFEA on the then 117 active centres, Baines¹⁴ identified 30 cases where the centre or the Person Responsible for a centre gave rise, in his opinion, for concern in relation to their adherence to the HFE Act or COP. Of those 30 cases, two had been granted licences for two years and 15 had been granted licences for three years by a licence committee at the time of the review. Thus, 56% of the centres then giving rise for concern must have previously achieved a numerical score on the CALI

index that indicated that they were of the gold standard referred to earlier. Furthermore of the 17 centres granted licence periods longer than one-year, two have, during their extended licence period, been involved in a reportable adverse incident with the centre at Leeds General Infirmary being one of them.

Initial licence applications

- 5.20 Any organisation that wishes to become a licensed centre must inform the HFEA (as they were also previously required by the VLA/ILA) that they want to do so. Upon receipt of such a request the candidate organisation is sent a document entitled *Manual for Centres* (MFC). The manual contains information regarding the application process amongst a number of other topics of which the Person Responsible of a potential centre needs to be aware. The inspector co-ordinator allocated to the candidate organisation will also offer to help the centre with its application.
- 5.21 Once a potential centre has submitted a formal application and the necessary supporting documentary information an HFEA administrative officer (AO) will commence making arrangements for a full inspection to be made by a HFEA inspection team.

Renewal licence applications

- 5.22 Several months prior to a centre's licence expiring an AO will contact the Person Responsible at a centre and begin the process of arranging for a full inspection to take place.

Interim licence applications

- 5.23 Similarly, to the process noted above an AO will commence making the arrangements for an interim inspection to take place three months before a centre's licence expires. The licence committee who undertook the last review of the centre concerned would have already agreed the focus of the inspection through discussion and the use of the CALI index methodology.

Variation or revocation of licence

5.24 Should a centre be found at anytime in breach of the statutory provisions of the HFE Act, a licence committee may vary or revoke a licence.¹⁵ There is however evidence to suggest that the resolve of licence committees to use these provisions rigorously may have been undermined. This will be discussed in Chapter 7.

Licence appeals procedure

5.25 If as a result of an adverse inspection report or an adverse event investigation a licence committee was minded to revoke or suspend a centre's licence, section 20 of the HFE Act makes provision for an appeal. Section 20(3) provides that '*...no member of the Authority who took part in any of the proceedings resulting in the determination appealed against shall take any part in the proceedings on appeal.*' It is for this reason that the Members of a licence committee do not discuss the licence applications before them with other Members of the Authority, as this would debar those Members from sitting on an appeal committee. Furthermore, no Member of the Authority who takes part in a licence committee where it was decided to revoke or suspend a centre's licence may sit as a member of that appeals committee. Similarly, where a Member of the Authority was part of an inspection team that produced an adverse report then that Member may not sit on the appeal committee constituted to adjudicate on that issue.

Licence committees

5.26 The HFEA has a number of subcommittees. The most crucial one in the context of this report is the licence committee whose composition and remit are prescribed in section 9 of the HFE Act and in the *Human Fertilisation and Embryology Authority (Licence Committees Appeals) Regulations 1991*. LCM 2 stated that the function of a licence committee was:

*'...to make sure that the process of inspection has been done correctly, to look at the [inspection] report to make a judgement about whether it has been properly conducted, fair, thorough. And then we will look at their [inspection team] recommendations one by one and see whether they should be attached to a condition recommendation.'*¹⁶

Licence committee structure

- 5.27 Licence committees are organised several months in advance and the membership is changed on each occasion, this means that Authority Members never attend two successive licence committee meetings. Thus it is unlikely that any Member of the Authority will be on the same centre's licence committee two years in succession.
- 5.28 Licence committee meetings take place approximately every two weeks and discuss the issuing of licences to those organisations that wish to become centres, any alterations that licensed centres wish to make to their current licence (for example adding a new treatment procedure) and any other investigations or business that have may have been carried out prior to that particular licence committee meeting.
- 5.29 Although the HFE Act permits the Authority to discharge some of its functions through a variety of actors, only Members of the Authority may be members of a licence committee. The Chairman of the Authority appoints a Chairman for each licence committee and each licence committee must have at least one Member who is a layperson.
- 5.30 In general the format of a licence committee meeting is similar in type to that of the committees set up by VLA/ILA and should ideally be comprised of 5 of the 21 Members of the Authority, but in fact only three are required for a licence committee to be quorate. There are no specific criteria by which Members of the Authority are selected for any particular licence committee although an attempt is made to try to ensure that the appropriate expertise is available on each occasion. For example, if a centre were applying for a research licence then every effort would be made to ensure that a research scientist would be a member of that particular committee.
- 5.31 However, as noted in Chapter 4 the system used to select potential Members of the Authority by the DH has included the need to ensure the HFEA has the most appropriate specialists amongst its Members to provide advice on forthcoming issues of national and international importance in reproductive medicine. Therefore, the balance of the nine Members of the Authority with a professional interest in the work that the HFEA regulates may reflect that bias in the selection process.

5.32 Thus, while the intention is always to ensure that the appropriate balance of expertise is available to each licence committee this is not always possible. There have been occasions when a Member or Members of the Authority have not been able to attend a licence committee meeting at short notice and this has made an ideal balance difficult if not impossible to attain. Thus, in order not to hold up the licensing process it has been reported by LCM 3 that there have been occasions when there was:

*'...nobody on the licence committee who had worked in a clinic. It could happen. You could even have the situation where five people are appointed, including both clinical and embryology expertise, but on the day neither were available...'*¹⁷

5.33 Furthermore, LCM 3 stated that:

*'To discover, from the point of view of a person who works in a clinic, that your licence is being considered possibly by a psychiatrist, a social worker, a retired civil servant and a lawyer was a bit of a revelation.'*¹⁸

5.34 LCM 3 also asserted that prior to her appointment to the Authority, *'...there was no one with technical knowledge of working in an embryology laboratory, I was the first.'*¹⁹

5.35 In order to test this assertion Dr Gearon carried out an analysis of the type of work undertaken by the Members of the Authority who have had a professional interest in the work that the HFEA regulates. Dr Gearon's research revealed that LCM 3 was indeed the only person ever appointed to the Authority who at the time of their appointment and during their tenure had significant and current professional experience of working in an assisted conception services embryology laboratory.

5.36 When questioned as to why this situation had arisen LCM 3 stated:

*'I think it is understanding that there are specific discrete set of skills associated with human clinical embryology that are possessed by clinical embryologists and by nobody else that has been a difficult one to get across.'*²⁰

Guidance to licence committees

5.37 During the Review attempts were made by the Panel to ascertain if there were any explicit criteria to guide licence committees regarding the processes they should adopt when evaluating a centre's application for a licence. Initially, our enquires proved fruitless. The inspector co-ordinators who present the inspection reports to the licence committees were asked:

'To your knowledge, did the HFEA licence committees have any minimum explicit predefined structured technical or other processes against which the ACS licence application was evaluated?'

5.38 None of the inspector co-ordinators interviewed could recall any form of explicit guidance document used by licence committees. Subsequently a copy of a document entitled *Review of Licensing 2* (HFEA (95) 3) was produced by LCM 1 from her own records. Annex 1 of that document is entitled *Guidance for licence committees* - the guidance however relates to a small number of mainly administrative issues.

5.39 The Review Panel could not find any evidence of explicit guidance provided for the use of licence committee members so as to ensure that every licence committee covered the issues relevant to the inspection of assisted conception services in a structured way. Indeed, LCM 3 recalled that:

*'...I must admit that when I became a Member of the HFEA it was a shock to me the way in which the system of licence committees operate...Simply because of the lack of balance of expertise, and the fact that there were no checks and balances and there were no written protocols.'*²¹

5.40 While LCM 1 stated that, *'...the agenda [for a licence committee] is set by the inspection reports that would come in from either interim visits or renewal visits to the licensed centres.'*²²

5.41 Thus, as with the inspector co-ordinators a great deal of reliance is placed by licence committees upon the expertise possessed by the external specialist inspectors.²³

Licence committee meetings

5.42 To assist licence committees in their deliberations regarding whether or not to grant a licence to a centre a range of documents are provided. These include the minutes of the centre's previous licence committee, the current inspection report, the centre's regulatory history, application form and any relevant correspondence. The agenda for a licence committee and all relevant documents are sent to the Members of a licence committee a week before the meeting. Additionally, the inspections protocols completed by the external specialist inspectors during their inspection should also be made available to a licence committee on the day of the meeting.²⁴ There is however some confusion as to whether the inspection protocols have always been used by external specialist inspectors and whether or not they have been made available to licence committees on all occasions and this will be discussed in Chapter 6.

5.43 The inspector co-ordinator responsible for a centre applying for a licence will verbally present the findings of the inspection report to the members of the licence committee. During the presentation an inspector co-ordinator will endeavour to place the report in context by, for example, relating their view as to the atmosphere prevailing at a centre or highlighting specific problems.

5.44 Once an inspector co-ordinator completes their verbal presentation LCM 1 stated that:

*'It would then be usual for the members to ask for clarification of any points that were not clear or had come up in the papers or they felt had not been addressed. Then the decisions would be made on the inspection report, bearing in mind any other information that had been made available.'*²⁵

5.45 It should be noted however that LCM 2 drew the Review Panel's attention to the fact that '*...what is not minuted is the discussion around what the inspection was like.*'²⁶ Similarly LCM 1 noted in relation to the licence committee's presentation that '*I think we always have quite a detailed discussion about a lot of this, which does not necessarily come through in the minutes.*'²⁷

5.46 Whereas Annex 1, *Review of Licensing 2 – (HFEA (95) 3)*, item 1.d titled *Licence Committee Minutes and Information to be recorded therein* states:

'The minutes of the licence committee are the legal document which records the licence committee's consideration of the centre and the outcomes of that consideration. Licence committee minutes should accurately reflect the full discussion and decision of the licence committee.'

- 5.47 However, as LCM 1 and LCM 2 observe, the licence committee meeting minutes currently produced do not contain the kind of detail recommended in the guidance noted above.

Licence committee recommendations

- 5.48 Although the HFE Act only makes provision for a licence committee to give centres directions or impose conditions on their licence it has become common practice where failings have been identified in a centre's operations for a licence committee to send them a letter with the licence making recommendations as to the areas that they wish to see improve. LCM 2 noted that:

*'...recommendations are meant to be complied with and they are not as strong as conditions. But in the next inspection the clinic has to say why they have not complied with it.'*²⁸

- 5.49 All the licence committee members interviewed noted that whether a condition was placed on a centre's licence or a recommendation was made depended on the severity and importance of the observed breach by the licence committee concerned. Making sure that a licence committee's actions were proportional to a centre's breach of the HFE Act was also a key issue. LCM 2 made the point that *'...there are different weights for sins in a way. There are some sins that are very bad.'*²⁹

- 5.50 There is however some confusion among the inspector co-ordinators as to the status of recommendations, for example IC 4 stated that:

*'The idea with recommendations...was that if there were recommendations in one year they could not suddenly become a condition of a licence the next year; the idea being that if it was a condition now it should have been a condition then.'*³⁰

- 5.51 On the other hand LCM 3 was of the opinion, *'...if they [the centre] did not comply with the recommendation it will then become a condition.'*³¹ Similarly, LCM 2 said, *'...clinics should have known what it meant [a recommendation], which is compliance, they should comply with it, and if*

they do not comply with it, it becomes a condition.’³² However, IC 1 was of the opinion ‘...it is for them [the licence committee] to decide whether it is mandatory [a condition] or just a recommendation.’³³

Activities post licence committee meetings

- 5.52 Following a licence committee meeting a draft licence is drawn up and sent to the Person Responsible at the centre. The draft licence contains details of the assisted conception services that the centre is allowed to perform and any additional conditions that may have been imposed by a licence committee. If a licence committee does impose additional conditions on a centre and the Person Responsible does not agree with them then, as described above, the centre can appeal against them.
- 5.53 The recommendations of a licence committee on the other hand are not part of the conditions of the centre’s licence and are included in the letter sent to the Person Responsible. Providing the Person Responsible of the centre agrees to the terms of the draft licence then a licence is issued.
- 5.54 The inspector co-ordinator allocated to the centre will manage any outstanding issues such as additional licence conditions or recommendations to be implemented by the centre. However as noted in Chapter 3 there is some confusion among inspector co-ordinators as to what process should be used. While some inspector co-ordinators diarise implementation issues other licence committees pick them up in the paper work at the next inspection of the centre.

Observations

- 5.55 The creation of a risk-based inspection regime by the HFEA was born of economic necessity, a desire to improve the efficiency of the inspection process and to simplify procedures in line with the Government’s deregulation initiatives. This aspiration was strengthened by the belief of the first QQR team that the inspector co-ordinators employed at that time had the knowledge and experience to form a professional inspectorate. This view was also endorsed by the Ginnings report, the second QQR and the internal audit report commissioned by the Department of Health. However, given that the Baines report presents evidence that 25% of centres or the Persons Responsible managing them gave rise for concern, the adverse events that have occurred at The Leeds Teaching Hospitals NHS Trust, the Hampshire Clinics and elsewhere,³⁴

suggests that the CALI driven risk-based inspection regime has not had the success originally envisaged. This supports the thesis that the arithmetical modelling of risks to organisations is not without its difficulties.

- 5.56 The potential bias created by the Department of Health selection policy with regard to the appointment of Members to the Authority and the fact that some Members of the Authority fail to attend licence committee meetings at short notice, may have been contributory factors on some occasions that has led to licence committee meetings where the most appropriate balance of knowledge and experience has not been available.
- 5.57 The potential bias in the selection of Authority members, as noted earlier, arises from the need for the HFEA to have specialists with the necessary expertise to inform its deliberations regarding forthcoming assisted conception issues. Thus, the evidence suggests that where a new Member is required to support the advisory role of the HFEA this may conflict with the need to ensure that an appropriate balance of expertise is available to meet the regulatory Membership requirements of licence committees.
- 5.58 Essentially the function of a licence committee is to carry out an audit of the report produced by the inspector co-ordinator following the inspection of a centre since they are not usually present at the inspection itself. However, licence committees do not appear to have any explicit framework, *aide memoir* or protocol to ensure that all the issues relevant to the provision of assisted conception services within centres are discussed on every occasion. Rather there is a presentation of the inspection report by the inspector co-ordinator concerned followed by a licence committee discussion. However this discussion is not minuted in any detail thus making it difficult if not impossible at a later date for others, who have not been involved with a particular licence committee, to establish why a specific decision has been made. This should be of particular concern as the composition of licence committees change on each occasion and it is therefore highly unlikely that the same Members of the Authority will review the licence of any centre two years in succession.
- 5.59 Licence committees appear to use informal Recommendations as a form of sanction rather than the formal Conditions and Directions provided by the HFE Act as a means to direct centres to the type of improvements or changes that a licence committee wishes to see adopted. However, given the level of non-compliance with the HFE Act and Code of Practice discovered by Baines it would appear that this approach is not sufficiently

persuasive to oblige all centres to comply. Moreover there appears to be some confusion between the licence committee members and the inspector co-ordinators as to the significance of a recommendation and as to whether or not a recommendation can be up upgraded into an additional licence condition.

- 5.60 The licence committees appeared not to be aware of the document *Review of Licensing 2* (HFEA (95) 3) but LCM 1 produced a copy from her own records. Thus it would seem that the licence committees may not be cognisant of all the documents that relate to their proceedings.
- 5.61 Different approaches appear to be used by the inspector co-ordinators with regard to following up the implementation of licence committee recommendations or additional licence conditions. Some use a diary system while others pick them up the following year in the paperwork. While there is no evidence to suggest that follow up issues have been missed by inspector co-ordinators using the latter method, an explicitly dated reminder, it can be argued, is the more robust of the two methodologies.
- 5.62 The demand for assisted conception services continues to rise and as a result so do the demands placed upon the HFEA's resources.

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Chapter 6

Human Fertilisation and Embryology Authority inspection procedures

- 6.1 Prior to the issue of the HFEA *Licensing Procedures Handbook* (LPH) in December 2000 there had been no explicit corporate procedures regarding the processes to be followed by the HFEA Executive when preparing for the inspection of a centre. Each member of the Executive involved in arranging inspections had previously used procedures that had built up through custom and practice. In producing the LPH the Executive codified the procedures in use at the time and thus introduced an explicit formal system to which all those involved in the administration of licensing centres should then adhere.
- 6.2 It was noted that the pattern of the inspection processes described by the HFEA Authority Members, inspector co-ordinators and external specialist inspectors interviewed during this Review and the procedures described in the LPH closely resemble those used by the VLA/ILA discussed in Chapter 2. Evidence to support this view can be found in the statement of LCM 1 who said:

*'I think overall the inspection process is based on what was set up initially.'*¹

Inspection preparation

- 6.3 Following receipt by the Authority of a formal application to become a licensed centre the inspector co-ordinator allocated to that establishment will check that the HFEA has received all documentation required from the candidate organisation. The inspector co-ordinator will also ensure that the person nominated as Person Responsible of the potential centre is aware of all the procedures to be followed during the processing of their application. In addition the inspector co-ordinator will contact the HFEA administration officer (AO) and request that a full inspection be arranged. The inspector co-ordinator is also required to provide advice to the AO on the timing of the inspection and any suggestions they may have regarding the inclusion of specific external specialist inspectors in the inspection team.

6.4 The AO will then contact the nominated Person Responsible of the establishment to be inspected and a suitable date will be made for the inspection to take place. External specialist inspectors will then be contacted and arrangements made for them to attend the inspection.

6.5 The HFEA *Licence Procedures Handbook*, with regard to an inspector co-ordinator's duties states that:

*'The inspection papers, inspection protocols should be issued to the members of the inspection team no later than one week before the inspection is due to take place.'*²

6.6 The documentation required for full inspection however could, according to IC 3 be:

*'...anything from 200 pages to well over 1000 [pages] depending on the size of the clinic. For an interim inspection, again for some clinics it can be near the 800 [pages] mark. The time that they should receive it can vary. Ideally it should be a minimum 10 days beforehand.'*³

6.7 However, ESI 1 stated:

*'...the time could vary – it is rarely more than a week, and occasionally it [the inspection document package] arrives the day before [the inspection]'*⁴

6.8 ESI 2 also observed that inspection documentation could arrive:

*'...for an inspection on a Monday, the previous Friday, and not often more than a week in advance.'*⁵

HFEA inspection team structure

6.9 Initially, Members of the Authority, like the Members of the VLA/ILA, carried out and chaired all inspection visits at centres. However, as observed in Chapter 4, the sheer number of statutory inspections required once the HFEA had commenced fulfilling its regulatory role precluded such a situation from continuing. As a consequence, the HFEA created a national pool of specialist external scientific, clinical, nursing and counselling inspectors to carry out the work. These external specialist inspectors work in different parts of the United Kingdom and are paid a fee for their services. This pool arrangement remains in operation at the time of this review.

- 6.10 A full inspection team typically consists of a clinician, a scientist, and a counsellor, as well as an inspector co-ordinator and a chairman. The chairman is frequently a Member of the Authority. However, where such a Member possesses the requisite professional expertise they typically act as both chairman and as a member of the inspection team. As discussed in Chapter 4, while there does appear to be some confusion between the current HFEA job description for an inspector co-ordinator and the inspector co-ordinator's own understanding of their duties, a central function of the inspector co-ordinator's post is to provide administrative support to the inspection teams visiting centres and to the Members of licence committees.

Checklists

- 6.11 As discussed earlier, a VLA inspection team would routinely be provided with an *aide memoir* or checklist to guide them as to what activities should be inspected. However Maureen Dalziel, when the HFEA Chief Executive, informed the Review Panel that:

*'During the period 1991-1995 inspectors used checklists for visits [to centres]. That suddenly stopped in 1995 but it has not been possible to ascertain the reason for that.'*⁶

- 6.12 However, LCM 1 in a written submission to the Review Panel produced evidence that Section 4, *HFEA Manual for Inspectors* (MFI) dated 27 March 1996 contained a number of documents including checklists that were to be used by external specialist inspectors when on inspection visits at centres.
- 6.13 Subsequently during interview LCM 1 also stated that, '*...Officially they [checklists] were in place until the new protocols were introduced in 2000...*'⁷
- 6.14 Additional evidence to support the view that checklists should have been used during the inspection process after 1995 is to be found in the HFEA's *Manual for Centres* dated March 1996. As noted in Chapter 5 a copy of the manual is sent to each potential centre's Person Responsible, by the HFEA Executive, on receipt of a request by an establishment that they wish to provide assisted conception services. MFC, section 1, paragraph 9, *Initial Inspection*, states:

'On a visit [to a centre] the inspection team will be expected to cover all areas outlined in the checklist enclosed at Annex 12.'

6.15 While MFC, section 1, Paragraph 10, *Consideration by a licence committee*, states:

'The committee will look at the centre's application and supporting documents. It will also see a record of the centre's past performance where applicable, the completed checklist and the report of the inspection team...'

6.16 Finally, MFC, section 1, paragraph 12, *Review Inspections*, states: *'A review inspection will generally follow the same format as the initial inspection (see section 9 above).'*

6.17 However, in the *Manual for Inspectors* dated 25 March 1996 and sent by the HFEA Executive to the Review Panel at the Chairman's request, while the contents list of Section 4 as noted above by LCM 1 states that checklists are part of that section none were present in the document received. The letter from the HFEA dated 10 January 2003, that accompanied the MFI noted that:

'To the best of our knowledge, the last recruitment round of inspectors took place in 1996/7 and this manual was given out to them then. Some parts have been updated – others are seriously lacking timely information. Other inspectors have joined our ranks since then but no one here is able to enlighten us on what they may have been given – sorry.'

6.18 Moreover, when asked the question by the Review Panel:

'To your knowledge, did the HFEA licence/Inspection committee have any minimum explicit predefined structured technical or other processes against which inspection visits were evaluated?'

IC 1 stated: *'To my recollection in 1997/1998 there were not. There were some protocols introduced, I can't remember the exact date, it was probably during 1999.'*⁸

While IC 4 reported:

*'For the main time, no, you drew them up [checklists] again from your own knowledge of the [HFE] Act and Code and what was required... The protocols came about from the changing licence system that occurred when the risk assessment process [CALI] was brought in.'*⁹

ESI 1 was of the opinion that:

*'We had inspection protocols. I have no precise memory of when they came in... I would be fairly convinced they would have been in 99.'*¹⁰

On the other hand ESI 2 believed that *'To the best of my knowledge, I do not think I would have had those available [inspection checklists] in December 2000.'*¹¹

6.19 The reason for the different opinions voiced above regarding the use of checklists is perhaps reflected in the opinion of LCM 1:

*'To be honest, I think in general it is only more recent years, when we have had clinical governance introduced, that protocols have begun to be used more widely.'*¹²

Checklist questions

6.20 The checklists that have been produced by the HFEA to assist external specialist inspectors during their inspection of centres are a useful *aide memoir*. However they contain few objective standards for use during inspections. For example, following the HFE Act and COP, both the original and relaunched inspection protocols contain evaluative criteria, such as *'Are the laboratory conditions of a **sufficiently** high standard?'*, *'Is **appropriate** laboratory space available?'*, *'Are **suitable** written protocols available for all laboratory procedures?'*. Similarly, the *Accreditation Standards and Guidelines for IVF Laboratories* published by the Association of Clinical Embryologists uses phrases such as: *'There should be **adequate** working and circulation space...'* and *'**In general facilities** should meet the prevailing standards **expected** of health care laboratories'* (emphasis added).

6.21 Thus, the checklist questions noted above invite external specialist inspectors to make subjective judgements about the nature of the facilities that they are inspecting rather than objective measurements. ESI 1 remarked that during inspections:

*'...you [an external specialist inspector] are also using what is in your head because it is not defined in terms of you must have precisely this much space, you must have a piece of equipment that works precisely to this level. So you are using a degree of professional judgement about what is appropriate.'*¹³

6.22 Similarly, IC 4 noted that when external specialist inspectors inspected centres the criteria used by them in the evaluation of a centre '*...was taken literally from people's own experience of what was required to [complete] this particular task effectively.*'¹⁴ Likewise ESI 2 remarked, '*I think that, as with any accreditation or inspection process in healthcare, at the moment nearly all of them are subjective.*'¹⁵

6.23 LCM 1 also made a similar point regarding the subjective nature of the inspections of centres when she observed that:

*'...there has never been any set criteria or parameters for what laboratory facilities should be available, so we have never had anything to judge appropriate facilities against. It has always been a matter of the scientific inspector, because it is obviously the inspector whose information we rely on in these cases, making a judgement of the facilities that are there, the equipment that is there. And it does, I am afraid, vary enormously, because it goes back to the way the whole field has evolved and the fact that laboratories had different types of equipment and functioned differently in the early days, and it has been a case of working towards a more standardised procedure.'*¹⁶

Inspection process at centres

6.24 On arrival at a centre the inspection team have a private meeting at which they discuss the documentation provided by the centre, previous inspection reports and licence committee minutes regarding that centre. During this discussion the inspection team identify any issues that appear to require a detailed investigation. Following their preliminary meeting the external specialist inspectors then meet with the Person Responsible and some or all of the centre's staff. The inspection team

then, either together or individually, tour the centre before having a final private meeting to discuss their findings. At some point during the inspection one or more of the inspection team examines a number of sets of patients' notes to determine whether or not statutory consent forms have been completed by the patients and to assess whether or not there is any conflict between the male and female partner's consent forms. The findings of the inspection team are then verbally fed back to the Person Responsible before the team leaves the centre. During the inspection of a centre the inspector co-ordinator takes notes of the proceedings and ensures all relevant issues are recorded.

- 6.25 It should be noted however that patients undergoing treatments are at the time of this review not involved in the inspection process, i.e. the inspection team does not seek the views of assisted conception services patients regarding their treatment experience.

Difficulties associated with the inspection of centres

- 6.26 A number of difficulties associated with the full inspection of centres have been identified during this Review. Perhaps the most important of these is the amount of time that an inspection team has on site. In order to keep travelling and subsistence expenses to a minimum, wherever practicable, a visit to a centre is accomplished in one working day. The second QQR states that this typically results in an inspection team only spending:

*'...3.5 hours on site, with as little as 2 hours spent interviewing and questioning the Person Responsible and other staff, examining procedures, protocols facilities, patient records and so on.'*¹⁷

- 6.27 Regarding this relatively small amount of time available for full inspections ESI 1 stated that:

*'It has been my view that the inspection process cannot fulfil its role on the basis of something being as short as two hours...it was not possible to look at every aspect of the Code of Practice, the [ACE] Accreditation Guidelines, the [HFE] Act within the timescales available for inspections.'*¹⁸

- 6.28 LCM 2 also reinforced this point when noting from her own experience as Chairman of an inspection that, *'You cannot cover everything and we did not have more than half a day or a whole day at the most. But they would cover what they could.'*¹⁹
- 6.29 A second difficulty faced by inspection teams, caused through time constraints, is that they did not observe a centre's staff working. ESI 1 was of the opinion that:

*'I certainly believe that inspections should take longer, I think they [external specialist inspectors] should look at a clinic working. Because when you look at a piece of paper your judgement about how adequate that is, is really irrelevant if it's not actually being followed. Inspections are done in such a way that usually the clinic will stop working in order for an inspection to happen. It has always been my belief that the snapshot [inspection] is not adequate to fulfil the role that is expected of it.'*²⁰

- 6.30 Similarly, the second QQR Team reported that during their visits to centres:

*'In four out of five inspections observed, no routine activities were being undertaken at the centre. This is apparently not an unusual situation... This means that the inspection team often has no means of assessing actual compliance against the centre's written procedures and protocols.'*²¹

- 6.31 Another problem arises because as with members of licence committees, the same external specialist inspectors generally do not assess or inspect the same centre two years in succession and people can have differing views when examining the same issues. For example, LCM 2 highlighted this problem when she noted that:

*'It is just an observation that one of the reasons the recommendations were often not seen to quite carry as much weight as perhaps they ought to have done is... that one [inspection] team would come and recommend something one year... and the next year someone else would come and they would fail to agree.'*²²

6.32 Furthermore, as noted in Chapter 3 there are Members of the Authority and external specialist inspectors that are employed in centres. ESI 1 observed that, ‘*The people who are inspecting in this business [ESIs and the Authority Members] we virtually all know each other.*’²³ While IC 4 stated that, ‘*...it is such a small world [ACS] that you will know everybody.*’²⁴ While it has not been suggested that any member of an inspection team has allowed their judgement of a centre to be consciously affected by a personal relationship it is of concern that Leslie reports that inspector co-ordinators have alleged that:

*‘...on inspections the general practice is to accept uncritically what has been said by the centres or facilities.’*²⁵

6.33 Additionally, on some inspections, particularly in the Home Counties, there have been occasions where a member of the inspection team has worked for a centre that was effectively in competition to the one being inspected. This has been seen as a source of friction and there have been calls, for both Members of the Authority and external scientific inspectors, not to participate in the inspection of centres where there may be a potential conflict of interests.²⁶

6.34 To this end the HFEA request that Members of the Authority and external specialist inspectors make a declaration where they believe a conflict of interest may exist. However, people change employers without informing friends and acquaintances. This raises the possibility that quite inadvertently an external specialist inspector or a Member of the Authority could arrive at a centre to carry out an inspection only to find someone who they know quite well is a member of staff or the Person Responsible.

ICSI inspections

6.35 As noted in Chapter 1 ICSI treatment has to be licensed by the HFEA and such treatment cannot be undertaken unless the HFEA is satisfied about the competence of the practitioner in carrying out this technique. In principle the procedures to arrange and carry out an ICSI inspection are similar to those for any inspection except that in this case an ICSI qualified external specialist inspector carries out the inspection. Following an ICSI inspection the external specialist inspector writes a report and sends it to the inspector co-ordinator associated with the centre where the inspection took place. The inspector co-ordinator in turn then presents the report to a licence committee.

- 6.36 The ICSI inspection consists of an explicit standard test. The practitioner has in the first instance to demonstrate their practical ICSI skills using equipment such as that discussed in Chapter 1. Following this the practitioner is given an oral examination on the theory, difficulties that may be encountered, and the law relating to the provision of ICSI services
- 6.37 Once a practitioner has been approved to practice ICSI, at the end of their first three months of clinical practice they must submit a data return to the HFEA on the work they have carried out during that time. Providing their performance is satisfactory they are then allowed to continue practising ICSI. The HFEA also monitor the effectiveness of ICSI practitioners on an annual basis. Each practitioner is required to submit a summary of the data they have collected during the year relating to their ICSI performance. However, the HFEA do not have any explicit objective measures against which the summary data of practitioners' effectiveness is compared. Therefore, a decision to revoke or suspend a centre's licence in respect of ICSI is again essentially subjective in nature.

Post inspection processes

- 6.38 Following an inspection, either full or interim, the inspector co-ordinator present at the inspection writes the report of the visit. Once completed the draft report is then sent to the Person Responsible of the centre concerned and to all members of the inspection team to check for its accuracy. Once all parties agree that the inspection report accurately reflects the findings of the inspection team the report is then signed by the Chairman. The inspector co-ordinator who attended the inspection subsequently presents the agreed inspection report to a licence committee.

Observations

- 6.39 The administration and inspection processes used by the HFEA and external specialist inspectors are still essentially similar to those developed by the VLA/ILA who did not have a statutory regulatory enforcement role.

- 6.40 External specialist inspectors are typically individuals who work full time in some particular aspect of the work regulated by the HFEA. It is therefore difficult to comprehend how, perhaps with limited time at their disposal, they are able to read and digest up to 1000 pages of information relating to a centre's activities, in some cases only a matter of a few days before the inspection is due to take place.
- 6.41 The evidence also suggests that checklists should have been used by external specialist inspectors when carrying out inspections since their inception in 1991 and presented to licence committees as explicit evidence of their findings. Yet there appears to be a great deal of confusion as to whether this has been the case more recently.
- 6.42 Similarly, the *Manual for Inspectors* is out of date and at the time of this review the Executive does not appear to know whether or not all external specialist inspectors have received a copy of the document. Consequently there may be external specialist inspectors that do not fully understand their role or what is expected of them. Thus, there can be no confidence that all centres have been or are at the time of this review being inspected to a consistent standard as required by the HFE Act and COP.
- 6.43 The checklists that have been developed by the HFEA and the Association of Clinical Embryologists whilst helpful as *aides memoir* are generally subjective in nature. Thus the way they are applied to a centre's activities is left open to the interpretation of the external specialist inspector concerned. Therefore, diverse standards may have been applied by different external specialist inspectors when checklists have been used. Furthermore, patients' views of their treatment have never been included as an inspection item in the checklists that have been produced.
- 6.44 The cost associated with external specialist inspectors travelling to centres to carry out inspections has been a major concern to the HFEA. Therefore, the aim has been to try to keep travelling costs to a minimum. This has resulted in external specialist inspectors on occasions having fewer than four hours on site. As a result there have been occasions when an inspection team has not been able to cover all the issues that they should have done.

- 6.45 Similarly, the shortage of time on site has also in part been responsible for external specialist inspectors not being able to witness a centre's staff carrying out their normal activities. In any case centres tend not to open their clinic on days when there is an HFEA inspection. This means that inspection teams have in general not been able to directly observe whether the personnel at centres comply with their own protocols and procedures.
- 6.46 Because there is no continuity in the external specialist inspectors who inspect a particular centre and inspections are, to a lesser or greater extent, subjective in nature there are occasions in the course of inspections when centres may not receive a consistent message regarding the interpretation of the HFE Act and COP from those who represent the HFEA.
- 6.47 The suggestion that inspection teams appear to accept uncritically what they are told at centres is of concern and this will be revisited in the context of the HFEA's organisational culture in Chapter 7.
- 6.48 The fact that some Members of the Authority and external specialist inspectors work in centres may on occasions create conflicts of interests because of the commercial aspects associated with assisted conception services.²⁷ However, whilst the HFEA has made efforts to minimise such problems conflicts may still occasionally occur.
- 6.49 Whilst the HFEA does collect data to monitor the performance of ICSI practitioners, there are no explicit objective standards that define the points at which an ICSI practitioner will either be subjected to retraining, a suspension or the clinic will have their licence in respect of ICSI revoked.

References

1. LCM 1, transcript, p.70.
2. *Licensing Procedure Handbook*, note 1.07(8).
3. IC 3, transcript, p.117.
4. ESI 1, transcript, p.31.
5. ESI 2, transcript, p.90.

6. Dalziel, M (25 July 2002), letter to Review Panel, p.3.
7. LCM 1, transcript, p.63.
8. IC 1, transcript, p.8.
9. IC 4, transcript, p.10.
10. ESI 1, transcript, p.9.
11. ESI 2, transcript, p.65.
12. LCM 1, transcript 2, p.76.
13. ESI 1, transcript, p.11.
14. IC 4, transcript 2, p.21.
15. ESI 2, transcript, p.103.
16. LCM 1, transcript 2, p.49.
17. *Second QQR*, paragraph, 5.25.
18. ESI 1, transcript, p.57.
19. LCM 2, transcript, p.10.
20. ESI 1, transcript, p.57.
21. *Second QQR*, paragraph, 5.27.
22. LCM 2, transcript, p.30.
23. ESI 1, transcript, p.30.
24. IC 4, transcript, p.28.
25. Leslie, A. (April 2002), paragraph, 74.
26. *Second QQR*, paragraph 8.7.
27. *Second QQR*, paragraph 5.34.7.

Human Fertilisation and Embryology Authority miscellaneous issues

Organisational culture

- 7.1 In a very general sense the concept of culture is widely used in social science and a multiplicity of definitions are available. For present purposes, culture can be regarded as being the collection of beliefs, norms, attitudes, roles and practices of a given group, organization, institution or society. A culture is created and recreated as members of it repeatedly behave in ways which seem to them to be the natural, obvious and unquestionable ways of acting, and as such will serve to construct a particular version of risk, danger, and safety. Waring draws the conclusion from his research that, *'Culture is not a 'thing' but a complex and dynamic property of human activity systems.'*¹
- 7.2 Thus an organisation's culture does not spring into existence overnight as a mature phenomenon. It takes time for the complex sets of individual and collective perceptions to develop and coalesce into a system of commonly shared values.

Development of the HFEA's organisational culture

- 7.3 Within the newly established corporate body in the early 1990s the only practical experience in the inspection and licensing of centres was that possessed by those who had been members of the VLA/ILA. Therefore, it is perhaps not surprising that the new regulatory body, as noted earlier, drew upon the experience of the VLA/ILA when creating its inspection and licensing regime. For as Louis argues:

*'...it seems particularly important for newcomers to have insiders who might serve as sounding boards and guide them to important background information for assigning meaning to events and surprises.'*²

- 7.4 Therefore, it can be argued that one of the unseen influences to be embedded into the fabric of the HFEA's organisational life from the very beginning would have been the ethos of the VLA/ILA, i.e. the use of

persuasion rather than diktat to ensure centres comply with the HFE Act and Code of Practice. Tentative evidence to support this contention is to be found in Ginnings review of the HFEA where he notes that some of those whom he interviewed were of the opinion that an:

‘...informal advisory role can often be more influential in identifying and discussing individual clinical or technical concerns, or in improving treatment practices, than the more formal process of inspection and licensing – which can be seen by centres as confrontational and threatening.’³

Culture of confidentiality

7.5 A second influence on the HFEA’s way of life would have been the culture of confidentiality discussed in Chapter 3. While this discussion was in the context of patient confidentiality and the provisions of section 33 of the HFE Act, this influence appears to have spread to many aspects of the Authority’s work. For example the Second QQR observes that in the context of transparency:

‘There is, however, still a view that decision-making is too secretive and that the Authority needs to be seen to be acting openly.’⁴

7.6 LCM 1 however, was of the opinion that when:

‘...for instance the licence committees pick up that there are difficulties in one clinic that may be applicable to other centres that would be fed back through the inspector co-ordinator...and that would be translated into policy change that would go into the Code of Practice.’⁵

7.7 However, a contrary view was expressed about recent practice by an Interim Regulatory Manager (IRM 1) at the HFEA who stated that in April 2002 she had received an email from an assistant Director that:

‘...referred to the need to maintain ‘Chinese walls’ between the departments at the HFEA. We were instructed that detailed regulatory knowledge in relation to an incident should NOT be disclosed to other departments without prior agreement.’⁶
(Emphasis in the original)

Groupthink

- 7.8 Another influence to affect the HFEA's culture, as discussed in Chapter 3, would be the fact that there are those within the medical profession who appear to be reluctant to publicly criticise their colleagues. Rosenthal reported that during her research into medical negligence a Regional Director of Public Health had observed that, *'Groups of specialists develop a very strong group feeling together, particularly small groups...and this inhibits criticism.'*⁷
- 7.9 Similarly, it was noted in the report of the Bristol Royal Infirmary Inquiry (BRI), chaired by Professor Ian Kennedy, into the management of care for children receiving complex heart surgery that, *'There was an insular 'club' culture, in which it was difficult for anyone to stand out, to press for change or raise questions and concerns.'*⁸
- 7.10 Each of the observations noted above, relating to the behaviour of clinicians in groups, appears to correspond to a social psychological concept known as *Groupthink*.⁹ Groupthink is a socially created dysfunctional mindset that can affect groups when they are seeking agreement on a particular issue. Janis observes that:
- 'The more cohesive the group, the greater the inner compulsion on the part of each member to avoid creating disunity, which inclines him to believe in the soundness of whatever proposals are promoted by the leader or by a majority of the group's members.'*¹⁰
- 7.11 Therefore, in general, victims of Groupthink - in order to preserve unity - tend to engage in self-censorship and do not challenge decisions that the group arrive at, regardless of how flawed these decisions might be. However, where a member of such a group does challenge a decision social pressure will often be explicitly applied in the form of urging the person to remain silent if they cannot reconcile their own views with those of the group.
- 7.12 As observed in Chapter 4 the continuity of personnel within an organisation can be a considerable advantage. However, if Groupthink should inadvertently become established then the longer the members of that group remain together the greater the opportunity for a flawed decision to be made. And thus, if a member is to be considered for appointment to the Authority for a third three-year term this is one of the factors that should be considered by the selection committee.

Evidence of Groupthink

- 7.13 Evidence to suggest that some Members of the Authority may have been unconscious victims of Groupthink is to be found in the internal report by Leslie who stated that:

*'During my time at the Authority situations have arisen where members [of the Authority] have indicated that they are aware of information about a centre but have declined to share this with the regulation team, believing that they have discretion in this area.'*¹¹

- 7.14 Leslie's observations reflects the notion of the club culture as noted in the BRI report where people are seen as either belonging to the group or excluded from it. Clearly where people are not considered to be part of the club then it is highly unlikely that information would be shared with them.

- 7.15 Members of the medical profession however are not the only people who make up the membership of the Authority and licence committees. In fact the majority are lay Members. However, as Allsop and Mulcahy point out: '*...with lay members there is always the possibility of professional capture*'.¹² Professional capture occurs when one group of people take on the values of another group with whom they are in close contact.'

- 7.16 Evidence to support the notion that professional capture and a reluctance to criticise centres may have taken place in the Authority on occasions can be drawn from the review of the HFEA's regulatory functions conducted by Baines. In his review Baines notes that in 70 centres where additional conditions had been imposed by a licence committee, 49 of those centres (70%) either failed to implement the conditions fully or in part but:

*'On no single occasion was a centre's licence suspended or revoked because of its failure to comply but in a tiny proportion of cases a licence was granted for a restricted term.'*¹³

- 7.17 Such a finding suggests that licence committees are reluctant to use the enforcement provisions of the HFE Act, for to do so they would have to be critical of the centre to which they were applied. Moreover, as licence committees have to be unanimous in their decisions relating to the grant of licences, lay Members of the Authority must have consistently agreed with clinical Members not to apply the sanctions that were available to them. Indeed, LCM 3 stated that:

*'I would certainly say there is an element of reluctance to remove licences, put limits on licences...'*¹⁴

7.18 Other evidence to suggest that the Authority may have been reluctant to use all the powers at its disposal is to be found in the *HFEA Members Briefing Notes* where, when discussing the fact that the revocation of a centre's licence is the principal means of the Authority to ensure compliance with the HFE Act and Code of Practice, it is stated that:

*'...HFEA's aim is to ensure that centres provide treatment according to the required standards not to close them down.'*¹⁵

7.19 While this is a good and proper action, it should not be pursued to the extent that it prevents the HFEA from exercising the sanctions available to it where appropriate.

Adverse event reporting system

7.20 There is no explicit provision in the HFE Act for centres to report breaches of the HFE Act or Code of Practice to the HFEA. However, the Code of Practice, Part 2, 2.24, entitled *Maintaining and Improving Standards* does state that, '*Centres should inform the Authority as soon as possible of any breach of the Code of Practice or of any serious problem that has occurred at the centre.*'

7.21 Thus, the COP does not make the reporting of possible breaches of the HFE Act or COP mandatory. The use of the word '*should*' in the COP can be interpreted as giving a person who is aware of a breach of the HFE Act and COP the choice as to whether or not to report their knowledge to the HFEA.

7.22 This point was raised at a licence committee meeting in 1993, the minutes of the meeting recording that:

'It was noted that centres were sometimes unclear as to when to inform the HFEA of problems which had occurred. The Code of Practice Committee had been asked to consider including guidance on this issue in the next revision of the Code of Practice.'

7.23 However, when asked by the Review Panel:

‘To your knowledge were the staff at ACSs provided with explicit instructions as to what the HFEA believed constitutes an adverse event and what actions they should take if such an event occurs?’

IC 3 answered ‘no’.¹⁶ While IC 4 replied,

‘There is not, that I am aware of, anything like the serious untoward incident process you would have in the NHS when something went wrong.’¹⁷

7.24 Similarly, when the Review Panel asked the HFEA Executive in 2002 for details of any adverse events that had occurred over the lifetime of the HFEA, other than those that are the subject of this review, the HFEA replied that they had experienced difficulties in locating adverse events that had been reported and that:

‘The details on licence committee minutes are not as specific or detailed as we would wish. The same is true of previous incident reports and actions taken... We have exhaustively searched for all information we can find. If you require any more detail...we will try to do more detective work...’¹⁸

7.25 There is however conflicting evidence as to the level of detail that was recorded at the time these previous adverse events took place and it is recognised that the archiving system needs to be updated. Thus, the paucity of information regarding adverse events may be as a result of failings in the filing system for as the second QQR observed at the time:

‘...the Authority’s procedure documents are not under an integrated system of document control, designed to ensure, for example, that invalid and obsolete documents are prevented from being available for unintended use whilst those necessary for knowledge preservation are suitably identified.’¹⁹

7.26 However, when questioned regarding whether or not an explicit adverse event reporting system was in place, IC 3 stated: *‘More recently, yes; in the past I do not know.’²⁰* IC 2 noted that: *‘The actual procedure around critical events was brought in later when I was an inspector co-ordinator... There was work on that area, I could not comment on it, I am sorry.’²¹* IC 1 remarked that, *‘Certainly, there is a system currently.’²²*

- 7.27 An interim regulatory manager, who has been employed by the HFEA for several years, however informed the Review Panel that typically it was the staff at the centre where an adverse event had taken place that would carry out the investigation and they would then report their findings back to the HFEA. The inspector co-ordinator associated with a centre that had experienced an adverse event would only carry out an examination of the circumstances surrounding that incident at the next inspection, which could be many months later.
- 7.28 Of the nine adverse events identified by the HFEA Executive, there were no incidents similar to Cases A or B. There were however seven adverse events where patients had received the wrong embryos due to errors in the identification of embryos or patients. In two of those cases the error had been caused through staff not following the written protocol that had been provided. It is of interest to note that in one of the other five adverse events the licence committee varied that centre's licence to include the condition that, '*...a fail-safe protocol should be devised for identifying patients prior to embryo transfer. The protocol must be submitted to the HFEA for approval.*'²³
- 7.29 With regard to the introduction of a fail-safe protocol at that centre a subsequent *Summary Report to Licence Committee of Inspection Visit*, noted that, '*The unit has complied.*'

Witnessing

- 7.30 Following Cases A and B it was decided by the HFEA to introduce compulsory double-checking into the procedures of all centres in the expectation that if an error gets by one person it will be caught by the other. Double-checking is also known as witnessing, as the second person involved witnesses the actions of the first.
- 7.31 However, the British Committee for Standards in Haematology, Blood Transfusion Task Force argue that rather than reducing the possibility of errors by using two members of staff, it may actually increase the risk of errors being made as, '*Two members of staff may rely upon the other to be rigorous, resulting in neither giving the task their full attention.*'²⁴

7.32 Similarly, Linden and Kaplan observe that:

*'Unless carefully configured to prevent it, in a system in which two people are responsible for the same task, neither person is truly responsible. Paradoxically, such safety procedures may provide less, rather than more assurance.'*²⁵

7.33 Moreover, in a study undertaken by Krause *et al* it was reported that only a small benefit was found by requiring a second nurse to verify the medications that were being dispensed. The study, conducted over 46 weeks and 129,234 administered medications observed error rates for the administration of 1,000 medications by two nurses was 2.12, but for one nurse 2.98. However, while there is a statistically significant improvement using two nurses the error rate is still greater than 2.00 per 1,000 doses.²⁶

7.34 Furthermore, at the request of the Review Panel, Murphy²⁷ arranged to have the data discussed in the *Annual Report of the Serious Hazards of Transfusion 2001-2002* (SHOT) analysed for the number of incidents of incorrect blood components that had been transfused where two members of staff had been involved in the checking procedures. Of the 307 incidents reported to SHOT during the period 1996-2001, 238, i.e. 77% of the adverse events involved, at least 2 members of staff carrying out identification checks.

7.35 However, in a study published in 2003 by Turner, Casbard and Murphy into the use of barcode patient identification technology as a means of improving the safety of blood transfusions, it was found that:

*'The baseline audit revealed poor practice, particularly in patient identification. Significant improvements were found in the procedure for the administration of blood following the introduction of barcode patient identification, including an improvement from 11.8 to 100 percent in the correct verbal identification of patients (p £ 0.001)...'*²⁸

7.36 Improvements were also found in a number of other important factors such as the number of patients correctly identified before blood samples were collected and the number of blood samples labelled correctly.

Nominal licensee

7.37 The Nominal Licensee is the person who holds the centre's licence. As noted in Chapter 1 the Person Responsible of a centre does not have to be the licence holder although many are. However, in a Chair's letter²⁹ to the Persons Responsible of centres it was suggested that the senior management of healthcare organisations may be unaware of the financial and operational concerns of the centres even though they are part of their organisation. It was therefore argued that one way to improve communications on such matters would be to have a member of the senior management team appointed as the Nominal Licensee. LCM 1 observed that it could be:

*'...very valuable to have somebody from the Trust aware that a centre may not be operating at the optimum because of resource constraints from the Trust.'*³⁰

7.38 In addition, it was also noted in the Chair's letter that where the Person Responsible is also the licence holder should the Person Responsible have an accident then the only course of action available to the HFEA is to revoke the licence. This is because only the Nominal Licensee can apply to a licence committee to vary the centre's licence in order to designate another individual to be the Person Responsible. Thus, where centres are operating in hospitals or other healthcare settings it could prove to be an advantage by having someone other than the Person Responsible as the Nominal Licensee.

Potential conflicts of interest

7.39 As noted earlier inspector co-ordinators act as both advisors and regulators to the portfolio of centres for which they are responsible. Therefore on the one hand they have to establish a relationship with those centres that is supportive but on the other hand participate in the inspection of those same centres as a dispassionate member of a regulatory inspection team. The situation becomes particularly sensitive during interim inspections when an inspector co-ordinator can be acting as the inspector or Chairman of the inspection team, because as the second QQR concludes, *'This places them in a potentially conflicting position...'*³¹

ACS professional organisations

7.40 As noted earlier, the purpose of the HFEA Code of Practice is to provide centres with guidelines regarding the provision of assisted conception services. The fifth edition of the COP however notes, for the first time, that centres should also refer to relevant professional guidelines as, *‘In some respects these are more far reaching than the HFEA Code of Practice, covering, for example, areas of professional standards and training.’*³²

7.41 LCM 1 emphasised the important of professional guidance when noting:

*‘I think it is very important that the professionals in the particular discipline set standards for procedures because they have expertise and they know what is going to happen in practice...I think it is the role of the professional bodies to set these standards.’*³³

7.42 However, while the HFEA does take informal soundings from the various professional bodies whose members deliver assisted conception services there have been no formal arrangements for those organisations to be consulted on a regular basis and for their advice to be incorporated into the Checklists used by external scientific inspectors as well as into the COP.

HFEA approval of the Person Responsible at a centre

7.43 In the first instance the individual nominated to be the Person Responsible of a centre is assessed for their competence to hold the position by a licence committee inspecting their *curriculum vitae*. There is thus no formal examination of a person’s ability to fulfil satisfactorily all the requirements of that role.

7.44 However, the COP, Part 1.5 states that:

‘The Person Responsible will need to have sufficient insight into the scientific, medical, legal and other aspects of a centre’s work to enable them to supervise its activities properly, but the qualities of integrity, responsibility and managerial capability are more important than any particular professional qualification. The HFEA will expect the Person Responsible to take whatever specialist advice is necessary.’

7.45 Similarly, the MFC section 1, *Treatment Licence Application*, item 3 states:

*‘Person Responsible. This is the person under whose supervision the activities authorised by a licence will be carried out. The Person Responsible need not be a medical practitioner but should have sufficient insight into **all** aspects of the centre’s work.’* (Emphasis in the original)

7.46 When questioned about what areas of knowledge a Person Responsible should possess in order to supervise a centre, IC 2 replied, *‘All of them.’*³⁴ While IC 1 when asked the same question stated, *‘...the Person Responsible should have an intimate knowledge of both the [HFE] Act and Code of Practice in order to fulfil their function appropriately.’*³⁵

7.47 On the other hand, when asked if a Person Responsible should have insight into all the activities under their supervision, LCM 1 held the view that:

*‘You are never going to get any one person who is going to have that level of expertise in all those areas...I think that is why the continuing professional development, which is something we check on during inspections and the liaison with their peer groups...is important...’*³⁶

7.48 IC 4 however observed that:

*‘...by and large Persons Responsible were already in the system, they were people that you knew about...so people that came to it fresh were rare...They always had some background in it...you could say it was a subjective understanding of what the legislation require and what the Code required you to do, but there was no sort of formal [training].’*³⁷

Training of Persons Responsible

7.49 The HFEA provide no training for Persons Responsible apart from an annual one-day conference at which attendance is voluntary.

Embryologist training

- 7.50 The basic training of all embryologists is carried out in-house at centres where assisted conception services are provided. Prior to 1 October 2000 an individual could become a practising embryologist through a number of different routes none of which were compulsory or regulated by the HFEA. After 1 October 2000 anyone wishing to work unsupervised as an embryologist in the NHS or as a contractor to it must be registered as a Clinical Scientist with the Health Professions Council (HPC).
- 7.51 In order to qualify for registration with the HPC a candidate must follow an approved course of study and undertake the requisite amount of supervised work to meet the formal requirements for the award of a *Certificate of Attainment* (COA) by the Association of Clinical Scientists. Once awarded a COA an individual may then proceed to become registered as a Clinical Scientist with the HPC thus meeting the requirements of the NHS to work unsupervised.
- 7.52 One of the routes to qualify for a COA is for a candidate to meet the criteria for the award of an Association of Clinical Embryologists Certificate of Competence, which is accepted by the Association of Clinical Scientists as an approved training scheme.
- 7.53 However, the legislation that created the HPC also contained provision for unregistered professionals, who have not taken an approved course, to apply for admission to the register provided that they meet certain criteria. All those individuals making such an application will be considered for registration *via* the transitional arrangements or grandparenting route.
- 7.54 It should be noted that a practising embryologist working in private practice and who is not involved with any work for the NHS does not at the present time have to register with the HPC.

Risk management

- 7.55 With regard to the HFEA's approach to the management of risk the second QQR reported that, '*The HFEA should prepare, establish and maintain a risk management plan detailing its approach to the risk management process.*'³⁸ However, a DH Internal Audit report on corporate governance within the HFEA notes that in June 2002:

*'The Authority has not yet embedded a formal risk assessment and management policy nor undertaken an exercise to fully identify the nature and extent of the risks facing it.'*³⁹

7.56 The HFEA's Policy and Communications Director⁴⁰ (PCD 1) has also recently reported that an exercise of that nature has yet to take place. Furthermore, the HFEA has at the time of this review no formal self-assessed risk process to identify risks or a register of the major risks that they face and the methods used to control them. PCD 1⁴¹ also observed that neither the HFE Act nor the Code of Practice requires centres to have formal risk management processes in place.

Observations

7.57 The evidence suggests that the organisational culture of the HFEA has been influenced by a number of different philosophies. These include the ethos of persuasion used by the VLA/ILA to influence centres and from which several of its founding Members came. The confidentiality provisions of the HFE Act and the small group structure of licence committees also seem to have helped shape an organisational culture that made the sanctioning of centres a difficult task to accomplish.

7.58 Over time the 'culture of confidentiality' generated by the provisions of the HFE Act appears to have become internalised within the HFEA to such an extent that it has become transformed into a 'culture of secrecy' where, more recently, even their own personnel may not be informed when an adverse event has taken place without prior approval from senior managers.

7.59 There is ambiguity as to whether a centre has to inform the HFEA of adverse events or deal with them as part of their own complaints process and reveal them at the next inspection. Similarly, there is doubt as to whether the procedures used regarding the reporting of adverse events to the HFEA by centres forms an explicit formal reporting and investigation system. However, it should be recognised that it is only recently that the National Patient Safety Agency (NPSA) was formed to collect and analyse data at a national level on adverse events that take place within the NHS.

7.60 The archiving system that holds inspection reports, documents relating to licence committees and the activities surrounding adverse events appears to be less than optimal. The review panel is also uncertain as to the level of detail that was originally recorded on adverse events in the past and the actions that were taken with regard to them.

- 7.61 The evidence illustrates that the misidentification of patients and gametes by staff at centres is not a new phenomenon. However, the HFEA do not appear at the time of this review to have issued any specific advice to centres on how such incidents might be prevented in future even though one of the centres concerned had produced a fail safe protocol to prevent such an event recurring and this had been approved by the HFEA.
- 7.62 Research seeking to evaluate the reduction of human error in the misidentification of patients through the use of witnessing has revealed that this practice is not a complete solution to the problem as such errors continue to occur. Use of the emerging patient identification barcode technology does however appear to offer a way forward.
- 7.63 Many centres providing ACS are located in larger establishments, such as NHS Trusts and private hospitals. The appointment of a member of the Management Board of such an establishment to be the Nominal Licensee of the centre could be of advantage to both the centre and the organisation concerned. But while the senior management team of the establishment may be aware that a centre has resource or staffing problems, this does not mean that the resources to alleviate them will be made available. This will be discussed in Chapter 9.
- 7.64 Because inspector co-ordinators act as both advisors on and enforcers of the HFE Act and COP to the same centres a tension exists between the two roles and hence a potential conflict of interest is created.
- 7.65 While the HFEA considers the professional bodies concerned with scientific and other personnel who deliver assisted conception services are important, there appear to be no formal arrangements for regular consultations to take place or mechanisms for the explicit incorporation of their standards within the COP.
- 7.66 A Person Responsible for a centre is required by the COP to have a sufficient understanding of all the disciplines regarding the provision of assisted conception services in order to be able to supervise all the activities. However, the HFEA do not require a candidate to demonstrate to their satisfaction that the individual possesses such knowledge and skills, e.g. by attending an assessment panel. Rather, a licence committee decides whether to approve an individual to undertake the duties of Person Responsible on the basis of her or his *curriculum vitae*.

- 7.67 There is no training provided by the HFEA or any other organisation to prepare an individual to undertake the role of a Person Responsible. Similarly, there is no compulsory continuing professional development for Persons Responsible in respect of their duties for the HFEA. There is however a one-day annual conference organised by the HFEA at which attendance is voluntary.
- 7.68 Embryologists must be registered with the Health Professions Council if they are to carry out unsupervised work in or on behalf of the NHS. However, they do not need to be registered if they work solely in private practice. Because of the additional training costs involved leading to registration with the HPC, the cost to centres undertaking NHS work is potentially greater than the cost to centres that are solely involved in private practice. This is contrary to one of the central concepts of regulation, which is to ensure that a level playing field is maintained in all matters including the costs of working within a particular industry.⁴²
- 7.69 The HFEA have no formal risk management policies or arrangements for identifying, evaluating, treating and monitoring the risks to their organisation.
- 7.70 Centres are not required by the HFE Act or COP to ensure formal risk management arrangements are in place to assess, manage and monitor that their risk strategies are implemented.

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Chapter 8

Human Fertilisation and Embryology Authority conclusions and recommendations

- 8.1 Patient safety is paramount. Consequently, during the course of the review a dialogue was maintained with the HFEA about emerging conclusions and key recommendations. This was in order to ensure that particular risks identified by the Review Panel were addressed at an early stage rather than at the conclusion of the review. It is therefore important to note that the HFEA has already implemented significant changes in the regulatory process and there is evidence of a changing culture. This change process positively supports the detailed recommendations made by the review panel as set out below.
- 8.2 **It also bears repeating that these conclusions are concerned with the period prior to July 2002 when this review was commissioned.**
- 8.3 The Authority will, of course, be responsible for ensuring that the recommendations are properly implemented and monitored for effectiveness.
- 8.4 The conclusions that I have drawn as Chairman from the evidence presented to the Review Panel with regard to the HFEA's vulnerabilities are noted in plain text, while recommendations are shown in *bold italic*.

The HFEA's organisational culture

- 8.5 Because of its unique history and function the organisational culture of the HFEA has developed in a way that appears to make it difficult for some licence committees to censure centres using the full extent of the regulatory tools available.

Recommendation 1:

The HFEA should retain a panel of solicitors whose individual members can be called upon in rotation to sit with licence committees and advise where the activities of a centre have breached the HFE Act or Code of Practice. In these circumstances the licence committee's legal advisor should draft the terms of the condition or conditions to be applied to the licence.

- 8.6 The way in which the confidentiality provisions of section 33 of the HFE Act have been interpreted over the years has led inadvertently from a culture of confidentiality to a culture of secrecy being developed. This has had a detrimental effect on the ability of the HFEA to discharge its duties in an open and effective way.

Recommendation 2:

The Government should seek to amend the confidentiality provisions found in section 33 of the HFE Act. The amendment must continue to secure the confidentiality of patients seeking assisted conception services and any children resulting from that treatment, but should permit information on assisted conception services to be shared by all those individuals and institutions that have a legitimate reason for requiring access to it.

Recommendation 3

In the interim the Authority should seek legal advice about the limits of the confidentiality requirements in the HFE Act. On the basis of this advice they should then develop a policy on the sharing of information both within the Authority and more widely that is consistent with their regulatory and advisory functions.

Recommendation 4

All inspection reports, adverse event investigations and the minutes of licence committees together with their conclusions, suitably anonymised, should be published on the HFEA website.

Authority Members' selection

- 8.7 The need for new Members of the Authority who can provide expert advice in areas of assisted conception services where it is currently weak, may conflict with the need to select new Members with expertise essential to the regulatory work of licence committees.

Recommendation 5

When making appointments to the Authority, the Secretary of State for Health should ensure that any advice he receives about the future requirements of the Authority takes fully into account all the expertise it requires across all its functions.

Recommendation 6

Within the limits of the HFE Act consideration should be given to the greater use of seeking expert advice externally, including co-opting individuals as necessary to provide the Authority with such advice on specific issues.

Authority Members' training

- 8.8 Although some induction training is provided for new Members to the Authority there is no explicit formally structured programme of induction or continuing professional development that covers the range of topics with which they need to be conversant.

Recommendation 7

A formally structured induction training programme should be implemented as soon as possible to ensure that all new Members of the Authority are appropriately briefed. The induction training programme should include not only the regulatory and legal aspects of the provision of assisted conception services but also an understanding of the structure and organisation of assisted conception service centres with particular regard to skills mix, training, expertise and staffing.

Recommendation 8

A formally structured continuing professional development programme should be implemented as soon as possible to ensure that all Members of the Authority are kept appropriately briefed.

Licence committees

- 8.9 There are no explicit formal protocols for licence committees to use when assessing licence applications from centres wishing to carry out work in the field of assisted conception.

Recommendation 9

Working with the relevant professional bodies the HFEA should develop as a matter of some urgency explicit objective formal protocols that cover all the different aspects of assisted conception services that a licence committee is required to consider when discharging its legal obligations.

- 8.10 Currently the minutes of licence committee meetings do not contain details of the discussion held by members regarding the reasons for awarding or varying the conditions of a centre's licence.

Recommendation 10

The minutes of all licence committee meetings should reflect in detail the discussions held when reviewing a centre's licence.

- 8.11 The use of recommendations instead of conditions does not appear to have persuaded some centres to comply with their obligations under the HFE Act. Additionally, there is confusion amongst the inspector co-ordinators as to whether or not a recommendation can be turned into a condition if a centre does not comply with it.

Recommendation 11

The use of recommendations by licence committees should cease immediately with licensing requirements and breaches of the HFE Act or COP being the subject of specific licence conditions.

Recommendation 12

Where it is believed that a centre is not engaging in best practice a separate letter should be sent by the licence committee concerned advising the centre where improvements could be made. The advice in the letter should be discussed with the centre at the next inspection.

- 8.12 There have been occasions on which some licence committees have not implemented the recommendations made by the external specialist inspectors who carried out the licence inspection. The reasons for taking such action however have not been recorded in the minutes of the meeting.

Recommendation 13

The Review Panel recognises that licence committees are not obliged to follow the recommendations of external scientific inspectors. However, where such a decision is taken the rationale supporting it should be clearly stated in the minutes of the meeting.

- 8.13 There is confusion as to whether all licence committees use the HFEA inspection checklists completed by the external specialist inspectors during their inspection of a centre.

Recommendation 14

The Authority should ensure that licence committees are consistent in their approach to the evaluation of all licence applications.

- 8.14 Inspector co-ordinators have different views as to what follow-up procedure should be used by them to monitor a centre's compliance with the recommendations or variations to a licence that a licence committee has made.

Recommendation 15

An explicit protocol outlining the action to monitor compliance with licence committee instructions should be drawn up and all inspector co-ordinators made aware of this.

- 8.15 Licence committees have on some occasions sat without the appropriate balance of Authority Members' skills and experience.

Recommendation 16

Licence committees should not make decisions regarding licences where they do not have members present with the expertise and experience to cover all the skill areas to be discussed.

Recommendation 17

The area of expertise possessed by each member of a licence committee should be recorded on the minutes of that meeting, for example, clinician, embryologist, counsellor and so on.

Inspector co-ordinator's role

- 8.16 It is not possible for an inspector co-ordinator to fulfil the role specified in the job description provided by the HFEA to this Review Panel.
- 8.17 The current inspector co-ordinator job description does not correspond with the information provided to external specialist inspectors in the *Manual for Inspectors* regarding the role of inspector co-ordinators nor does it accord with the inspector co-ordinators' own understanding of their role.

Recommendation 18

The present inspector co-ordinator job description should be discarded and the role of inspector co-ordinators urgently reviewed. Following the review, a job description should be composed to reflect accurately the role that the Authority requires inspector co-ordinators to undertake. In the interim the role of inspector co-ordinators should be limited to that depicted in the Manual for Inspectors.

- 8.18 At the present time inspector co-ordinators carry out the roles of advisor and regulator to the portfolio of centres that they have been allocated. This creates a potential for a conflict of interest to arise that might inadvertently lead to their judgement being affected.

Recommendation 19

The Authority should consider formally separating the advisory and regulatory roles of inspector co-ordinators, or provide clear explicit guidance about the respective roles so as to avoid conflicts occurring.

Inspector co-ordinator training and assessment

8.19 Prior to joining the HFEA those employed to be inspector co-ordinators typically have no experience of the work carried out in a centre providing assisted conception services. Furthermore, while some form of induction training is provided for inspector co-ordinators they do not follow any explicit formally structured course of induction training or professional development that covers the range of topics with which they need to be familiar.

Recommendation 20

While it is not essential for inspector co-ordinators to have prior experience of assisted conception services, the fact that many do not underlines the importance of formal induction training and continuing development programmes. These should be introduced as a matter of urgency to ensure that inspector co-ordinators have a proper understanding of the law, of regulatory requirements and, where appropriate, relevant scientific and medical issues.

Recommendation 21

The Authority should consider arranging for inspector co-ordinators who have no experience of working in centres to undertake a brief secondment to gain an awareness of the context in which the HFEA regulatory framework is applied.

8.20 Inspector co-ordinators are not formally tested as to their ability to carry out the role before they are allowed to work unsupervised nor are they periodically assessed onsite as to their proficiency in that role.

Recommendation 22

Formal assessments should be introduced to ensure that all inspector co-ordinators meet the standard required by the Authority and continue to do so throughout their career.

Selection of external specialist inspectors

8.21 The HFEA's sole use of *curriculum vitae* to ascertain the suitability of applicants who wish to undertake the role of an external specialist inspector may lead to candidates being appointed who if subjected to a wider range of assessment criteria, could be found unsuitable.

Recommendation 23

The Authority should introduce, in consultation with the appropriate professional bodies, a formal appointment process for external specialist inspectors that reflects the needs of the post and enables selectors to make decisions on the basis of a broad range of data collected with a variety of methods. This should be a rigorous process with assessment going beyond the scientific specialism of the individual to include an understanding of the relevance of issues relating to risk assessment and quality assurance techniques.

External specialist inspectors training and assessment

- 8.22 There is no explicit formally structured induction training or professional development programme for external specialist inspectors that covers the range of topics with which they need to be acquainted.

Recommendation 24

The Authority should develop and introduce, following consultation with the appropriate professional bodies, a formal induction and continuing professional development programme to ensure that external specialist inspectors are competent to carry out the role and are up to date with the latest developments in their respective fields. Attendance at these events should be mandatory to ensure that the inspectorate works as effectively as possible.

- 8.23 External specialist inspectors are not formally tested as to their ability to carry out the role before they are allowed to undertake inspections unsupervised nor are they periodically assessed onsite as to their proficiency in that role.

Recommendation 25

The Authority should develop and introduce, following consultation with the appropriate professional bodies, formal assessments of external specialist inspectors to ensure that they are proficient in their role and are up to date with the latest developments in their respective fields.

- 8.24 Some information provided to external specialist inspectors in the *Manual for Inspectors* is not complete and it is uncertain if all external specialist inspectors have a copy to refer to.

Recommendation 26

A complete review of the information required by an external specialist inspector in order to carry out an effective investigation should be undertaken with some urgency. Once the information requirements of external specialist inspectors have been established all external specialist inspectors should be contacted to ascertain if they are in possession of that information.

- 8.25 A very small number of the external specialist inspectors employed by the HFEA may not possess the entire skill set required to undertake a full inspection in their area of expertise.

Recommendation 27

All external specialist inspectors should undertake the formal induction training recommended above and then be formally assessed as to their competence in the role. There should be periodic assessments to ensure that consistency is maintained.

External specialist inspectors' inspection documentation

- 8.26 External specialist inspectors may receive up to 1,000 pages of information regarding a centre's procedures just one working week or less before an inspection takes place.

Recommendation 28

The Authority should undertake consultation with external specialist inspectors to determine the time they consider is required to familiarise themselves fully with the contents of papers for full and interim inspections.

External specialist inspectors' inspection checklists

- 8.27 There is some confusion as to whether the checklists developed by the HFEA are always completed by all external specialist inspectors when carrying out inspections.

Recommendation 29

It should be a requirement for inspector co-ordinators to ensure that the checklists have been properly completed after each inspection.

- 8.28 The inspection checklists currently in use are generally subjective in nature and thus open to the interpretation of individual external specialist inspectors. This may inadvertently result in different standards being applied to the same assisted conception services' activity.

Recommendation 30

The Authority should develop and introduce, following consultation with the appropriate professional bodies, checklists that contain as many objectively measurable standards as possible.

- 8.29 The views of patients are not a requirement of the current inspection regime and therefore are not canvassed.

Recommendation 31

The Authority should ensure that the views of patients and their experiences are at the heart of the inspection regime. Therefore the practice of centres closing on inspection days should be stopped and inspection teams should set aside time to discuss with patients or their representative(s) matters of importance to them.

Recommendation 32

The discussion with patients or their representative(s) should be made an item on the inspection checklists.

Inspection of centres

- 8.30 The 'lighter touch' regulatory regime introduced by the HFEA and the CALI methodology, developed for selecting centres where the approach would apply, has not been as successful as originally envisaged. Moreover interim inspections (that take place between full inspections) only cover a small portion of the assisted conception services that centres provide and therefore cannot identify the potential risks that a full inspection might.

Recommendation 33

All centres should be subject to a full inspection each year until the HFEA has developed and validated a robust risk based assessment methodology in order to determine those centres which are suitable for a more targeted inspection regime.

- 8.31 The time allowed at a centre is not sufficient for an inspection team to thoroughly inspect a centre.

Recommendation 34

The Authority should, in consultation with external specialist inspectors, review the time required to carry out comprehensive interim and full inspections.

Recommendation 35

The review should take into account the best practice models that have become available since the setting up of the HFEA.

- 8.32 Inspection teams do not have time to observe directly whether a centre's personnel comply with their own protocols and procedures.

Recommendation 36

The Authority should ensure that the time allowed for all inspections is sufficient to allow external specialist inspectors to observe directly a centre's personnel performing their duties.

- 8.33 There are occasions when inconsistent advice is given to centres by external specialist inspectors.

Recommendation 37

The Authority should adopt the recommendations made in this report about formal training and development. This will help ensure that external specialist inspectors use a consistent approach in the application of the HFE Act and Code of Practice to assisted conception services.

- 8.34 Conflicts of interests may arise on occasions between the centre being inspected and external specialist inspectors on the inspection team.

Recommendation 38

The Authority should ensure that all centres are informed well in advance of the external specialist inspectors who will undertake the inspection at their centre and declare whether they believe there is a conflict of interest.

Recommendation 39

The Authority should ensure that all external specialist inspectors are informed well in advance of the names of the personnel at the centre they are to inspect and declare where they believe there is a conflict of interest.

- 8.35 Conflicts of interests may arise on occasions between the centre being inspected and the Member of the Authority chairing the inspection team.

Recommendation 40

The Authority should reconsider the role of Members on inspections and whether they should continue to have a formal role in the inspection of centres.

Code of Practice

- 8.36 The COP does not provide centres with clear unambiguous guidance on the difference between legal compliance and advice on good practice.

Recommendation 41

The Authority should, in consultation with the relevant professional bodies, amend the COP so that it clearly articulates the relationship between the legal requirements of the HFE Act, guidance on compliance with the Act and advice on good practice.

- 8.37 Ambiguity is introduced into the interpretation of the COP because in following the HFE Act some parts of the guidance provided is simply a repeat of the subjective terminology used within the HFE Act.

Recommendation 42

The Authority should consider seeking professional assistance with the rewriting of the COP to make its provisions clear to centres and to the public. The COP should also make clear what the minimum requirements of the Authority are where the Act uses words such as 'suitable'.

- 8.38 The guidance in the COP with regard to centres reporting adverse events to the HFEA can be interpreted as being discretionary rather than mandatory.

Recommendation 43

The COP should make clear the criteria for those events that must be reported to the Authority without delay and those for which immediate reporting is not required.

Recommendation 44

The Authority should also ensure that all centres, whether private or NHS, have protocols in place to deal with adverse events including a clear procedure for reporting within the organisation and to the HFEA where appropriate.

Communication

- 8.39 On occasions there is inconsistency in the provision of advice and information by the HFEA to centres and the public.

Recommendation 45

The Authority should ensure that only nominated members of the Executive who have undertaken and are subject to formally structured programmes of training such as those recommended for inspector co-ordinators provide advice and information to centres and the public.

Adverse events

8.40 The robustness of the HFEA system for ensuring that all the circumstances surrounding an adverse event at a centre are investigated, recorded and the lessons learned disseminated and implemented in all other centres is unclear.

Recommendation 46

The Authority should immediately undertake a review of its adverse event procedures and systems. The review should produce clear guidance as to how an adverse event is to be recorded and investigated and how the lessons learned are to be disseminated by the HFEA. The HFEA should also provide clear guidance as to how the implementation of such guidance is to be monitored.

Prevention of adverse events

8.41 The act of one individual witnessing the actions of another in an attempt to reduce the likelihood of an adverse event occurring is not a complete solution to the problem of misidentification of patients or gametes.

Recommendation 47

The Authority should, in consultation with the relevant professional bodies, seek to develop comprehensive standardised protocols for all stages of assisted conception services treatments in conjunction with a training programme and a protocol monitoring system.

Recommendation 48

The HFEA should introduce 'active' witnessing to centres rather than the 'passive' system currently in use, i.e. each person involved should take an active role in identifying the patients and their gametes by each witness taking it in turn to read out the patient's details and the other person confirming or refuting them.

Recommendation 49

The Authority should, in consultation with the relevant professional bodies, investigate the possible use of Patient Identification Bar Code technology in assisted conception services settings.

Recommendation 50

The Authority should, in consultation with the relevant professional bodies, investigate the possibility of using human reliability techniques to identify the potential for human errors to be made in assisted conception services settings.

Recommendation 51

The Authority should seek to identify and form relationships with institutions that are concerned to investigate and learn from adverse events, such as the National Patient Safety Agency.

Document archive

8.42 There are difficulties in retrieving documents from the HFEA archiving system currently in use and the completeness of some documents is in doubt.

Recommendation 52

The Authority should undertake a review of its document storage and retrieval policy and systems.

Monitoring of ICSI practitioners

8.43 While the HFEA does collect data on ICSI practitioners there is no objective methodology for assessing whether or not a given individual continues to be competent or not, and if the latter whether he or she should be allowed to continue practising or be subjected to retraining.

Recommendation 53

The Authority should, in consultation with the appropriate professional bodies, develop minimum criteria against which an ICSI practitioner's performance can be evaluated for licensing purposes.

Assisted conception services: related professional bodies

8.44 The HFEA does not have an explicit formal programme of consultations with the professional bodies whose members provide assisted conception services.

Recommendation 54

The Authority should introduce a formal programme of consultation with all the appropriate professional bodies to discuss areas of mutual interest and concern.

Risk management

8.45 The HFEA does not have a robust formal risk management system in place.

Recommendation 55

The Authority should ensure that a robust formal risk management system is developed and introduced as soon as possible. The identification and reporting of potential risks to management should be a feature of every member of staff's job description.

Recommendation 56

The Authority should seek to promote a risk aware culture throughout the HFEA.

Oversight of the HFEA

8.46 The DH is the HFEA's sponsor and therefore informal and formal arrangements are in place for reviews of the HFEA's performance to be carried out. These current arrangements failed to identify a number of potential vulnerabilities in the HFEA's regulation and licensing regime.

Recommendation 57

The DH should ensure through its formal liaison with the HFEA that the Authority has established a robust and effective regulation and licensing regime. This should be monitored as part of the accountability arrangements between the Department and the Authority and in the course of other reviews such as the five-yearly review of the Authority's functions.

8.47 The composition of the HFEA QQR inspection teams to date may not have been the optimum for this particular NDPB, given the vulnerabilities exposed by this review.

Recommendation 58

The DH should reassess the composition of inspection teams that carry out reviews of the HFEA's functions.

Resources

8.48 The demand for assisted conception services continues to rise and as a result so do the demands placed upon the HFEA's resources.

Recommendation 59

While recognising the considerable pressures on public funding, particularly in the health sphere, if the HFEA's regulatory function is to work effectively - as required by Parliament and the Department of Health and expected by patients and the public alike – then it must be funded properly. Such funding must be based on a sound business case complying fully with the necessary Government requirements and must represent value for money.

Recommendation 60

The Department and the Authority should review funding at least annually, based on the Authority's business and corporate plans, to ensure that the Authority's requirements are fully considered in the light of developments in assisted conception services themselves as well as in risk management procedures.

Centres

- 8.49 There is no explicit formally structured programme of induction training or professional development for Persons Responsible that covers the range of topics of which they need to be aware.

Recommendation 61

The Authority should develop and introduce, following consultation with the appropriate professional bodies, a formal induction and continuing professional development programme to ensure that Persons Responsible are competent to carry out the role and are up to date with the latest developments in assisted conception services. Attendance at these events should be mandatory to ensure that centres work as effectively as possible.

- 8.50 Persons Responsible are not formally assessed as to their ability to carry out the role before being allowed to provide assisted conception services to patients.

Recommendation 62

The Authority should develop and introduce, following consultation with the appropriate professional bodies, formal assessments of Persons Responsible to ensure that they are proficient in their role and are up to date with the latest developments in their respective fields.

- 8.51 A centre may be isolated from the senior management of the organisation to which it belongs and this can lead to financial and other decisions being made about assisted conception services by remote management.

Recommendation 63

The Authority should consider making it a condition of granting a licence that a member of the senior management team of the organisation concerned be nominated as the Nominal Licensee or is otherwise closely engaged in the work or management of the centre.

- 8.52 The HFEA does not at present require centres to have a robust risk management system in place.

Recommendation 64

The Authority should require all centres to have a robust risk management system in place. The identification and reporting of potential risks to Persons Responsible in centres should be a feature of every member of staff's job description.

Recommendation 65

The Authority should seek to promote a risk aware culture throughout all centres.

8.53 At the present time embryologists who are employed solely in private practice can work unsupervised without being state registered with the Health Professions Council.

Recommendation 66

The Authority should require all embryologists who work unsupervised in either the NHS or private practice to be state registered with the Health Professions Council as Clinical Scientists (Embryology). Embryologists who are not registered should be allowed to practise only when supervised by a state-registered embryologist.

Chapter 9

Overview of the centres at Leeds General Infirmary and St James's University Hospital

- 9.1 When reviewing the circumstances that surround the adverse events that have occurred at Leeds General Infirmary (LGI) and St James's University Hospital (SJH), which are described later in this report, the reader should keep in mind the backdrop to those events as described in this chapter.
- 9.2 As mentioned previously in the Report, the reader should also remember that this review commenced in July 2002. Thus the evidence provided and conclusions drawn relate to the period prior to that date.
- 9.3 Originally, assisted conception services were provided at LGI and SJH as two completely independent centres. However, when The Leeds Teaching Hospitals NHS Trust was formed through the General Infirmary at Leeds and St. James's University Hospital being merged, while the two centres physically remained at their own locations they were brought into the same management structure. Following the formation of the Trust, it was believed by the Persons Responsible in charge of the two centres that the assisted conception services they provided would be brought together to form a much larger single centre providing assisted conception services. However, the physical merger of the two centres has not taken place at the time of writing this report.
- 9.4 The reason for this is because the two centres are not self-governing autonomous bodies and do not control their own capital expenditure. Consequently when substantial financial capital was required to fund the project to merge the two centres a business case had to be put to the Management Board of the Trust. However, as there were other medical services at the Trust that the Management Board considered to have a higher priority, funds were not allocated to the project.

Laboratory facilities at LGI centre

- 9.5 The centre at LGI has built its clinical expertise in the various assisted conception services techniques over the years, and as its expertise has grown so has the numbers of patients that it has been able to treat.

Thus, the premises that were originally occupied by the centre eventually became too small and the centre was relocated into accommodation more appropriate for the patient numbers being treated at that time. However, the number of patients at the centre continued to grow and so, once again, those who provided assisted conception services found themselves in cramped and fragmented accommodation.

- 9.6 Indeed, the reports submitted by HFEA inspection teams drew to the attention of licence committees that:

'The laboratory facilities [at the centre] were extremely small in relation to the equipment contained within the laboratories and the number of personnel working in the facility.'

- 9.7 Furthermore, the HFEA inspection teams also recorded in their reports that the Person Responsible of the LGI centre had told them that by making such a recommendation in their reports that, '...[the] documentation would then provide supporting evidence for him in his discussions with the Trust...' to proceed with the merger of the two centres.

- 9.8 The reason the Person Responsible had requested that the HFEA inspection team make the improvements to the centre's facilities a condition of the licence was because over the years he had put several business plans to the Trust's management board but his requests, so he informed the Review Panel, *'fell on deaf ears.'*¹

- 9.9 However, while the inspection teams raised the issue of the centre's cramped facilities on two separate occasions with licence committees, the improvements to the facilities were not made a condition of the centre retaining its licence.

- 9.10 When asked by the Review Panel as to why licence committees had not granted the Person Responsible's request for improvements to the centre facilities to be made a condition of the licence being renewed, LCM 2 replied:

*'...I would say that we were justified in not putting a condition on this licence [LGI] because we were not told that patient safety is being compromised...'*²

- 9.11 Furthermore LCM 2 also thought that the decision of the licence committees not to insist on improvements being made to the centre was because:

*'...the whole context of that merger was informing the licence committee decision. If that merger had not been promised, it would have been a very different story.'*³

9.12 Similarly, when asked why the request by the Person Responsible to make the improvements to the centre a condition of the licence being granted, LCM 1 stated:

*'...there had never been any suggestion that the laboratory facilities were entirely unsuitable to clinical practice or unsafe; it was a reference to the fact that they were not ideal in terms of space...the unit was functioning well, the staff had not indicated that there were difficulties or there were any problems for them, and on the basis of this merger that was expected quite quickly, we would have considered it appropriate to continue to bring it to their attention, referring to the Code of Practice, that this should be addressed.'*⁴

9.13 In the event, the Trust's Management Board did eventually agree to fund the improvements called for and architects were called in to draw up plans. The project was abandoned however when the Trust's management committee decided that another clinical speciality required as a priority the space that had been allocated to the centre. This is perhaps an example of the concern voiced earlier by Dame Mary Donaldson when, as Chairman of the VLA, she wrote in her Foreword to the fourth annual report that the VLA were concerned that, *'...Health Authorities with limited budgets will give infertility services little if any priority.'*⁵

9.14 Indeed, a member of the Senior Management Team (SMT 1) at the Trust, when giving evidence to the Review Panel, remarked that over the previous four years the Trust was in a position, *'...where [we] had a huge number of competing demands on what capital [we] had [available]...'*⁶

9.15 Later SMT 1 stated that:

*'I suppose if you said to me...would I rather sort out people waiting with open wounds or sort out laboratory space in the RMU [Reproductive Medicine Unit] I think I would go for the open wounds frankly...I think it is that sort of thinking which has driven the [Trust] board to devote what little capital it had at its disposal to other areas.'*⁷

9.16 Such sentiments however are not unusual as Lee and Morgan demonstrate when quoting the views of Marsden Wagner of the World Health Organisation European Office and Patricia St Clair from the Department of Health at the University of Washington:

‘No country can afford to transplant every failing heart, dialyse every failing kidney, or offer [IVF] to every infertile woman. If money is spent on [IVF], then some other service cannot be funded...’⁸

9.17 Later, Wagner and St Clair when again making their argument regarding the allocation of public funds observed, *‘The inability to conceive a child may be emotionally traumatic but it is not a threat to health...’⁹*

9.18 Similar sentiments regarding the allocation of resources have also been expressed recently in the media following the publication of the National Institute for Clinical Excellence (NICE) recommendation that IVF treatments should be made more widely available on the NHS.¹⁰

9.19 However, the Person Responsible at LGI suggested that the centre was not a drain on the Trust’s budget as it had contracts with a number of Health Authorities as well as fee-paying patients. In fact, the Person Responsible stated that the centre had generated:

‘...about £1.2 million per year in extra revenue because we are bringing in non-NHS income into the Trust. This is new monies. It is not tied into contracts.’¹¹

Robustness of protocols and procedures at LGI

9.20 As noted in Chapter 7, it was suggested that the Person Responsible of a centre should have sufficient knowledge to supervise all aspects of a centre’s work. However the Person Responsible at LGI centre remarked that:

‘...as a practising clinician who has never worked in a laboratory, I do not know everything about a laboratory...I have left the laboratory staff, who are well versed in laboratory practice, to develop the laboratory protocols and procedures.’¹²

9.21 Furthermore, in order to comply with the provisions of the HFE Act, the Person Responsible employed staff to lead the embryology team whom he knew to be qualified, experienced and highly regarded within their field of expertise. For example, when the ICSI technique became available the Person Responsible at LGI identified a person within the centre to lead that speciality who was then enrolled on the most authoritative ICSI scientific training course of the day. After successfully completing the ICSI training course that person returned to the centre and using her experience and the documentation from the course, developed the centre's own ICSI Laboratory protocols.

9.22 The Person Responsible also commented that:

*'...I have an embryologist who has prepared protocols which have been passed every year for nine to ten years by the HFEA as being protocols that they are happy with and, therefore, they have been reviewed by peers, scientific peers, and therefore who am I to criticise that they are not adequate.'*¹³

9.23 Moreover the Person Responsible, who is also employed by the HFEA as an external specialist inspector, said:

*'...having looked at other people's protocols, they are no different to ours. In other words, our protocols must be at least as good as everybody else's.'*¹⁴

9.24 Furthermore, when the Review Panel asked inspector co-ordinators, external specialist inspectors and licence committee Members about their understanding of the safety and performance of a centre when its licence to operate is renewed, they responded that they were of the opinion that, where a centre's licence is renewed, it would meet the same operating standard as other centres.

9.25 LCM 2 was of the opinion that:

*'This [LGI centre] is a clinic with good success rates; it is a clinic with a good reputation at the time, in fact an international reputation. It is a compliant clinic...'*¹⁵

9.26 The actual protocols that relate to the adverse events that have taken place at the LGI centre will be discussed below as part of the review of those particular incidents.

LGI nominal licensee

9.27 While the centre did have a Nominal Licensee who was not the Person Responsible as recommended by the HFEA that person was not a member of the Trust's Board.

Laboratory facilities at SJH

9.28 The development of the centre at SJH is similar to that described above in relation to LGI. From modest beginnings SJH has built up its expertise and grown in both size and patient numbers. Like LGI it has developed over the years and although remodelled some years ago is once again housed in cramped and fragmented quarters. A second phase of redevelopment was planned to take place but, as noted above, the LGI and SJH hospitals merged into the one Trust and the development plans for the centre at SJH were shelved in favour of creating a larger unified facility.

9.29 Additionally, the Person Responsible at SJH noted that, '*...administrative support from the Trust has been very poor, at times extremely low.*'¹⁶

9.30 For example, the Person Responsible at SJH remarked:

*'There have been long gaps when the jobs [administrative posts in the centre] have been left unfilled because the Trust has [for] various reasons, management reasons, the cost is one, if you leave the job empty you save money. There are still jobs unfilled and then sometimes they are filled with temporary staff who do not really know what they have to do.'*¹⁷

9.31 The Person Responsible of SJH, like that of LGI, was of the opinion that the centre was not a drain on Trust funds in that:

*'...we [SJH] bring in quite significant income to the Trust and we are self supporting in our own expenses, yet in terms of space requirements our needs are not being quite as easily fulfilled.'*¹⁸

Robustness of protocols and procedures at SJH

9.32 The quality of the protocols and procedures developed at the centre are reflected in the minutes of a licence committee meeting that took place a few months before the adverse event:

‘The licence committee [LC] commended the laboratory protocol and the counselling service... The committee agreed to grant a 3 year licence...’

9.33 It should also be noted that the centre has had its own witnessing programme in place for the last six years. The actual protocols that relate to the adverse event that took place at SJH will be discussed in the review of Case C.

SJH nominal licensee

9.34 The centre had a Nominal Licensee who was not the Person Responsible as recommended by the HFEA. However that person was not a member of the Trust’s senior management team.

Observations

9.35 While the expected merger between LGI and SJH centres had not taken place at the time of writing this report and it is acknowledged that the working conditions in both centres are not ideal, there is no direct evidence that they were the root cause of any of the adverse events that are the subject of this Review.

9.36 The reason that a single centre has not been created at the Trust is because other clinical specialities are considered to have a higher priority for the resources available by the Trust’s Management Board.

9.37 The licence committees did not make the improvements to the centre a condition of the licence because they had been told that the merger of the two centres would be taking place soon and such improvements would be addressed at that point. Additionally, there was no evidence to suggest that patient safety or any other aspect of the assisted conception services provided by the centre were being compromised by the cramped conditions.

- 9.38 Neither centre has a Nominal Licensee who is a member of the Trust's senior management team. However, both centres generate income from the assisted conception services that they provide and this forms part of the Trust's revenue. The centres do not however have any direct input to discussions about the Trust's financial plans.
- 9.39 In Chapter 7, LCM1 observed, in relation to the knowledge a Person Responsible is supposed to possess regarding the different disciplines at work in a centre that, '*You are never going to get any one person who is going to have that level of expertise in all those areas.*'¹⁹
- 9.40 However, others took the view that a Person Responsible should be knowledgeable in all of them. The Person Responsible of LGI pointed out that the embryologists that have been and are currently employed at the LGI centre have far more knowledge in that area than he. Consequently it is they who wrote the protocols for use in the embryology laboratory.
- 9.41 Sections 17(d) and (e) of the HFE Act state that Persons Responsible must secure '*...that suitable practices are used in the course of the activities, and that the conditions of the licence are complied with.*' However, this appears to impose a considerable burden on the Person Responsible, who cannot possess all the necessary expertise as those he employs. It is unlikely therefore that without further guidance the Person Responsible could know the requirements for fulfilling the condition of section 17.
- 9.42 The Person Responsible of the LGI centre had no reason to think that there were any problems in the embryology laboratory until he received a written warning from the lead embryologist (LE) about pressures of work before the incident involving Case B occurred. This is discussed in Chapter 11. Indeed successive licence committees had consistently renewed the centre's licences without conditions being appended to them and an extended licence had been granted.
- 9.43 Similarly, the Person Responsible at SJH had no sign that there were any weaknesses in the procedures used in the centre until the adverse event occurred. Again, their procedures had been commended by the last licence committee on their thoroughness.

Conclusions and recommendations

- 9.44 The conclusions that I have drawn as Chairman from the evidence presented to the Review Panel are noted below in plain text, while recommendations are shown in ***bold italic***.

9.45 The licence committee reviewing the licences at both centres did not make improvements to the centres' facilities a condition of their licences being renewed. This was because while they were not optimal they had not been judged unsafe by any inspection team. Additionally, the licence committee were under the impression that the merging of the two centres was imminent and that the new single centre would address such issues. However, the two centres, at the time of writing, have not merged and therefore the facilities remain in a sub-optimal condition.

Recommendation 67

The HFEA should inspect both centres to ascertain if the facilities at the two centres are in breach of the HFE Act and COP.

9.46 Neither centre has representation at Board level or a Nominal Licensee who is a member of the Trust's senior management team. However, both centres appear to contribute substantial income to the Trust's revenue.

Recommendation 68

The Trust should nominate a member or members of the Trust's senior management team to be Nominal Licensee(s). Both centres will then have representation on the Trust's Executive Board.

9.47 There is confusion about the breadth and depth of knowledge that a Person Responsible should have across the range of specialities found in centres in order for her or him to comply with their legal obligations under the HFE Act.

Recommendation 69

As set out in recommendations 61 and 62 the Authority should, following consultation with the appropriate professional bodies, provide clear guidance on how section 17(1), of the HFE Act should be interpreted with regard to the discharge of a Person Responsible's duties.

9.48 Other than a letter warning about the pressure of work in the embryology laboratory at LGI just days before the incident involving Case B, neither centre's Person Responsible had any indication to think that the operational procedures used in their individual centres were anything other than highly robust.

Recommendation 70

The centres should develop and implement a robust risk management system at the earliest opportunity.

Recommendation 71

As part of establishing a robust risk management system all those who work in the two centres should actively and continually seek to identify where there may be potential weaknesses in their operating protocols and procedures. The active identification and reporting of potential risks to Persons Responsible in the centres should be a feature of every member of staff's job description.

Recommendation 72

The Person Responsible and senior management should seek to promote a risk aware culture throughout the centre.

Recommendation 73

As set out in recommendation 64, the Authority should require all centres to have a robust risk management system in place. The identification and reporting of potential risks to Persons Responsible in centres should be a feature of every member of staff's job description.

Recommendation 74

As set out in recommendation 65, the Authority should seek to promote a risk aware culture throughout all centres.

- 9.49 As noted previously patient safety is paramount. Consequently, during the course of the review a dialogue was maintained with the centre, the Trust's senior management and the HFEA about emerging conclusions and key recommendations. It is therefore important to note that as a result the recommendations above have, where possible, been implemented as the Review has progressed.
- 9.50 The centre, the Trust and, where appropriate, the HFEA will, of course, be responsible for ensuring that all the recommendations are properly implemented and monitored for effectiveness.

References

1. PR, LGI, transcript, p.115.
2. LCM 2, transcript, p.8.
3. LCM 2, transcript, p.20.
4. LCM 1, transcript, p.48.
5. Donaldson, Dame M, (1989) *The Fourth Report of the Voluntary Licensing Authority for Human in vitro Fertilisation and Embryology*, p.2.
6. SMT 1, transcript, p.9.
7. SMT 1, transcript, p.12.
8. Morgan, D. and R.G. Lee (1991) p.121.
9. Ibid, p.122.
10. *Financial Times* (27 August 2003)
11. PR, LGI, transcript, p.225.
12. PR, LGI, transcript, p.217.
13. PR, LGI, transcript, p.218.
14. PR, LGI, transcript, p.218.
15. LCM 2, transcript, p.8.
16. PR, SJH, transcript, p. 63.
17. PR, SJH, transcript, p.64.
18. PR, SJH, transcript, 65.
19. LCM 1, transcript, p.60.

Case A – The Centre at Leeds General Infirmary

Terms of reference

10.1 To investigate the circumstances leading up to the fertilisation and implantation of embryos fertilised during the intracytoplasmic sperm injection procedure using sperm belonging to someone other than the husband.

Introduction

10.2 As noted in Chapter 1, following successful assisted conception treatment, twins were born to a Caucasian couple. Shortly after the birth the parents became concerned that the children possessed physical features that did not match their own genetic background. Subsequent genetic testing revealed that while the female partner was the children's biological mother the male partner was not their biological father.

Witnesses

- Mr and Mrs A's Consultant
- Person Responsible for the centre.
- Lead Embryologist at the centre.
- Embryologist who prepared all semen samples on the day of the adverse event.
- Two ICSI laboratory embryologists who carried out all the ICSI procedures on the day of the adverse event.
- Inspector co-ordinators who attended the inspections carried out at the centre.

- Embryology external specialist inspector who attended the inspections carried at the centre.
- Members of the licence committee who reviewed the centre's licences.

Reliability of evidence

10.3 It was some time after the ICSI treatment took place before questions were raised about the possibility of an adverse event having occurred. Thus, it is perhaps not surprising that when questioned the clinical staff involved in the treatment of patients on that day had no recollections regarding the specific events that took place. Similarly, the inspector co-ordinators', external specialist inspectors' and licence committee Members' memories of the inspections and of the licence committee meetings that took place were also vague. Thus, the verbal evidence provided by the witnesses is for the most part, generic and based upon indistinct memories of what they believed occurred at that time.

10.4 For example, the evidence provided by the embryologist (E 2) who worked in the Sperm Treatment Laboratory regarding the gender of the name that would always be written on a test tube containing sperm, conflicted with that given by the two ICSI laboratory embryologists who were also present on the day of the adverse event. The Sperm Treatment Laboratory embryologist was convinced that the name written on the test tube containing sperm was always that of the male partner. On the other hand, the two ICSI laboratory embryologists who gave evidence were equally convinced that it was the surname of the female patient.

10.5 However, when later asked about these conflicting accounts E 2 wrote to the Review Panel stating that:

*'Labelling of samples is something we would not have done differently as it would have caused problems and hence I do believe that we all followed the same labelling, i.e. if it was decided to use the woman's name for this purpose we all did.'*¹

10.6 Thus the evidence suggests that the only reliable information available to the Review Panel relating to the circumstances surrounding the adverse event has been that obtained from the patient's confidential medical records and other documentary sources.

Background to the adverse event

- 10.7 In keeping with the confidentiality provisions of the HFE Act the couple who had two children as a result of the adverse event will be referred to as Mr and Mrs A and the couple, the male partner of which has now been established, through genetic testing, as the biological father of Mrs A's children as Mr and Mrs B.
- 10.8 Mr and Mrs A had elected to receive infertility treatment provided by the LGI centre located at the Trust. Subsequently, Mrs A gave birth to twins and as the babies were premature, they required treatment on the special baby unit. During this time, it was observed that the children had a number of physical features that were inconsistent with the genetic characteristics of their parents. However, at the time of the children's birth the consultant responsible for Mr and Mrs A's infertility treatment reassured the parents that a mix up in the IVF-ICSI procedure was unlikely.
- 10.9 This was because, upon hearing the parents concerns about the physical characteristics of their children, Mr and Mrs A's consultant had requested that the staff at the centre check their records to see if there had any been any patients treated on the same day as Mr and Mrs A whose ethnic origin might reveal that an error had been made. At the time, no record of any such patients was found. Thus, provided with an assurance that all was well, although the children's skin colour was darker than expected, Mr and Mrs A declined the DNA testing that the Trust offered to provide.
- 10.10 It should be noted that there are children born with features that do not immediately resemble the genetic makeup of their parents but such characteristics gradually fade away. As time passed however, the Medical Director of the Trust where Mr and Mrs A had received their infertility treatment was informed that Mr and Mrs A were concerned that the expected changes to their children's features had not yet materialised. The couple stated to their consultant that they dearly loved their children and intended to bring them up as such. However, they felt it was necessary to know the genetic origin of the children particularly if an error had been made so that they could advise the children in the future. Consequently, Mr and Mrs A agreed to undertake genetic testing where it was discovered that while Mrs A is the biological mother of the children to whom she gave birth, her husband Mr A, is not the biological father.

10.11 It subsequently came to light that on the afternoon that Mr and Mrs A underwent treatment using the ICSI technique another couple, Mr and Mrs B, who are of a different ethnic origin, also had this same treatment. Mr B's genetic characteristics appeared to resemble more closely those of the children born to Mr and Mrs A and thus there was evidence to suggest that Mr B could be the biological father of Mrs A's children and, as noted above, this has proved to be the case.

Adverse event chronology

10.12 The general sequence of events for an IVF-ICSI procedure in the LGI centre is as follows. On the day of his female partner's egg retrieval the male partner is taken to the Sperm Production Room where he produces a semen sample via masturbation. The sample is produced into a sterile non-toxic container that is then sealed with a lid and labelled with the name of the female patient. The container is then placed and sealed in an envelope that displays details identifying the man and his partner on the outside (Plate 3).

10.13 The sealed envelope containing the semen sample is then taken by him and left in an unlocked semen sample collection box attached to the door of the Sperm Treatment Room. This procedure had been adopted so that the embryologist working in the laboratory would not be distracted by patients constantly knocking on the door to hand in their samples of semen. The embryologist carrying out the sperm preparation collects the samples of semen left there by patients at frequent intervals, as dictated by their level of activity.

10.14 On the day of the adverse event Mr A and Mr B following the pattern described above, were taken at slightly different times to the Sperm Production Room and asked to produce a sample of semen. Once the sample had been produced, the semen container and envelope would have been taken by them and placed in the unlocked collection box outside the Sperm Treatment Laboratory. The documentation seen by Dr Gearon shows that Mr A produced his semen sample 32 minutes before that of Mr B.

10.15 It should also be noted that on the day in question 18 patients in total attended the LGI centre. Records for the day show that nine semen samples were processed in the Routine Semen Analysis Laboratory. The remaining nine samples went to the Sperm Treatment Laboratory so that they could be prepared for use later that day. Therefore, as well as Mr A's and Mr B's semen, there were seven other samples in the Sperm Treatment Laboratory that day.

- 10.16 Once in the Sperm Treatment Laboratory the process of preparing the sperm samples would have begun. There are a number of slightly different preparation techniques that could have been used. However, the point to note with regard to these procedures is that there are several points where the sample of sperm is transferred from one test tube to another.
- 10.17 The centre had two sets of written protocols in force at the time of the adverse event. One set of protocols was entitled *Assisted Conception Unit Laboratory Protocols* and the other *Laboratory Manual for Intracytoplasmic Sperm Injection*. In the latter manual, there are no explicit instructions as to what identifying checks or labelling procedures an embryologist should make while working in the Sperm Treatment Laboratory or the ICSI Laboratory.
- 10.18 However, the instructions in the *Assisted Conception Unit Laboratory Protocols* in the section entitled *Sperm Preparation – Day of Egg Collection* do instruct the embryologist while carrying out one of the processes to ‘*Label CLEARLY with the patient’s name.*’ Once again, however, there are no explicit instructions in the protocol as to what identifying checks or labelling procedures should be completed while the embryologist is carrying out the various task associated with the preparation of a sample of sperm. Nor is it made explicit which name should go on the containers.
- 10.19 Thus, all the embryologists in the centre when working in the Sperm Treatment Laboratory used an informal protocol. However, IC 1 who had been part of the inspection teams reviewing the centre was of the opinion that, ‘*There should actually be no unwritten protocols procedures...*’² but clearly there was.
- 10.20 The procedure adopted at the centre was to use a chinagraph pencil to write the surname of the female patient on the test tube containing the male partner’s sperm. This form of labelling was undertaken so that when the eggs of a female patient were taken to the ICSI Laboratory the name on the dish containing her eggs and the name on the sperm sample to be used in the injection procedure would be identical.
- 10.21 When engaged in processing a sample of sperm the embryologist should check the name of the person written on the test tube by holding the sperm sample against the name written on the test tube that is going to receive the sample of sperm. Thus, in theory - when people are taking great care - sperm samples should not mistakenly be put in a test tube with a different name written on it.

10.22 The evidence presented at the Review, both documentary and oral, suggests that Mr A and Mr B's semen samples could have been in the Sperm Treatment Laboratory and processed simultaneously at some point during the preparation process. Patient documentation also suggests that of the nine patients whose semen was processed in the Sperm Treatment Laboratory on that day five were Caucasian and the ethnic origin of four was not known.

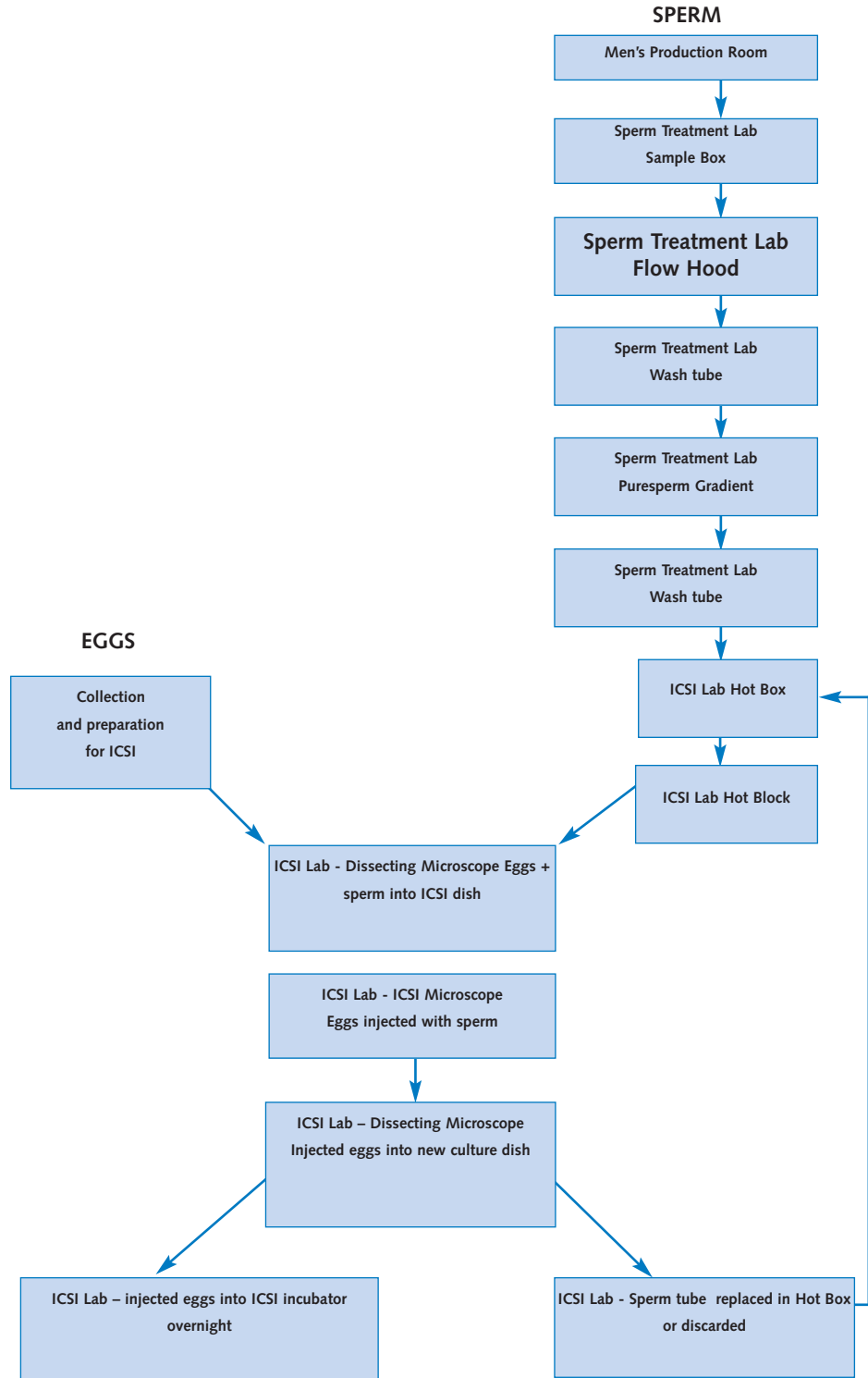
ICSI process

10.23 Once the sperm samples had been prepared, they would have been taken from the Sperm Treatment Laboratory to the ICSI Laboratory and put in a device known as a Hot Box (Plate 8). This procedure is to ensure that the sperm samples are kept in a temperature-controlled environment. When a particular sperm sample is required for the ICSI process the sample is removed from the Hot Box. The name written on the test tube (Plate 9) holding the sample of sperm is then checked against that couple's medical documentation after which the sperm sample is put into a device known as a Hot Block (Plate 10) to regulate the temperature of the sperm while it is out of the Hot Box.

10.24 The name on the sperm sample test tube should then be checked against the name on the label of the dish containing his partner's prepared eggs (Plate 2) that have been brought from the ICSI incubator (Plate 5). Once those checks have been completed, the female partner's eggs are then placed into a working dish under a Dissecting Microscope (Plate 1) and the male partner's sperm is added to the dish. The test tube containing the sperm would then be replaced in the Hot Block until the eggs had been injected using an ICSI Microscope (Plate 4).

10.25 After all the eggs have been injected, they are transferred using the Dissecting Microscope (Plate 1) into a new culture dish that has been pre-labelled with the female patient's surname. The number of eggs injected is then recorded on the lid of the dish, after which it would have been replaced in the ICSI incubator and left overnight for fertilisation to take place. At this point in the process, the sperm sample was either discarded or put back in the Hot Box. However, neither of the witnesses who worked in the ICSI Laboratory could recall what the precise procedure was at that time. The flow diagram in Figure 4 illustrates this part of the procedure.

Figure 4: Flow chart - ICSI process at time of adverse event



- 10.26 Of the nine sperm samples prepared for use in the Sperm treatment Laboratory on the day of the adverse event, five were subsequently used in the ICSI process. An examination of these five patients' confidential medical notes revealed that three were Caucasian and the ethnic origin of the other two was unknown.

Potential errors in sperm treatment laboratory

- 10.27 Human beings are fallible and during the sperm preparation process used at the time sperm was moved from one container to another on three occasions. Firstly, from the semen sample container into a test tube so that the sperm can be centrifuged and washed, a second time to be centrifuged on 'Puresperm' density gradient and a third time for a second centrifugal wash to be carried out. Each time the sperm sample is moved from one test tube to another there is an opportunity for an error to be made, particularly when, as on the day of the adverse event, the sperm samples of nine patients were present in the Sperm Treatment Laboratory.
- 10.28 However, for an error during a transfer to go unnoticed two separate errors have to be made. The first error is that Mr A's sperm sample would have to be placed in a test tube intended for one of the other samples. The second involves a reciprocal error, i.e. the sample displaced by Mr A's sperm would have to be put into Mr A's test tube. Although such a mistake is unlikely, there is a chance of it occurring. Furthermore, once such a double error has occurred there are no further safeguards in place to prevent the sperm being injected into the wrong eggs.

Potential errors in the ICSI process

- 10.29 If the embryologist carrying out the ICSI process misread the name on one of the five test tubes containing a sperm sample this could have led to the sperm from that test tube being erroneously injected into the eggs of Mrs A. Replacing the test tube in the Hot Box would compound such an error. This is because by placing the test tube back in the Hot Box, the sperm would still be available to inject the eggs that the sample was originally intended for (Figure 4). However, if each sperm sample had been discarded immediately after use it would not have been available for use a second time, and the mistake should have been noticed.

- 10.30 A fact that may also be of relevance is that the surnames of Mrs A and Mrs B start with the same letter of the alphabet.
- 10.31 It should also be noted, as embryologist E 1 remarked with respect to correctly identifying a patient's gametes, *'You can only rely on the labelling.'*³ However, while the dish containing the eggs of the female patient would have their names written on the lid using an identifying colour code, for example green and the number of eggs injected written in black, the identifying details on the test tube containing her partner's sperm would only be written in black (Plate 9). However, if the name written on the test tube containing the sample of sperm had been written in the same colour as that used on the dish containing the eggs then there would have been an additional check to prevent misidentification. For not only would the names on the test tube and dish have to match but the colour of the name on both containers would also have to be the same. A difference in colour would flag up the possibility that an error had occurred.

Volume of work in embryology laboratory

- 10.32 When asked by the Review Panel about their workload E 1 replied, *'I know when I left it was heavy and that was one of the reasons I left.'*⁴ While E 2 when asked if the embryology laboratory was busy or not at that period stated that *'It was quite busy. We had some extremely busy days.'*⁵ When asked if there had been concern over the workload and whether it had been reported to the centre's management, E 2 replied that:

*'I believe that the unit manager, not the Person Responsible...knew about the workload, but we had to keep constant income for the unit, so we could not cut down on the numbers. Because there were people always leaving the unit, embryologists leaving, the jobs were being advertised, but the workload was not being cut down at that time, but we were lower on staff.'*⁶

- 10.33 Evidence to support E 1's and E 2's contention that workload was heavy came from the Lead Embryologist (LE) who stated that: *'I have never felt our laboratory was adequately staffed, and I am on record as saying that for a long time.'*⁷

10.34 However, the Person Responsible, when asked by the Review Panel whether the HFEA laid down minimum staffing requirements for ‘X’ number of patients, replied as follows, *‘No, nothing at all...they never said to me that’s too much work for one person to take on.’*⁸

Inspector co-ordinator

10.35 IC 1 could not recall with any clarity the events that took place during inspections at the centre other than to outline the inspection format noted in previous chapters and refer the Panel to the inspection reports.

Embryology external specialist inspector

10.36 Similar to IC 1, ESI 1 could not remember details of the inspections at the centre with any precision except to describe the general form discussed in earlier chapters and refer the Panel to the inspection reports.

Licence committee members

10.37 LCMs 1 and 2 could not remember the specific licence committee where the centre’s performance was discussed except to reiterate that the reports of the inspections teams had not revealed any serious potential problems and that, as noted earlier, the centre was held in high esteem nationally and internationally.

Observations

10.38 The document check on the ethnicity of patients requested by Mr and Mrs A’s consultant did not reveal that Mr and Mrs B had received treatment on the same day as Mr and Mrs A when in fact they had.

10.39 Using an unlocked box for semen samples is not a desirable practice.

10.40 It cannot be established at which point in the IVF–ICSI treatment of the two couples that the adverse event occurred. The embryologist working in the Sperm Treatment Laboratory could have made a double reading error while processing Mr A’s sperm, i.e. during the sperm preparation process Mr A’s sample could have been unintentionally

transferred into a test tube labelled with the name of Mr B and vice versa. Similarly, the embryologist who carried out the ICSI procedure on Mrs A's eggs may have inadvertently selected the wrong sperm sample to use and then replaced the sperm back in the Hot Box thus compounding the error.

- 10.41 The labelling of gametes is a crucial part of the IVF–ICSI process and consequently there needs to be an explicit formal protocol to ensure that it is done correctly on each occasion. The use of colour coding for the name and patient number on the containers holding a couple's sperm and eggs would appear to be one practical way forward. This is because if the patient's colour code was red and the name and number of the test tube containing sperm about to be used was green there would be a greater probability of identifying an error than if those details had been written in black. However, there are of course people who are colour blind and colours are not always obvious under certain lighting conditions thus the use of colour coding is not a complete solution. But the way in which that could be addressed, at least in part, is by having the patient's number and name colour coded and written on the containers holding their gametes.
- 10.42 As noted earlier the HFEA has now instructed all centres to use witnessing in an effort to reduce the chances of misidentification of patients and their gametes. However, the witnessing that takes place is typically passive, i.e. one person actively checks the details by reading aloud and the other person silently reads the same information.
- 10.43 LGI has two sets of protocols that refer to the same assisted conception services techniques but provide different information. However, while both protocols inform staff what tasks they need to perform neither protocol tells them how to accomplish them. Therefore the staff have developed informal unwritten protocols, which they used to supplement the instructions available.
- 10.44 There is evidence to suggest that the embryology staff felt that the volume of work was too high for the number of embryologists available. However, there were and still are at the time of writing this report no professional or regulatory guidelines as to the number of staff required for a given number of patients. This issue will be discussed again in relation to Case B.

Conclusions and recommendations

10.45 The conclusions that I have drawn as Chairman from the evidence presented to the Review Panel with regard to this adverse event are noted below in plain text, while recommendations are shown in ***bold italic***.

10.46 The document archiving and retrieval system at the centre did not facilitate the accurate recovery of Mr and Mrs B's documentation when first requested by their consultant.

Recommendation 75

The centre should undertake a review of its document storage and retrieval policy and systems.

10.47 Patients were using an unsealed box into which semen samples were placed.

Recommendation 76

Patients should not leave samples of their semen in an unsecured place of storage.

Recommendation 77

A secure location should be provided at the centre where patients can leave their semen samples.

10.48 Mr B's sperm was incorrectly thought to be Mr A's sperm in either the Sperm Treatment Room or ICSI Laboratory where it was injected into Mrs A's eggs. The clear unambiguous labelling of patients' gametes and their correct identification is crucial in the provision of assisted conception services.

Recommendation 78

The centre should develop an explicit protocol for the labelling of all containers that hold patients' gametes. They should consider using a system that incorporates colour coding and the use of the names and patient numbers of both partners to identify containers holding gametes and embryos belonging to them.

Recommendation 79

As set out in recommendation 48, the centre should introducing 'active' witnessing rather than the 'passive' system currently in use as recommended by the HFEA, i.e. each person involved should take an active role in identifying the patients and their gametes. Each witness would take it in turn to read out the patient's details and the other person would confirm or refute them.

Recommendation 80

All the protocols used in the centre should be explicit. The centre should ensure that only one set of protocols is used in the embryology laboratory and that they address not only what activities a reader is to complete but also the manner of how they are to be accomplished.

Recommendation 81

As set out in recommendation 50, the Authority should investigate, in consultation with the relevant professional bodies, the possibility of using human reliability techniques to identify the potential for human errors to be made in assisted conception services settings.

Recommendation 82

As set out in recommendation 49, the use of Patient Identification Bar Code technology should be explored.

10.49 The practice of placing sperm back in the Hot Box after some of it has been used for insemination creates a situation where it is highly likely that if the wrong sperm were used to inseminate a woman's eggs that the error would be undetected.

Recommendation 83

Once sperm has been used to inseminate eggs it should either be discarded immediately in line with the centre's policy on such matters or retained in a separate Hot Box clearly labelled for such a purpose perhaps in another room. Once a sample of sperm has been used in the ICSI procedure it should never be returned to the Hot Box holding the sperm samples still waiting to be processed.

- 10.50 For comments on workload and staffing levels within centres see the conclusions and recommendations regarding Case B in Chapter 11.
- 10.51 As noted previously patient safety is paramount. Consequently, during the course of the review a dialogue was maintained with the centre, the Trust's senior management and the HFEA about emerging conclusions and key recommendations. It is therefore important to note that as a result the recommendations above have, where possible, been implemented as the Review has progressed.
- 10.52 The centre, Trust – and where appropriate the HFEA - will, of course, be responsible for ensuring that all the recommendations are properly implemented and monitored for effectiveness.

References

1. E 2, personal communication.
2. IC 1, transcript, p.42.
3. E 1, transcript, p.52.
4. E 1, transcript, p.32.
5. E 2, transcript, p.69.
6. E 2, transcript, p.70.
7. LE, LGI, transcript, p.94.
8. PR, LGI, transcript, p.121.

Case B – The Centre at Leeds General Infirmary

Terms of reference

- 11.1 To investigate the circumstances leading to the wrong sperm being used to inject 11 eggs.

Introduction

- 11.2 Prior to being aware that Case A had occurred LGI instituted an informal policy of witnessing when undertaking tasks such as ICSI. However, due to the pressure of work, a lack of staff and clinical necessity a very experienced embryologist at the centre decided to carry out an ICSI procedure on a patient's eggs without a witness being present. It was discovered a short time later, when a colleague returned to the laboratory and was asked retrospectively to witness the procedure, that the wrong sperm had been used to inject the eggs.

Witnesses

- Person Responsible for the centre.
- Lead Embryologist at the centre.
- Embryologist who carried out the ICSI procedure.
- Embryologist who was subject to a needle injury.
- Embryologist who discovered the adverse event.
- Inspector co-ordinator who attended an inspection carried out at the centre.
- Embryology external specialist inspector who attended an inspection carried out at the centre.
- Members of the licence committee who reviewed the centre's licences.

Background to the adverse event

- 11.3 Five days prior to the adverse event taking place the centre's Lead Embryologist (LE) had written to the Person Responsible stating that:

'I am writing because I am concerned that the embryologists are not managing to cope with the workload at the moment. I am worried that something may go wrong in the lab and it may be due to the fact that we have too many responsibilities which we are unable to fulfil properly. If we have one embryologist on leave or away ill we find we cannot cope with all the tasks that we have booked for us.'

- 11.4 The letter continued by giving a specific detailed example of the workload that was undertaken at the assisted conception services on a particular day prior to the adverse event; the writer concluded with the opinion that, *'To do this with only four embryologists is dangerous.'*

- 11.5 At the time of the adverse event, the centre had funding for six embryologists. However, one post was vacant and was in the process of being advertised while another embryologist was away on annual leave. Thus, there were four embryologists on duty the day the adverse event took place.

- 11.6 Furthermore, because of the heavy workload in the centre the lead embryologist had approached the Trust's management in an attempt to have one of the embryologists re-graded to a higher level than might normally be granted but the request had been refused. The lead embryologist in her letter to the Person Responsible stated that:

'It was very difficult for me [the LE] to accept the view of managers [Trust management] who have no idea of the stress levels that my team works under when we are so busy.'

- 11.7 Later in the letter, the lead embryologist notes that the centre has:

'...not been able to fulfil many of our HFEA requirements recently. We would hope to rectify this over the Xmas break but this may not be possible as many embryologists now need to arrange some holiday to recover from the difficulties recently experienced.'

11.8 The lead embryologist continued:

I am also trying to re-write all laboratory protocols which have not been updated...I hope to have the revised protocols finished before I go on holiday next week...and I am working flat out to achieve this.'

11.9 However, while the letter had been discussed with the lead embryologist no immediate action was taken because as the Person Responsible stated:

*'We were at that stage about four weeks from stopping for the Christmas break, and it would be very difficult for patients already on medication to stop at that point in time.'*¹

11.10 Assisted conception treatment cannot simply be started and stopped like some other medical interventions. There is typically a four-week lead-in period when female patients are administered drugs prior to egg collection. Additionally, besides the physical responses to the drugs administered to patients their emotional needs must also be considered. Therefore stopping treatment is a serious matter and not one to be undertaken lightly. Furthermore, there may be patients who have been given appointments three to four weeks in advance of starting their treatment and the inconvenience to these patients needs consideration. In the event, it was decided, at least in the short term, to continue with the arrangements then in place.

11.11 Therefore, it would appear that on the day the adverse event took place the staff of the centre's embryology service, with only four embryologists on duty, would have been under pressure to complete the work allocated to them.

Adverse event chronology

11.12 On the day in question, the embryologist involved in this incident prepared five semen samples in the Sperm Treatment Laboratory for use in different IVF treatments. Two of these five samples were to be used for patients who required the ICSI technique to be performed on their eggs. Having completed the preparation of the two sperm samples, the embryologist took them from the Sperm Treatment Laboratory and put them in the Hot Box in the ICSI Laboratory.

- 11.13 Meanwhile the eggs of the two female patients were being prepared for the procedure in the ICSI Laboratory. It was while preparing the eggs of one of these two patients that another embryologist (E 3) accidentally stabbed his finger with a hypodermic needle while carrying out one of the tasks. Consequently, E 3 had to stop work immediately and carry out the centre's prescribed health and safety procedures for staff sustaining such an injury.
- 11.14 One of the actions that has to be undertaken by staff who have been injured in such a way is to attend the Trust's Occupational Health and Safety Unit (OHSU) for treatment. Thus, E 3 who had been preparing the patient's eggs for the ICSI procedure had to leave the centre to go to the OHSU.
- 11.15 As it was not known how long E 3 might be away from the centre, another embryologist (E 4) was asked to complete the preparatory work on the patient's eggs. Having completed the remaining tasks on the patient's eggs E 4 then went to a prearranged meeting to discuss the treatment schedules of patients. A third embryologist (E 5) on duty that day was also out of the centre performing other duties. This meant that the only embryologist left in the centre was the one scheduled to carry out the ICSI procedures.
- 11.16 The fact that one of the embryology team had been injured, another would be leaving early and some of the other tasks were starting to run behind time put even more pressure on the embryologist who was left in the laboratory. One of the duties of that embryologist was to schedule the tasks that had to be performed on a daily basis. Therefore, besides carrying out the ICSI procedures, one of her tasks was to consider how to reorganise the work for that day in case E 3 who had been injured could not return to work that afternoon.
- 11.17 Some months earlier (although none of the witnesses could remember exactly when) the centre had instituted an informal programme of witnessing certain IVF procedures including ICSI. However, given that the centre had a heavy workload to get through that afternoon, there were staffing problems and time was passing so rather than wait for one of the other embryologists to come back to the centre and risk running even more behind time the embryologist who was left in the laboratory decided to revert to the centre's previous method of carrying out the ICSI procedures, i.e. without a witness.

- 11.18 Subsequently, the embryologist set up the ICSI Laboratory to carry out the procedures. Once the preparatory work had been undertaken the embryologist took what she believed to be the correct sample of sperm from the Hot Box, read the name on the Eppendorf test tube (Plate 11) (which is a test tube significantly smaller - thus requiring smaller writing - than the usual test tube shown in Plate 9) and placed the sperm sample in the Hot Block so as to be ready for use. The embryologist then went to the ICSI incubator, took out the eggs scheduled to have the ICSI procedure first and took them to the ICSI Laboratory. The embryologist then carried out the ICSI procedure.
- 11.19 Upon returning to the centre E 4, who had been at the meeting concerning patient treatment schedules, was asked by the embryologist who had just carried out the ICSI procedure to witness the name and number of the patient whose sperm had just been used in the ICSI procedure. Picking up the sample of sperm, E 4 read out aloud the name written on the Eppendorf test tube. It was at this point that the embryologist who had completed the ICSI procedure realised that an error had been made. As she told the Review Panel, *'It was not the name I expected to hear.'*²
- 11.20 The Person Responsible was immediately told that an incident had occurred and a decision was taken at once that under the circumstances the eggs should be prevented from fertilising. To that end the HFEA approved procedure to prevent the eggs fertilising was put into operation after which the eggs were humanely discarded.
- 11.21 The patients were quickly informed that an adverse event had taken place and arrangements were made for them to see the Person Responsible. The HFEA was also informed of the incident and the report generated from the Trust's own internal inquiry was subsequently sent to the Authority. The HFEA reviewed this adverse event at the centre's next inspection several months later.

Inspector co-ordinator

- 11.22 IC 4 noted that the inspection immediately prior to the adverse event had been an interim inspection. This had focused on the centre's Preimplantation Genetic Diagnosis (PGD) programme. This is a technique that can identify a number of serious genetic disorders in an embryo. The inspection included the external specialist inspector observing a member of the centre's staff carry out the procedure.

- 11.23 While there were a number of matters which the inspection team wished the centre to attend to it was recommended by the inspection team that the centre's licences to undertake PGD and other IVF treatments should be continued.
- 11.24 The inspection team also noted that the Person Responsible had told them that merger of the two centres was imminent.

Embryology external specialist inspector

- 11.25 Similarly to IC 4, ESI 2 noted that the inspection was solely focused on observing a member of the centre's staff carry out a PGD procedure and referred the Review Panel to the inspection report.

Licence committee members

- 11.26 LCM 2 and 3 both recalled that they had been informed that the two centres at the Trust were about to be merged and that the inspection team had recommended that the centres' licences be renewed.

Observations

- 11.27 As noted in Chapter 9, the hoped-for merger had not taken place. As a result the facilities at the centre were not the optimum for the amount of embryology work being undertaken. There was a constant shortage of embryology staff and high demand for embryology laboratory services.
- 11.28 Additionally, on the day of the adverse event one member of the embryology team was injured and had to leave the centre to attend the OHSU and two other members of the embryology staff were also absent. Work activities were falling behind schedule thereby creating an even more stressful working environment than was normal. Thus, in an attempt not to drop further behind with the work, a very experienced embryologist decided that it was necessary to suspend the informal witnessing protocol that had been instituted by her.

11.29 The adverse event occurred because the embryologist - who was working under highly stressful conditions - misread the name on the Eppendorf test tube containing sperm and there was no witness present who might have prevented the error from occurring. Interestingly, Nguyen and Bibbings argue that:

*'It is accepted and proven that errors lead to accidents and that stress can lead to errors. It follows logically, therefore, that stress must also contribute to accident causation.'*³

11.30 Moreover, Nguyen and Bibbings suggest that the stress factors that increase the likelihood of an accident taking place include, a restricted work space, high workloads, distractions, interruptions, insufficient staffing levels, and fatigue. All these factors appear to have been present the day the adverse event took place.

11.31 It is problematic both ethically and medically for a clinician to stop treating patients who have already commenced a programme of infertility treatment unless, of course, they are in immediate danger. At the time of writing there are no professional or regulatory guidelines for calculating the number of embryology staff required at a centre having regard to their workload. Thus, it can be argued that it is unlikely that any centre would stop treating patients because of what appears to be a short term staffing problem. It should however be noted that a research paper presented at the ACE Annual Conference by Harbottle⁴ suggests that 71% of embryology units could be understaffed.

11.32 The HFEA did not immediately send an inspection team to investigate this adverse event. Rather it waited until the centre's next inspection was due and in the intervening period relied upon the centre's own investigation into the circumstances surrounding it.

Conclusions and recommendations

11.33 The conclusions that I have drawn as Chairman from the evidence presented to the Review Panel with regard to this adverse event are noted below in plain text, while recommendations are shown in ***bold italic***.

11.34 The merger has not proceeded at the time of this review and the working environment of the embryology laboratory remains unsatisfactory. Additionally there are a number of stress factors that could have led to the adverse event occurring and therefore need to be addressed.

Recommendation 84

The HFEA should inspect the centre to review the facilities and the volume of patients being treated to ascertain whether or not the centre's licences need to be varied.

11.35 The embryologist correctly identified the patient's eggs but misread the name on the test tube containing the sperm. Therefore the wrong sperm was used to inseminate the eggs. Thus the clear unambiguous labelling of a patient's gametes and their correct identification is crucial in the provision of assisted conception services.

Recommendation 85

The centre should develop an explicit protocol for the labelling of all containers that hold patients' gametes. They should consider using a system that incorporates colour coding and the use of the names and patient numbers of both partners to identify containers holding gametes and embryos belonging to them.

Recommendation 86

The centre should introducing 'active' witnessing rather than the 'passive' system currently in use as recommended by the HFEA, i.e. each person involved should take an active role in identifying the patients and their gametes. Each witness would take it in turn to read out the patient's details and the other person would confirm or refute them.

Recommendation 87

All the protocols used in the centre should be explicit. The centre should ensure that only one set of protocols is used in the embryology laboratory and that they address not only what activities a reader is to complete but also the manner of how they are to be accomplished.

Recommendation 88

The use of Patient Identification Bar Code technology should be explored as set out in recommendation 49.

- 11.36 There are no professional or regulatory guidelines concerning embryologists' workloads.

Recommendation 89

The HFEA should, in consultation with the appropriate professional bodies, consider guidelines about embryologists' (and other staff's) workloads.

Recommendation 90

The HFEA should, in consultation with the appropriate professional bodies, determine what the time scale should be for the replacement or recruitment of an embryologist before patient numbers must be reduced to match the resources then available.

- 11.37 There have been occasions when the HFEA has not conducted an investigation of an adverse event until a centre's next inspection.

Recommendation 91

The HFEA should undertake a robust but proportionate investigation of any serious adverse events as soon as it is reported.

- 11.38 Interim inspections (that take place between full inspections) only cover a small portion of the assisted conception services that centres provide and therefore cannot identify the potential risks that a full inspection might.

Recommendation 92

This concern is addressed by Recommendation 33 at paragraph 8.30 and will be met if that recommendation is implemented.

- 11.39 As noted previously patient safety is paramount. Consequently, during the course of the review a dialogue was maintained with the centre, the Trust's senior management and the HFEA about emerging conclusions and key recommendations. It is therefore important to note that as a result the recommendations above have, where possible, been implemented as the Review has progressed.

- 11.40 The centre, Trust - and where appropriate the HFEA - will, of course, be responsible for ensuring that all the recommendations are properly implemented and monitored for effectiveness.

References

1. PR, LGI, transcript, p.214.
2. Embryologist who carried out the ICSI procedure, transcript, p.155.
3. Nguyen, L. and R. Bibbings (2002) 'Exploring the links between stress and accidents in the workplace: a literature review', *Journal of the Institution of Occupational Safety and Health*, Vol. 6, Issue 2, p.18.
4. Harbottle, S. (January 2003) 'Are you working too hard', *Association of Clinical Embryologists Annual Conference*, Glasgow

Case C – The Centre at St James's Hospital

Terms of reference

- 12.1 To identify the circumstances which led to the destruction of six embryos contrary to the patient's wishes.

Introduction

- 12.2 Section 14(1)(c) of the HFE Act requires:

'...that no gametes or embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish...'

- 12.3 Schedule 3 to the HFE Act provides that:

'A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with this consent.'

'An embryo, the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the storage of this embryo and the embryo is stored in accordance with the consent.'

- 12.4 Thus, it is clearly a breach of the HFE Act for any centre to store gametes or embryos where they do not have consent to do so. Nor may they store such material after the period of consent has expired or once the statutory storage period has been reached.

- 12.5 The guidance given to centres in the COP with regard to the storage of genetic material is that:

‘Centres should carry out a periodic review of the status of stored gametes and embryos at least once a year. The purpose of this review is two-fold. The first is to reconcile the centre’s records with the genetic material actually in storage. The second is to review the purpose and duration of storage and identify any action that needs to be taken.’¹

- 12.6 A couple, C, consented to have their embryos put into cryopreservation at the SJH centre for a period of one year. Three months prior to the expiry date of their consent the Database Administrator (DA) at the centre contacted couple C by letter and asked them what they wished to do with their embryos. However, couple C returned the consent form that had been sent to them unsigned and arranged to have a consultation with the Person Responsible instead. Following the consultation with the Person Responsible couple C decided to extend the storage period of their embryos by one year, paid the storage fee by credit card over the telephone and wrote a letter to the centre confirming their decision.
- 12.7 On receiving the letter from the couple confirming their decision to store the embryos for a further year, the letter was passed to the database administrator so that the couple’s computer record could be updated. However, while couple C’s computer record was updated, the letter was not filed with the patient’s medical notes. Thus, during the course of an audit on the genetic material held at the centre when couple C’s medical notes were checked it looked as though the one-year period of consent given by a couple C to store their embryos had expired. A check of the consent storage date recorded on the centre’s patient computer database was requested but due to a misunderstanding this was not carried out.
- 12.8 Having no knowledge of the letter extending couple C’s storage consent date and believing all the necessary consent checks had been carried out, a Senior Embryologist (SE), with a Junior Embryologist (JE) acting as a witness, destroyed couple C’s embryos contrary to their wishes.

Witnesses

- Person Responsible for the centre.
- Senior Embryologist in charge of humane disposal of couple C’s embryos.

- Database administrator.
- Inspector co-ordinator who attended the inspection carried out at the centre.
- Member of the licence committee that reviewed the centre's licences.

SJH protocol for discarding a patients' genetic material

- 12.9 Three months before the annual date of consent to store their genetic material expires the patient computer record data administrator sends a letter to all patients with embryos kept in storage at the SJH centre asking if they wish to continue to have their embryos stored, donate them for research, donate them for use by another couple or have them discarded. Where permission to discard embryos is given or if the embryos have passed the statutory storage period and the patients cannot be contacted, then the medical notes of those patients are retrieved from the document files, checked against the clinic's computer database for the storage expiry date and placed in a pile on the senior embryologist's desk for their attention.
- 12.10 On the day the genetic material is to be destroyed a senior embryologist, with a witness, checks each patient's medical notes to make sure that all the proper consents for disposal of the embryos have been obtained or alternately that it is clear that all appropriate letters have been sent to which the patient has failed to reply. Once this process has been completed, the embryos are discarded following an explicit procedure that ensures that the embryos are afforded the dignity of potential human life.

Adverse event chronology

- 12.11 While it is usual for patients to give consent for their embryos to be stored for a period of five years, couple C only gave consent for their embryos to be stored for one year. While this fact had been recorded on couple C's consent forms, it had not been noted on couple C's computer patient record form by the database administrator. This was because when inputting patient information into a new database the database administrator did not have the time physically to check the consent dates in the medical records of several hundred patients. The database administrator stated that: *'I had to presume that the patients had consented to five years...unless I was told otherwise.'*²

12.12 Thus, in accordance with SJH procedures three months before the expiry of couple Cs annual date of consent a letter was sent by the database administrator asking them what they wished to do with their stored embryos. Couple C however returned the consent form that had been sent to them unsigned and arranged to have a consultation with the Person Responsible so that they could discuss all the options open to them regarding their embryos.

12.13 Following the consultation with the Person Responsible couple C telephoned the centre to say that they now wanted to have their embryos stored for a further year and paid the centre's storage fee by credit card at the same time. Couple C also wrote a letter to the Person Responsible confirming their desire to have the embryos kept in storage for a further year. When the letter from couple C was received at the centre it was passed to the database administrator so that the information could be entered on to the patient's computer record, which was done.

12.14 However, because patients' medical notes are stored in different rooms and on different floors their files are difficult to access. The database administrator remarked that:

*'Due to space constraints, the notes are filed in various places, unfortunately... We have got quite a few places where notes are stored... the notes are spread about in four different places, and in those four different places there are quite a few different areas... So the notes, it is horrendous.'*³

12.15 Furthermore, as noted in Chapter 9, pressures of work and staff shortages meant that there was little time left for clerical duties such as filing. The database administrator noted that:

*'...from September last year until about February this year we have been extremely short staffed and we were two receptionists down and have been a secretary down, so therefore we have had to prioritise. So, like, my job is important but if you have got patients at reception, booking in, they need appointments... therefore that had to take priority... So people have had to cover the staff shortage.'*⁴

12.16 As a result the database administrator did not immediately file couple C's letter of consent in their medical notes but placed it in a lever arch file with other correspondence and documents to be filed in the patient's medical notes later.

12.17 However, the database administrator also observed:

*'The filing had been looked at. Because I was covering a few people's other positions, if I looked at the filing myself, it would not be that often...because when we had temps in the office they were asked to look through the filing and to file in the notes. Being temps, they were shown where to look for the notes and everything else, but that would not be as good as a permanent person really.'*⁵

12.18 It should also be noted that a copy of the letter sent by the database administrator to couple C asking them what they wanted to do with their embryos, which should have been in their medical notes, was also in the lever arch file. Thus, patient C's medical notes continued to show that the consent period for the storage of their embryos was one year and that it had expired.

12.19 Therefore, when an audit of genetic material was undertaken sometime later it was noted that couple C's one-year consent date had expired. It was also observed that a letter had been sent to couple C requesting that they inform the centre as to what they wished to do with their embryos. However, as the response from couple C had still not been filed with their medical notes the person undertaking the audit assumed that there had been no reply from them.

12.20 Not sure of what action to take, the auditor asked a senior embryologist for advice. After reviewing couple C's file, the senior embryologist suggested that the auditor should take couple C's medical notes to the database administrator to check what was recorded on the patient's computer record.

12.21 It should be noted however that it is by no means uncommon for patients who have received treatment for infertility not to respond to letters from the centre regarding the treatment of their embryos. Thus, to all the staff involved in reviewing couple C's file there were no obvious signs that anything was wrong.

12.22 As suggested by the senior embryologist the auditor immediately went to ask the database administrator to check the patient database record for couple C's embryo storage expiry date. However, the database administrator had left work for the day. As there was no one else to ask for advice, the auditor returned to the senior embryologist's office and, as he was not present, placed couple C's file on the top of a pile of medical notes already on his desk. However, what the auditor did not realise at the time was that the pile of medical notes on the senior embryologist's desk...

on which she had placed couple C's medical notes, had been put there by the database administrator and were the notes of patients where it had already been established that the genetic material should be discarded.

- 12.23 When the senior embryologist arrived next morning and saw couple C's medical notes on the discard pile, he did not check with the database administrator if this was correct as he assumed that the auditor had confirmed this the night before. In a similar vein, the auditor had assumed that when the senior embryologist saw couple C's medical file that he would check with the database administrator whether couple C's storage consent had expired or not. Furthermore, the auditor was now on leave and therefore did not see the senior embryologist the next day to inform him of what had occurred on the previous night.
- 12.24 Eventually, when the senior embryologist had gathered the medical notes of patients whose genetic material was to be disposed of, the senior embryologist, with a junior embryologist acting as a witness, disposed of all the gametes and embryos in the prescribed manner. After disposing of the genetic material the medical notes belonging to those patients went to the database administrator to have their computer records updated. It was while the database administrator was updating the computer records of couple C that it was recognised that the embryos should not have been destroyed and that an adverse event had occurred.
- 12.25 Subsequently couple C were informed of the mistake and an apology given. It should be noted that this adverse incident was not reported to the HFEA because the Person Responsible was of the opinion that it was a matter between the Trust and couple C. The Person Responsible indicated her intention to advise the HFEA of the adverse event at the centre's next annual inspection.

Inspector co-ordinator

- 12.26 IC 2 recalled that on the inspection prior to the adverse event the inspection team had audited a sample of patients' files. However when the Review Panel asked:

'To your knowledge, during the HFEA Inspectors visit to ACS 63...was an audit conducted on the active process used by the Data Controller in the administration filing system at the ACS so as to ensure that incoming correspondence filing was up to date?'

IC 2 replied 'no.'⁶

12.27 IC 2 noted that she had left the post of inspector co-ordinator some months ago. IC 2 was however, able to provide the Review Panel with a generic outline of the process of inspecting a centre as discussed earlier.

Licence committee

12.28 Although the licence committee did make a number of recommendations that the centre needed to address, the minutes of the meeting state:

'The Committee commended the centre on the laboratory protocols and the counselling service... The Committee agree to grant a 3 year licence to expire 30/06/05 under the standard licence conditions to carry out...'

Observations

12.29 The protocol and witnessing process used by the senior embryologist to establish whether or not couple C's embryos met the criteria for their humane disposal was applied rigorously. It was however not realised at the time that a delay in the document archiving system could lead to the mistaken disposal of a patient's embryos.

12.30 It is time consuming for the staff at the SJH centre to locate patients' medical files because medical records are held in several different locations and there is no system to identify the precise location of any given patient's medical records. Additionally, staff shortages and the pressures of work have led to the filing of correspondence and other documents to patients' medical files receiving a low priority. As a consequence, the letter from couple C extending the storage consent date of their embryos was not filed in their medical notes by the time of the audit.

12.31 The auditor was unable to check the storage consent date on couple C's computer record because the database administrator was not available. Thus, the auditor left couple C's medical notes on the SE's desk assuming that he would realise that a check would need to be made with the database administrator as to couple C's storage consent date when he arrived the following morning.

- 12.32 There was no indication on the pile of medical notes on the SE's desk that these were cases where it had already been established that the genetic material held in storage for patients should be destroyed or allowed to perish.
- 12.33 Couple C's embryos were mistakenly allowed to perish because (i) the letter extending the consent date for the storage of their embryos had not been filed in couple C's medical notes and (ii) the senior embryologist had assumed that the auditor's check against the computer database had confirmed that couple C's storage consent date had expired.
- 12.34 It was not until after couple C's embryos had been allowed to perish and their medical records were being updated that the DA recognised that an adverse event had taken place.
- 12.35 The Person Responsible of SJH centre is of the opinion that she does not need to report the mistaken destruction of patients' embryos to the HFEA and that it is a matter for the Trust to deal with. However, it has been confirmed by the HFEA's Director of Regulation that this adverse event should have been reported to them. It is therefore an example, as discussed in Chapter 7, of the uncertainty surrounding the type of incident Persons Responsible should report to the HFEA but on occasions do not.

Conclusions and recommendations

- 12.36 The conclusions that I have drawn as Chairman from the evidence presented to the Review Panel with regard to this adverse event are noted below in plain text, while recommendations are shown in ***bold italic***.
- 12.37 A combination of scattered document storage facilities an uncoordinated archiving system for medical records plus staff shortages and pressure of work at the centre led to the letter from couple C, authorising the extension of the storage consent date of their embryos, not being filed with their medical notes before the second audit.

Recommendation 93

The centre should introduce an archiving system that records the physical location of each patient's medical notes.

Recommendation 94

The centre should implement a policy that all correspondence and documents for filing in patients' medical records is completed each day.

Recommendation 95

The Trust should seek to provide the centre with facilities to enable reasonable access to patients' medical records.

Recommendation 96

The Trust should seek to ensure that the levels and quality of administrative staff are maintained to ensure the smooth running of treatment services at the centre.

- 12.38 The medical notes on the senior embryologist's desk were not visibly identifiable as belonging to a group of patients whose genetic material was to be discarded.

Recommendation 97

The centre should implement a policy that the medical notes of patients whose genetic material is to be disposed of are put in a place of storage specifically designated for that purpose.

- 12.39 Had couple C's medical records been checked against the storage consent date recorded on the centre's database the adverse event would have been averted.

Recommendation 98

The centre should implement a policy whereby no genetic material can be disposed of until a formal safety check has been made against a patient's database record and this check has been signed off by an appropriate person.

- 12.40 As noted in Chapter 7, it is not always clear to Persons Responsible when an adverse event should be reported to the HFEA.

Recommendation 99

The HFEA should implement the recommendation made in Chapter 8 regarding the Code of Practice making clear those adverse events that should be reported immediately and those where a later report is acceptable.

- 12.41 As noted previously patient safety is paramount. Consequently, during the course of the review a dialogue was maintained with the centre, the Trust's senior management and the HFEA about emerging conclusions and key recommendations. It is therefore important to note that as a result the recommendations above have, where possible, been implemented as the Review has progressed.
- 12.42 The centre, Trust - and where appropriate the HFEA - will, of course, be responsible for ensuring that all the recommendations are properly implemented and monitored for effectiveness.

References

1. (2001, Fifth edition) HFEA Code of Practice, p.45.
2. DA, transcript, p.37.
3. DA, transcript, p.41.
4. DA, transcript, p.39.
5. DA, transcript, p.40.
6. IC2, transcript, p.60.

Case D – The Centre at Leeds General Infirmary

Terms of reference

- 13.1 To identify the circumstances that led to the failure of the cryopreservation freezing process, compromising seven embryos undergoing that procedure.

Introduction

- 13.2 Working alone for the first time on a Sunday in the LGI centre laboratory an embryologist (E 5) was required to freeze seven embryos. Believing that she had completed the manual pre-freezing procedures successfully E 5 placed the prepared embryos in a device known as a Cryogenic Freezer (CF) (Plate 6) and initiated the freezing programme.
- 13.3 After the freezing programme had finished E 5 found that the CF had run out of liquid nitrogen approximately 20 minutes before the freezing programme had finished and the solution in which the embryos were suspended had then begun to thaw. As a consequence, E 5 immediately plunged the embryos into a container of liquid nitrogen in an attempt to maintain their integrity. Following this remedial action E 5 put the embryos into cryostorage (Plate 7). It was however considered to be a high probability that the quality and viability of the embryos had been compromised.

Witnesses

- Person Responsible for the centre.
- Lead Embryologist at the centre.
- Embryologist who carried out the freezing procedure.
- IC who attended inspection carried out at the centre.
- Embryology external specialist inspector who attended the inspection carried out at the centre.

Background to the adverse event

- 13.4 The embryologist (E 5) joined the LGI centre approximately four months prior to the adverse event, having previously worked in the field of embryology in different capacities for ten years. Thus, E 5 was an experienced embryologist.
- 13.5 Upon joining the LGI centre E 5 did not receive any formal structured induction training but shadowed a number of embryologists, i.e. had in-house training which included the carrying out of clinical procedures under supervision, discussing the difference between the procedures that she had used before and the ones in use at LGI and becoming familiar with all the protocols used in the laboratory, including the CF and its associated liquid nitrogen storage tank.
- 13.6 Prior to E 5 being allowed to work on her own over a weekend, the lead embryologist (LE) sought E 5's work colleagues' opinions as to her abilities. The lead embryologist also drew on her own experience of how E 5 had carried out her duties while working at the centre and also asked E 5 if she felt confident about working on her own. E 5 replied that she had worked on her own in her previous employment and that she now felt ready to work unsupervised at the centre. There was however no formal test or assessment of E 5's ability with respect to the work that she would be carrying out unsupervised.

Adverse event chronology

- 13.7 On the day prior to the adverse event a colleague working with E 5 used the CF on two occasions to freeze embryos and this reduced the level of liquid nitrogen available for subsequent use.
- 13.8 On the day of the adverse incident E 5, working on her own for the first time at the centre, prepared a patient's embryos for the freezing process by manually passing them through a series of freezing solutions before loading them in the CF. E 5 then carried out a number of pre-freeze checks on the CF and the storage tank holding the liquid nitrogen and then initiated the freezing programme.

13.9 When the freezing programme had finished E 5 went to the CF and took out the embryos and upon inspecting them realised that they were not frozen. E 5 observed that:

*'...what had probably happened is they did actually freeze but because there was not enough liquid nitrogen to keep them frozen, the machine then started warming up...'*¹

13.10 Realising that the embryos had been frozen, but were now in the process of thawing, E 5 plunged the embryos into a container of liquid nitrogen in an attempt to preserve their integrity. After immersing the embryos in liquid nitrogen E 5 placed them in cryostorage (Plate 7).

13.11 As to how the adverse event had taken place, E 5 stated that:

*'I just completely forgot to check the level of the nitrogen in there [the tank holding the liquid nitrogen] ...it appeared to have been completely depleted of liquid nitrogen, so the machine did not have any more liquid nitrogen to complete the whole freezing run.'*²

13.12 E 5 also noted that there were handwritten instructions on a piece of paper stuck on the wall behind the CF that stated, 'Check N₂ [liquid nitrogen] level in dewar [liquid nitrogen storage tank] – should be 1/2 full'

13.13 E 5 also reported that:

*'...I was not busy, [there] was quite a steady flow to the day. I was certainly was not rushed, I was not under pressure, and at the stage where I was then freezing the embryos, that was pretty much the last job of the day. I did not have any time restraints so I felt confident, I did not feel under pressure.'*³

13.14 When asked by the Review Panel as to why she had not used the written protocol that had been provided E 5 replied that:

*'It is a protocol you do not read it every time you set up the freeze machine. It is a protocol, like a lot of equipment in the laboratory, you just know off by heart. It is so automatic when you walk into the lab in the morning how to set up to start the day's work. It does kind of become automatic pilot...I cannot tell you why I forgot to check it that day. It would be nice to have an excuse but being unsupervised at the weekend is no excuse at all. I was not under pressure.'*⁴

13.15 In a similar vein, when discussing the use of protocols in Case A, E 2 had remarked:

‘Well, we had the unit protocols, but we had the protocols in front of us only when we started, when we were trainees. After that, we did not need the protocols in front of us.’⁵

HFEA inspection

13.16 When asked by the Review Panel if the inspection just prior to the adverse event had considered any aspects of weekend working at the centre IC 3 replied, *‘The workload of the embryologists was discussed in general, both week day and weekend cover.’⁶*

13.17 However, when asked by the Review Panel:

‘...to your knowledge, have any of the HFEA inspection teams raised the issue of the competence of people working on their own for a weekend or any other time?’ the lead embryologist stated, *‘No, definitely not.’⁷*

13.18 Similarly, when asked if weekend working was discussed during the inspection ESI 1 replied, *‘I do not recall specifically discussing weekend working.’⁸* There is also no record of weekend working at the centre being discussed in the *Report to Licence Committee of Inspection Visit* for that inspection.

Observations

13.19 E 5 was an experienced embryologist, confident in her ability, not under time pressures and had a written protocol to hand, stating the steps that should be taken when using the CF, yet the adverse event occurred.

13.20 E 5 does not know why she forgot to check the tank holding the liquid nitrogen, but she acknowledges that she did not think to use the written protocol that was to hand. Interestingly, E 2 and E 5, both experienced embryologists, hold similar views as to why they might not use written protocols each time they carry out a task, i.e. because they believe protocols become so familiar that it is possible to remember them accurately. However, Reason and Mycielska note in relation to absent-minded errors of the type experienced by E 5 that:

*'They are a characteristic of highly skilled or habitual activities. In short, they are a problem for the expert, not the novice. Although this seems to run contrary to common sense, skills are things we acquire with much effort and practice in order to avoid making mistakes.'*⁹

13.21 As to how absent-minded errors might be avoided Reason and Mycielska observe that:

*'...there are no simple remedies. These mistakes are the price we pay for being able to carry out so many complex activities with only a small investment of conscious attention. They are the inevitable penalty of the necessary process of automatization.'*¹⁰

13.22 The centre has no formally structured induction or formal assessment to ascertain if an embryologist is sufficiently experienced to work unaccompanied.

13.23 When only one person is working witnessing cannot be carried out.

13.24 There is some confusion as to exactly what may have been discussed regarding weekend working and by whom at the inspection prior to the adverse event.

Conclusions and recommendations

13.25 The conclusions that I have drawn as Chairman from the evidence presented to the Review Panel with regard to this adverse event are noted below in plain text, while recommendations are shown in ***bold italic***.

13.26 The evidence suggests that the potential for human beings to make absent-minded errors is ever present and therefore careful adherence to formal written protocols, where they are provided, is an important discipline.

Recommendation 100

In order to reduce the likelihood of absent-minded errors occurring, all personnel at the centre should follow written protocols where they are provided.

- 13.27 There is no formally structured induction training or assessment process to test that experienced embryologists, recruited from another centre, are conversant with all local working practices before being allowed to work unsupervised at weekends.

Recommendation 101

The centre should develop and introduce a formal induction training and assessment programme to ensure that experienced embryologists recruited to the centre are familiar with all local working practices before they are allowed to work unsupervised.

- 13.28 Where there is only one person working in the centre - usually at the weekend - witnessing cannot be carried out.

Recommendation 102

Work requiring witnessing not should be carried out at the centre (including weekends) unless sufficiently qualified staff are available to act as witnesses.

- 13.29 There is some confusion as to whether the HFEA inspection regime explicitly covers all aspects of weekend working.

Recommendation 103

The Authority should require all centres to develop and introduce a formal induction training and assessment programme to ensure that embryologists recruited from one to centre another are familiar with all local working practices before they are allowed to work unsupervised.

- 13.30 As noted previously patient safety is paramount. Consequently, during the course of the review a dialogue was maintained with the centre, the Trust's senior management and the HFEA about emerging conclusions and key recommendations. It is therefore important to note that as a result the recommendations above have, where possible, been implemented as the Review has progressed.

- 13.31 The centre, Trust - and where appropriate the HFEA - will, of course, be responsible for ensuring that all the recommendations are properly implemented and monitored for effectiveness.

References

1. E 5, transcript, p.231.
2. E 5, transcript, p.231.
3. E 5 transcript, p.238.
4. E 5, transcript, p.239.
5. E 2, transcript, p.65.
6. IC 3, transcript, p.105.
7. LE, LGI, transcript, p.250.
8. ESI 1, p.27.
9. Reason, J. and K. Mycielska (1982) *Assent Minded? The Psychology of Mental Lapses and Everyday Errors*, Prentice-Hall, p.17.
10. Ibid, p.243.

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Plate 1: Dissecting Microscope



Plate 2: Reconstruction of a dish containing a patient's eggs



Plate 3: Reconstruction of a semen sample container and envelope



Plate 4: ICSI Microscope



Plate 5: Egg Incubator



Plate 6: Cryogenic Freezer



Plate 7: Cryopreservation Storage Unit (Dewar)



Plate 8: Hot Box



Plate 9: Reconstruction of a test tube containing sperm



Plate 10: Hot Block



Plate 11: Eppendorf test tube



The Human Fertilisation and Embryology Authority's guidance to employees regarding section 33 of the HFE Act

Section 33 of the Human Fertilisation and Embryology Act

Guidance to Employees of the HFEA

1. This statement of legal position has been prepared for the purpose of giving guidance to employees who have been asked to attend an independent inquiry. It summarises the restriction on disclosure of information that apply to them by virtue of section 33 of the Human Fertilisation and Embryology Act 1990 ('the 1990 Act').

Section 33

2. Section 22 of the 1990 Act restricts the disclosure of certain types of information by employees of the HFEA.
3. Employees of the HFEA are prohibited from disclosing information that falls within the scope of section 33, except in certain specified circumstances. Disclosure of information contrary to section 33 is a criminal offence.

What information falls within the scope of section 33?

4. Section 33(1) forbids the disclosure of two types of information held by an employee of the HFEA in his or her capacity as an employee. These are as follows:
 - a. Any information contained or required to be contained in the HFEA's register;
 - b. Any other information obtained by the employee on terms or in circumstances requiring it to be held in confidence.

a. Information required to be contained on the register

5. The following information falls within the first category (see section 31(2)):
 - a. Information relating to the provision of treatment services for any identifiable individual;
 - b. Information relating to the keeping or use of the gametes of any identifiable individual or of any embryo taken from any identifiable woman;
 - c. Information showing that any identifiable individual was, or may have been, born in consequence of treatment services.
6. The prohibition on disclosure applies to these categories of information, whether or not the information has actually been placed on the register.
7. These categories of information can be disclosed only in the circumstances set out at section 33(3) of the 1990 Act. None of these permits the disclosure of information relating to the treatment of identifiable patients to an independent inquiry.

b. Confidential information

8. The following information falls within this category:
 - a. Any information received on the basis of an agreement that it would be kept confidential;
 - b. Any information received in circumstances in which the recipient knows or ought to know that the person to whom the information relates can reasonably expect to have his privacy respected. It is impossible to give an exhaustive list of such circumstances.
9. Confidential information may be disclosed with the consent of the party whose confidence would otherwise be protected, or if it has already lawfully been made public.

Practical implications

10. Section 33 does not restrict or prevent HFEA employees from giving information about their own regulatory actions or responses to information received, including the conduct of inspections, or about HFEA meetings, protocols or practices.
11. Section 33 does prevent HFEA employees from disclosing factual information concerning the treatment of specific individuals to any third party, except in the very limited circumstances set out at section 33(3) of the 1990 Act. None of these would permit the disclosure of such information to a body carrying out an inquiry into particular incidents at a licensed clinic.

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List of Abbreviations

ACE	Association of Clinical Embryologists
ACS	Assisted conception services
AO	HFEA administrative officer
BRI	Bristol Royal Infirmary Inquiry
CALI	Centre Activity and Licensing Index
CF	Cryogenic freezer
COA	Certificate of Attainment
COP	Code of Practice
CPD	Continuing professional development
DA	Database administrator
DH	Department of Health
DHS	Department of Health sponsor
E	Embryologist
GMC	General Medical Council
HCSTC	House of Commons Science and Technology Committee
HFE Act	The Human Fertilisation and Embryology Act 1990
HFEA	The Human Fertilisation and Embryology Authority
HPC	Health Professions Council
ICSI	Intracytoplasmic sperm injection
ILA	Interim Licensing Authority for Human <i>in vitro</i> Fertilisation and Embryology
IVF	<i>in vitro</i> (in glass) fertilisation techniques
IRM	Interim regulatory manager
JE	Junior embryologist
LC	Licence committee
LCM	Licence committee member
LE	Lead embryologist

LGI	The General Infirmary at Leeds
LPH	Licensing Procedures Handbook
MFC	HFEA Manual for Centres
MFI	HFEA Manual for Inspectors
MRC	Medical Research Council
NDPB	Non-Departmental Public Body
NPSA	National Patient Safety Agency
OCPA	Office of the Commissioner for Public Appointments
OHSU	Trust Occupational Health and Safety Unit
PCD	Policy and Communications Director
PGD	Preimplantation Genetic Diagnosis
PR	Person Responsible
PZD	Partial Zona Dissection
QA	Quality assurance
QQR	Quinquennial Review
RCOG	Royal College of Obstetricians and Gynaecologists
S	Solicitor
SE	Senior embryologist
SHOT	Annual Report of the Serious Hazards of Transfusion 2001-2002
SJH	St James's University Hospital, Leeds
SLA	Statutory Licensing Authority
SMT	Trust senior management team
SofS	Secretary of State for Health
SUZI	Subzonal insemination
Trust	The Leeds Teaching Hospitals NHS Trust
UKCC	United Kingdom Central Council for Nursing, Midwifery, and Health Visiting
VLA	Voluntary Licensing Authority for Human in vitro Fertilisation and Embryology



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40216 *Independent review of the circumstances surrounding four adverse events that
occurred in the Reproductive Medicine Units at The Leeds Teaching Hospitals NHS Trust,
West Yorkshire* is available on the department's website at: www.dh.gov.uk/

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Professor Brian Toft