Adverse incidents in fertility clinics: **lessons to learn**

2010 – 2012

Contents

Introduction

The role of the Human Fertilisation and Embryology Authority (HFEA) in incident reporting

More than 60,000 cycles of IVF treatment are carried out each year in the UK. The vast majority of those cycles are carried out without any problem occurring. However, as in any clinical setting, mistakes can happen. As this report shows, the number of incidents which occur each year is relatively low – around 500 (or less than 1% of treatment cycles carried out). Of those incidents, very few are of the most serious type.

Clinics and the HFEA take adverse incidents very seriously. We have a rigorous process for reporting, handling and investigating adverse incidents and near misses. Reporting adverse incidents in IVF is a statutory requirement but it is also recognised as one of the best ways of ensuring that incidents and their causes are identified and the opportunity for them to happen again is reduced. All fertility centres are required to report the details of incidents to the HFEA within 12 hours for a serious incident and 24 hours for all others. The HFEA then logs and grades the incident (see annex A) and carries out an incident investigation if needed.

> Our guidance for clinics describes an incident as “any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos/sperm/eggs or to staff of a licensed centre”. This includes incidents which are clinical, laboratory-based or administrative.

Purpose of this report

This report forms part of our work to promote transparency and maximise opportunities for learning from incidents. Many incidents are caused by diligent, hardworking people trying to provide a high quality service for their patients. We do not focus upon who is at fault. Instead, we have worked hard to promote an open learning culture in which clinics are encouraged to report incidents. The result has been an improved rate of reporting over the past few years.

Our approach seeks to identify error-prone situations and settings and to implement systems that help to prevent staff from making errors, to catch errors before they cause harm, or to mitigate harm from errors before they impact on patients.

In this report we look back over three years of incidents reported to the HFEA, based on the latest information available. We identify themes and trends in relation to the three most reported categories of incidents with a view to promoting improvements in practice.

We also set out how we plan to improve our methods of sharing information about incidents and lessons learned with the sector and the wider public.

Incident reporting and grading system

When a clinic reports an incident to us, we grade it as A (the most serious), B, C or as a 'near miss', taking into account the severity of the outcome, or potential outcome, and the likelihood of a reoccurrence. We use an incident grading matrix to guide this process (see annex A). It should be noted that the matrix is a guide to grading and each incident is considered in the context of all the available information. This means that the incident gradings can sometimes change in the course of an investigation or that two incidents that appear superficially similar are assigned different gradings.

The grading of an incident determines the action that follows. We investigate all A grade incidents and carry out an inspection of the clinic, a report of which is presented to our Licence Committee. B grade incidents are investigated by the clinic, which prepares a report to the HFEA. Depending upon the circumstances, we may carry out an inspection. C grade incidents and 'near misses' are logged for trends analysis. We take this differential approach to responding to incidents because we want to focus our attention on the most serious incidents, which have a very negative impact upon patients. Whilst we take other incidents seriously, a more proportionate response is to allow the clinic to investigate further and for us to take action if we regard their investigation as unsatisfactory.

What is an A grade incident?

These are the most serious events. They happen infrequently[1] and examples may include a patient being implanted with an embryo that is intended for someone else, the death of a patient, or an incident which affects a number of patients (e.g. when a storage unit malfunctions which may irretrievably damage the embryos, eggs or sperm of a number of patients).

How are they dealt with?

When an A grade incident is reported, we immediately contact the centre to obtain further information and agree what further action needs to be taken. An incident inspection visit is undertaken to review why the incident occurred and the action needed to minimise the risk of a similar incident reoccurring in the future.

Following the visit and the review of the clinic's own investigation, we produce a root cause analysis report. This, together with the centre's response, is presented to the HFEA's Licence Committee, who in turn determine whether any further regulatory action is warranted.

Depending on the incident, the HFEA sometimes works with other regulators to investigate incidents. The Medicines and Healthcare Products Regulatory Authority (MHRA) has responsibilities for the regulation of equipment and medical devices used by HFEA-licensed clinics and the UK Accreditation Service (UKAS) has responsibility for the accreditation of

[1] For the calendar year 2011, one A grade incident was reported in relation to 66,607 treatment cycles.

laboratories that carry out blood and embryo screening tests on behalf of HFEA-licensed centres. Where incident investigations require collaboration with these and/or other agencies, the incident inspection may be carried out by the most suitable agency and the results of the inspection shared with all parties.

Since October 2009 reports relating to all A grade incidents, along with the associated Licence Committee minutes, have been published on our website (in the Choose a Fertility Clinic section on the clinic's page alongside other inspection reports). The exception to this practice is where the information is considered potentially patient identifying. This change was initiated as part of our drive to ensure greater transparency in our work.

What is a B grade incident?

B grade incidents are serious adverse events or reactions such as the loss of embryos for one patient, breaches of confidentially where sensitive personal data or data relating to more than one patient is sent to the wrong recipient, or when a piece of equipment malfunctions affecting the quality of a patient's embryos.

How are they dealt with?

We require clinics to investigate these incidents and provide us with their report within 10 working days. We may carry out an incident inspection visit to review events and actions proposed to prevent a similar incident occurring. We discuss the findings in the report with the clinic and then monitor how well their actions have been implemented. We may also follow up at our next inspection.

What is a C grade incident?

These are adverse events or reactions such as one of many eggs rendered unusable during processing (for example the moving of an egg between dishes). Another example of this grade of incident would involve a patient developing mild Ovarian Hyperstimulation Syndrome (OHSS).

How are they dealt with?

The incident report is logged onto the incident database for the purpose of trend analysis. While the HFEA does not require clinics to submit their investigation reports, we do expect one to have been carried out. As with B grade incidents, C grade incident information is reviewed and informs the focus of inspections.

What is a ‘near miss’?

A ‘near miss’ is considered an unplanned event that did not result in injury, illness, or damage – but had the potential to do so. Only a fortunate break in the chain of events prevented an injury, fatality or damage; in other words, a miss that was nonetheless very near. The incorrect donor sperm being prepared for a patient and this error picked up prior to the insemination taking place could be considered as a ‘near miss’.

How are they dealt with?

The near miss report is logged onto the incident database for the purpose of trend analysis. While the HFEA does not require clinics to submit their investigation reports, we do expect one to have been carried out.

What is meant by ‘not an incident’?

Some incidents are graded as ‘not an incident’ meaning that they do not strictly fall within the HFEA’s definition of an adverse incident: “any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff of a licensed centre.”

Incidents reported as ‘not an incident’ include patients that have headaches, abdominal pain over scars, patients suffering from miscarriages, ectopic pregnancies and exacerbation of pre-existing medical conditions not related to fertility treatment. Clinics should log and review these as part of their commitment to learning and improving patient care.

Monitoring incident reporting

The HFEA Code of Practice (COP) requires clinics to record data on adverse incidents and to report the details to us within 12 hours for a serious incident and 24 hours for all others. We monitor reporting in the course of licence renewal inspections as clinics must have an incident reporting protocol in place. At renewal inspections, our inspectors review the internal incident reporting log to ensure incidents have been appropriately reported to the HFEA.

Any complaints the HFEA receive from patients are assessed to see if these involved an incident that has not been reported by a clinic.

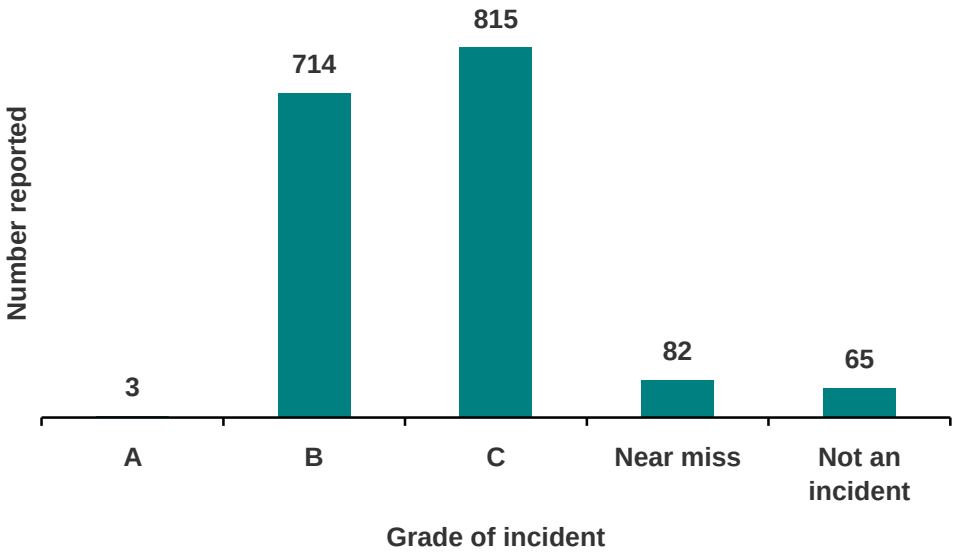
Themes, trends and lessons to learn

How many incidents were reported and how severe were they?

The HFEA receives reports of between 500-600 incidents each year. Roughly 60,000 cycles of fertility treatment are carried out in the UK annually, suggesting that an estimated 1% of cycles are affected by some sort of adverse incident.

In the period covered by this report (1 January 2010 to 31 December 2012), we received reports of 1,679 incidents. All incidents were graded in relation to severity and during this time period there were three A grade incidents; 714 B grade incidents; 815 C grade incidents and 147 that were either classified as near misses or were not incidents (see figure 1[2]).

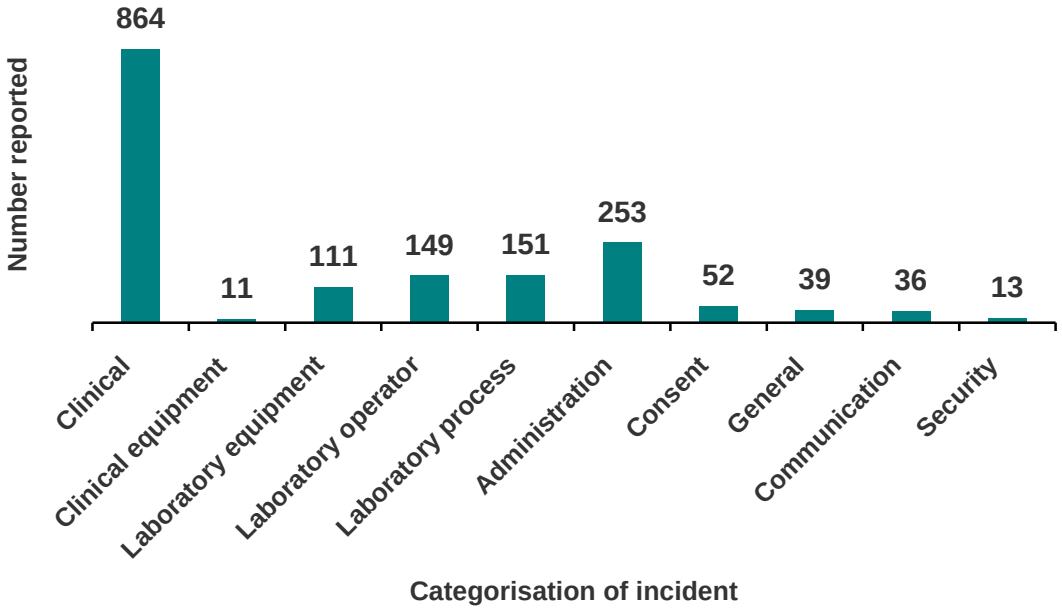
Figure 1: Number of incidents reported to the HFEA between 1 January 2010 and 31 December 2012



Of the 1,679 reported incidents, 864 were clinical incidents, 411 were due to errors in the laboratory and 253 were administrative errors. There were a further 151 incidents falling into none of those categories (see figure 2 below for a full breakdown of incidents reported between 1 January 2010 and 31 December 2012).

[2] Please note that some incidents fall into more than one category. However, to avoid double counting, we assign the incident to the single category we consider most relevant.

Figure 2: The categorisation of incidents reported to the HFEA between 1 January 2010 and 31 December 2012



The next sections of this report consider each of the three most frequently reported categories of incidents in turn.

Clinical incidents

Most incidents (51%) reported to the HFEA are clinical. They include hospital admissions due to Ovarian Hyperstimulation Syndrome (OHSS) or a failure to follow clinical protocols or guidance in the HFEA COP. The number of clinical incidents has remained constant over the past three years, with approximately 300 incidents reported each year (see annex B for a further breakdown).

OHSS

The majority of clinical incidents relate to OHSS, a side effect of the drugs taken in fertility treatment which ranges in severity from mild through to severe[3]. Mild OHSS is characterised by fluid accumulation, abdominal swelling and discomfort. Moderate OHSS is associated with nausea and vomiting[4]. Severe OHSS can include thrombosis, renal and liver dysfunction and, in very rare circumstances, Acute Respiratory Distress Syndrome (ARDS)[5]. Each year approximately 60 instances of severe OHSS and 150 cases of moderate OHSS are reported to the HFEA[6].

Other clinical incidents

Other clinical incidents in this category were as follows:

- patients starting a treatment cycle before all of their screening results were returned and reviewed;
- screening results not being checked or being misinterpreted; and
- donors being accepted and matched with a recipient without the screening results being available or checked, or screening results being misinterpreted.

A common contributory factor in this category of incidents was the failure to complete checklists to ensure all the patient/donor results had been received before proceeding with treatment. On other occasions, there was an absence of an effective checklist or procedure for checking laboratory results.

Other incidents reported in this category included instances where donors were screened in line with professional body guidelines but later contacted the centre to inform them that they had been diagnosed with a previously unsuspected genetic disease or later identified as a

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[3] OHSS severity grading is taken from the *Management of Ovarian Hyperstimulation Syndrome*, Green Top 5, Sept 2006, Royal College of Obstetricians & Gynaecologists.

[4] Coupled with symptoms described for mild OHSS.

[5] Deaths as a result of critical OHSS are very rare. Please refer to the above document for further information.

[6] It should be noted that clinics are only required to report incidents of OHSS that result in a hospital admission and that have a severity grading of severe but clinics do continue to report moderate episodes of OHSS: http://www.hfea.gov.uk/docs/2011-10-01_General_directions_0011_-_Reporting_adverse_incidents_and_near_misses_-_Version_2.pdf

carrier of a harmful recessively inherited condition (for example, following the birth of an affected child). This category of incident is clearly not a result of poor practice or systems failures on behalf of centres and these incidents are therefore classified as serious adverse reactions. The number of such incidents is low, but the impact is often great and requires careful handling by centre staff.

A few incidents concerned the misplacement of an embryo during embryo transfer, ovarian abscesses following egg collection, vaginal bleeding and urinary tract infections as well as allergic reactions to medications. Also included in this category were infections found in embryo cultures that originated from the patient or their partner. These types of incidents were infrequent and, as above, may not indicate poor practice on the part of clinics. Infections do unfortunately occur in healthcare settings even where appropriate precautions are in place.

Key learning points:

Clinics should:

- have a protocol for the management of patients presenting with OHSS and provide patients with specific information about the risks, signs and symptoms of OHSS and who to contact if they think they are developing it (including out of hours contact details);
- inform patients of the potential risks and complications relating to their clinical care and the limitations of screening tests (this information is inspected by the HFEA);
- have protocols that clearly define who is responsible for checking that screening results have been returned and reviewed;
- consider having a checklist for the front of patients' notes to include screening results, completed consent forms and welfare of the child assessments;
- ensure that staff are aware of how to escalate abnormal or ambiguous screening results; and
- ensure that staff are suitably trained and that their competence to carry out egg collections and other procedures is assessed and documented.

Administration incidents

The number of incidents reported in this category has increased from 77 in 2010 to 89 in 2012.[7] The majority of incidents reported related to a breach of patient confidentiality resulting from errors ranging from the wrong patient label being attached to a drug prescription to a database of information being emailed to the wrong recipient.

Most incidents relating to a breach of patient confidentiality involved information being posted to an incorrect address. Such information included: clinical consultation reviews, letters to GPs, consent forms, invoices for treatment and/or storage fees, blood results, scan findings and complete sets of medical records.

A sample[8] of incident investigation reports highlighted the following factors as contributory to these incidents:

- staff working on more than one set of notes/letters/invoices at a time;
- staff distracted from the task at hand by being called away to deal with a query or answer the telephone;
- a lack of adherence to Standard Operating Procedures (SOPs) (using less than the recommended number of identifiers which is especially important when several patients have the same surname);
- booking appointments outside of the normal booking procedure; and
- staff being unfamiliar with the appointment booking system and/or not having the patient's notes at hand to cross reference the name and address before posting out the letter.

The consequences of incidents of this nature meant that patients received information about other peoples' treatment cycles, blood tests/scan results and/or information about the person such as their name, date of birth, contact telephone number and address. A further undesired effect of incidents of this nature is the patient's loss of confidence in centre staff.

Email errors are increasing. Emails have been sent to patients instead of the intended recipient (usually another member of staff) with details of patient complaints and treatment schedules. The main contributory factor here was the use of predictive email addresses.

Incidents relating to breaches of patient confidentiality also constitute a breach of data protection legislation.[9] Since 26 May 2011, certain organisations are required to notify the Information Commissioner's Office of personal security breaches.

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[7] NHS England data revealed that in 2010 (for England & Wales) 42,184 incidents involving consent, communication and confidentiality were reported. For the following year 44,748 incidents were reported.

[8] 10% of incidents reported from each year.

The Information Commissioner is taking a much tougher stance with data protection breaches in the healthcare sector.[10] Two healthcare organisations were recently issued with penalties of £60,000-£70,000. Both had sent sensitive information (medical reports) containing personal details relating to a patient's health to the wrong address.[11]

On the basis of this information and from discussions with the Information Commissioner's Office, the HFEA advises clinics who report serious breaches of patient confidentiality (e.g. medical records sent to the wrong address or large amounts of sensitive data sent to the wrong recipient) to also report these to the Information Commission's Office. This organisation will be able to offer further advice and review data protection issues.

Key learning points:

Clinics should:

- consider including a non-identifying PO Box on envelopes sent out to patients (containing personal information including test results, treatment plans and invoices) so misaddressed letters can be returned without being opened;
- ensure that medical records are always sent by recorded or special delivery, or that patients are asked to attend the clinic to collect the notes in person;
- consider disabling the auto-complete function on computers to avoid emails being sent to the wrong person;
- ensure that sensitive information held on databases is never sent via email (it is safer to save the information to a secure server and direct staff to where the information is held); and
- consider whether the content of an email should be encrypted or password-protected before sending sensitive data.

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[9] The Data Protection Act 1998 defines sensitive personal data as racial or ethnic origin, political opinions, religious beliefs, trade union memberships, health, sexual life or offences.

[10] The Department of Heath defines a serious untoward incident in relation to personal identifiable data, as, "any incident involving the actual or potential loss of personal information that could lead to identity fraud or have significant impact on individuals"'. *Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents*. Jan 2010, gateway ref: 13177

[11] http://ico.org.uk/news/latest_news/2012/ico-takes-action-after-medical-examination-results-are-sent-to-the-wrong-address-12072012

http://ico.org.uk/news/latest_news/2012/ico-issues-first-penalty-to-the-nhs-following-serious-data-breach-30042012

Laboratory incidents

The quality of the service clinics provide to their patients is critically dependent on the quality of the methods and equipment used in the laboratory. Eggs and embryos are very small – just 0.1mm in diameter – and fragile. Eggs, sperm and embryos are sensitive to small changes in temperature, pH and the physical properties of the medium in which they are cultured. Given their delicate nature, incidents can, and do, occasionally happen. Laboratory incidents are further categorised according to whether they arise as a result of equipment failure, operator or process errors. When grouped together they form the third most reported cohort of incidents. The frequency of such incidents reported has remained fairly static over the time period covered by this report.

Equipment failure

The most commonly reported incident in this category related to equipment faults and failures. Included in this category were:

- failures in the alarm and 'auto-dial' systems connected to vessels used to store eggs, sperm and/or embryos (these alarms are activated if the storage unit is compromised and an auto-dialler automatically calls a member of staff to alert them when a tank starts to fail);
- power failures;
- equipment being moved or disconnected in the course of the general laboratory cleaning;
- pipes/tubes supplying essential gases to incubators to maintain the quality of embryos becoming distorted, leading to the quality of embryos being comprised; and
- faulty transport incubators.

Key learning points:

- It is vital that equipment is serviced regularly.
- Equipment that is not in use or that is waiting to be re-validated/re-calibrated and tested before being put back in service should be clearly identified as such and moved from the work area if possible.
- Once equipment has been serviced, it should be checked to confirm the settings are in the correct position before it is put back in use.
- It is important to check that equipment is in the correct place and that tubing and leads at the back of a machine have not become detached or kinked. On the basis of incidents of this nature, several centres have included this action in their cleaning checklists.
- Auto-dial systems connected to alarms should be tested by clinic staff on a regular basis.
- Transport incubators should be checked to ensure they are fully charged before use. It should also be made clear who has responsibility for maintaining and servicing transport equipment.
- It is also important for clinics to have a comprehensive contingency plan in case a power failure is severe enough to warrant patients being transferred to another unit to complete their treatment. If the clinic is part of an NHS trust it is important that the estates department informs the unit of any planned generator test so that the staff can prepare for any interruption in their power supply.

Operator error

Incidents in this category result from human error. The number of incidents reported in this category has remained fairly static over the time period covered by this report.

Examples of incidents falling into this category include:

- dishes containing eggs or embryos that were knocked or dropped;
- pipettes that were accidently knocked whilst moving eggs or embryos (causing damage or loss of samples);
- failure to operate equipment properly;
- turning off a piece of equipment mid-cycle;
- incorrectly labelling pots or tubes;
- failure to inject or inseminate eggs;
- forgetting to move samples from temporary storage vessels/storing in the wrong vessel; and

- selecting the incorrect embryo for transfer (e.g. not the best quality embryo or an embryo affected by a condition that should have been screened out via the pre-implantation genetic diagnosis (PGD)[12] process).

The common theme cited for the majority of these incidents is lack of attention or staff being distracted from their tasks.

Just as incidents of this nature can have a devastating effect on patients, staff involved in such incidents may also need support. Staff members can sometimes need counselling, or may need to stand down from a particular task until they have received further training and supervisory support to continue in their role. Depending on the nature of the incident, it may also be helpful for staff involved to participate in preparing a case study and presenting the findings to the rest of the team, as a way of sharing their experience and learning from the incident.

It is rare for incidents to occur solely because a member of staff has made an error and root cause analysis can sometimes reveal underlying systems failures like poor training, workload pressures and inadequate SOPs. It is important to maximise opportunities for learning so that clinics do not adopt a culture of simply blaming an individual for an incident. It is crucial that any underlying systems failures are identified if the risks of an incident reoccurring are to be mitigated successfully.

Key learning points:

Clinics should:

- ensure that their protocols for handling and moving oocytes and embryos take account of the possible accidental loss of material;
- when large numbers of oocytes or embryos are being handled, move them in small batches so that the impact of loss is reduced;
- balance the risks of trying to handle and process gametes and embryos rapidly against the risk of material being exposed to prolonged sub-optimal conditions (e.g. temperature, pH, medium);
- supervise trainees during training in the handling and moving of embryos;
- make every effort to ensure embryologists are not distracted whilst performing procedures; and
- Clinics should consider holding ‘pipetting master classes’ to ensure the proper technique is being used.

[12] PGD is a technique that enables people with a specific inherited condition in their family to avoid passing it on to their children. It involves checking the genes of embryos created through in vitro fertilisation (IVF) for this genetic condition.

Process error

Incidents in this category included failure to follow laboratory protocols or the use of procedures that were not compliant with the 1990 Human Fertilisation and Embryology Act (as amended) or HFEA COP.

Omissions included failure to carry out specific witnessing steps. An example might be a sample being moved between dishes without the labelling on the new dish being checked by a witness. Or where cryopreserved material is moved from one location to another without the movement being witnessed, or without the logs documenting the storage location being updated. Incidents like these have led to patients being informed that their gametes or embryos are no longer in storage or have been 'lost'. This has caused patients a considerable amount of distress and is considered likely to have resulted in their losing confidence with the service.

In other incidents staff have failed to: follow protocols for freezing, use the correct medium, cover microdroplets with oil which prevents culture medium evaporating, or inseminate eggs.

Key learning points:

- Clinics should ensure that different types of media are kept in clearly labelled and distinctively shaped bottles/flasks. Where there is a possibility of media being misidentified, products should be stored separately.
- At the end of an egg collection procedure, when eggs are moved to prepared culture dishes, all eggs should be accounted for. All dishes should be inspected before discarding to ensure that they are empty. Clinics should consider modifying the lab record to record that all eggs have been inseminated.

If there is an incident that causes loss or damage to gametes or embryos, senior staff should:

- discuss the situation with the patient;
- offer an apology and explanation;
- explain what measures have been put in place to minimise the risk of reoccurrence; and
- explain what further support the patient will be offered.

Learning from A grade incidents

Since October 2009, we have published the details of A grade incidents on our website, except where the information may identify the patient involved. Three A grade incidents have been reported in this time frame as follows:

- A member of staff removed frozen sperm from storage while it was still within its consent period.[13]
- A family seeking to have treatment with donor sperm to have a genetically related sibling were provided with treatment using the sperm of a different sperm donor. This meant that the resulting child had a different genetic father than their sibling[14].
- Dishes with embryos of 11 patients were observed to be contaminated with cellular debris that may have contained sperm.[15]

A member of staff removed frozen sperm from storage while it was still within its consent period

The investigation revealed that there was poor adherence to audit requirements, poor and inconsistent documentation, as well as poor leadership and lack of supervision. It also showed that the culture within the unit led to lack of cohesion with wider NHS trust governance processes. In addition, shortage of trained staff was a contributory factor.

This incident highlighted not only the need for a robust, well integrated quality management system[16], but also the need for a comprehensive system to verify that before removing material from storage the correct procedures had been followed.

Key learning points:

Clinics should:

- review their 'bring forward system' to ensure there is a clear process in place; and
- aim to foster a culture where staff are empowered to challenge if procedures are not being followed and to escalate their concerns accordingly.

[13] http://www.hfea.gov.uk/docs/2010-10-28-LC-report-and-minutes-0190.pdf

[14] The report and Licence Committee minutes are not in the public domain as they are considered patient identifying.

[15] http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=429&merge=1

[16] A quality management system ensures that patients receive an agreed standard of care throughout their treatment and that clinics continually improve the way the service is delivered, ensuring consistency throughout.

A family seeking to have treatment with donor sperm to have a genetically related sibling were provided with treatment using the sperm of a different sperm donor

In 2012, an A grade incident was reported to us, in which a family seeking to have treatment with donor sperm in order to have a genetically related sibling were provided with the sperm of a different donor. This meant that the resulting child had a different genetic father than their sibling.

The HFEA investigated the matter fully and placed a condition on the clinic's licence that is still active: the condition restricts use of sperm donated around the time this incident occurred. The incident investigation provided evidence that the clinic had made substantive changes to its practices in the time between the sperm being donated and stored with an incorrect label and used in the patient's treatment. In combination with the condition on the clinic's licence, these changes were considered appropriate to minimise the possibility of such an incident reoccurring and as a result the HFEA considers the matter closed.

This situation was reported in the media contemporaneously, although with very few substantive facts as it was essential for the protection of the family, and in particular the children involved, that all identifying details were redacted. No HFEA minutes or reports in relation to this incident have ever been published for similar reasons. The need to protect the family's anonymity remains, and so while the HFEA acknowledges both the seriousness of the incident, and the public interest in open and transparent investigations as a general rule, in the best interests of the family concerned no further information will be given in this instance.

Key learning points:

- Clinics providing a donor recruitment service should have dedicated reception staff to meet and greet donors or to verify their identity.
- Clinics should have a robust appointment system in place to help manage workloads and ensure sufficient staff are available to run the service.
- No more than one sample should be collected at a time and the samples should be processed in chronological order in relation to procurement.
- Staff should be fully trained and work within the SOPs in relation to witnessing, processing and freezing donor samples.

Dishes with embryos of 11 patients were observed to be contaminated with cellular debris that may have contained sperm

This type of incident has not been seen before at this clinic and the level of contamination observed was very low. The root cause analysis did not identify clear contributory factors but in the absence of any other explanation, it was considered likely that a pipette may have been contaminated with sperm during a different process. The clinic changed its practices to minimise the possibility of similar contamination; dishes are now prepared in a workstation

with pipettes and pipette tips dedicated to dish preparation. No other processes are performed in this workstation or using the pipettes allocated to it. This arrangement removes any potential source of cellular contamination from the dish preparation process, which is the most effective risk control measure which could be implemented.

In response to this incident and the investigation, the clinic's SOPs have also been updated to emphasise the importance of decontaminating pipettes between processes and dealing with gametes and/or embryos from different patients.

Key learning points:

- Clinics may want to review their own procedures and update their own SOPs for preparing culture dishes.
- All laboratory staff should follow good laboratory practice in relation to pipetting; for example filtered pipette tips should be used.
- Pipetting techniques should be observed and audited on a regular basis to ensure good laboratory practice is being adhered to.

Our next steps in incident reporting and monitoring

We are committed to encouraging clinics to report incidents to build up our knowledge of why incidents happen and share learning. As part of this commitment, we intend to develop and expand on the information that is fed back to clinics in relation to incident reporting.

Over the next 12 months we intend to:

- communicate the learning from this analysis with clinics;
- hold local events to make sure that learning from incidents is understood and embedded;
- develop the clinical governance section on the Clinic Portal[17] to include aggregated data on incident trends to give centres a more immediate overview of what is happening across the sector;
- produce an annual incident report[18];
- produce quarterly 'snap shot' incident reports throughout the year, each time focusing on a particular category of incident;
- produce short reports for A grade incidents that are considered patient identifying which provide details of the nature of the incident and recommendations (to be published on our website alongside the accompanying Licence Committee minutes);
- develop and expand how we monitor incident follow-up reports and action plans in the course of inspections;
- develop the clinical governance section of the HFEA website so that our processes are transparent; and
- review whether there is more learning from B and C grade and near miss incidents.

[17] Clinic Portal is a secure HFEA website where clinics can submit and retrieve information about themselves; e.g. update their clinic's details, apply for licences and read incident alerts etc.

[18] 2013 report to be published later this year

Summary conclusions

There is no ‘correct’ number of patient safety incidents and it should never be assumed that the total numbers of incidents are representative of totals across the sector.

This analysis has identified where there are opportunities for the fertility sector to learn from incidents that have happened across the sector and we will continue to work closely with clinics to make sure this learning is shared.

We consider that the incident reporting system is embedded in clinics’ clinical governance systems. When centres are inspected, their internal incident log is reviewed to ensure all incidents that should be reported to the HFEA are. There are very few discrepancies. On the whole clinics report incidents in a timely fashion and display a commitment to learn from incidents.

Annex A: Risk grading matrix

The following risk matrix is used to assess the severity of incidents and near misses and the likelihood of a reoccurrence:

Step 1

Taking account of the current controls in place and their adequacy, how likely is it that this particular incident will occur again? Is this at this particular clinic or all clinics?

Probability of reoccurrence:

Level	Descriptor	
5	Almost certain	Likely to occur on many occasions
4	Likely	Probable but not persistent
3	Possible	May occur occasionally
2	Unlikely	Not expected to happen but possible
1	Rare	Difficult to believe it could happen again

Step 2

Again, taking account of the conditions and current controls in place and their adequacy, how severe would the consequences be if this incident occurred again?

Level	Descriptor	Actual or potential impact on individual	Actual or potential impact on organisation	Numbers affected	Potential for complaint or litigation
5	Severe	Death of patient/staff, loss of all samples for many patients	Multi-agency investigation, adverse publicity, prosecution, loss of HFEA licence.	One (e.g. death) or many e.g. major storage tank failure	Litigation expected/ certain. Possible prosecution.
4	Major	Major harm, professional misconduct, loss of all samples for few patients, recurrent significant breach of COP.	Costs, reputation damage, impact on staff morale, disciplinary hearings, loss of HFEA licence or conditions on practice.	Smaller numbers 2-5	Litigation expected/ certain. Action taken by professional organisations e.g. Health and Safety Executive (HSE), MHRA* or General Medical Council (GMC).

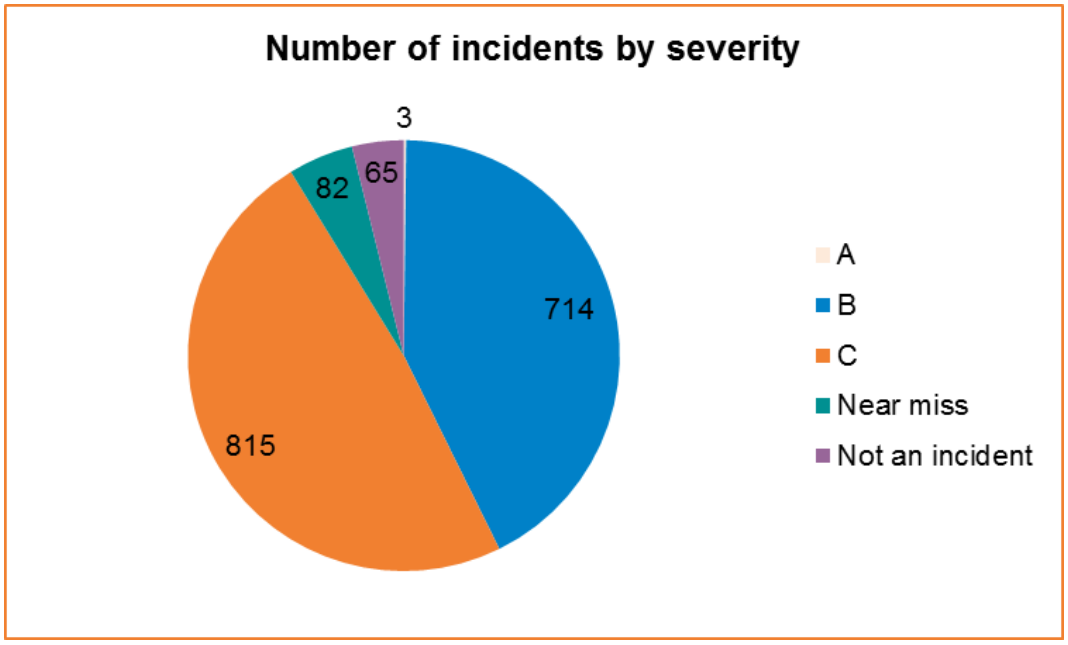
3	Moderate	Semi-permanent harm, loss of all samples for one or loss of most samples for some patients, significant breach of COP	RIDDOR± or MHRA* reportable, compensation costs (complimentary cycle).	1-2	Litigation possible but not certain. High potential for complaint.
2	Minor	Short-term injury, minor breach of COP, avoidable risk, loss of one of many samples for a patient.	Minimal risk to organisation.	1	Complaint possible, litigation unlikely.
1	Insignificant	No injury or adverse outcome.	No risk to the organisation	1	Complaint and litigation unlikely.

± Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013
* Medicines and Healthcare products Regulatory Agency

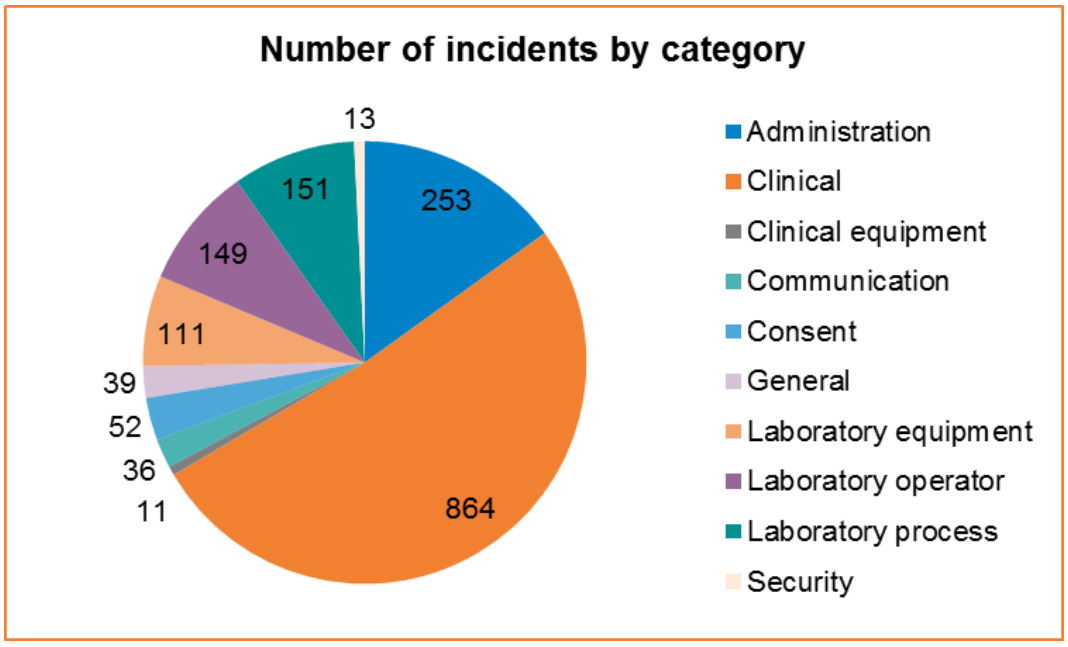
Annex B: Breakdown of all incidents by severity and category – 1 January 2010 to 31 December 2012

1 January 2010 to 31 December 2012

The total number of incidents reported during this period was 1,679. A breakdown of these incidents by severity and category is shown below.

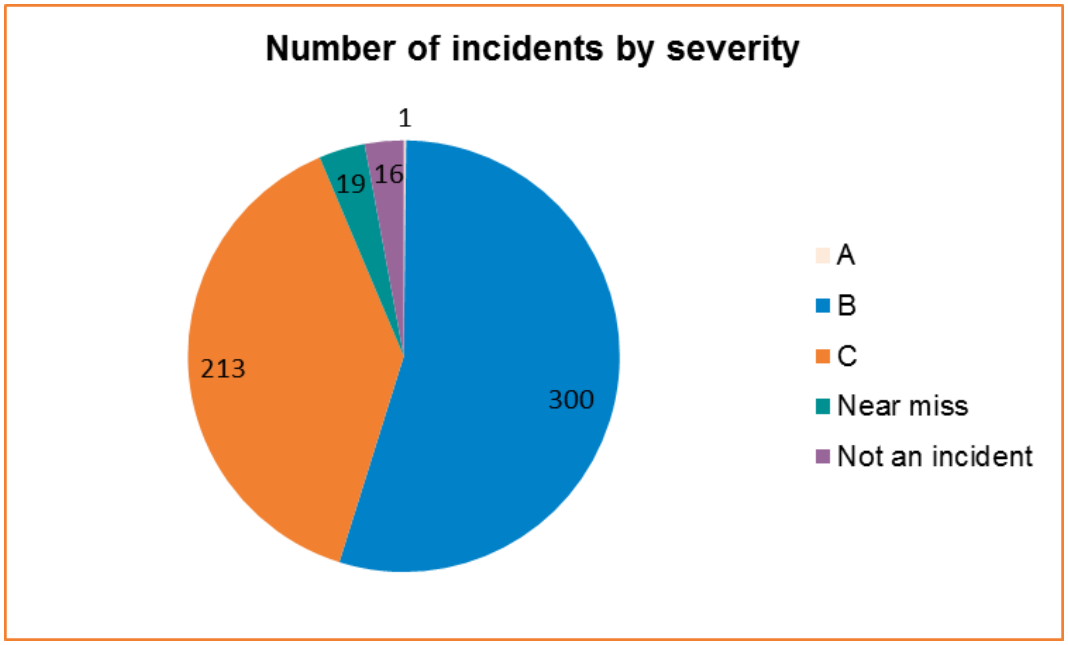


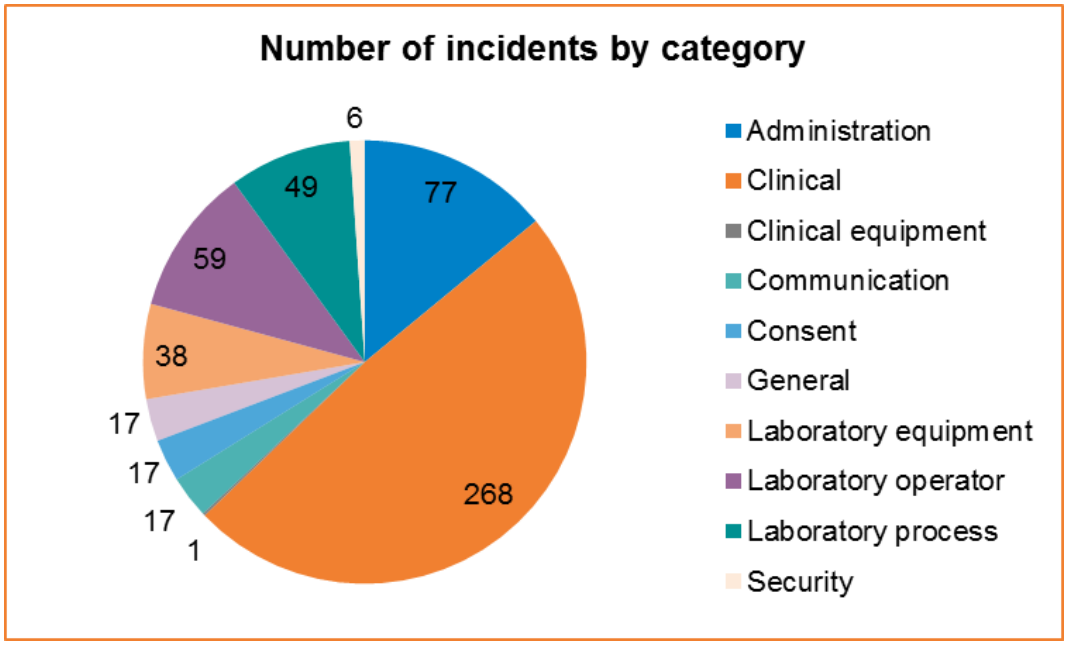
Note: Some incidents fall into more than one category. To avoid double counting, we assign the incident to the single category we consider most relevant. See annex A for the severity and categorisation fields.



2010

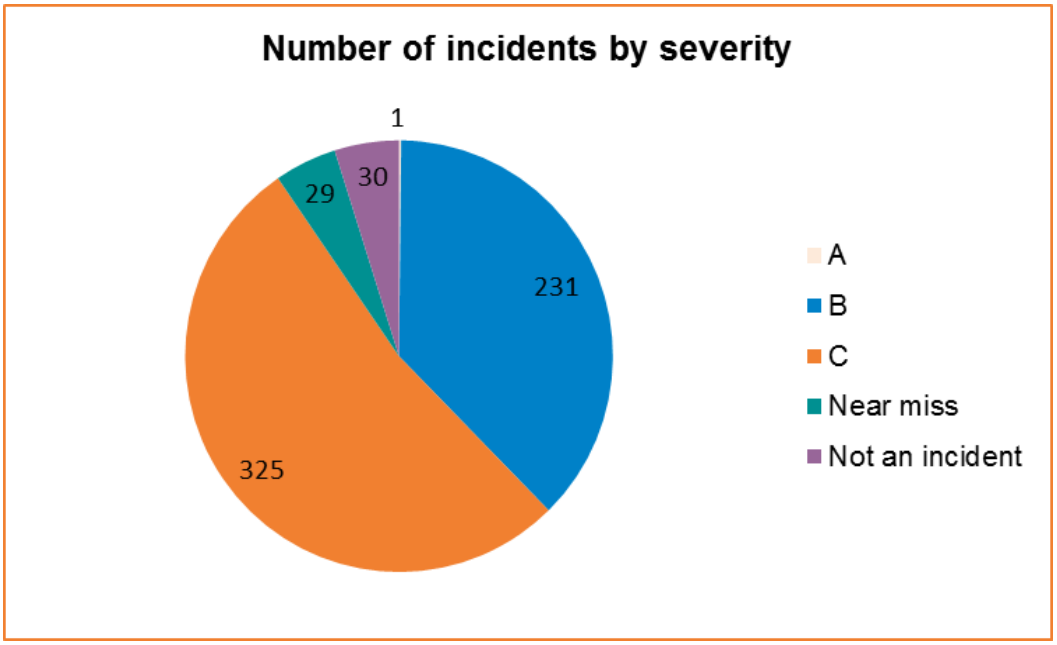
The total number of incidents reported in the calendar year 2010 was 549. A breakdown of these incidents by severity and category is shown below.

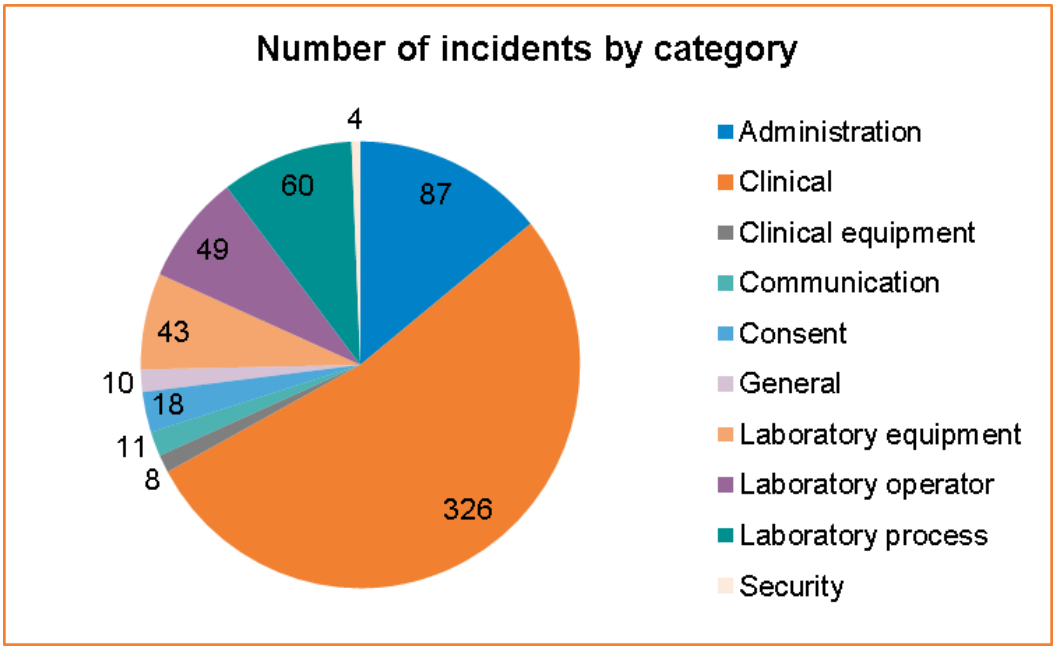




2011

The total number of incidents reported in the calendar year 2011 was 616. A breakdown of these incidents by severity and category is shown below.





2012

The total number of incidents reported in the calendar year 2012 was 514. A breakdown of these incidents by severity and category is shown below.