

Adverse incidents in fertility clinics: lessons to learn

January-December 2013



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Introduction

In July this year we published our [first report into adverse incidents at fertility clinics](#). The report, which covered the calendar years 2010, 2011 and 2012, was intended to create a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other. It forms part of our work to promote transparency and maximise opportunities for learning from incidents to improve quality of care for patients.

In line with this, we decided to make the report an annual one. This report is the first in the annual series and looks back on the 2013 calendar year. Publishing these reports in quick succession allows us to provide the sector with the most up-to-date information. Our next report, looking back on 2014, will follow shortly after in early 2015.

While incidents are rare¹, the impact on both patients and clinic staff is upsetting and in some cases, devastating. It's therefore vitally important that clinics do everything they can to learn from mistakes to prevent them reoccurring. At the end of the first report, we made a commitment to communicate the lessons learned with the sector and we have already begun an engagement process with clinics to ensure those lessons are embedded in their routine working practices. This process will take time and we recognise that while any changes may not immediately be reflected in the reported figures², the move towards openness and transparency will continue to encourage a culture of learning and improvement.

The themes, trends and lessons to learn in this report remain very similar to the previous report. We therefore encourage clinics to consider this report in parallel with the [2010–2012 report](#) to get a full picture of how they can continue to prevent incidents from occurring.

Key facts

- 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.
- We have a rigorous process for reporting, handling and investigating adverse incidents and near misses. For more information about this, and information about how incidents are graded, log on to our [website](#).

¹ More than 60,000 cycles of IVF treatment are carried out each year in the UK. An estimated 1% of these cycles are affected by some sort of adverse incident.

² The incidents contained within this report relate to 2013, before our first report into adverse incidents at fertility clinics was published in July 2014. These figures will therefore not reflect any improvements made as a result of the learning from the report.

Themes, trends and lessons to learn

In the period covered by this report (1 January to 31 December 2013), we received reports of 516 incidents. All incidents were graded in relation to severity and during this time period there were four A grade incidents, 208 B grade incidents, 262 C grade incidents and 42 that were either classified as near misses or were not incidents.³

The overall number of incidents reported to the HFEA in 2013 is very similar to those reported in the previous year.⁴ There has been a slight increase in the number of B grade incidents reported this year⁵ and the number of C grade incidents reported has decreased slightly⁶. These variances are not significant and do not reflect a trend or theme; they are random variations.

More A grade incidents were reported in 2013 than in previous years and each of these is described later in the report. It is important to reiterate that incidents of this nature are, for the most part, due to a unique set of circumstances and are not usually foreseeable. This increase is therefore an unfortunate chance occurrence, rather than representing an overall trend or pattern.

Whenever A grade incidents occur, the HFEA and clinics make sure that there are systematic measures in place to respond to them. These measures protect patients, their gametes and embryos, and ensure that robust investigations are carried out so that organisations learn from these incidents and minimise the risk of them happening again.

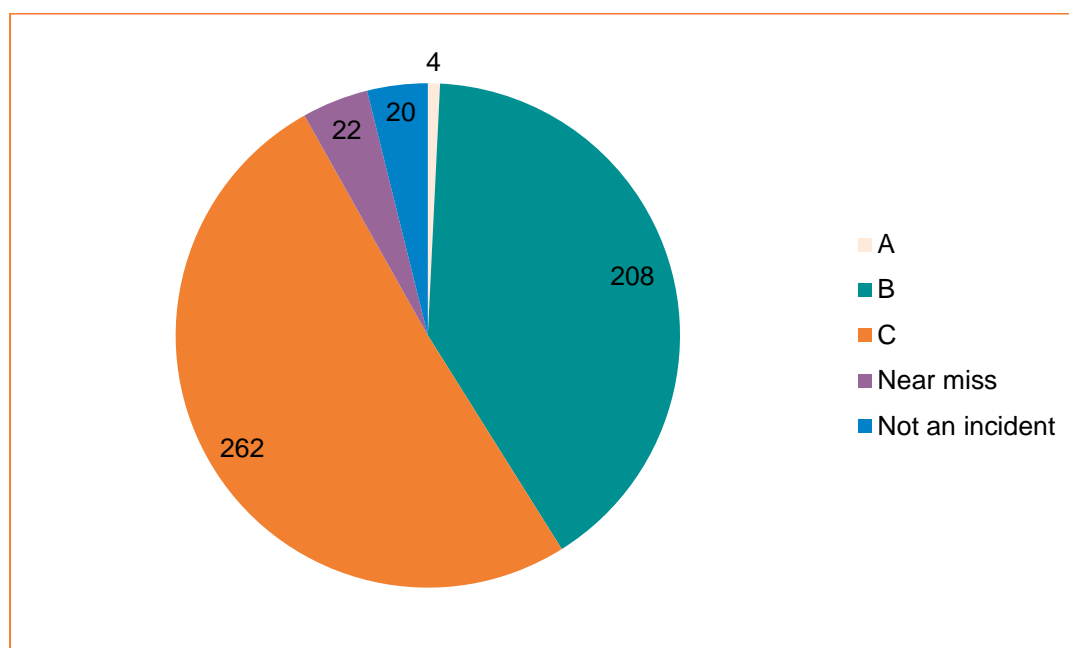
³ Some incidents fall into more than one category. However, to avoid double counting, we assign the incident to the single category we consider most relevant.

⁴ 514 incidents reported in 2012 compared to 516 in 2013.

⁵ 25 more B grade incidents reported in 2013.

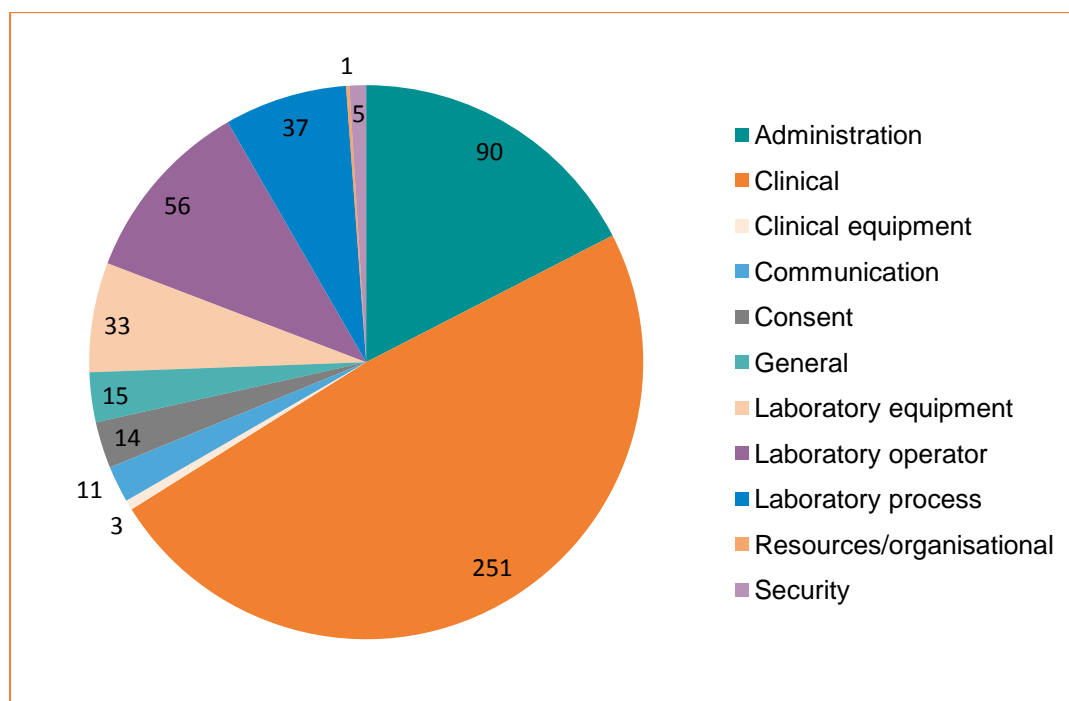
⁶ 15 less C grade incidents reported in 2013.

Figure 1: Number of incidents reported to the HFEA, January–December 2013



Of the 516 reported incidents, the three categories with the most incidents were clinical (251), errors in the laboratory (126) and administrative errors (90). There were a further 49 incidents falling into none of those categories. Figure 2 below provides a full breakdown.

Figure 2: Number of incidents by category, January–December 2013



The three categories with the most incidents are the same as the [2010–2012 report](#) and the figures for each are similar. Our analysis has shown that the type of incidents within these categories is also very similar, as are the contributory factors.

We will now examine each of these categories in turn. We would encourage clinics to once again review the [2010–2012 report](#) in parallel with this report to get a full picture of the lessons to learn and how they can improve practices to improve care for patients.

Clinical incidents

Just under half the incidents (49%) reported to the HFEA in 2013 were clinical.⁷ They included failure to follow clinical protocols or guidance in the HFEA Code of Practice (COP) and hospital admissions due to ovarian hyperstimulation syndrome (OHSS).

Another clinical incident of note was where a clinic reported that on three occasions male partners were found to have no sperm during the cycle of treatment (azoospermia). On further enquiry, it was found that the three were taking some supplements/protein shakes from their local gym that contained anabolic steroids.

The Person Responsible has also noticed a general increase in the number of men with azoospermia related to the consumption of anabolic steroids. If staff notice a similar pattern emerging in their clinic, they may want to consider asking patients if they are taking supplements or protein shakes and explain their rationale for this line of questioning.

OHSS

As we saw in the [2010–2012 report](#), 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. Mild OHSS is characterised by fluid accumulation, abdominal swelling and discomfort. Moderate OHSS is associated with nausea and vomiting⁸. Severe OHSS can include thrombosis, renal and liver dysfunction.

Most women with OHSS recover with simple pain relief and after being given fluids (either to drink or via an intravenous drip), but other treatments sometimes need to be given and sometimes fluid needs to be drained from the abdomen. The British Fertility Society recommends that clinics should have their own protocols in place to manage the risk of OHSS and the HFEA only requires clinics to report OHSS incidents that result in a hospital admission and that have a severity grading of severe⁹. However, clinics do continue to report mild and moderate episodes.

This year approximately 46 instances of severe OHSS were reported to the HFEA and 160 cases of mild/moderate were reported. This means that there was a slight decrease in the number of severe cases of OHSS¹⁰ compared to the previous year. The number of mild/moderate cases of OHSS increased slightly but this is not statistically significant.

⁷ 270 clinical incidents reported in 2012 compared to 251 reported in 2013.

⁸ As well as symptoms of mild OHSS.

⁹ See http://www.hfea.gov.uk/docs/HFEA_General_Directions_0011_-_Reporting_adverse_incidents_and_near_misses_v3.pdf.

¹⁰ 60 cases of severe OHSS and 150 cases of moderate OHSS were reported in 2012.

Key learning points reported by clinics:

For clinics that notice an increase in the number of patients developing severe OHSS:

- consider the use of an anti mullerian hormone (AMH) blood test to get a more reliable measure of ovarian reserve
- audit/review stimulation and monitoring policies
- consider the use of the antagonist protocol with a GnRH agonist trigger and modified luteal phase support for all polycystic ovary syndrome (PCOS) and non-embryo transfer (ET) patients such as egg donors and fertility preservation patients
- also consider the use of other evidence-based OHSS interventions that are available such as cabergoline.

Administration incidents

Ninety incidents were reported in this category, roughly the same as the previous year.¹¹ As with the [2010–2012 report](#), the majority of incidents related to a breach of patient confidentiality. This mainly involved information being posted to an incorrect address. This included clinical consultation reviews, letters to GPs, consent forms, invoices for treatment and/or storage fees, blood results/semen analysis results and scan findings.

A sample of incident investigation reports highlighted that the contributory factors to these incidents were the same as those found in the previous report (p10). The majority of these incidents are avoidable and yet the consequences can be very upsetting for patients. It's therefore vitally important that clinics work hard to implement the lessons learned from the previous report (p11).

Where we recognise a series of administrative incidents occurring at the same clinic, we are working with them to find appropriate solutions. This includes offering them our own analysis and recommending training packages provided by other government bodies such as the Information Commissioner's Office, the UK's independent authority on data protection compliance.

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. The number of laboratory incidents reported this year has risen compared to the previous year. The types of incidents have remained broadly the same.¹²

¹¹ As compared to 89 administration incidents reported in 2012.

¹² 113 laboratory incidents reported in 2012 compared to 126 reported in 2013.

Laboratory incidents are further categorised according to whether they arise as a result of equipment failure, operator or process errors, and we now examine these in turn.

Equipment failure

The most commonly reported incident in this category related to equipment faults and failures. The number of incidents reported in this category has increased slightly¹³ but this is not statistically significant. The types of incidents were the same as those reported in the [2010–2012 report](#) (p12) and so clinics should once again consider this report to ensure they get a full picture of the lessons to learn.

Operator error

Incidents in this category result from human error. The number of incidents reported in this category has increased slightly from the previous report¹⁴. Examples include:

- dishes containing eggs or embryos that were knocked or dropped
- pipettes that were accidentally 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
- selecting the incorrect embryo for transfer (eg, not the best quality embryo or an embryo affected by a condition that should have been screened out via the pre-implantation genetic diagnosis (PGD¹⁵) process).

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

More information about the importance of supporting staff involved in such incidents and root cause analysis is included in the [2010–2012 report](#). Clinics should continue to embed the key learning points for this type of incident which were outlined on p14 of that report.

Process error

The number of incidents in this category has remained broadly the same.¹⁶ Therefore clinics should continue to work on the key learning points from the [2010–2012 report](#) (p15).

¹³ 30 equipment failure incidents in 2012 compared to 33 reported in 2013.

¹⁴ 41 laboratory operator incidents reported in 2012 compared to 56 reported in 2013.

¹⁵ PGD is a technique that enables people with a specific inherited condition in their family to avoid passing it onto their children. It involves checking the genes of the embryos created through IVF for this genetic condition.

¹⁶ 42 process errors in 2012 compared to 37 reported in 2013.

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.

There were four A grade incidents reported in 2013, an increase on the three previous years¹⁷. By their very nature, A grade incidents are difficult to predict and those reported this year do not illustrate a reoccurring theme. However, by reviewing this and the previous report, clinics can reflect on what learning can be applied to their own practice, ensuring they do everything possible to avoid mistakes happening.

The A grade incidents reported in 2013 were as follows:

- A storage tank failed, which affected donor sperm samples belonging to 250 patients.
- An equipment failure meant that embryos for seven patients did not progress as expected and therefore were not suitable for embryo transfer.
- An affected embryo was replaced in error during a PGD treatment cycle.
- A baby was born with a condition following the transfer of a frozen PGD embryo.

Both PGD-related incidents occurred at the same clinic and involved the same testing laboratory¹⁸. We conducted a full management review and were satisfied that the clinic had made sufficient changes to its practices to reduce the risk of future reoccurrences. We also engaged the help of Clinical Pathology Accreditation (CPA) to investigate matters relating to the third party laboratory involved and it concluded that errors made at the testing laboratory were as a result of individual 'operational error' rather than any larger systemic failure.

It is important to note that one of the incidents, although reported in 2013, followed a frozen embryo replacement of embryos created and tested in 2008.

Further details about each case can be found on our website (the links are provided on p10 of this report).

A storage tank failed, which affected donor sperm samples belonging to 250 patients

The investigation revealed that a valve supplying liquid nitrogen¹⁹ to the storage tank containing the samples had been left closed, preventing liquid nitrogen from entering the system. In turn this led to the liquid nitrogen running out earlier than expected. There was also a damaged connection hose, resulting in the liquid nitrogen evaporating in the hose and emptying the entire supply tank while not filling the storage tank.

¹⁷ One A grade incident was reported in each of 2010, 2011 and 2012.

¹⁸ The incidents relating to PGD are currently the subject of ongoing investigations by the clinic. It is possible therefore that, depending on the outcome of those investigations, the incidents may need to be reclassified at a later stage.

¹⁹ Liquid nitrogen is used in many cooling and cryogenic applications. In fertility clinics it is used as the coolant in storage tanks to keep samples frozen.

This incident highlighted the need to make sure that laboratory staff understand how to use the supply tanks and have further training in the use of liquid nitrogen, especially in relation to identifying potential problems. The investigation reports and Licence Committee minutes can be found at <http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5456> and <http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5491>.

Key learning points:

Clinics should:

- test the alarm systems are working every week
- check all supply tanks to make sure the contents indicators are working correctly
- check pipes and feeder tubes regularly to make sure there are no kinks or twisting to ensure a free flow of essential gasses.

An equipment failure meant that embryos for seven patients did not progress as expected and therefore were not suitable for embryo transfer

Laboratory staff noticed that eggs and embryos being cultured and stored in a specific incubator had failed to progress. The clinic found that all conditions were the same with regard to consumables and media²⁰ and therefore the only variable was the oxygen concentration within the incubator. This should have been 5% but was found to be 3% when the level was checked with an oxygen monitor.

The clinic concluded that it was likely that the eggs and embryos did not progress because too much nitrogen had entered the incubator, causing too low an oxygen concentration. This was not picked up by the incubator's oxygen sensor and further investigation found it to be faulty. The investigation reports and Licence Committee minutes can be found on our website at <http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5604>.

Key learning points:

Clinics should:

- ensure all laboratory equipment is regularly checked and in good working order
- consider fitting independent oxygen probes on incubators.

An affected embryo was replaced in error during a PGD treatment cycle

A patient had several embryos tested for a genetic condition through PGD. The outcome of this analysis misdiagnosed the affected embryos leading to an incorrect (affected) embryo being replaced. The investigation noted that the circumstances in this particular case made diagnosis technically difficult.

²⁰ Fluid used to culture embryos.

The investigation reports and Licence Committee meeting minutes for this incident can be found at <http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5492> and <http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5557&merge=1>.

Key learning points:

Clinics should:

- ensure they have an understanding of the risks of misdiagnosis and make sure these are properly communicated to patients
- give consideration to how they will monitor the performance of testing laboratories.

A baby was born with a condition following the transfer of a frozen PGD embryo

A patient underwent a PGD treatment cycle in 2008 and used a frozen embryo from that cycle for further treatment in 2013 at another clinic. Following this, the patient gave birth to a child with the genetic condition that had been tested for by PGD.

This incident may have occurred because of the type of testing that was used at the time the embryo was created. The diagnostic test used by the laboratory for PGD is now much more robust than the test used in 2008.²¹ It was not possible to confirm the original PGD diagnosis of the embryo therefore the clinic's ability to investigate this incident was limited. The investigation reports and Licence Committee meeting minutes for this incident can be found at <http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5492> and <http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5557&merge=1>.

Key learning point:

- When patients return for a frozen embryo transfer using embryos that have been genetically tested, the clinic should inform the testing laboratory of the case so that the status of the embryos can be reviewed to see whether re-testing should be carried out.

²¹ It would be desirable to have genetic testing of the embryo carried out to confirm the status of the embryo as there is also a possibility that the baby could have a genetic variant that differs from the mutations carried by the parents that has not been tested for.

Summary conclusions

The overall number of incidents in 2013 remained fairly static compared to the previous year and the categories with the most incidents have also remained similar.

It is important to reiterate that the vast majority of fertility treatment is carried out without any problem occurring; an estimated 1% of IVF treatment cycles are affected by some sort of adverse incident. The number of A grade incidents has increased, but this is an unfortunate chance occurrence, rather than representing a reoccurring theme. The number of B grade incidents has increased slightly and the number of C grade incidents has decreased slightly. These are random slight variations.

Our aim is to share learning so that clinics can do everything possible to protect their patients. In line with this, we are continuing to make progress on our next steps in incident reporting and monitoring which we highlighted in our [2010–2012 report](#) (p19).

To date this has included:

- Developing the clinic incidents page on our website so that all the published A grade incident material is in one place. This means that clinics are able to access this information more readily, to review the information provided and reflect and improve on their own practices.
- Adding the risk grading matrix and incident grading descriptions to the clinic incidents page on our website as another resource for clinics to use.
- Developing Clinic Portal²² to act as a repository for previous Clinic Focus²³ articles regarding incidents. This will make this information easier to access as it is all in one place. We have also added training materials to the portal in the form of incident scenarios which clinics can practice grading.
- Focussing on the clinics who report the most frequent amount of administration errors to understand what particular barriers are faced and how we can work with them to improve compliance in this area.
- Calling upon clinics to contribute to a reduction in the number of C grade incidents by reflecting upon their own practices and improving systems.²⁴

Our next report on the 2014 incidents data will be published in spring 2015. In the meantime, we would once again encourage clinics to review both this and the previous report, to discuss the contents at team meetings, and reflect on how they can continue to embed the lessons to learn to continually improve the quality of care for patients.

²² Clinic Portal is a secure HFEA website where clinics can submit and retrieve information about themselves; eg, update their clinic's details, apply for licences and read incident alerts etc.

²³ The HFEA's monthly electronic newsletter to clinics.

²⁴ Our Director of Compliance and Information wrote to all Persons Responsible on 4 August 2014 urging them to review the previous report and reflect on how they can incorporate the lessons learned into their own practices.