Human Fertilisation & Embryology Authority

Adverse incidents in fertility clinics: lessons to learn

January-December 2015

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Introduction

This is our latest annual report of adverse incidents in fertility clinics covering incidents reported to us in 2015[1]. Our intention in publishing this report is to continue our work in promoting transparency and maximising opportunities for clinics to learn from incidents to improve the quality of care for patients.

The vast majority of fertility treatment (there were over 70,000 treatments in 2015) is carried out without any problems occurring. But, as in any hospital or clinical setting, mistakes can happen. Most people understand that there are risks associated with all forms of healthcare, and equally expect that healthcare professionals take seriously the opportunities to learn from incidents where mistakes have happened so they can be avoided wherever possible.

We classify incidents that take place within a clinic as 'adverse incidents' or 'near misses'. Adverse incidents deemed serious must be reported to us within 12 hours and all other incidents or near misses within 24 hours.

As the regulator, we monitor the number and nature of adverse incidents and near misses. For any incident that occurs we require the clinic to produce an incident report so we can determine if it has understood the 'root causes' of the incident and has started to think about how changes in practice could prevent a reccurrence.

If we have concerns, or notice a trend, we work with the clinic to identify what's going wrong so improvements are implemented. Whenever there is a serious incident, we carry out an inspection. When we inspect clinics, we now spend more time understanding their approach to incident reporting, the quality of their analysis of the root causes of an incident and, crucially, whether the learning has been embedded within the clinic so that the potential for incidents happening is minimised.

Reporting adverse incidents is recognised as one of the best ways of ensuring that errors and their causes are identified and the opportunity for them to happen again, in that clinic – and in other clinics – is reduced. We publish this report every year so that clinics can learn from each other and improve the quality of care for patients.

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 please see our website.

1. Our previous annual reports can be found at: http://www.hfea.gov.uk/9449.html.

Themes and trends

In the period covered by this report - January to December 2015 - we received reports of 517 incidents, out of approximately 72,000 cycles. Whilst incidents make up less than 1% of treatment, any incident is one too many and is one of the reasons we produce this report.

The number of incidents reported to us in 2015 is set out in figure 1[2]. For the first time since we publically reported on incidents, there have been no grade A incidents reported.

Figure 1: Number of incidents reported January-December 2015 compared to 2014

Grade	2015	2014
A	0	2
B	200	165
C	267	232
Near miss	30	44

However, the total number of incidents reported to us in 2015 increased slightly from the previous year. This should not be viewed in isolation as the number of treatment cycles also increased in this time period – and there is a relationship between the number of treatment cycles undertaken and the number of reported incidents. After adjustment for the increase in treatment cycles, this represents an increase of approximately 4% compared to 2014.

How incidents are graded

Grade A: the most serious type of incident. They happen infrequently 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, for example, when a storage unit malfunctions.

Grade B: 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.

Grade C: adverse events or reactions such as one of many eggs rendered unusable during processing (for example the moving of an egg between dishes).

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

As well as a slight increase in the number of B and C grade incidents reported this year, there was a slight increase in the number of severe ovarian hyperstimulation syndrome (OHSS) cases reported. Severe OHSS is graded as a B grade incident.

Figure 2: Number of incidents by category January-December 2015 compared to 2014

Category	2015	2014
Administration	141	102
Clinical	198	212
Communication	8	2
Consent	18	15
General	10	10
Laboratory equipment	29	24
Laboratory operator	57	41
Laboratory process	52	49
Resources/organisational	1	2

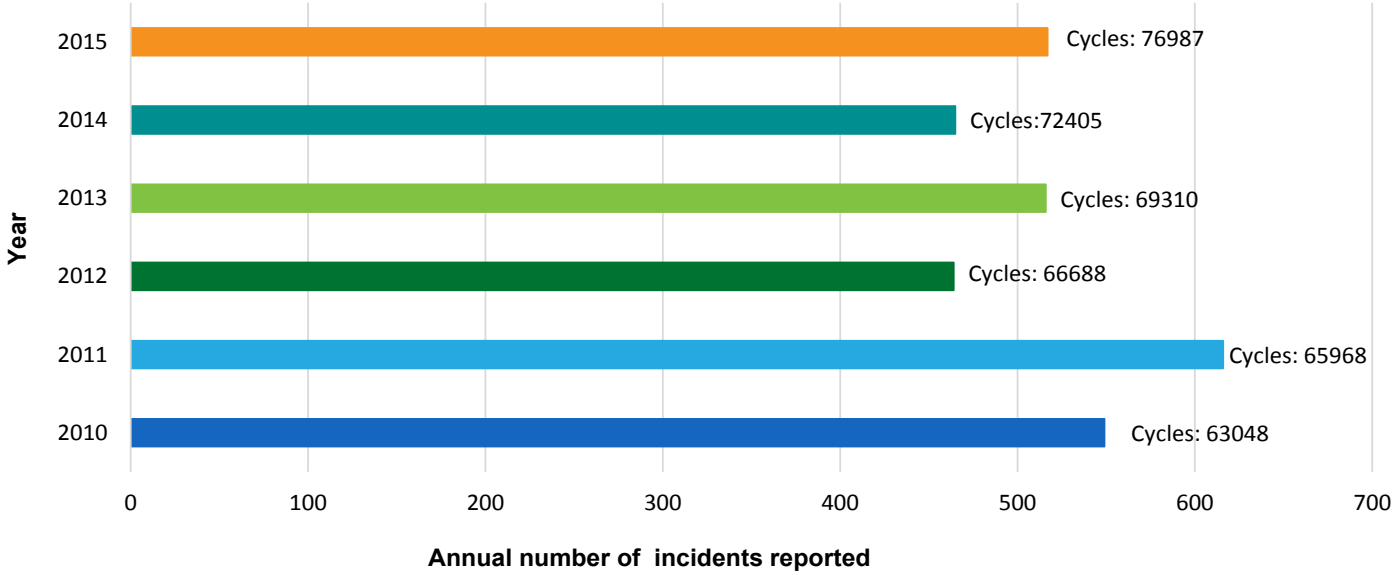
Of the 517 reported incidents, the three categories with the most incidents were clinical (198), administrative errors (141) and errors in the laboratory (138). There were a further 40 incidents falling into none of those categories.

The three categories with the most incidents are the same as in previous reports and the figures for clinical and laboratory incidents are similar. Our analysis has shown that the type of incidents within these two categories are also very similar to previous years, as are the contributory factors. In the conclusions, later in this report, we explain how we are going to tackle this.

Category	Example
Resources/organisational	Theatre list cancelled or rearranged, impacting on patients.
Communication	Incorrect information given to patient regarding medication, resulting in an abandoned cycle.
Security	Break ins and/or theft of equipment from clinics.
Clinical equipment	Clinical equipment malfunctioning.
General	Adverse weather conditions causing flooding in a laboratory or clinical area.
Consent	Embryos removed from storage without the patient's consent.
Laboratory equipment	Most commonly equipment faults and failures eg, dewar failure.
Laboratory operator	Dishes containing eggs or embryos knocked or dropped and failure to inject or inseminate eggs.
Laboratory process	Failure to follow laboratory protocols.
Administration	Breach of patient confidentiality.
Clinical	Hospital admissions due to ovarian hyperstimulation syndrome (OHSS) or a failure to follow clinical protocols eg, incomplete screening prior to treatment.

Viewed over the medium term, the number of incidents reported to us has remained broadly the same as the graph below shows.

Figure 3: Annual number of incidents reported: five-year trend 2010-2015



Key learning points for clinic staff

There is no obvious reduction in the type or number of incidents being reported in 2015 to those reported over the previous four years.

This suggests that too many clinic staff are still not learning from incidents, often avoidable incidents, taking place in other clinics. Some clinics may take the view that "it couldn't happen here". That view is misplaced.

We want all clinics to get into the habit of learning from the incidents that are taking place elsewhere, so as a first step we repeat our call to clinics to study this and previous reports with care. Where we need to do more, we will do so, and we set out our proposed actions later in this report.

Administrative errors

The most significant change in the number of incidents reported in 2015 has been in administrative errors, notably those involving breaches of patient confidentiality[3].

The majority of these incidents are avoidable and yet the consequences can be very upsetting for patients. The remainder of this section discusses the actions we expect clinics to take to reduce administrative errors.

Our analysis of the incidents reported in 2015 has shown that administrative errors are largely due to simple things like invoices and emails being sent to the wrong recipients. A sample of incident investigation reports highlighted the following contributory factors:

- 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
- staff not having the patient's notes at hand to cross reference the name and address before posting out the letter.

Our advice on how to reduce these types of incidents is to:

- consider disabling the auto-complete function on devices 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)

3. Of the 102 administrative errors reported in 2014, 59 involved breaches of patient confidentiality. Of the 141 administrative errors reported in 2015, 124 involved breaches of patient confidentiality.

- consider whether the content of an email should be encrypted or password-protected before sending sensitive data
- pay specific attention to the frequency and nature of these incidents as further training or Human Resources involvement may be required
- consider using the Information Commissioner's toolkit to assess compliance with data protection issues[4].

Over the past year, we have offered several clinics one-to-one support to improve their learning from breaches of confidentiality. This support has helped reduce the number of such breaches reported by these clinics.

We will continue to offer this support to clinics when we identify a trend. We encourage all clinics to review their data protection handling processes and this will continue to be reviewed as part of the inspection process.

It is vital that clinics review their root cause analysis procedures to ensure they identify effective corrective actions so that incidents involving breaches of confidentiality don't continue to happen.

We have learned that the most effective approach to deal with breaches of confidentiality is to visit the clinic and discuss occurrences with the team. We will be undertaking more of these interventions in relation to a wider range of incidents.

Consent to legal parenthood

A large number of clinics failed to ensure appropriate consent to legal parenthood was in place for particular categories of patients. This caused significant distress to the patients affected.

Since 6 April 2009, the partners of women treated with donor sperm or embryos, where the couple is neither married nor in a civil partnership, have had to give their written consent in order to become the legal parent of any child born as a result of treatment. Legal parenthood is important as it gives a lifelong connection between a patient and a child, and affects things like nationality, inheritance, contact and financial responsibility.

If this written consent is not obtained correctly, the partner may not be legally recognised as the parent of the child(ren) born.

While this would not be the case in every circumstance – the failure to take consent

4. See https://ico.org.uk/for-organisations/improve-your-practices/data-protection-self-assessment-toolkit/.

correctly does not automatically mean the partner is deprived of their status as legal parent (this would be a matter for the courts) – it highlights the seriousness of the matter. Not only is it devastating for the families affected, it can carry heavy legal costs for both them and the clinic.

What happened and what did we do?

The issue first came to light in a High Court case in May 2013, involving a same sex couple, where the partner of the woman treated with donor sperm was declared not to be the legal parent of the children born to her partner. In August 2013, we published an article in our newsletter to clinics, Clinic Focus, summarising the court case and required clinics to take immediate action to ensure their procedures for taking informed consent to parenthood were compliant with the HFE Act (1990).

Following a routine inspection of a further clinic in 2013, we found discrepancies in how consent to legal parenthood was obtained and processed. The clinic involved carried out a full audit of these consents and identified 14 cases in which there were deficiencies in the obtaining and recording of consent to parenthood. In these cases, the partners of the women treated might not have been the legal parents.

Given the problems that came to light in this clinic, coupled with the case in the High Court, we were concerned there may be other cases where legal parenthood consent was not correctly obtained and recorded.

We therefore required all licensed clinics to audit the records of patients who received treatment using donor sperm or embryos on or after 6 April 2009, who were neither married nor in a civil partnership[5].

The most common serious mistakes highlighted by the audit were cases of:

- absent HFEA consent forms (WP[6] or PP[7])
- WP or PP forms completed after treatment instead of before
- WP or PP forms completed by the wrong person
- the use of ‘in-house’ forms rather than our consent forms.

While we have seen examples of good practice where clinics have reviewed their policies and retrained staff, we have also seen examples of extremely poor practice were the patient has not been well supported by the clinic in question.

5. Outlined in a Chief Executive’s letter sent to clinics in February 2014: http://www.hfea.gov.uk/8659.html.
6. Your consent to being the legal parent form.
7. Your consent to your partner being the legal parent form.

The results of the audit[8] illustrated worryingly widespread instances of poor practice in this area. At the time of writing we are aware of 23 cases with legal parenthood consent anomalies which have been resolved, or are in the process of being resolved, by the High Court.

To promote improvement, we published a comprehensive list of legal parenthood questions and answers, as well as a case study highlighting best practice in our September 2014 Clinic Focus newsletter.

In addition, in November 2014 we organised a series of consent workshops for clinic staff to make clear what they are required by law to do. We also published a leaflet for patients and their partners to help them understand when they need to give consent to parenthood.

Where anomalies and/or potential court involvement is indicated to us, our inspectors will actively follow this up with the clinic to ensure the patient is supported throughout this process.

Legal parenthood is an inspection theme and embedding understanding of this process in clinics continues. Where a clinic has been the subject of a legal judgment, our inspectors will review the judgment and follow the finding up directly with the clinic in question.

Managing cases with anomalies

There have been no new cases reported of anomalies with the legal parenthood consent process for treatments carried out since September 2015. This suggests that clinics have improved their consent process.

However, mistakes can happen and how clinics respond is important. We expect clinics to support patients and be open and transparent with them if an anomaly is discovered. Clinics should:

- prepare a case summary of the patient's treatment history, outcome and consent issues
- have a plan in place for when and how to contact the patients
- take responsibility for the failure in taking consent and convey this as part of the apology to the patients at the earliest opportunity
- commit to support the patients emotionally and financially through the legal processes to attain legal parenthood status for the non-birth partner. This includes providing a letter summarising the findings and advising the patients to seek their own legal advice; signposting the couple to solicitors with the relevant expertise who have been involved in previous court proceedings. We also expect clinics to

8. Outlined in a Chief Executive's letter sent in September 2014: http://www.hfea.gov.uk/9150.html.

cover the legal costs incurred by patients during the process of securing legal parenthood status.

Lessons to learn

It is clinics' responsibility to ensure patients understand legal parenthood and that consent is properly taken and recorded. To ensure that such mistakes do not happen again, clinics should:

- make sure patients and their partners understand the importance of consent to legal parenthood and what might happen if it is not in place
- use our consent forms, WP and PP, not in-house forms
- offer counselling, give information and record this in the patient notes
- keep a copy of the consent form and give a copy to the patient and their partner.

Clinics should report any anomaly to us via the incident reporting system. Those clinics that have handled cases well will not face regulatory actions from us. However, we may take action against clinics who have not done so. We all make mistakes. It is how we deal with the consequences of those mistakes and how we learn from them that counts.

Conclusions

In the five years since we made public adverse incidents in fertility clinics we have seen a significant change in the culture of clinics. Incidents are more openly discussed and reported and we have seen evidence of a willingness to learn from mistakes. That is positive and is a credit to all those involved in clinics.

But as this latest report makes clear, the fertility sector still has some way to go. The overall number of adverse incidents reported to us over the last five years has remained consistent at around 550 per year – a figure that needs to be seen in the context of a steady increase in the number of treatment cycles carried out. And within the overall numbers, we still see too many of the same avoidable errors.

The purpose of open reporting is that lessons are learned by the clinic experiencing the incident and by other clinics which may suffer the same misfortune. We are not convinced this is always taking place. We all have to adapt accordingly.

Our role as regulator is to be alert to any specific trends reported by individual clinics and to work with the clinic in question to understand the root cause and therefore minimise the risk reoccurring.

We will continue to interrogate our data to better understand the clinics who have an open reporting culture, the clinics who are not learning from incidents and the clinics who report very few incidents, offering further support and regulatory input where required.

Clinics must embed incident reduction in their practices. Reviewing this report together with our previous reports will help to provide a full picture of the lessons to learn and how they can improve practices to enhance care for patients.

We have always known that reducing the number of recurring incidents will be a long process – it will take several years to embed learning and change practices. We have made real headway in promoting a culture of openness, transparency and learning by:

- publishing this report annually
- ensuring learning from incidents is a key part of inspections
- holding workshops with clinics focussed on root cause analysis and ‘human factors[9]’
- ensuring that clinics are candid with patients affected by incidents.

We will publish this report in October 2016 and in doing so issue a call to clinics to intensify their focus on incidents and to promote a more effective learning culture.

9. Human factors principles can be applied in the identification, assessment and management of patient safety risks, and in the analysis of incidents, to identify learning and corrective actions. For more information see www.england.nhs.uk/wp-content/uploads/2013/11/nqb-hum-fact-concord.pdf.

Incidents are always upsetting and in some cases, devastating, to patients and also clinic staff. It is therefore vital that clinics make sure they are doing everything they can to learn from mistakes. We strongly encourage clinics to reflect on how they can improve the quality of care for patients by maximising the opportunities to learn from incidents.

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