Human Fertilisation & Embryology Authority

Adverse incidents in fertility clinics: lessons to learn

January-December 2014

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Contents

Introduction

In July 2014 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 encourage a culture of openness and information sharing where clinic staff are empowered to report mistakes and learn from each other.

In line with this, we decided to produce this report annually. Last year's report was the first in the annual series and looked back on the 2013 calendar year. This report, looking back on 2014, continues our work in promoting transparency and maximising opportunities for learning from incidents to improve the quality of care for patients.

An estimated 1% of the 60,000 cycles of IVF treatment that are carried out in the UK each year are affected by some sort of adverse incident. Whilst incidents are rare, the impact on both patients and clinic staff is upsetting and in some cases, devastating. It is 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 learnt with the sector. Learning from incidents was one of the topics covered at our 2015 annual conference and this theme is now a key feature of our monthly Clinic Focus newsletter. Since April 2015 we have refreshed the focus of our inspections to promote a culture of learning from incidents in all licensed clinics.

Encouraging a culture of openness, transparency and learning will take time and we recognise that changes may not immediately be reflected in the reported figures. However we will continue to explore how an open culture of learning from incidents can be promoted by keeping the impact of our activities under review and by establishing relationships with other organisations with responsibilities for incident management and governance in a healthcare setting.

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 on how incidents are graded, see our website.

Themes, trends and lessons to learn

In the period covered by this report, 1 January to 31 December 2014, we received reports of 465 incidents. All incidents were graded in relation to severity and during this time period there were two A grade incidents, 166 B grade incidents, 232 C grade incidents and 65 that were either classed as near misses or were not incidents[1].

The overall number of incidents reported to us in 2014 has slightly decreased from the previous year[2]. As well as a slight decrease in the number of B[3] and C[4] grade incidents reported this year, there was a slight decrease in the number of severe ovarian hyperstimulation syndrome (OHSS) cases reported[5].

Fewer A grade incidents were reported in 2014 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.

Whenever A grade incidents occur, we work with the clinic to 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 clinics learn from these incidents and minimise the risk of them happening again.

1. 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.

2. 516 incidents reported in 2013, compared with 465 in 2014.

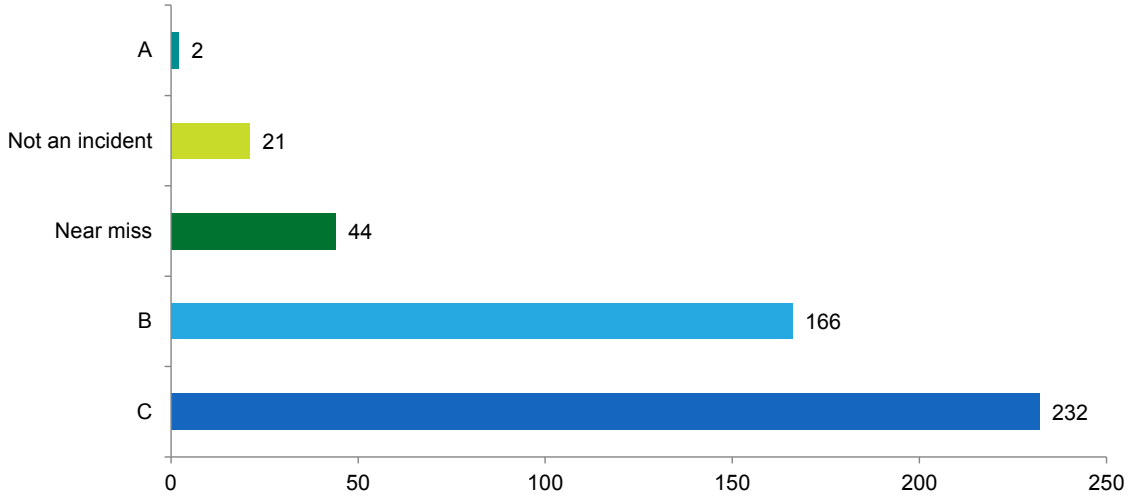
3. 42 fewer B grade incidents compared with 2013.

4. 30 fewer C grade incidents compared with 2013.

5. 46 cases of OHSS reported in 2013, compared with 42 cases reported in 2014

Of the 465 reported incidents, the three categories with the most incidents were clinical (212), errors in the laboratory (114) and administration errors[6] (102). There were a further 37 incidents falling into none of those categories. Figure 2 provides a full breakdown.

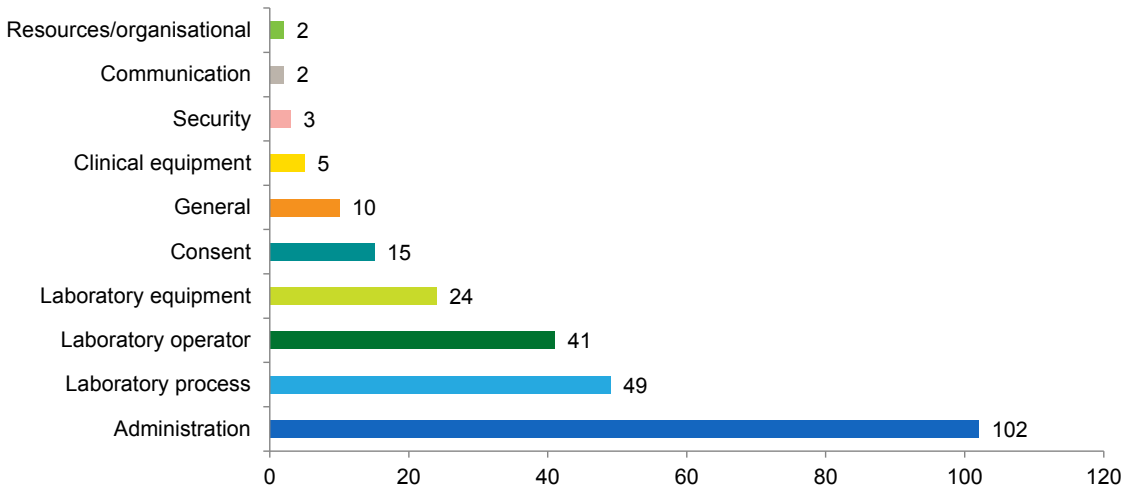
Figure 1: Number of incidents reported January-December 2014



6. Of the 90 administration errors reported in 2013 – 66 involved breaches of patient confidentiality. Of the 102 administration errors reported in 2014 – 59 involved breaches of patient confidentiality.

The three categories with the most incidents are the same as the 2013 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 would encourage clinics to once again review the 2010–2012 and 2013 reports in parallel with this report to get a full picture of the lessons learnt and how they can improve practices to enhance care for patients.

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



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 two A grade incidents reported in 2014, compared to four in 2013. By their very nature, A grade incidents are difficult to predict and those reported this year do not illustrate a recurring theme. The two A grade incidents were:

1. Embryo development for seven patients was lower than expected

Seven patients had egg collections and good fertilisation rates were initially observed in all seven cases. The embryos were transferred to (day 1) culture dishes. Laboratory staff noticed some cytoplasmic shrinkage in the embryos of one patient. Concern was noted by a member of staff regarding the quality of the culture media[7] in the dishes. As a result, culture dishes containing fresh media were prepared but the embryos were not transferred into these dishes until the following day.

The embryo development observed for these cases was poorer than expected. The clinic concluded that it was likely that the embryos were initially placed into dishes containing sub-optimal media. The investigation reports and Licence Committee meeting minutes for this incident can be found here.

Key learning points

Clinics should:

- Act on concerns promptly and appropriately. All members of staff are responsible for the safety of the gametes and embryos in their charge. If any member of staff is concerned that the appropriate action has not been taken this should be escalated to a more senior member of staff immediately. Senior members of staff must act on any concerns brought to their attention.
- Wherever possible, retain any relevant evidence such as the culture medium, flask and dishes, to assist in an investigation if this type of incident occurs.

7. Culture media is a fluid that contains a variety of salts, sugars, amino acids, protein and other nutrients essential for the maintenance of the egg (and sperm in IVF) during the process of fertilization (IVF and ICSI).

2. A patient underwent PGD for a chromosomal translocation[8]. Subsequent pre-natal diagnosis by chorionic villus[9] sampling showed that the pregnancy was affected by an unbalanced chromosome translocation.

Following a rigorous investigation in conjunction with our regulatory partners, we concluded this incident arose as a result of a recognised but rare failure of the testing technology and that there is no evidence of human error and/or weakness in the testing laboratory's systems and processes.

The investigation reports and Licence Committee meeting minutes for this incident can be found here.

8. A balanced translocation is a condition in which the correct number of chromosomes is present, but two pieces of chromosomal material have switched places. Where a translocation is unbalanced then there is an incorrect number of chromosomes that have switched places which can result in a serious genetic abnormality.

9. CVS is a test carried out during pregnancy most commonly to check the baby for disorders such as Down's syndrome and, where appropriate, rarer specific inherited disorders.

Conclusions

The overall number of incidents in 2014 has decreased slightly compared to previous years although the categories with the most incidents remain the same.

Our analysis of the data reveals the number and the type of incidents remains fairly static. Where apparently avoidable grade C incidents (particularly administration incidents leading to breaches of confidentiality) continue to recur we are concerned that clinics' root cause analysis may not be sufficiently robust to identify effective corrective actions.

As it is not enough to respond to an incident by adding additional layers of checks or administration, we continue to encourage clinics to absorb and implement the learning provided in this and the previous reports.

We remain committed to a reporting system that highlights what can go wrong and, most importantly, how clinics can improve care and safety for patients.

Key learning points

Clinics should:

- Review the adverse incidents reports for the calendar years 2010, 2011, 2012 and 2013 alongside this report to make sure that the learning identified in those reports is acted upon.
- Consider the following questions:
  - Could similar incidents happen in our clinic?
  - Do our procedures need to be reviewed in the light of the learning in these reports?
  - Have we done everything we can to prevent incidents (even those reported by other clinics) recurring?
  - Can we improve the quality of our root cause analysis?

We will:

- Offer one to one support to help clinics develop their root cause analysis procedures.
- Focus on incidents on inspection; looking for evidence of learning from incidents rather than focussing on clinics' processes for incident reporting.
- Comment in inspection reports on clinics' learning culture.
- Build links with the newly established NHS Improvement so that we learn wider lessons from others working in incident investigation in a healthcare setting.

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