Adverse incidents in fertility clinics

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (14/09/2016) 810		
Meeting date	14 September 2016		
Author	Paula Nolan, Clinical Governance Lead		
Output:			
For information or decision?	For information		
Recommendation	To note the actions we are taking to improve clinics capacity to report, and learn from, incidents in Sections 3 and 4		
Resource implications	In budget		
Implementation date	Through ongoing compliance activities		
Communication(s)	The annual adverse incident report will be published as part of a campaign utilising the Clinic Portal and Clinic Focus – as a 'call for action'.		
Organisational risk	☐ Low	☒ Medium	☐ High
	Annex 1: HFEA incident investigation template Annex 2: annual incident report (draft – not for publication)		

1. Background

1.1. Incidents happen in all healthcare settings. In recent years there has been considerable effort across different healthcare settings to learn from, and adopt techniques developed in, other industries where the mitigation of risk is crucial. And the HFEA has played its part in this process, since 2013 it has made public the reported incidents in the fertility sector and it has sought to encourage a culture of openness and learning. This paper summarises the incidents reported to the HFEA by clinics in 2015 and sets out the actions we propose to take to ensure that the sector continues to improve in reporting, reducing and, crucially, acting on any incidents.

1.2. The HFE Act provides a statutory framework in which incidents must be reported and analysed. The Person Responsible (PR) for an HFEA licensed clinic has a duty to report and analyse the causes of incidents[1]. Similarly, the Authority has a duty[2] to investigate and take appropriate control measures in relation to reported incidents[3].

1.3. The primary reason for reporting and investigating incidents is to improve safety for patients, embryos and clinic staff. Reporting an incident is not enough on its own: to be effective, learning should be extracted from each and every incident to minimise the risk of it happening again.

1.4. The HFEA has a national role in gathering information on incidents, identifying patterns and disseminating learning across the sector so that clinics can learn from the mistakes of others.

1.5. As noted above, in 2013 the Authority published for the first time information about incidents with the aim of promoting shared learning across the sector. In July 2014 we followed this up with a summary of incidents reported by clinics between 1 January 2010 and 31 December 2012[4]. The third annual report for incidents reported in 2015 will be published this month. Taken together, we have now five years of data on incidents in the fertility sector in the public domain and we need to decide what interventions will best drive further improvement.

2. What we have learnt

2.1. The number and type of incidents reported in 2015 is not significantly different from previous years. It is notable that no “A” grade incidents (the most serious) were reported in 2015.

2.2. However, the number of incidents by category suggests that too many in the sector are failing to learn from past errors, although it is not entirely clear why this is so. It may be that this is because clinics simply more need time to absorb the recommendations and “lessons learnt” included in previous incident reports, but that can be no excuse for failing to embed learning as quickly or effectively as we would like. There is evidence that the same type of incidents are occurring less at the clinic that reported them. In other words, where a clinic has direct experience of an incident it responds and changes its practice. Conversely, where a clinic’s experience of a problem is

[1] An incident is a serious adverse event or reaction as defined at 27.2 and 27.3 of the Code of Practice.
[2] S.15A of the Act.
[3] Further information on our approach to incident handling can be found at http://www.hfea.gov.uk/6678.html
[4] http://www.hfea.gov.uk/docs/Adverse_incidents_in_fertility_clinics_2010-2012_-_lessons_to_learn.pdf

indirect, through for example reading a report, some clinics may be taking the view that 'it couldn't happen here.' This is misplaced.

2.3. As a first response, we will repeat our call to clinics to study this and previous reports with care. Changes in the reporting and investigation culture will not happen overnight and it might be several years before real changes are identified.

2.4. We observe some lack of rigour in clinics undertaking root cause analysis – getting to the core of what failed. It is too easy to cite 'human error.' Rarely if ever is this the case – there will always be contributory factors.

2.5. We often observe the corrective actions implemented by clinics following incidents tend to impose additional administrative steps (checking, documenting, double and triple checking) which may be impractical to adhere to and ineffective in preventing recurrence of incidents. Again, if clinics fully engage with incident investigations to identify the root causes, using human factors[5] where appropriate, and implement corrective actions this is more likely to be effective.

2.6. We must adapt our response to have a greater impact on clinics' incident systems such that improvements flow. Section 3 sets out the steps we have instituted or will be taking.

3. Clinical governance developments in 2015/6

3.1. The system we have to report and deal with incidents works well in the main but it needs to develop if we are to have the impact we desire. To this end, we will continue to provide support to clinics, recognising that the number of incidents in relation to the number of treatment cycles is very small, and balance this, where necessary, with a greater focus on trends and at inspection.

3.2. Where clinics report a high number of administration incidents, especially breaches in patient confidentiality, we will continue to offer focused assistance by the Clinical Governance Lead. To date, this support has encouraged clinics to carry out in-depth analysis of the causes of incidents. (This endeavour was supported by a workshop provided by the Information Commissioner's Office on data protection at a well-attended session at the 2016 HFEA annual conference.) Several clinics have managed to reduce their administration incidents following a focussed site visit.

3.3. We will continue to provide bespoke workshops to clinics to improve their incident investigations. The HFEA Chief Inspector and Clinic Governance Lead have provided such workshops to several clinics shifting the clinic's focus from human error to arrive at the true root cause (system errors resulting in incidents). Removing the focus around human error and to steer the investigation towards human factors. A flow chart has been designed to help clinics in this task.

3.4. We will intensify our review of reports that clinics undertake of incidents and their subsequent investigation. We have developed a new incident investigation template (annex 1) to help clinics

[5] *Human Factors* is a discipline that explains the underlying reasons for human errors. It applies to human capabilities, limitations and behaviour for the purpose of increasing human performance, personal situational awareness and organisational awareness to eliminate where possible - and to reduce the risk for human error - in safe, efficient & cost effective operations.

produce more focused incident investigation reports and to appreciate better the root causes. This investigation template, introduced recently, also includes explanations around each stage of the investigation in order to provide guidance to the investigation team. Investigators of the incident are encouraged to consider preventive action or *risk based thinking* where the incident has the potential to occur elsewhere.

3.5. We will make better use of our data to carry out a body of work. We will assess the reporting culture of these clinics in seeking reassurance there is an open and transparent reporting culture. If we notice a trend of recurring incidents we will work with the clinic to try and resolve these issues. We will also shine a more focused light on clinics reporting a disproportionately low number of incidents in relation to the volume of activity undertaken.

3.6. On inspection our inspectors look for evidence that clinics have learnt from incidents rather than focussing on clinics' processes for incident reporting. Moreover, where clinics seem to be struggling to recognise when an incident should be reported to the HFEA the Clinical Governance Lead provides bespoke incident training sessions to individual clinics. This support will continue in 2015/16, but we will go further: where a clinic is not able to demonstrate that it is learning from experience we will reflect this in the inspection report and the recommendations relating to the licence.

3.7. We will also keep abreast of wider developments within the healthcare system. We aim to develop a collaborative working relationship with NHS Improvement which is establishing a new Independent Patient Safety Investigation Service to ensure that wider learning from colleagues working in patient safety in a healthcare setting feeds into our own ways of working. We will also explore how sectors such as the aviation industry deal with incidents.

4. Recommendation

4.1. The Authority is asked to note this report. In summary:

- We are seeking to influence the culture in licensed clinics so they develop an embedded learning and safety culture.
- We will ensure that our work on incident oversight reads across more comprehensively to our inspection activities.
- We are publishing a national report on incidents shortly, and we will use channels such as Clinic Focus and the clinic portal to maximise its impact.

Annex 1: HFEA incident investigation report template

Owner:	Raised Date:	Target Date to be completed:	Department/Area incident raised against	Define Severity of Incident (impact on patient)

Describe in detail the background surrounding the incident.

Is the incident reportable to any external regulatory bodies?
e.g., HTA, MHRA, HS&E & CCG
Date Reported: **Reported to who:** **Case Number:**
Action Required:

Remedial Action/Immediate Action:
Implement temporary counter-measures at the source of the problem.
Describe these temporary measures taken to immediately mitigate the Non-Conformity or incident.

Owner:

Date Completed:

Root Cause Analysis:
Use Quality Tools such as the 5 whys technique or brainstorming. Cause & Effect diagrams also known as Fishbone or Ishikawa diagrams. These can be used separately or combined.

Owner:

Date Completed:

Corrective Action/s:
Give details of actions implemented to mitigate the Root Cause Analysis.
Corrective Actions are a reactive process; the centre must take corrective action to eliminate the cause(s) or minimise the re-occurrence of similar incidents. Corrective actions should be appropriate to the effects of the nonconformities encountered.

Owner:

Date Completed:

Preventative Action/Risk based thinking. Preventative Action is a Pro-active process to prevent the potential for an incident occurring. This is '*Risk Based Thinking'* an approach to the management of potential incidents. The centre must determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions should be appropriate to the effects of the potential problems.
Owner:
Date Completed:
Annotate if no P/A required.
Monitoring: Detail any actions that may be required to ensure any corrected actions are embedded.
Owner:
Date Completed:
Annotate if no monitoring is required.
Final Approval: Person Responsible or delegated individual to close incident.
Owner:
Date Completed: