Incident Reports and Alerts
HFEA

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Contents

• History
• UK Authorities
• Role of HFEA
• HFEA experience and approach
• The way forward
History

- HFE Act 1990
- Code of Practice
- Toft Report
- Incident Reporting System
- Alert System (non-identifying)
- Grading System
UK Authorities

• HFEA
• HTA
• Regulatory Authority for Tissue and Embryos (RATE), 2008
Role of HFEA in incident management

- UK hub for ART incidents. Identify trends, patterns and underlying risk factors
- Share lessons across sector
- Help develop understanding of causes of incidents to inform policy
- Monitor clinics’ compliance with policies that promote safety – at inspection
Definition of incident

• CoP 2.24 “….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 or a licensed centre.”

• Near Miss - serious incident that had the potential to cause an adverse event but fails to do so because of “good luck” or because it is intercepted
How to encourage reporting?

- Experience of others - MHRA, NPSA, HTA, HSE, RIDDOR plus, for example, systems for reporting drug reactions, transfusion errors and EU requirements…
- One standard definition of an incident ‘an occurrence that is inconsistent with the routine care of the patient or the routine running of the organisation’.
- Electronic reporting – any forms
- System failures – non-identifying
- Evidence or under-reporting (patient complaints, A&E admissions, Inspections, Whistling)
Incidents reported per year against total treatment cycles

<table>
<thead>
<tr>
<th>Year</th>
<th>no. incidents</th>
<th>Total number of treatment cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>59</td>
<td>38281</td>
</tr>
<tr>
<td>2004</td>
<td>110</td>
<td>40804</td>
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<tr>
<td>2005</td>
<td>140</td>
<td>42127</td>
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<tr>
<td>2006</td>
<td>173</td>
<td>42397</td>
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</table>
Incident Categorisation Laboratory

- Laboratory operator (= human error) e.g. damage to gametes or embryos whilst handling
- Laboratory process. Failure to follow lab protocols or HFEA Act/CoP. e.g. screening
- Laboratory equipment e.g. batch variations, equipment malfunction

» Cont/d
Incident categorisation
Non-Laboratory

- Clinical - patient interface
- Breach of confidentiality
- Consent
- Legal - allegation of illegal activity
- Any Breach of the Act or failure to comply with CoP
Sample of incidents by category:

- Operator: 39%
- Process: 16%
- Equipment: 10%
- Non-laboratory: 35%
Risk scoring tool

• Severity v probability of recurrence (5x5 Matrix replacing a 3x3 matrix)
• Grade A (15-25 Severe)
• Grade B (6-12 Moderate)
• Grade C (1-5 Insignificant)
• Near Miss scored as above
• Scores may be adapted
• Multi-disciplinary perspective
GRADE A
• Incident Inspection necessary.
• Final report to License Committee
• Incident and trend analysis

GRADE B
• Incident investigation required.
  May require site visit
• Incident and trend analysis

GRADE C
• Add to database
• Acknowledge and close.
• Trend analysis
# Risk Assessment

## Risk Matrix

<table>
<thead>
<tr>
<th>Severity</th>
<th>Almost Certain</th>
<th>Likely</th>
<th>Possible</th>
<th>Unlikely</th>
<th>Rare</th>
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</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Major</td>
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<td></td>
<td></td>
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<tr>
<td>Moderate</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Minor</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insignificant</td>
<td></td>
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</tr>
</tbody>
</table>
Risk assessment

Reasonably practicable

Time
Money
Trouble

Severity
Consequences
Likelihood

X
Rise in reported incidents, decrease in severity

- **Apr. - Mar 04**: Near miss 8, C 56, B 21, A 25
- **Apr. 05 - Mar 06**: Near miss 11, C 71, B 35, A 23
- **Apr. 06-Mar 07**: Near miss 15, C 92, B 49, A 17

Period:
- Apr. - Mar 04
- Apr. 05 - Mar 06
- Apr. 06-Mar 07
Consider ALERT?

- Examine results of investigation of incident.
- What lessons can be learned?
- Could knowledge reduce opportunity for similar incident reoccurring?
- Will ALERT allow opportunity for clinics to develop or upgrade their protocols to avoid similar incident?
Purpose of an ALERT

Is to **share** with clinics:

- Information
- History
- Contributory factors and/or root causes
- Actions/Recommendations
- Responsibility of PR to ensure ALERT disseminated to staff and appropriate changes made and monitored
- Provides focus for inspection process
22 HFEA Alerts 2003-07

Include:

- Witnessing of gametes and embryos
- Transport of gametes and embryos
- Use of off label equipment
- Power supply and critical equipment
- Micromanipulation
- Storage of unscreened and screened samples
Conclusion

- Comprehensive – time consuming
- Supports patient safety – problems with hindsight
- Open process built on trust – recognise good reporters
- Shared learning through the ALERT process – need to share beyond UK
- Encouraging subsequent improvement in practice