Incident Reports and Alerts
HFEA

09 May 2007
TRIP Minisymposium
The Hague

Angela Sanford
Regulatory Inspector (Incidents)
Human Fertilisation and Embryology Authority

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Contents

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

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

History

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

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

UK Authorities

- HFEA
- HTA
- Regulatory Authority for Tissue and Embryos (RATE), 2008

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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

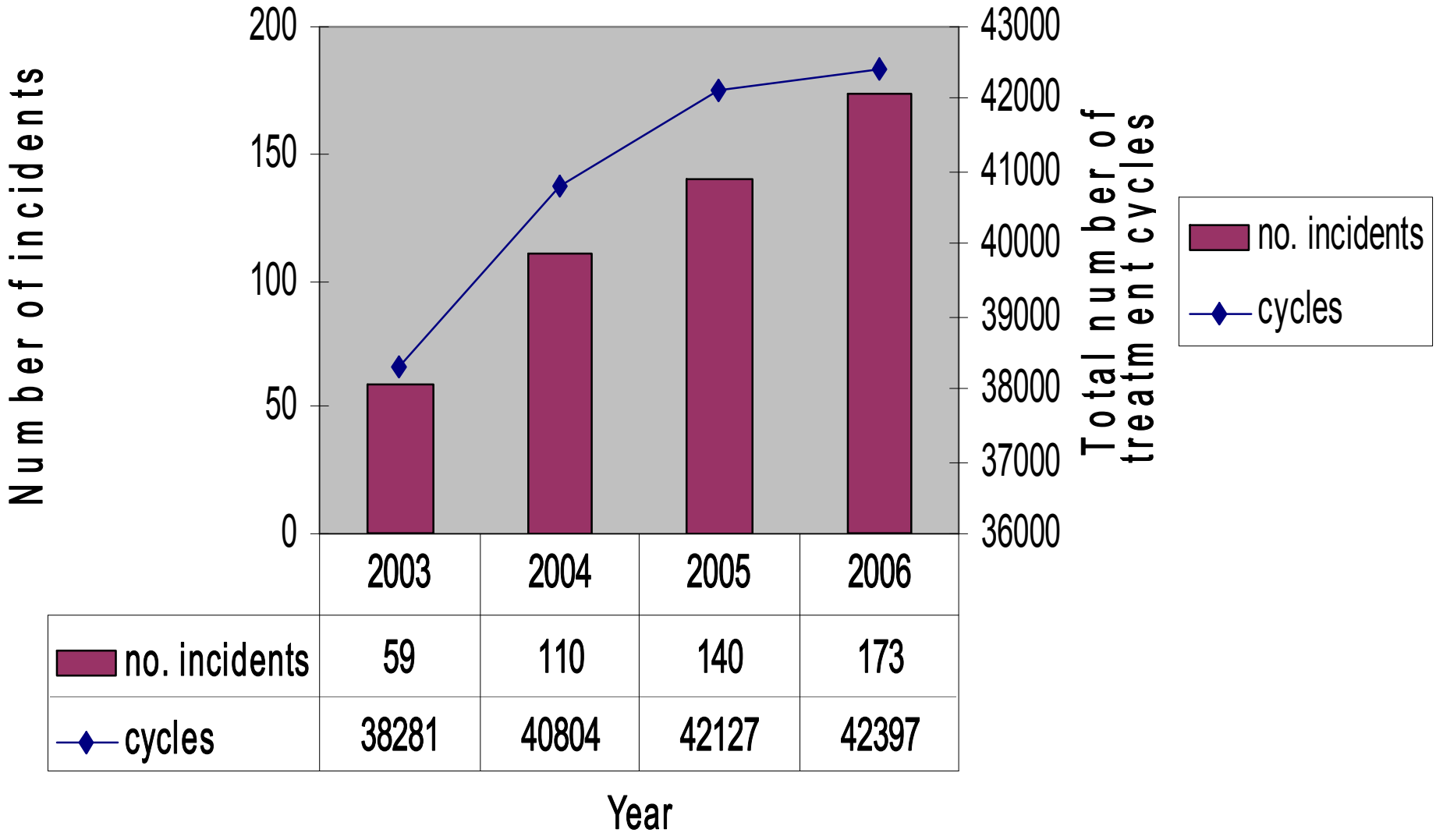
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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)

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Incidents reported per year against total treatment cycles



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

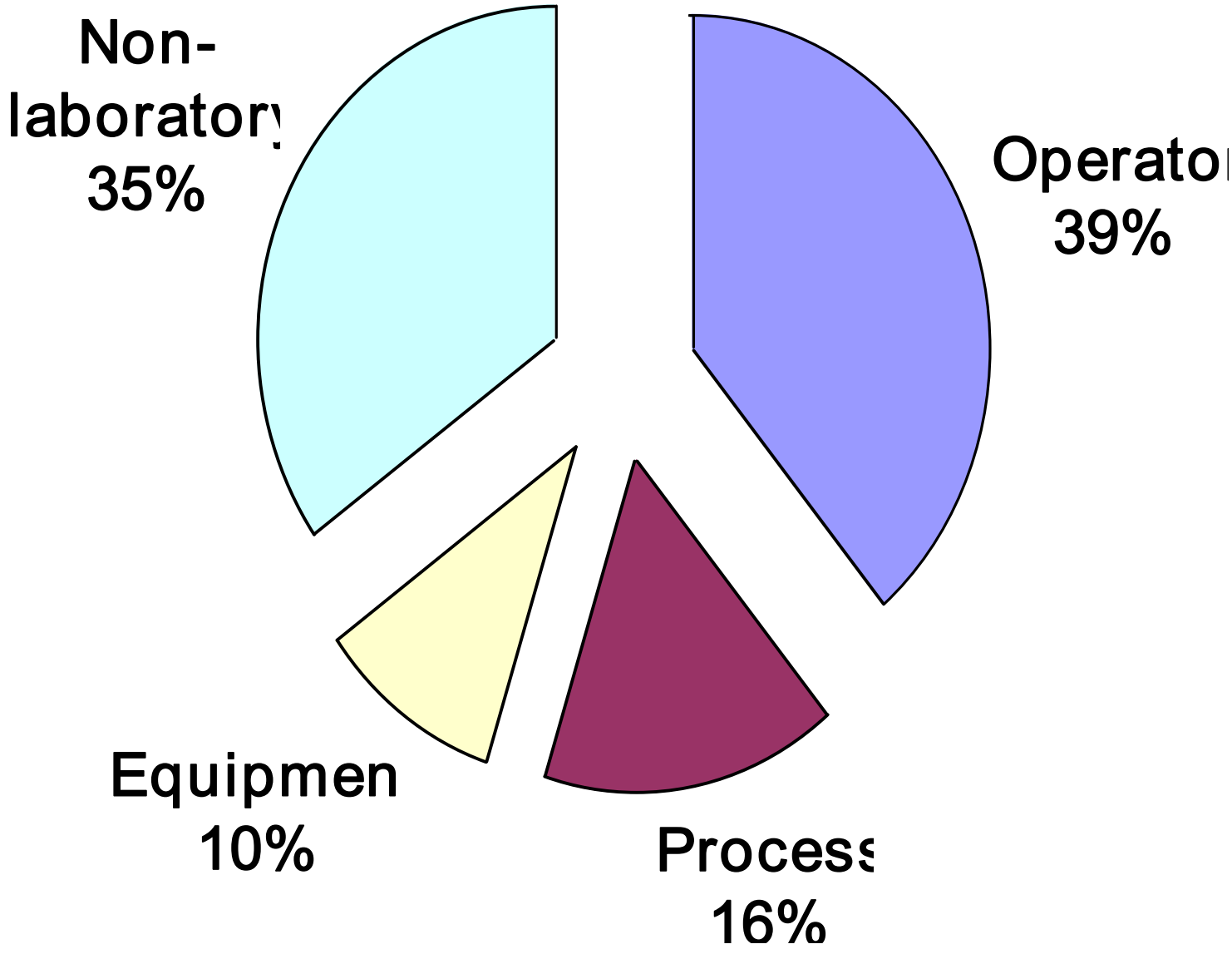
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Sample of incidents by categ



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

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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

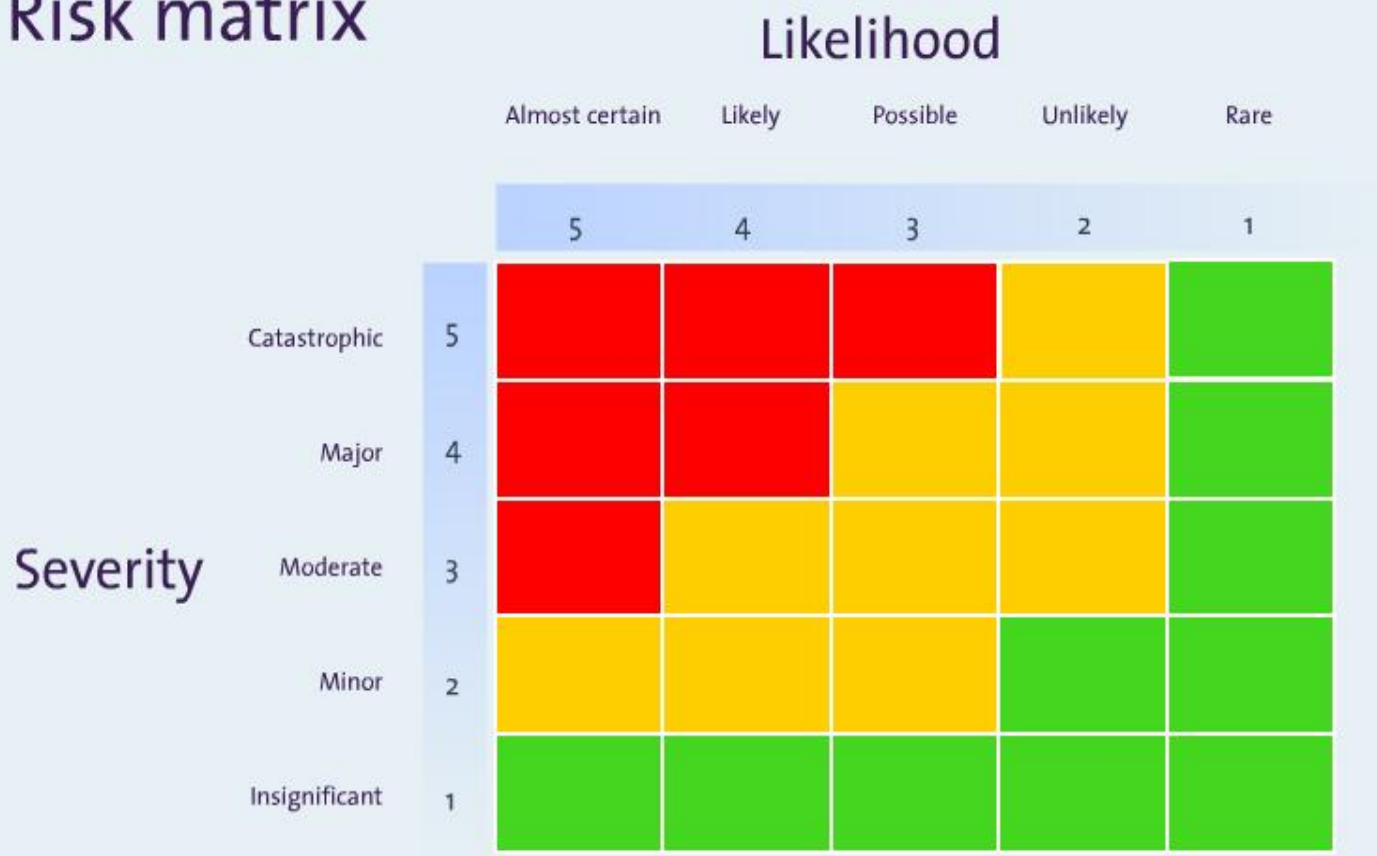
GRADE C

- Add to database
- Acknowledge and close.
- Trend analysis

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

Risk assessment

Risk matrix



Risk assessment

Reasonably practicable

Time

Money

Trouble

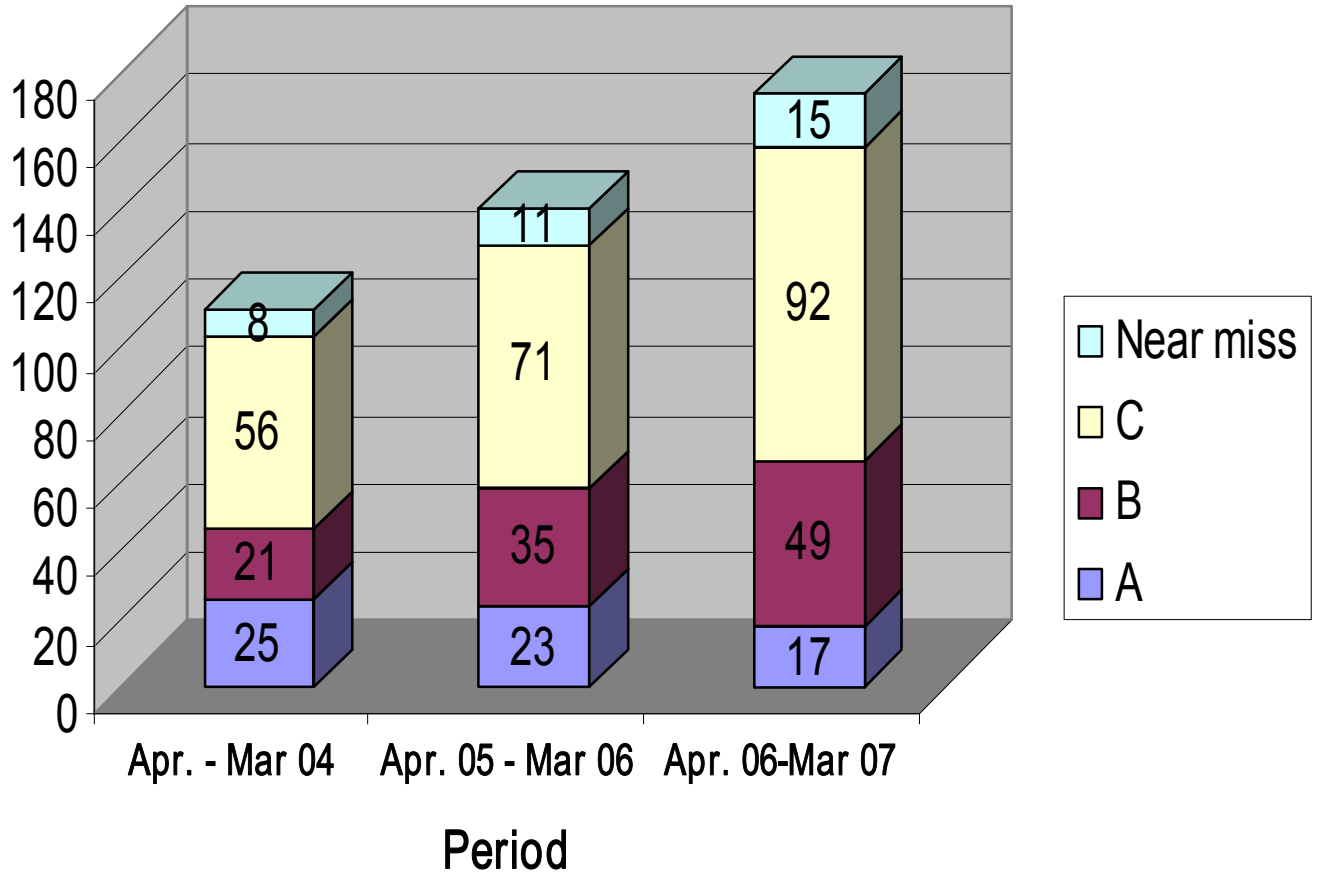
Severity

Consequences

X

Likelihood

Rise in reported incidents, decrease in severity



HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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?

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY