

Risk Management and Patient Safety Evolution and Progress

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Terminology

- ◆ Health and Safety
- ◆ Risk management
 - Legal and financial issues
 - Protecting the organisation
- ◆ Clinical risk management
 - Understanding and prevention of harm
 - Support for staff and patients
- ◆ Patient Safety

Consequences of serious adverse events for patients & families

- ◆ Death of neonates, children, adults
- ◆ Loss of womb in young women
- ◆ Untreated cancer, mastectomy
- ◆ Blindness
- ◆ Disability and handicap, children and adults
- ◆ Chronic pain, scarring, incontinence
- ◆ Profound effects on all aspects of their lives

In their own words

- ◆ Hysterectomy left me in pain and incontinent ... later I had ovaries removed and bladder repair op ...unable to empty my bladder completely as my urethra had been stitched almost closed ... major bowel problems , left with life-threatening condition and completely incontinent
- ◆ While under anaesthetic they apparently cut a blood vessel in my womb, which led to severe haemorrhage .. could only be stopped by giving me a hysterectomy so they say
- ◆ A swelling on my cheek was diagnosed as a malignant tumour and part of my jaw and extensive tissue was removed without my consent. The lab. test showed that it was not a tumour, malignant or benign

Facing up to the problem

- ◆ 1980s
 - Quality initiatives & monitoring of care
 - Rising litigation, financial and legal solutions
 - Little research: a case of negligence?
- ◆ Early 1990s -
 - Epidemiology
 - Analysis of claims
 - Awareness of underlying clinical problems

From risk management to patient safety

- ◆ Mid 1990s.
 - Clinical risk management
 - Human factors and understanding errors
- ◆ Late 1990s to present
 - Major reports in US, UK and Australia
 - UK National Patient Safety Agency
- ◆ World Health Organisation Resolutions
 - World Alliance for Patient Safety

An Organisation with a Memory

Learning from adverse events in the NHS

Every year in Britain:

- ◆ 400 people die or are seriously injured in events involving medical devices
- ◆ 10,000 reported serious adverse drug reactions
- ◆ 1,150 suicides by people in recent contact with mental health services
- ◆ NHS pays £400 million in litigation
- ◆ Hospital acquired infections cost nearly £1billion and 15% are regarded as preventable

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Reducing error
Improving safety

“Medicine used to be simple,
ineffective and relatively safe.
Now it is complex, effective and
potentially dangerous”

Chantler, Lancet 1999, 353:1178-81

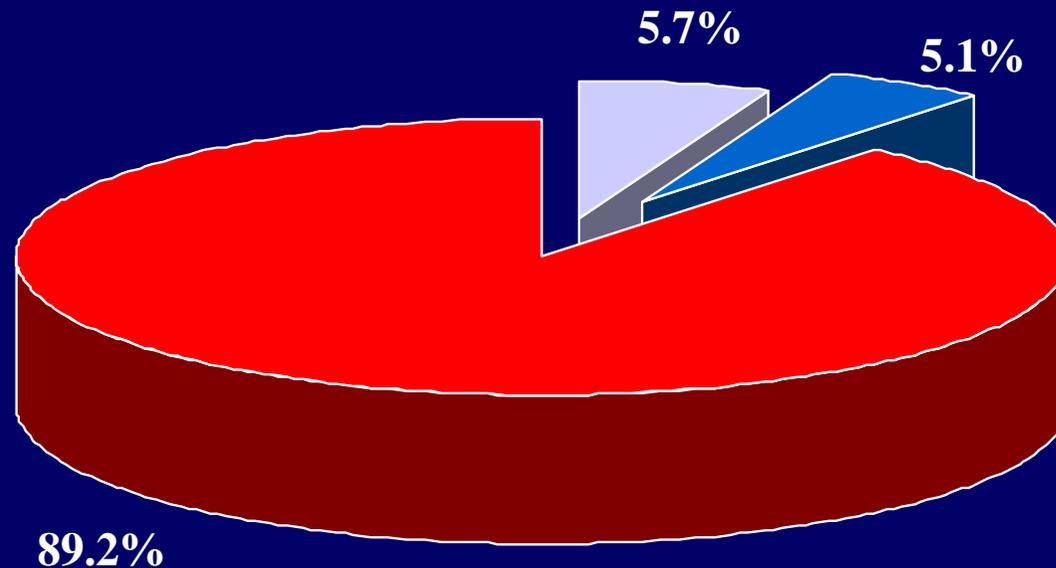
The Epidemiology of Harm

Harvard Medical Practice Study

- ◆ An unintended injury caused by medical treatment
- ◆ Two stage record review
- ◆ 3.7% of admissions involve adverse event
 - 13% of adverse events involve death
 - 7% lead to long term disability
 - 16 times as many negligent adverse events as paid claims

London Pilot Study

Percentage of patients who experienced an AE



■ Patients with unpreventable AE ■ Patients with preventable AE
■ No adverse event

Cost of adverse events

- ◆ 8 million admissions per year in England
- ◆ 856,000 adverse events
- ◆ Average of 8.7 extra days in hospital
 - Specialty costs £171 - 305 per day
- ◆ Cost in extra days in hospital
 - £2 billion per annum
 - £1 billion for preventable AEs

International Perspective

- ◆ Australia (1995) 16.6%
- ◆ United Kingdom (2001) 10.8%
- ◆ Denmark (2002) 9.0%
- ◆ New Zealand 11.2%
- ◆ Canada (2004) 7.5%

- ◆ `In effect a new public health risk`

Understanding Adverse Events

Person versus System explanations

◆ Person Centred View

- Focuses on those at the `sharp end`
- Individual responsibility and blame
- Countermeasures aimed at changing individuals' behaviour

◆ System View

- Human beings fallible, errors to be expected
- Focus on factors influencing errors
- Countermeasures aimed at conditions of work

|Obstetric example

Care delivery problems

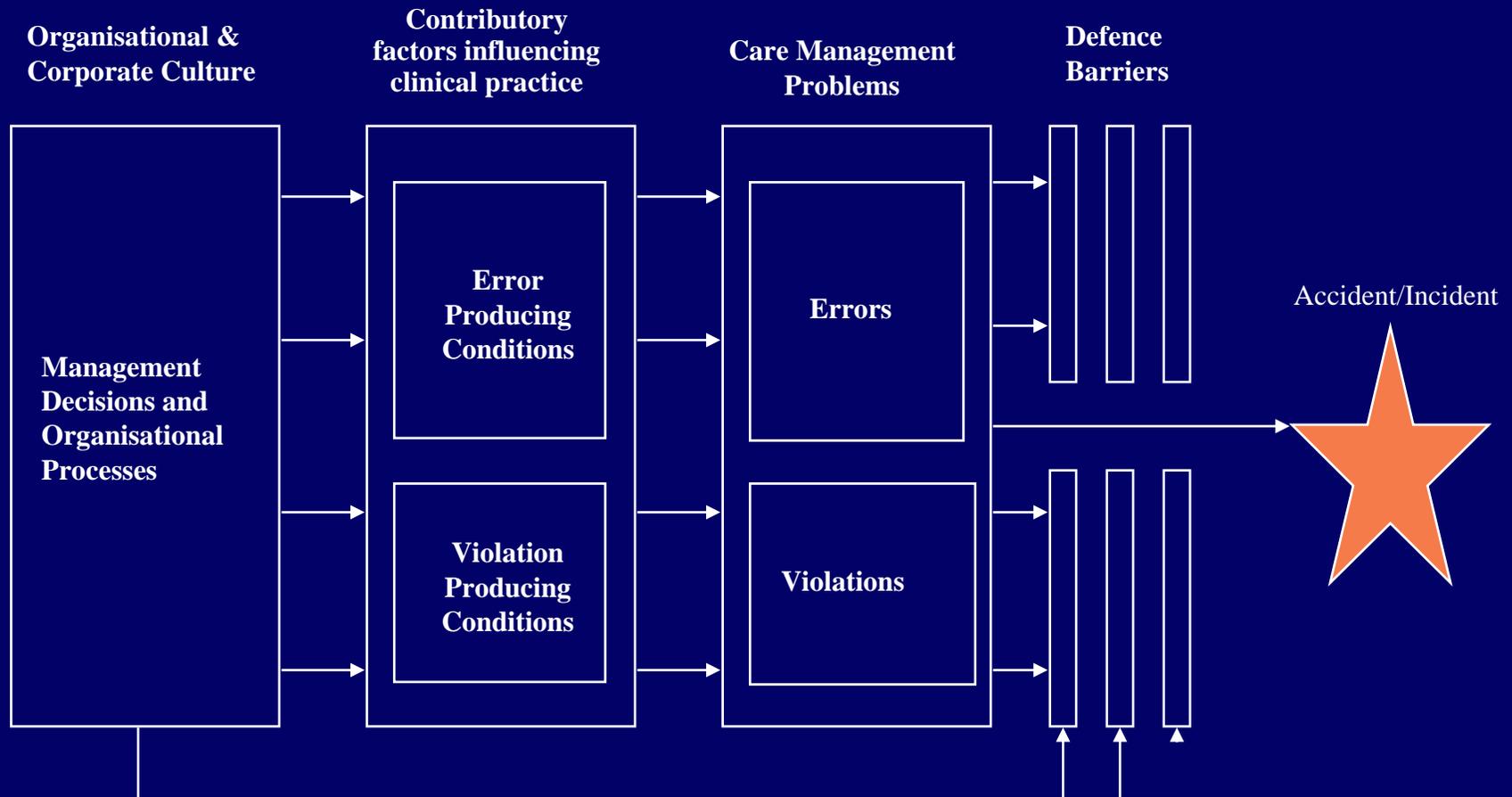
- ◆ The significance of the decelerations on the CTG trace were not given sufficient weight
- ◆ The midwife did not reduce the syntocinon as soon as she saw the deteriorating trace
- ◆ The consultant overrode the decision of the team without considering their arguments
- ◆ The sister was ‘forced’ to induce more evident signs of fetal distress

Wider features of the unit

Contributory factors

- ◆ No clear demarcation of roles and responsibilities and no agreed line of communication in a crisis
- ◆ Inadequate training for CTG interpretation
- ◆ Staff assumed faults in machines rather than fetal distress
- ◆ General acceptance of faulty equipment
- ◆ No system to ensure lessons learnt from serious incidents

Stages of development of organisational accident



Framework for the analysis of risk and safety in medicine

- ◆ Patient factors
- ◆ Task factors
- ◆ Individual staff factors
- ◆ Team Factors
- ◆ Work environment
- ◆ Organisation and management
- ◆ Institutional context

A Window on the System

- ◆ **Systems analysis** of clinical incidents
 - Root cause terminology highly misleading
 - Complexity of events and contributory factors
 - Moving away from blame
 - Looking to the future and
 - Generating plans for action

Enhancing safety

Incident reporting: local systems

- ◆ Assume massive under-reporting
- ◆ It's communication not counting
- ◆ Incident reports act to flag issues and to provide warnings
- ◆ Analysis of incidents often neglected but can be very informative

Beyond reporting

- ◆ Record review
 - Now feasible at local level
 - Systematic review of error and harm
- ◆ Executive walk rounds
- ◆ Case analysis
- ◆ Process analysis
 - Failure, modes and effects analyses
- ◆ Observation

UK National Patient Safety Agency

- ◆ National Reporting & Learning System
 - Frequency and contributory factors
 - Cultural importance
- ◆ Patient Safety Observatory
- ◆ Development of solutions
- ◆ Training in root cause analysis
- ◆ Open disclosure policy

Safety in practice: generic issues

- ◆ Are the foundations in place?
 - Safety awareness
 - Safety culture
- ◆ Leadership
 - Clinical
 - Management
 - National
- ◆ Regulatory pressure may assist

Culture and leadership

- ◆ Culture important but evidence weak
- ◆ No blame culture?
- ◆ `Open and fair' culture
 - To encourage reporting
 - To encourage discussion of error and harm
 - To support injured patients and staff
- ◆ High reliability culture?

Safety paradigms

- ◆ Clinical innovations
- ◆ Standardisation and process improvement
 - Automation
 - Information technology
- ◆ People create safety
 - Individuals
 - Teams

Specific Clinical Interventions

(Agency for Healthcare Research and Quality)

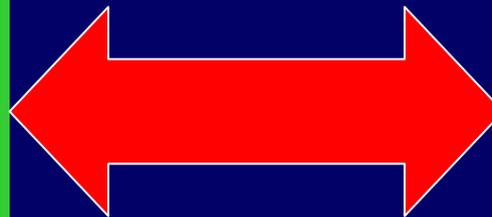
- ◆ Prophylaxis to prevent venous thromboembolism
- ◆ Perioperative betablockers to prevent morbidity
- ◆ Sterile barriers while placing central intravenous catheters
- ◆ Antibiotic prophylaxis in surgical patients

Prophylaxis to prevent venous thromboembolism

- ◆ VTE frequent, painful, dangerous, wastes resources and is sometimes fatal
 - Without prophylaxis occurs in 20% of surgical operations, 50% orthopaedic
 - In US 10% of surgeons never use prophylaxis
- ◆ Focus of patient safety is on the omissions rather than the clinical intervention

Conflicting Visions of Safety?

Replace or
support human
beings



Practitioners
create safety

How is safety achieved?

Contrasting visions

◆ Replace or support human beings

- Design and standardisation
- Protocols & guidelines
- Information technology
- Technical solutions

◆ Practitioners create safety

- New & enhanced skills
- High reliability organisations
- Mindfulness & hazard awareness
- Studying success and recovery

Reducing medication error

Multi-level interventions: Compliance with hand hygiene in Geneva

- ◆ Senior management backing
 - Funding and safety culture
- ◆ Working conditions
 - Availability of cleaning solution
- ◆ Team based interventions
- ◆ Educational campaign for individual staff
- ◆ Task
 - Design of new containers

Multi-level interventions: Reducing medical errors at Wimmera Hospital

- ◆ Senior management backing
 - Executive champions and dedicated staff
- ◆ Working conditions
 - Reviewing working hours and workload
- ◆ Multidisciplinary action team
 - Addressing levels of supervision
- ◆ Training in risk management and patient safety
- ◆ Task
 - Simplifying systems
 - Standardising procedures
 - Reminders and checklists

The Aftermath

- ◆ Caring for patients
 - Explanations, apology, making sure it does not happen again
 - Longer term support for some
- ◆ Supporting staff
 - Understanding of error
 - Professional and personal support
 - Potential long term effects

Sources & Information

- ◆ Research, books, papers and downloads of case analysis methods
 - www.csru.org.uk
- ◆ National Patient Safety Agency
 - www.npsa.nhs.uk
- ◆ Agency for Healthcare Research & Quality
 - www.ahrq.gov/clinic/ptsafety
- ◆ Institute for Healthcare Improvement
 - www.qualityhealthcare.org