Risk Management in the Hospital Environment

Prof dr Patrick Hudson
Prof dr Rene de Vries
Universiteit Leiden
Structure

- The Problem - patient safety
- Industry approach to risk analysis
- Analyzing Medical Risks
- Examples
- Conclusion
The UK NHS & USA
Failure rates in hospital medicine

- Conservative estimates (USA, UK, Australia) 3 x road traffic fatalities
- In the UK there are estimated to be about 900,000 events harming or potentially harming an in-patient every year
- The US estimated fatality rate for iatrogenic fatalities is 80,000 - 120,000 per year
Approaches to improving Patient Safety

• General approach - Find out what is going wrong, and fix it
• Typically involves reactive approaches
  – Incident reporting and registration
  – Incident investigation and analysis
• Reporting often felt to be personally or professionally threatening
• Often seen as somebody else’s problem
How does Industry do it?

- Systematic management of hazards and associated risks
- Development of a Safety Management System
- Identification of what needs to be managed
- Creation and use of systems intended to manage the significant risks
Piper Alpha
The next morning
Leadership and Commitment

Policy and Strategic Objectives

Organisation, Responsibilities
Resources, Standards & Documentation

Hazards and Effects
Management

Planning and Procedures

Implementation

Audit

Management Review

Corrective Action and Improvement

PLAN

DO

CHECK

FEEDBACK
How does industry manage risks?

- Hazard and Effects Management
- Identify - what are the hazards?
- Assess - how important are they?
- Control - how are they to be managed?
- Recover - what will you do if it goes wrong?
Risk analysis

• **We can work back from outcomes**
  – How could this happen? (e.g. PRISMA, ECFA+)
  – Reactive approach

• **We can work forward from hazards**
  – What could go wrong (e.g. FMEA)
  – Proactive approach

• Both of these rapidly become very complex
• The number of possible pathways to disaster is vast
• The process approach rapidly becomes impossible to oversee
Blood Transfusion

- The processes involved in blood transfusion are complex
- Some involve cycles
- The actors involved are highly differentiated
  - In time
  - In space
  - In position and profession
The Bow Tie Method

- The Bow Tie is a way of representing risks and how we can manage them
- Used in Oil and Gas, Nuclear, Aviation
- New to medicine
Bow ties: principles

- **Hazards** are what can cause harm
- **Consequences** are what we really wish to avoid
- **Threats** are ways in which hazards may be released
- **Top Events** are intermediate events we wish to avoid, where we start to lose control
- **Barriers** represent ways of preventing consequences
  - Preventative (controls) on the left - Top Event hasn’t happened
  - Mitigation (defences) on the right - Top Event has already happened
Bow-tie Concept

Undesirable event with potential for harm or damage

Engineering activities
Maintenance activities
Operations activities
Bow-tie - incident

HAZARD

Engineering activities
Maintenance activities
Operations activities

Top Event

BARRIERS

CONSEQUENCES
Escalation Factors

• Escalation factors reduce the effectiveness of a barrier

• We can identify what we need to do to ensure the escalation factor does not degrade the barrier

• Escalation factors are a type of threat

• The barriers represent the underlying causes of incidents we wish to manage
Application to Medicine

• Bow ties can be developed combining all available sources of information
• We can develop an overall picture of the risks
  – Strategic view
• We can assess how well we are managing those risks
  – Performance measurement
Clinical and non-clinical risks

• Clinical risks are well understood
  – Effects of a medicine or treatment are studied
  – Scientifically controlled evaluations with double-blind etc

• Non-clinical risks are ignored
  – The assumptions are that treatments are performed as per protocol being evaluated
  – Medications are given correctly
Medication Error
estimated failure rates

• 15% of medication administrations in error (Tissot et al 2003)
• 39% prescriptions in error (Leape et al, 1995)
• 49% intravenous administrations with at least one error (Taxis & Barber, 2003)
Critical States

- Wrong Patient
- Wrong Diagnosis
- Wrong Drug
- Wrong Dose
- Wrong Delivery
A Threat example

- Neonate twins kept in after birth
- One twin may get/not get medication intended for the other
- Risks are a function of
  - Frequency with which this threat occurs
  - Effectiveness of identification measures (e.g. bar coding)
  - Chance (50%)
  - Extent of use of bar coding by staff
  - Ability to detect if the wrong twin has been selected
Outcomes vary considerably

- Effects on patients are distributed
  - No effect
  - Marginal effect
  - Minimal side effects
  - Lack of improvement
  - Fatal effects

- Unexpected results in clinical tests
Example 1
The Operating Theatre

• Wrong patient scenario
• Discovery of inherent and current weaknesses in protocols
Blood Transfusion

• Originally chosen because of low failure rates
• Things still go wrong (Radboud Nijmegen)
• Discovery of problems and solutions
What are the biggest risks in blood transfusion?

• Not all hazards are important
• Some hazards are very unlikely
• Some outcomes are trivial
• Other outcomes are catastrophic
• Risk puts together probability (likelihood) and size of the potential outcomes

So, how can we understand our risks?
Top Events in Blood Transfusion

- Wrong product for the patient
- Wrong patient for the product
- Incorrect quality of product
- Wrong dose of product

- Non-preventable adverse event
  - A new issue
Wrong patient name on order form

Chaotic situation/stress

Haste/work overload

Inattention/sloppiness

ICT devices not functioning

Poor handwriting

Administrative double check (at bedside and in laboratory)

PR - Procedures

Example 1a: Wrong blood for this patient

Example 1b: Hemolytic transfusion reaction
Wrong patient name on order form

Administrative double check (at bedside and in laboratory)

PR - Procedures

Chaotic situation/ stress

Sufficient backup

QR - Organisation

Haste/ work overload

Sufficient personnel

QR - Organisation

Indiscipline/ sloppiness

Social support/ corrective colleagues

CO - Communication

ICT devices not functioning

Maintenance

QR - Organisation

Poor handwriting

Computerised application

QR - Organisation

Example 1: Wrong blood for this patient

Hemolytic transfusion reaction
Integrating Approaches

• The information gained from developing a complete risk assessment - clinical and non-clinical risks can be used for other tasks
• Incident investigation (MIP/ FONA) can be structured with the bow ties
• Audits can check whether controls are
  – In place
  – In operation
  – Effective
What can we do to assess the risks?

• Incidents provide information and can be analysed
• We can see if specific hazards and outcomes are being managed
• Do we have any controls?
• Do we have too much?
• How effective are the controls?
• Is the chance of bad consequences reduced to an acceptable level?
Extra questions

- Are there any hazards not managed?
- Are there points where control is excessive/expensive - doing too much?
- Are the opportunities for prevention used effectively - doing too little?
- Are there single point failure possibilities? E.g. a single nurse
- Are there common mode sensitivities? E.g. common factors that degrade all controls
Conclusion

• The systematic approach as used by high-risk industries offers great opportunities for managing medication error and many other medical risks
• We can assess what works and why
• SMS was proposed by the Sneller Beter team