Risk Management in the Hospital Environment

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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

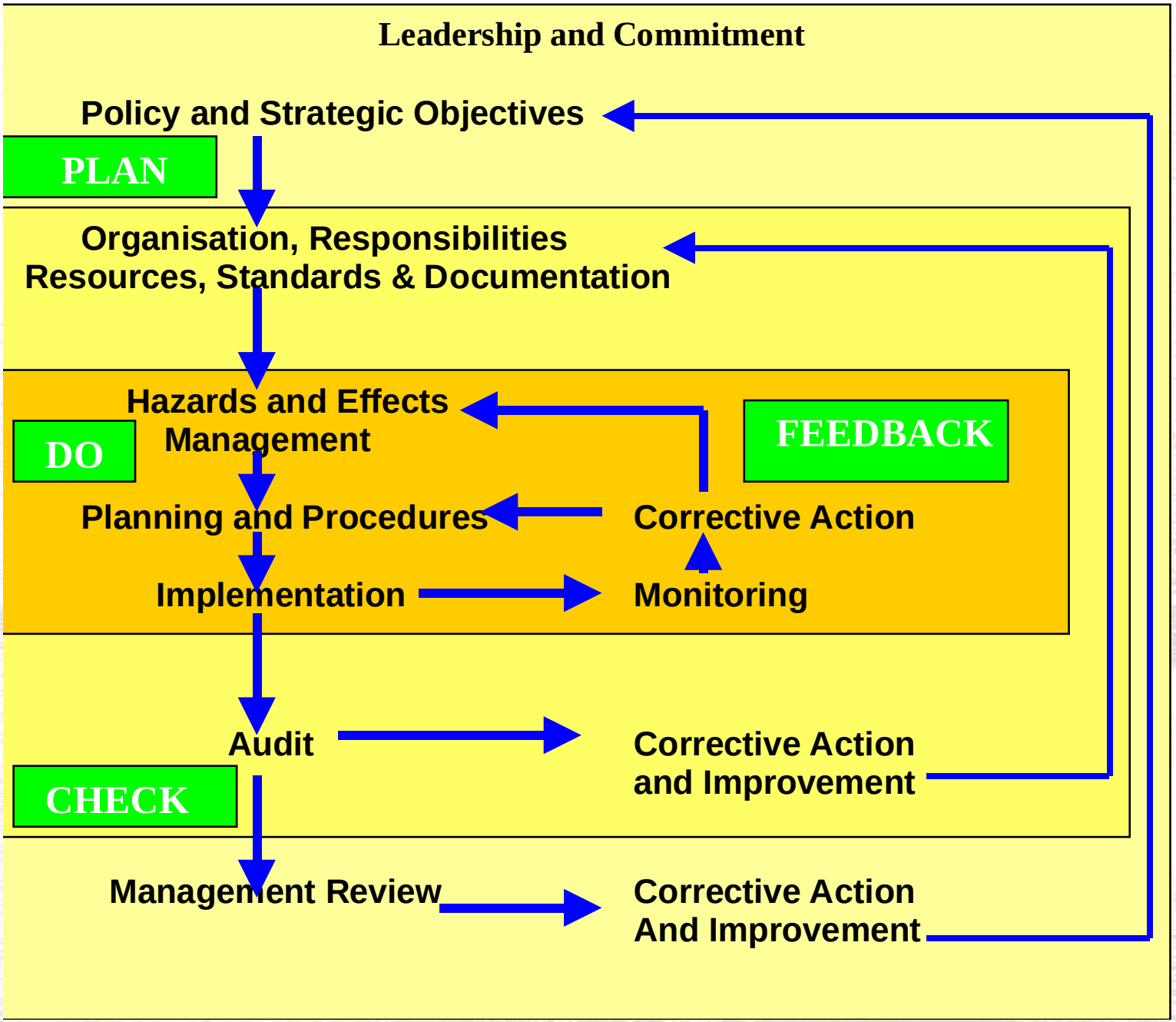
- General approach - Find out what is going wrong, and fix it
- Typically involves reactive approaches
  - Incident reporting and registration
  - Incident investigation and analysis
- Reporting often felt to be personally or professionally threatening
- Often seen as somebody else's problem

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
PLAN
Organisation, Responsibilities
Resources, Standards & Documentation
Hazards and Effects
Management
DO
FEEDBACK
Planning and Procedures
Corrective Action
Implementation
Monitoring
Audit
Corrective Action
and Improvement
CHECK
Management Review
Corrective Action
And Improvement

How does industry manage risks?

- Hazard and Effects Management

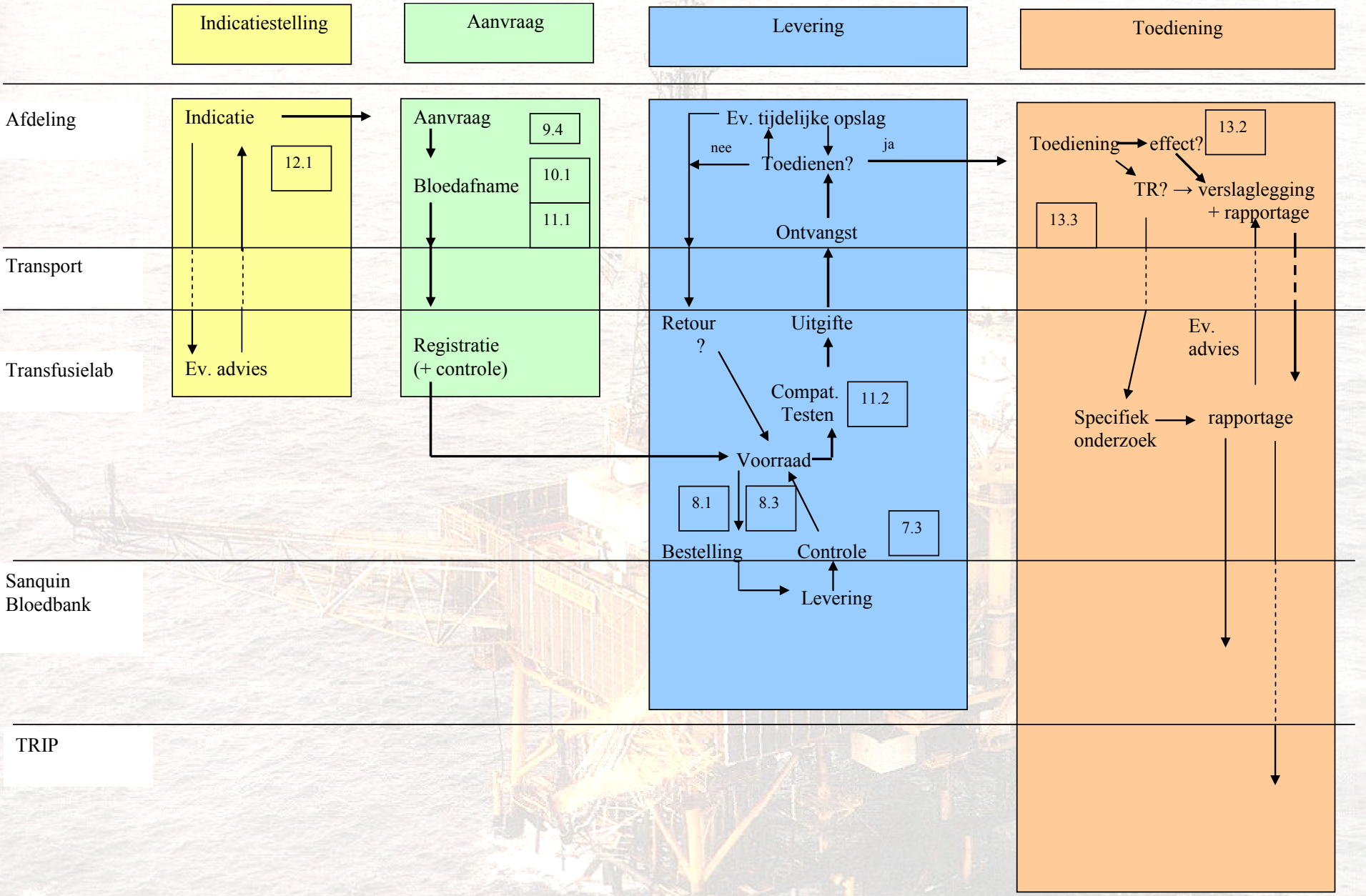
- Identify - what are the hazards?
- Assess - how important are they?
- Control - how are they to be managed?
- Recover - what will you do if it goes wrong?

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


Indicatiestelling
Aanvraag
Levering
Toediening
Afdeling
Transport
Transfusielab
Sanquin Bloedbank
TRIP
Indicatie
12.1
Ev. advies
Aanvraag
9.4
Bloedafname
10.1
11.1
Registratie (+ controle)
Ev. tijdelijke opslag
nee
Toedienen?
ja
Ontvangst
Retour ?
Uitgifte
Compat. Testen
11.2
Voorraad
8.1
8.3
7.3
Bestelling
Controle
Levering
Toediening
effect?
13.2
TR? → verslaglegging + rapportage
13.3
Ev. advies
Specifiek onderzoek
rapportage

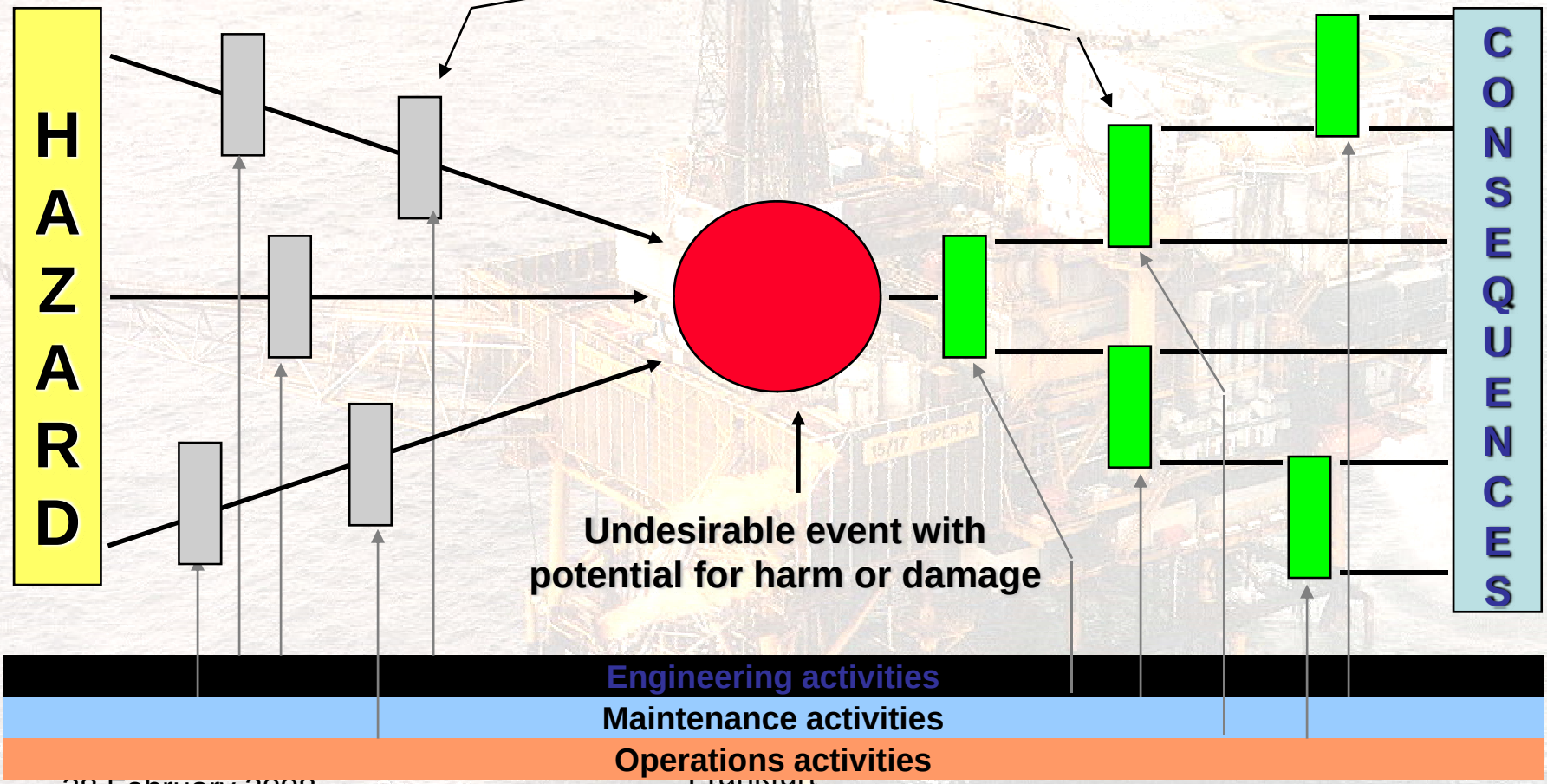
The Bow Tie Method

- 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

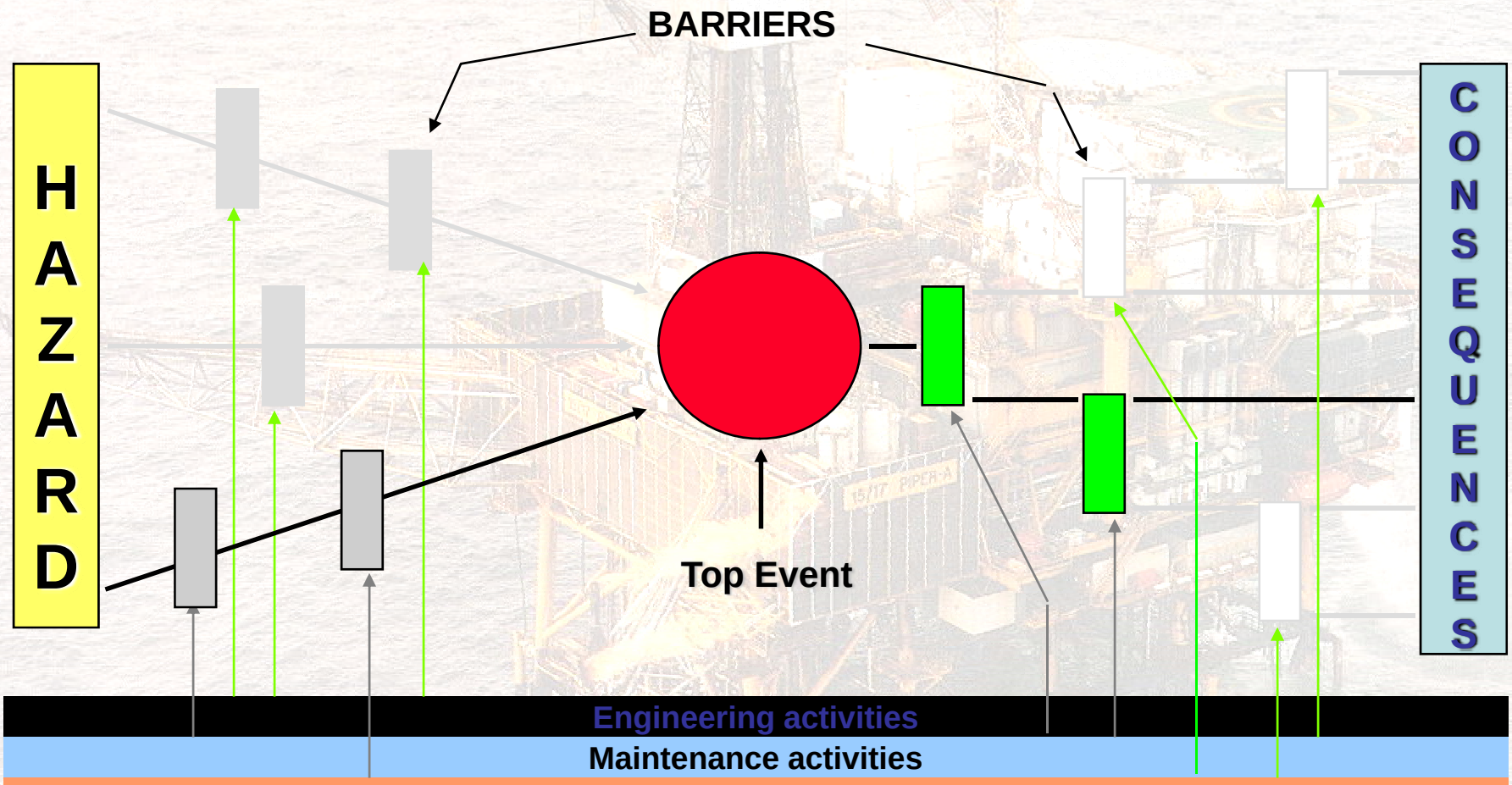
Bow ties:principles

- 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

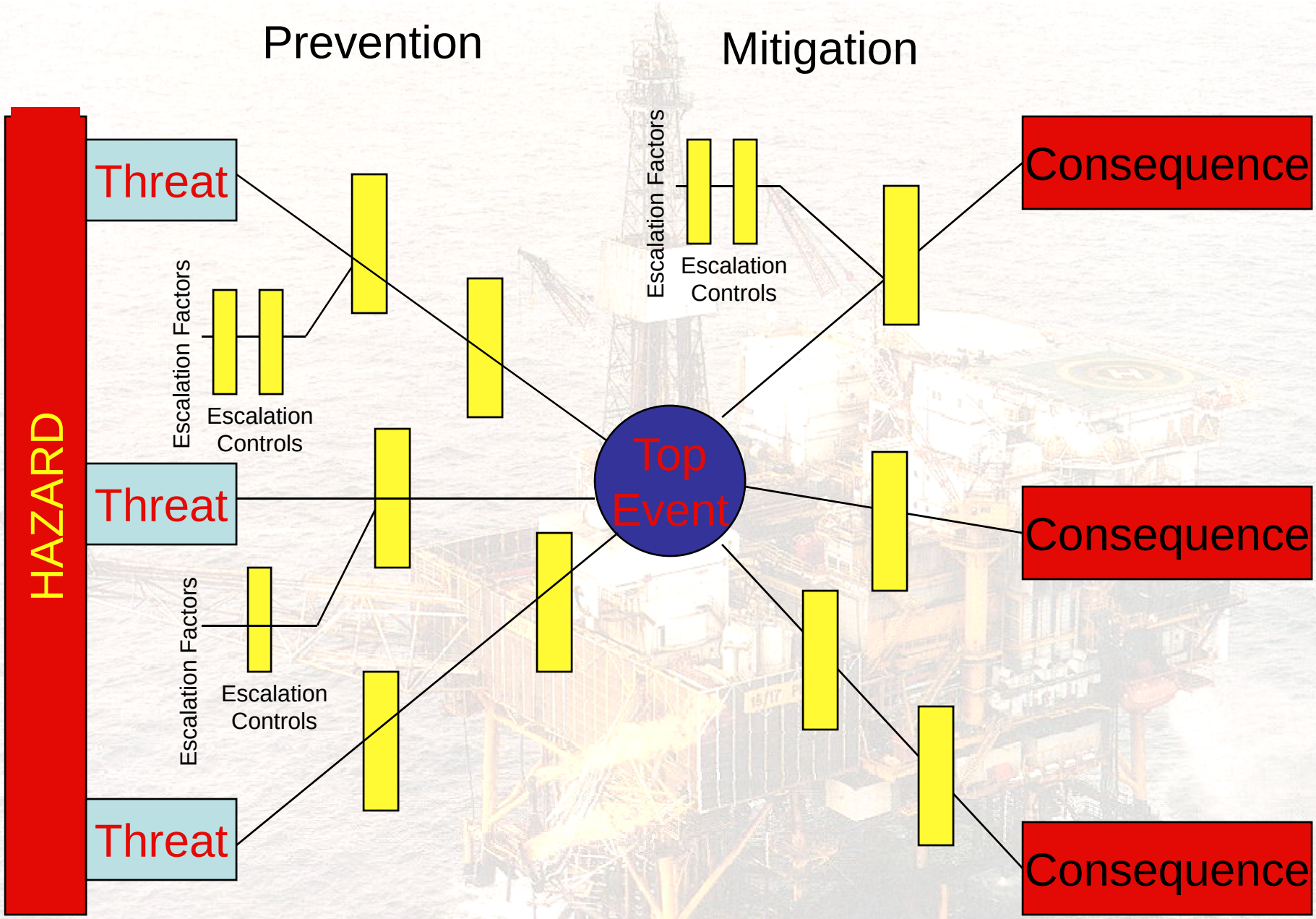


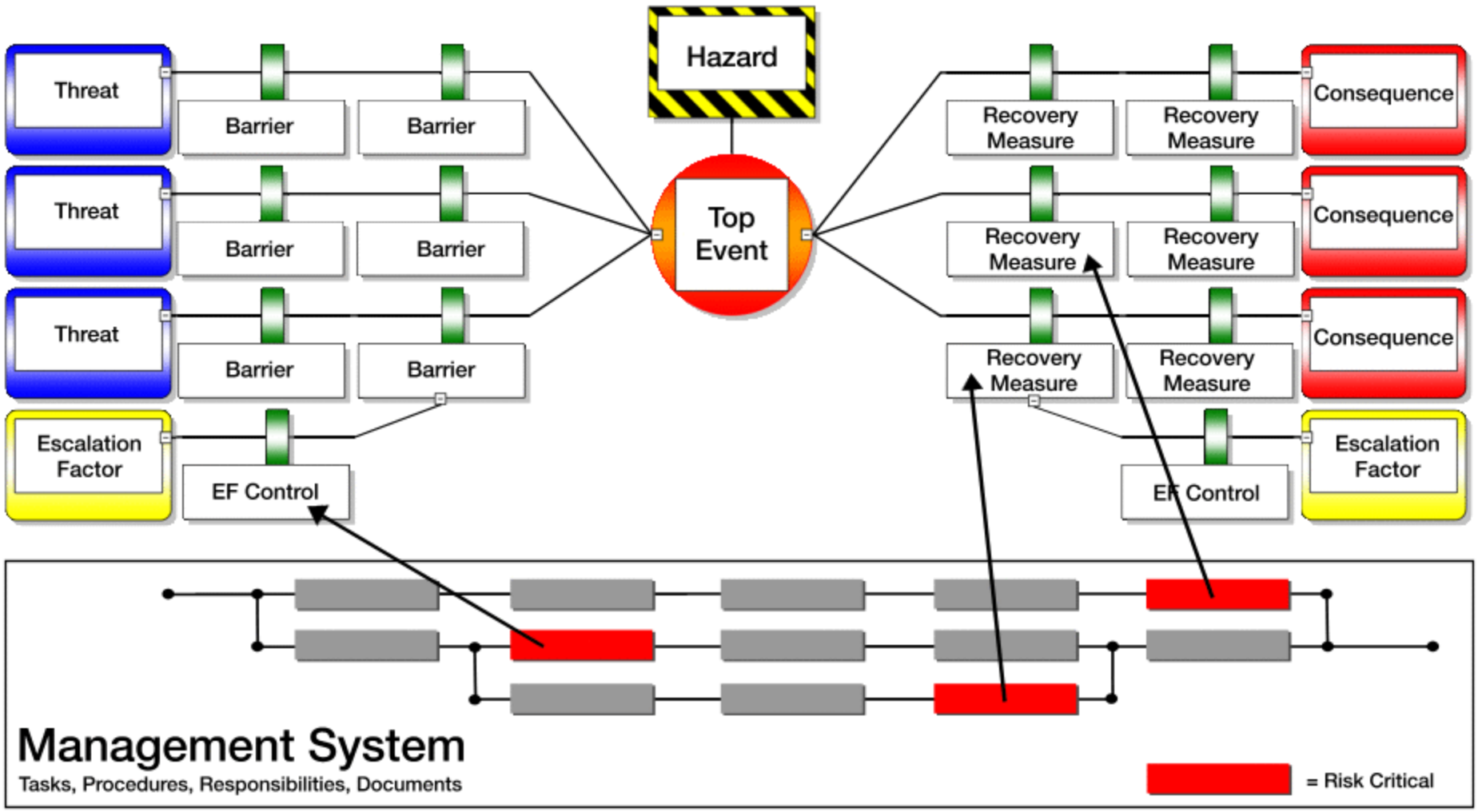
Bow-tie - incident



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


Prevention
Mitigation
HAZARD
Threat
Threat
Threat
Escalation Factors
Escalation Controls
Escalation Factors
Escalation Controls
Escalation Factors
Escalation Controls
Top Event
Consequence
Consequence
Consequence


Hazard
Top Event
Threat
Threat
Threat
Escalation Factor
Barrier
Barrier
Barrier
Barrier
Barrier
Barrier
EF Control
Recovery Measure
Recovery Measure
Recovery Measure
Recovery Measure
Recovery Measure
Recovery Measure
EF Control
Consequence
Consequence
Consequence
Escalation Factor
Management System
Tasks, Procedures, Responsibilities, Documents
= Risk Critical

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

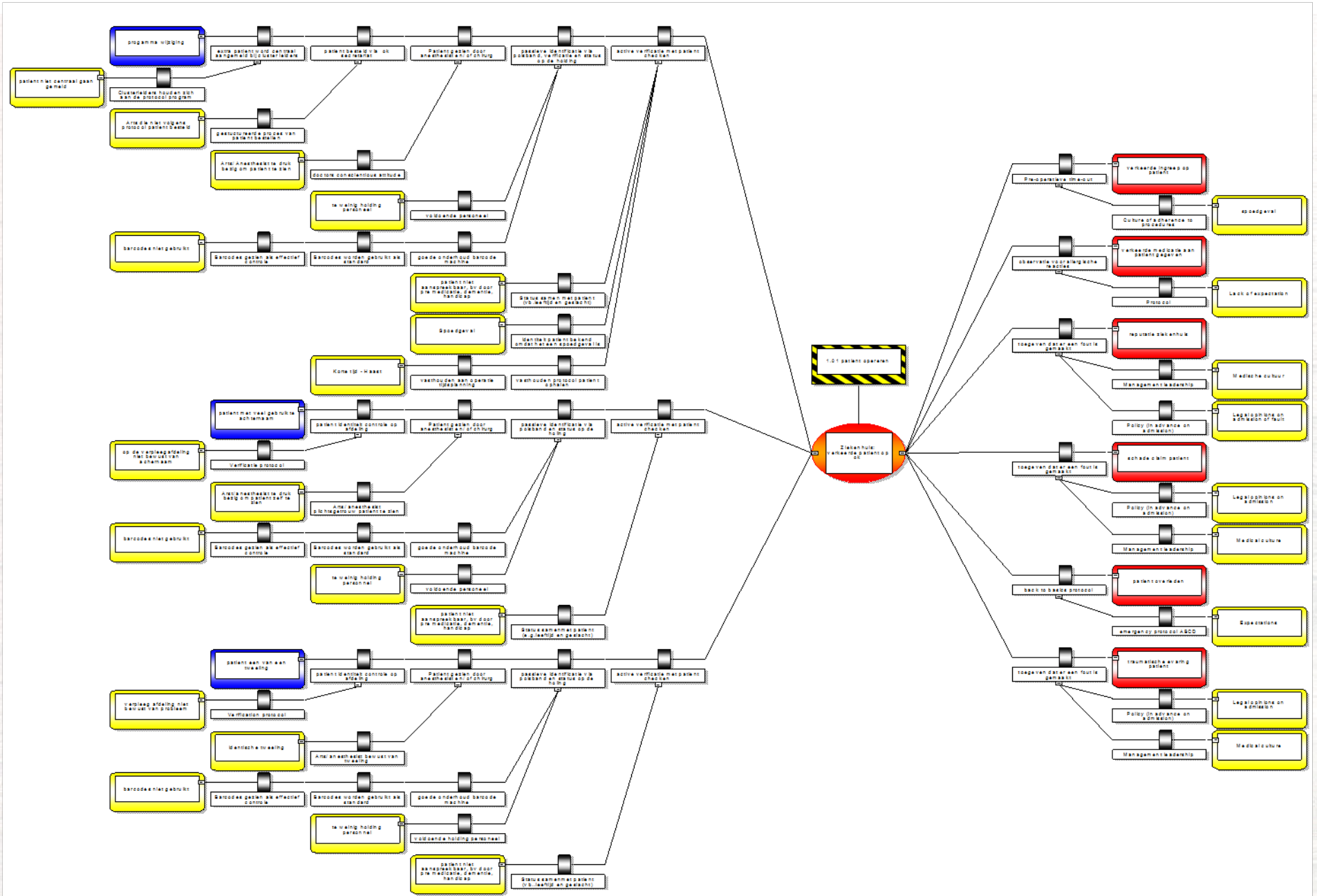
- Neonate twins kept in after birth
- One twin may get/not get medication intended for the other
- Risks are a function of
  - Frequency with which this threat occurs
  - Effectiveness of identification measures (e.g. bar coding)
  - Chance (50%)
  - Extent of use of bar coding by staff
  - Ability to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

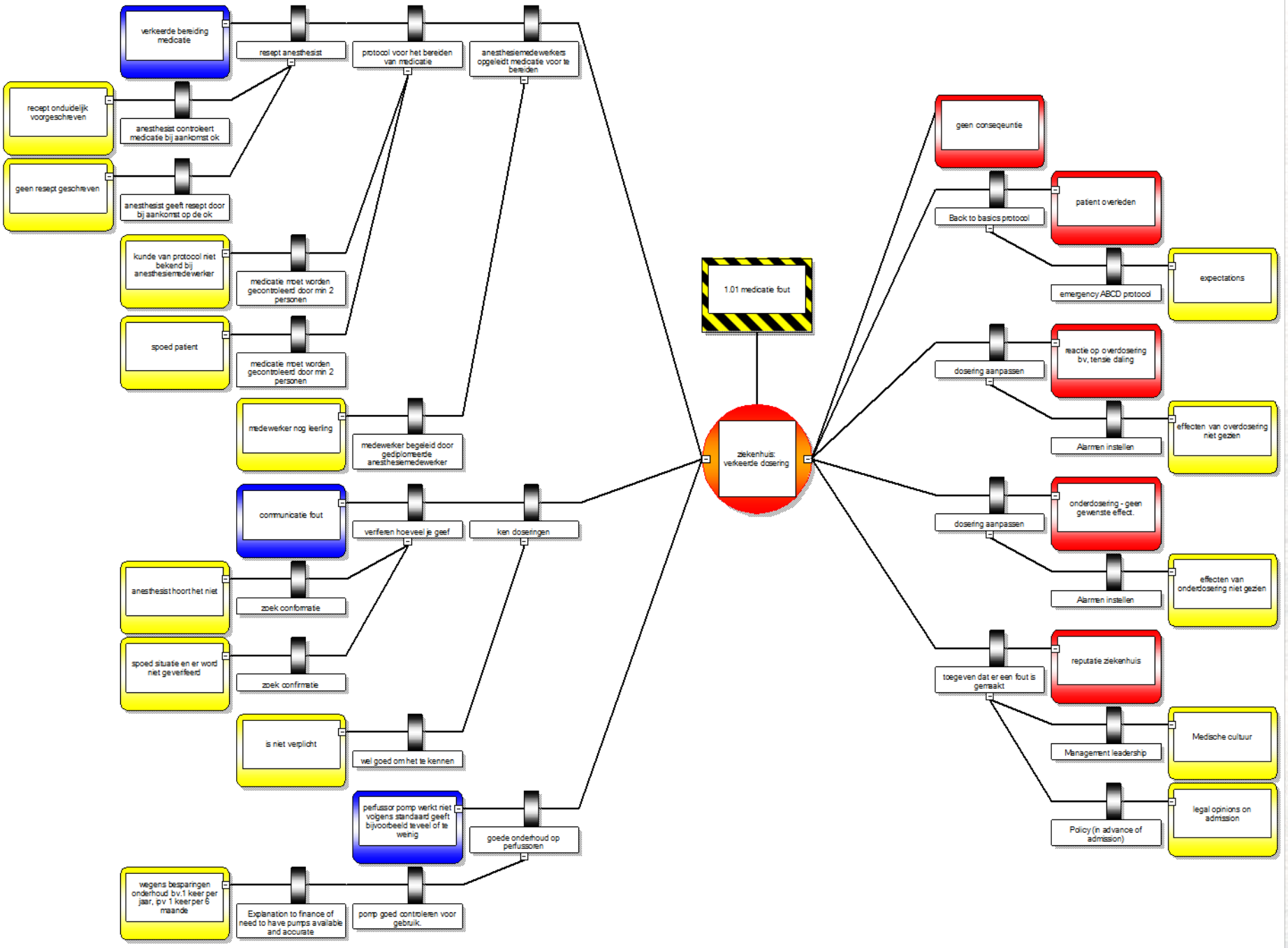
Outcomes vary considerably

- 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


programma wijziging
patient niet centraal gaan gemeld
extra patient wordt centraal aangemeld bij clusterhelders
Clusterhelders houden zich aan de protocol program
patient bestaat via ok secretariaat
Patient gezien door anesthesiemedewerker
passieve identificatie via polsband, verificatie en status op de holding
active verificatie met patient checken
Arts die niet volgens protocol patient beteld
gestructureerde proces van patient betellen
Arts/ Anesthesiste te druk bezig om patient te zien
doctors conscientious attitude
te weinig holding personeel
voldoende personeel
barcodes niet gebruikt
Barcodes gezien als effectief control
Barcodes worden gebruikt als standard
goede onderhoud barcode machine
patient niet aanspreekbaar, bv door pre medicatie, dementie, handicap
Status examen met patient (bv leeftijd en geslacht)
Spoedgeval
Identificatie patient bekend omdat er een spoedgeval is
Komt tijd - Kwaad
Vasthouden aan operatie rijdeplanning
Vasthouden protocol patient ophalen
patient met veel gebruikte achternamen
op de verpleegafdeling niet bekend van achternamen
Verificatie protocol
Arts/ anesthesiste te druk bezig om patient te zien
Arts/ anesthesiste plichtsgetrouw patiente zien
patient aan van een tweeling
verpleeg afdeling niet bekend van probleem
Verification protocol
Identieke tweeling
Arts/ anesthesiste bekend van tweeling
1.01 patient opereren
Ziekenhuis: verkeerde patient op ok
Pre-operatieve time-out
Verkeerde ingreep op patient
Culture of adherance to procedures
spoedgeval
observatie/ radiologische reacties
Verkeerde medicatie aan patient gegeven
Protocol
Lack of expectation
toegevoegd dat er een fout is gemaakt
reputatie ziekenhuis
Management leadership
Medische cultuur
Policy (in advance on admission)
Legal opinions on admission of fault
schade claim patient
Legal opinions on admission
Medical culture
back to basics protocol
patient overleden
emergency protocol ASCD
Expectations
traumatische ervaring patient
Legal opinions on admission
Medical culture


1.01 medicatie fout
ziekenhuis: verkeerde dosering
verkeerde bereiding medicatie
resept anesthesist
protocol voor het bereiden van medicatie
anesthesiemedewerkers opgeleidt medicatie voor te bereiden
recept onduidelijk voorgeschreven
anesthesist controleert medicatie bij aankomst ok
geen resept geschreven
anesthesist geeft resept door bij aankomst op de ok
kunde van protocool niet bekend bij anesthesiemedewerker
medicatie moet worden gecontroleerd door min 2 personen
spoed patient
medicatie moet worden gecontroleerd door min 2 personen
medewerker nog leerling
medewerker begeleid door gediplomeerde anesthesiemedewerker
communicatie fout
verferen hoeveel je geef
ken doseringen
anesthesist hoort het niet
zoek conformatie
spoed situatie en er word niet geverifeerd
zoek confirmatie
is niet verplicht
wel goed om het te kennen
perfussor pomp werkt niet volgens standaard geeft bijvoorbeeld teveel of te weinig
goede onderhoud op perfussoren
wegens besparingen onderhoud bv.1 keer per jaar, ipv 1 keer per 6 maande
Explanation to finance of need to have pumps available and accurate
pomp goed controleren voor gebruik.
geen conseqeuntie
Back to basics protocol
patient overleden
emergency ABCD protocol
expectations
dosering aanpassen
reactie op overdosering bv, tensie daling
Alarmen instellen
effecten van overdosering niet gezien
dosering aanpassen
onderdosering - geen gewenste effect.
Alarmen instellen
effecten van onderdosering niet gezien
toegeven dat er een fout is gemaakt
reputatie ziekenhuis
Management leadership
Medische cultuur
Policy (in advance of admission)
legal opinions on admission

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?

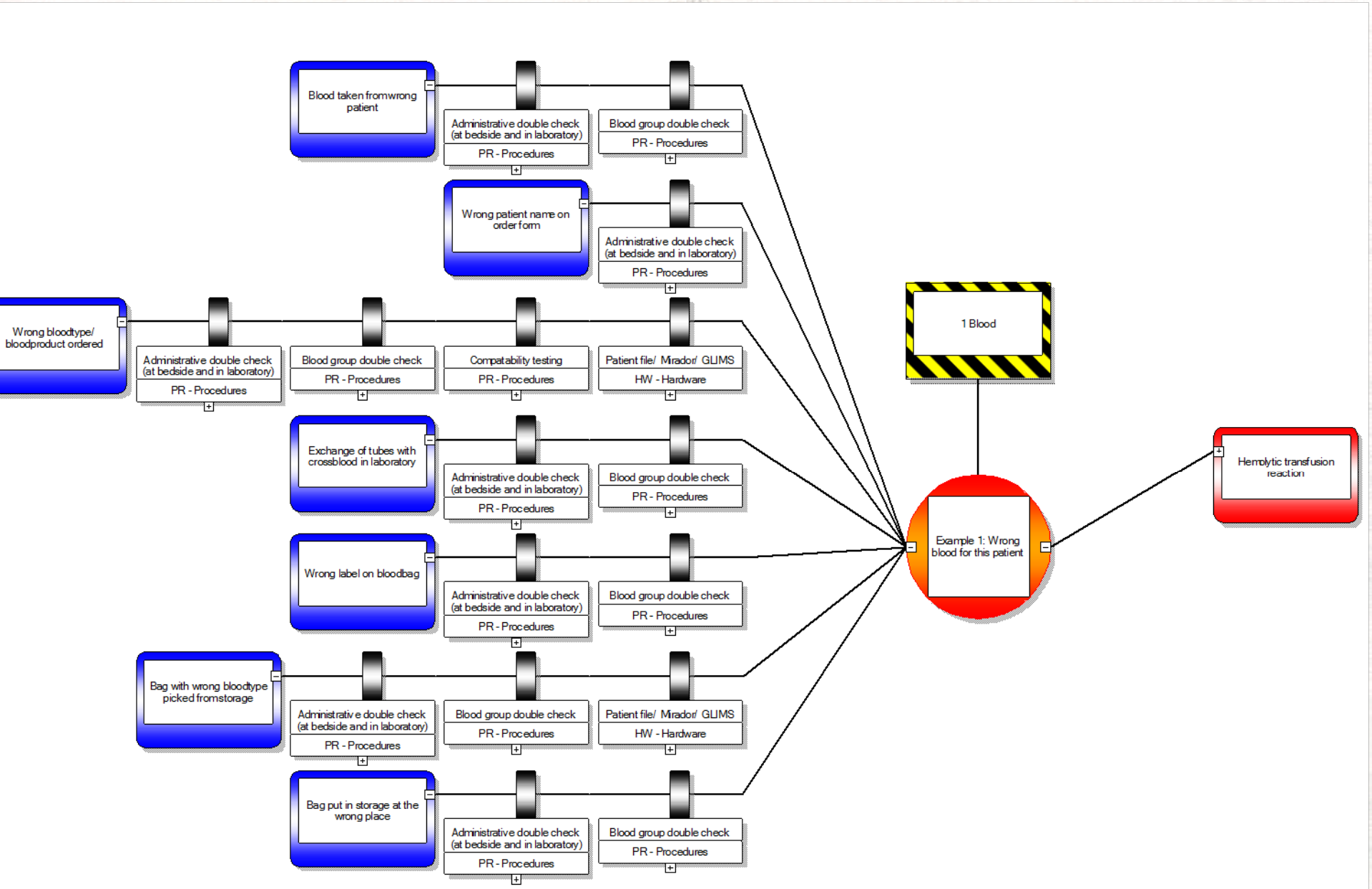
- Not all hazards are important
- Some hazards are very unlikely
- Some outcomes are trivial
- Other outcomes are catastrophic
- Risk puts together probability (likelihood) and size of the potential outcomes

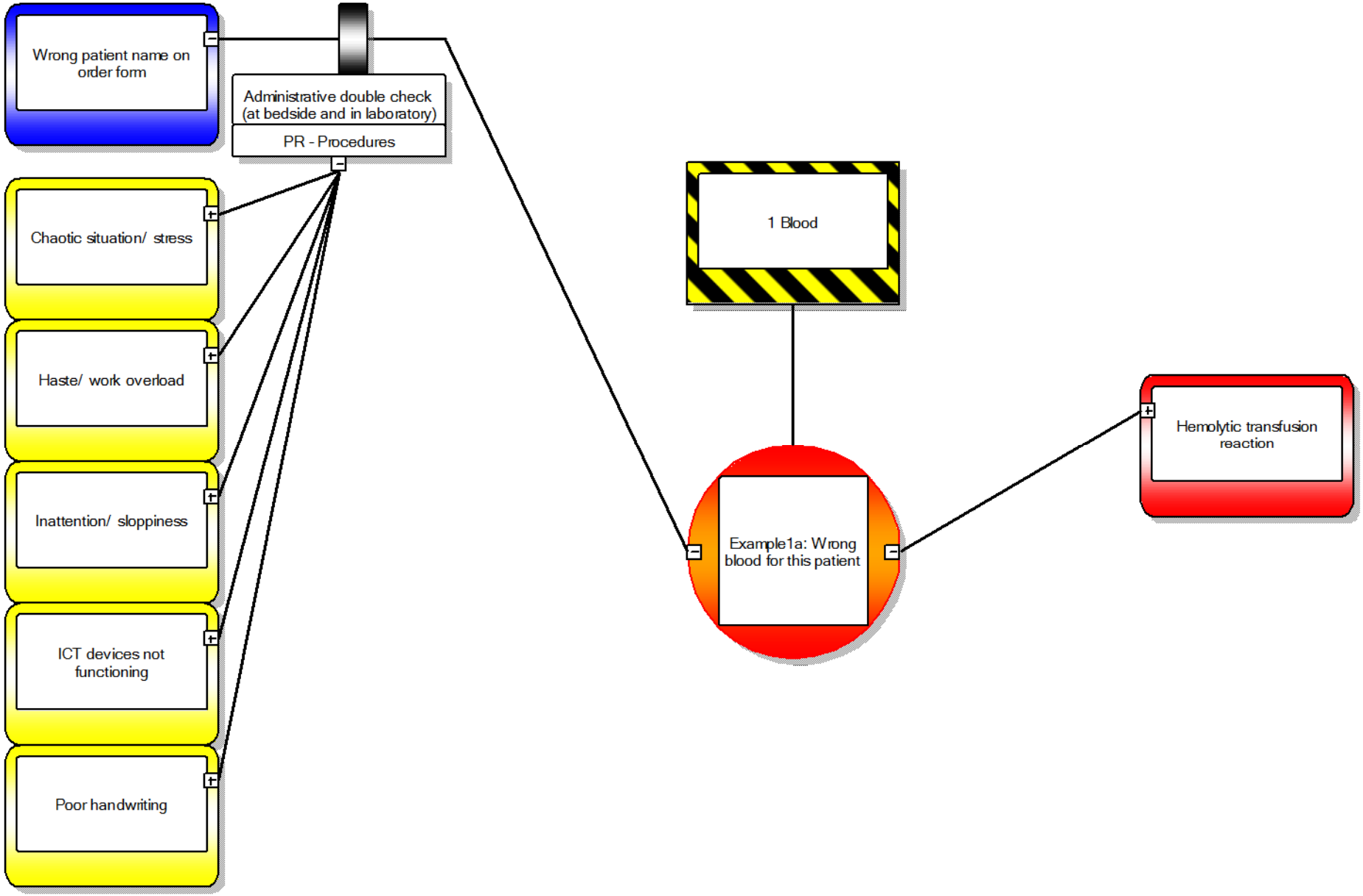
So, how can we understand our risks?

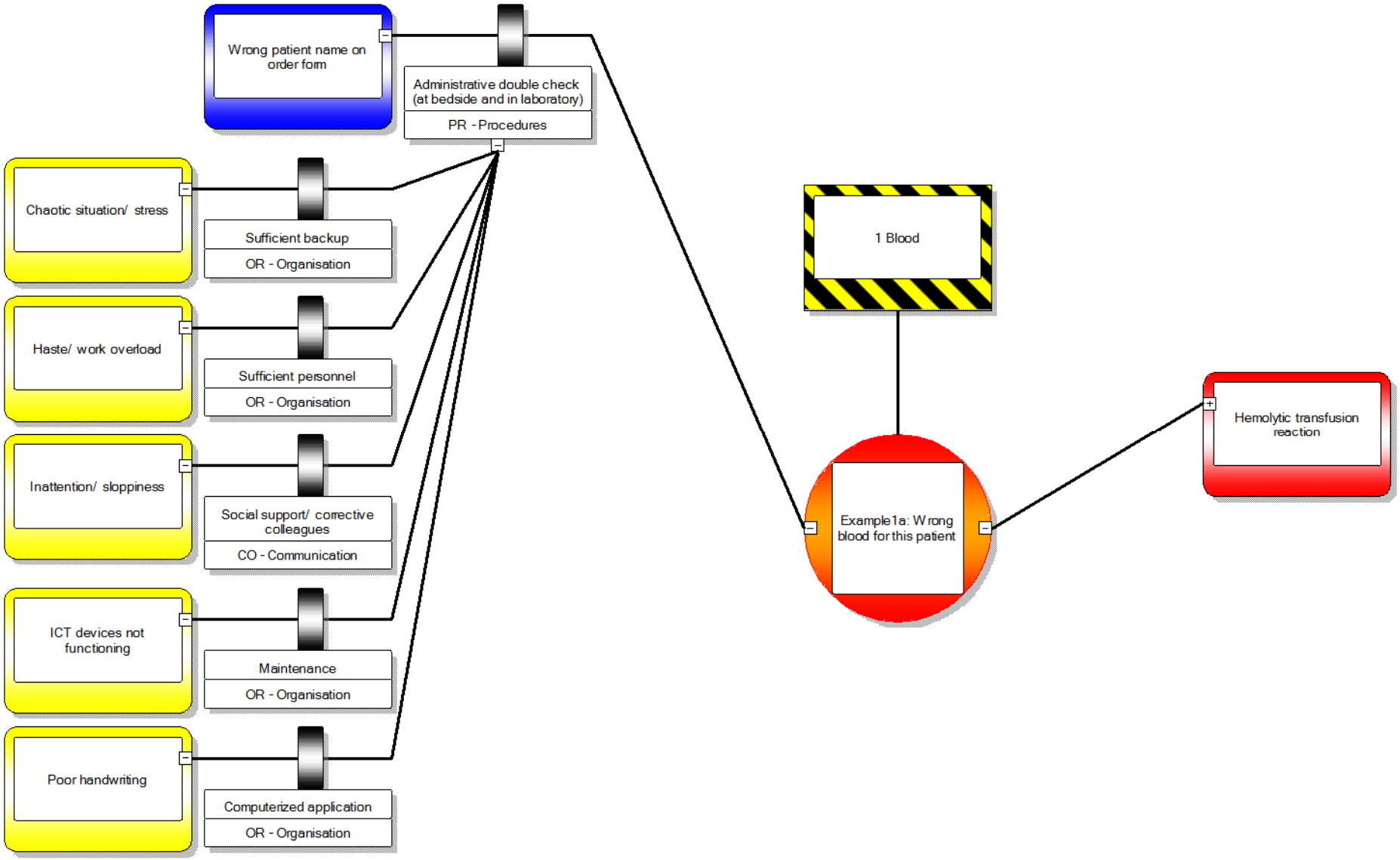
Top Events in Blood Transfusion

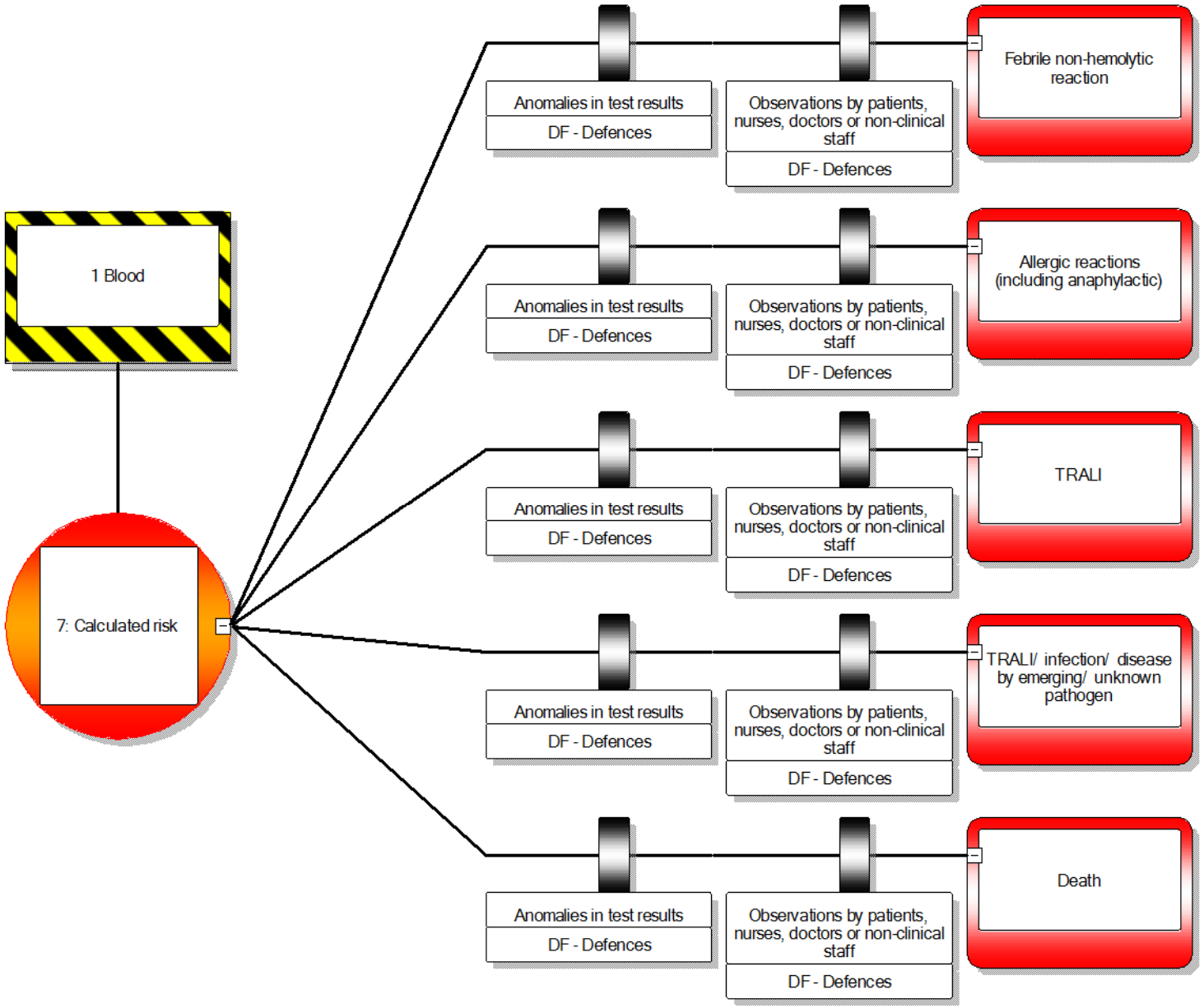
- Wrong product for the patient
- Wrong patient for the product
- Incorrect quality of product
- Wrong dose of product

- Non-preventable adverse event
  - *A new issue*


Blood taken from wrong patient
Administrative double check (at bedside and in laboratory)
PR - Procedures
Blood group double check
PR - Procedures
Wrong patient name on order form
Administrative double check (at bedside and in laboratory)
PR - Procedures
Wrong bloodtype/ bloodproduct ordered
Administrative double check (at bedside and in laboratory)
PR - Procedures
Blood group double check
PR - Procedures
Compatability testing
PR - Procedures
Patient file/ Mirador/ GLIMS
HW - Hardware
Exchange of tubes with crossblood in laboratory
Administrative double check (at bedside and in laboratory)
PR - Procedures
Blood group double check
PR - Procedures
Wrong label on bloodbag
Administrative double check (at bedside and in laboratory)
PR - Procedures
Blood group double check
PR - Procedures
Bag with wrong bloodtype picked from storage
Administrative double check (at bedside and in laboratory)
PR - Procedures
Blood group double check
PR - Procedures
Patient file/ Mirador/ GLIMS
HW - Hardware
Bag put in storage at the wrong place
Administrative double check (at bedside and in laboratory)
PR - Procedures
Blood group double check
PR - Procedures
1 Blood
Example 1: Wrong blood for this patient
Hemolytic transfusion reaction


Wrong patient name on order form
Administrative double check (at bedside and in laboratory)
PR - Procedures
Chaotic situation/ stress
Haste/ work overload
Inattention/ sloppiness
ICT devices not functioning
Poor handwriting
1 Blood
Example1a: Wrong blood for this patient
Hemolytic transfusion reaction


Wrong patient name on order form
Administrative double check (at bedside and in laboratory)
PR - Procedures
Chaotic situation/ stress
Sufficient backup
OR - Organisation
Haste/ work overload
Sufficient personnel
OR - Organisation
Inattention/ sloppiness
Social support/ corrective colleagues
CO - Communication
ICT devices not functioning
Maintenance
OR - Organisation
Poor handwriting
Computerized application
OR - Organisation
1 Blood
Example1a: Wrong blood for this patient
Hemolytic transfusion reaction


1 Blood
7: Calculated risk
Anomalies in test results
DF - Defences
Observations by patients, nurses, doctors or non-clinical staff
DF - Defences
Febrile non-hemolytic reaction
Anomalies in test results
DF - Defences
Observations by patients, nurses, doctors or non-clinical staff
DF - Defences
Allergic reactions (including anaphylactic)
Anomalies in test results
DF - Defences
Observations by patients, nurses, doctors or non-clinical staff
DF - Defences
TRALI
Anomalies in test results
DF - Defences
Observations by patients, nurses, doctors or non-clinical staff
DF - Defences
TRALI/ infection/ disease by emerging/ unknown pathogen
Anomalies in test results
DF - Defences
Observations by patients, nurses, doctors or non-clinical staff
DF - Defences
Death

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