
Methodologies underlying patient safety

How can we learn from, and
prevent, medication errors?

Bryony Dean Franklin
Julien Duquesne

Conflict of interest statement

- Nothing to disclose

Questions

- Retrospective and prospective methods can be complementary • Yes / No
- Retrospective analysis of incident report data can be used to obtain information on error rates • Yes / No

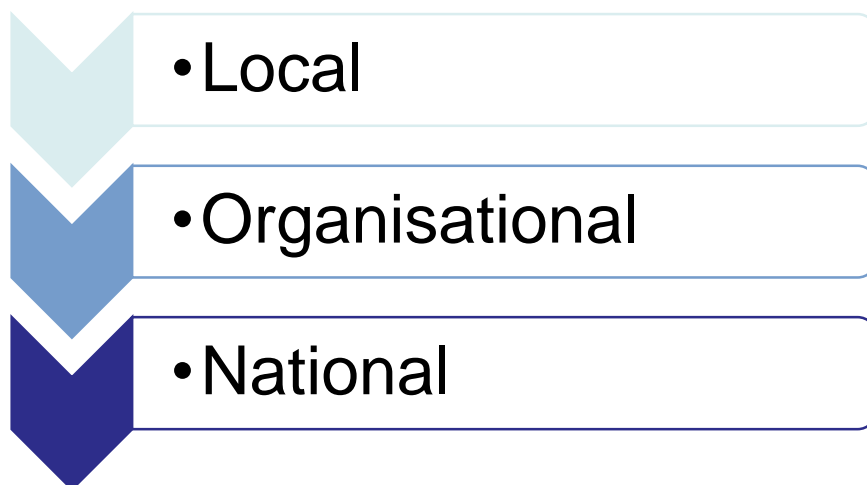
Overview

- Retrospective approaches
 - Studying errors that have *already happened* to find out why, and how they could have been prevented
- Prospective approaches
 - Studying where errors *could* occur in a process
- Bringing the two approaches together

Methodologies underlying patient safety: retrospective approaches

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Incident reporting systems



Incident Reporting Systems

- **Local** - within your pharmacy
 - Record and review incidents and near misses
 - Identify local actions needed
 - Include pharmacy manufacturing, medicines information...
 - Important to facilitate shared learning and “free lessons”
 - Newsletters
 - Team meetings




Incident Reporting Systems

- **Organisational**
 - Within hospital or group of hospitals
 - Eg using incident reporting software
 - Variable quality and quantity of reported data
 - Designated pharmacist or medication safety officer reviews all medicine related incidents
 - Include pharmacists’ interventions to correct errors as ‘near misses’!

Avoid errors in generalisability patients: good generalisability of the findings
 (The proportion of cases in which a patient is included in the analysis of the procedure)

Can you spot the error?



The error:

- The generalisability parameter (Number of patients / Number of cases) is double the measurement error. The measurement error is double the measurement error (Number of cases / Number of patients) and is not well adjusted.
- The measurement of Number of patients (N) is not well adjusted.
- The measurement of Number of cases (N) is not well adjusted.

The solution for generalisability: Number of patients / Number of cases is a good N.

Practising tips:

- Remember to use a common unit of measurement and standard.
- Number of patients is a dependent variable and Number of cases is an independent variable.
- Define the type of error: Number of cases and Number of patients.
- The measurement of N is not well adjusted (N) is not well adjusted. This is not a measurement of Number of cases (N) is not well adjusted.


Number of cases	Number of patients	Number of cases	Number of patients	Number of cases	Number of patients
100	100	100	100	100	100
100	100	100	100	100	100
100	100	100	100	100	100
100	100	100	100	100	100
100	100	100	100	100	100
100	100	100	100	100	100

Remember to use your common sense to check your results when generalising.

Shine

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Shine

Incident Reporting Systems

- **National** – eg National Reporting and Learning System for England and Wales: 11 million reports since 2003. www.nrls.npsa.nhs.uk
 - Data uploaded from individual healthcare organisations
 - Incidents and near misses can also be reported directly – by healthcare professionals and patients
 - Used to create national patient safety alerts and other guidance
- Sweden: National register of medical incidents
- Switzerland: Critical incident reporting system

Investigation

1. Analysis of individual cases locally
 - Various approaches – often all referred to as ‘root cause analysis’
 2. Collective analysis of multiple similar cases
 - Locally, organisationally or nationally
-

1. INVESTIGATION OF INDIVIDUAL CASES

Investigation of individual cases

- Need a **structured** and **systematic** approach
- It sometimes seems straightforward to identify a particular action or omission as the immediate problem
- However, closer analysis usually reveals a more complex picture and a series of events leading to an adverse outcome

Root cause analysis

- Various approaches to asking: What? How? Why?
- Aim to identify the fundamental issues which have led to an incident happening, and which must be addressed
- Aim is not to apply blame, but to learn how to prevent similar incidents happening again
- Usually requires a team approach – multi-professional, with a facilitator to co-ordinate investigation - patient should also be invited

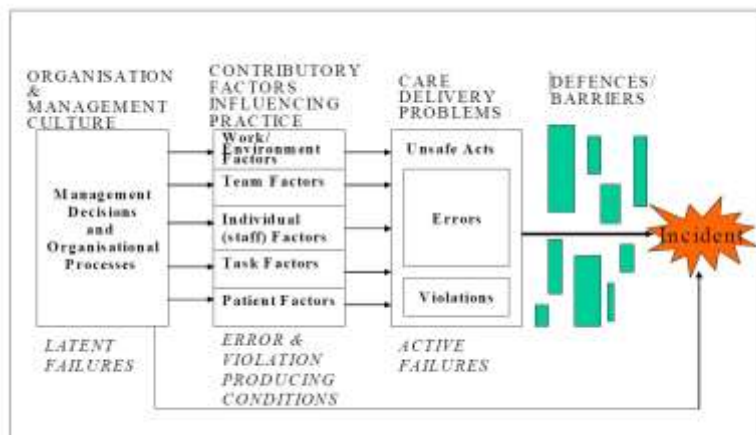
Root cause analysis

- Many methods, often all (rightly or wrongly!) called 'root cause analysis'
 - London Protocol
 - NPSA toolkit
www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/
- Do not assume that 'root cause analysis' means only one (or a small number) of root causes

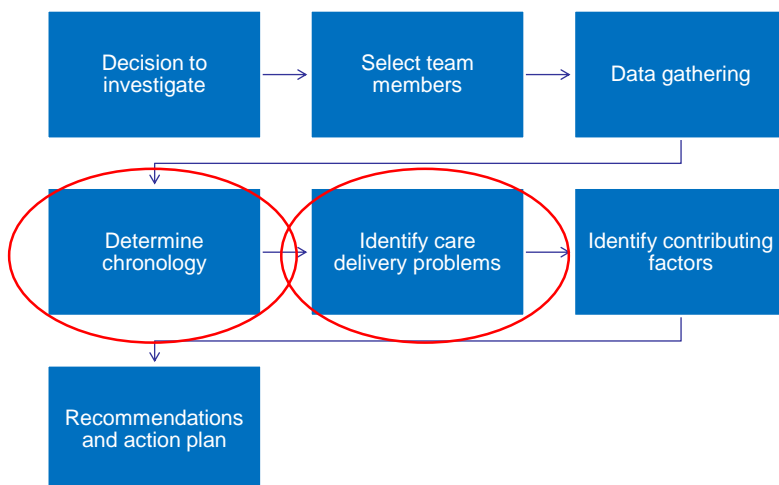
London protocol

- A process of incident analysis and investigation
- Focus on a 'systems analysis' (rather than root cause analysis), and identifying factors which have greatest potential for causing future incidents
- Free to download and available in a number of languages:
http://www1.imperial.ac.uk/cpssq/cpssq_publications/resources_tools/the_london_protocol/
- Suggests focus on 'care delivery problems' as a more neutral term than 'incidents' or 'errors'

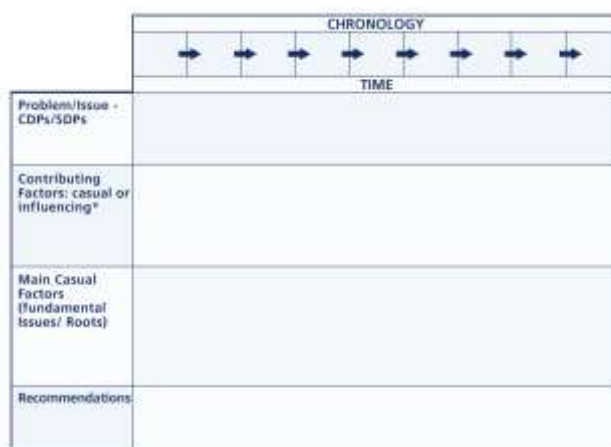
London protocol: organisational accident model (James Reason)



London protocol: flowchart

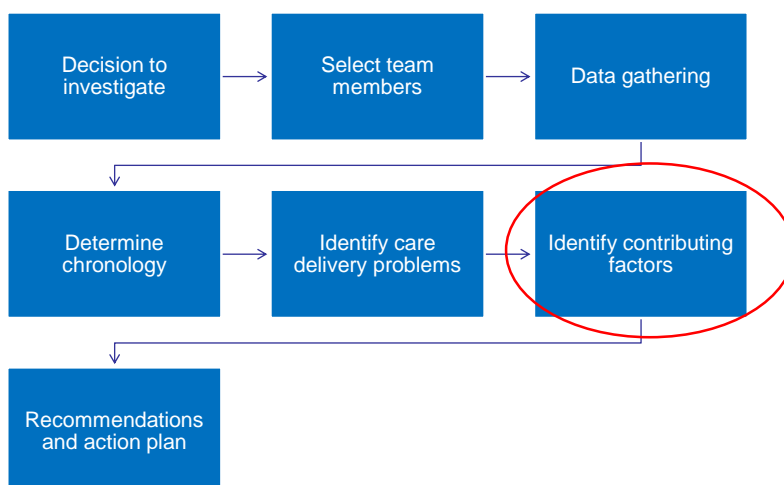


London protocol: chronological mapping

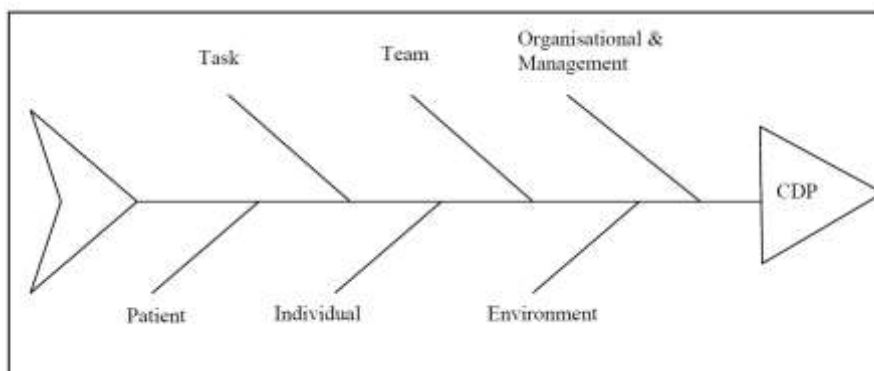


NHS
National Patient Safety Agency

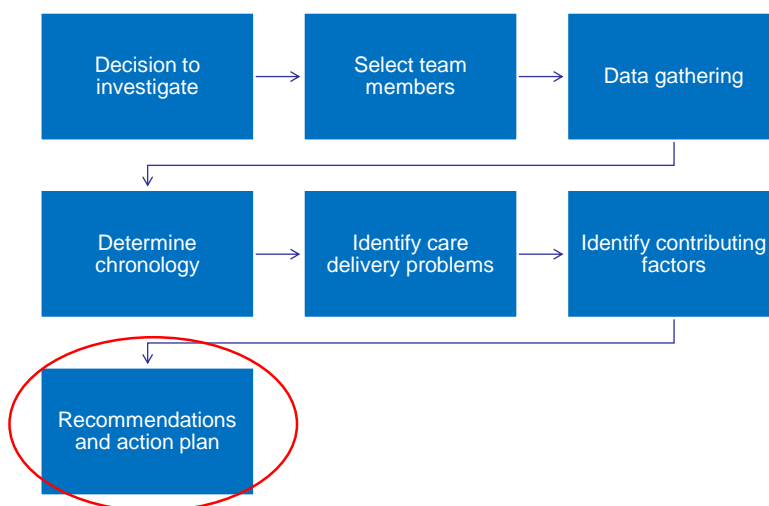
London protocol: flowchart



London protocol: fishbone diagram



London protocol: flowchart



London protocol: action grid

Contributory Factors	Actions to Address Factors	Level of Recommendation (Individual, Team, Directorate, Organisation)	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off

Other tools: “five whys”

Why?

Why?

Why?

Why?

Why?

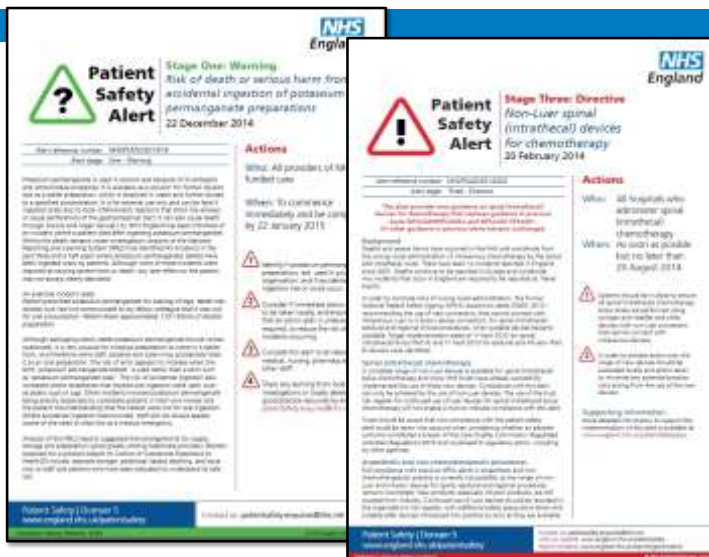


2. COLLECTIVE ANALYSIS OF RELATED CASES

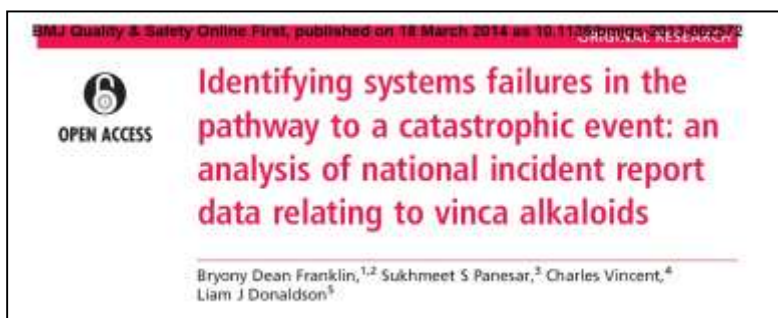
Collective analysis of related cases

- Central alerting system for England
- Stage 1: “Alert: Warning”
 - warns organisations of emerging risks
- Stage 2: “Alert: Resource”
 - provision of resources, tools, learning materials
- Stage 3: “Alert: Directive”
 - organisations required to confirm that specific actions have been implemented

Collective analysis of related cases



Collective analysis of related cases



- Identified 38 incidents involving administration of vinca alkaloids in patients also receiving intrathecal medication
- Analysed according to national protocol

DEFENCES	STAGES INVOLVED
Administration only in designated centres : (1) Designated lead (2) Written local protocol, based on national guidance	All
Only those on local register can prescribe, dispense, issue, check or administer IT chemotherapy: (1) Induction training, annual competency review (2) Training grades cannot prescribe	All
IT chemotherapy on separate prescription with accompanying checklist and audit trail	Prescribing Documentation
IV and IT chemotherapy separated in time : (1) Administered at separate times - IV then IT (2) Signature to confirm all IV chemo for that day given before IT released to the doctor who will administer it	Prescribing Supply, transport and storage Administration Documentation
IV and IT chemotherapy separated in location : (1) Separate storage in pharmacy and ward areas, with IT doses in a dedicated locked fridge (2) Separate transport of IT in distinctive container (3) Administration in separate clinical areas	Dispensing
IV & IT chemotherapy differentiated in appearance : (1) IV vinca alkaloids for adults and adolescents prepared in minibags, not syringes (2) Labelling of medication with route of administration printed in bold "for intrathecal use only" and "for intravenous use only"	Prescribing Dispensing Administration
Under normal circumstances, administered during working hours only . Authorisation and reporting of any exceptions	Administration Documentation
Administration checks : (1) Documented patient review prior to IT administration (2) Documented second check by separate member of staff on local register, using formal checking procedure (3) Involve patient in checks if he/she chooses to do so	

Which was the main defence breached in each case? (n=35)

Documentation - 1 case

Separated in **time** - 15 cases

Separated in **location** - 7 cases

Different **appearance** - 6 cases

Other - 6 cases

Barriers to incident reporting

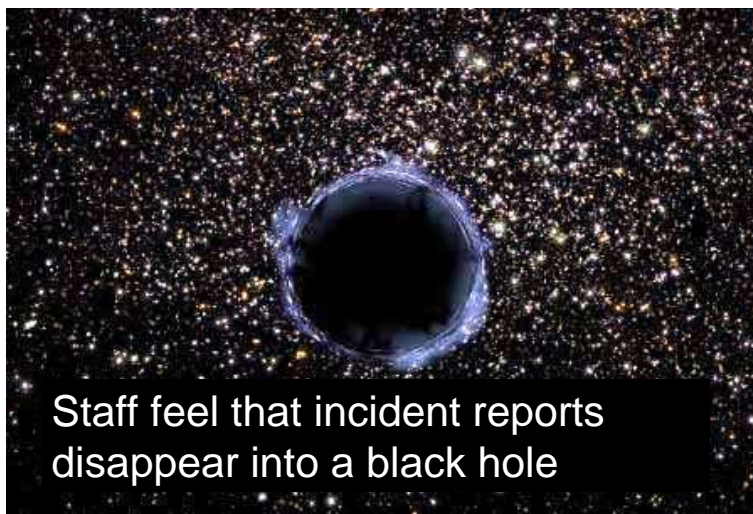
- Spontaneous reporting misses about 99% of medication errors
- Discuss with the person next to you
 - What are the main barriers?
 - And how could they be overcome?



Reasons for under-reporting

- Not being aware that an error has occurred
- Not knowing how to report it
- Actual and/or perceived lack of time to report
- Fear of blame

Reasons for under-reporting



Staff feel that incident reports disappear into a black hole

Solutions

- Feedback to staff
 - Response to individual incidents reported / actions taken
 - Collective feedback on themes and actions
 - A constructive approach / fair blame
 - Reward high reporting rates (rather than low reporting rates!)
- Note that incident report data cannot be used for **quantitative** data on error rates

WHO guidelines

- WHO Draft Guidelines for Adverse Event Reporting and Learning Systems:
 - www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf
- Includes guidance on potentially controversial issues:
 - Voluntary versus mandatory
 - Anonymous versus confidential
 - Resource allocation



PROSPECTIVE APPROACHES: BASICS AND PROSPECTS

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PROSPECTIVE APPROACHES

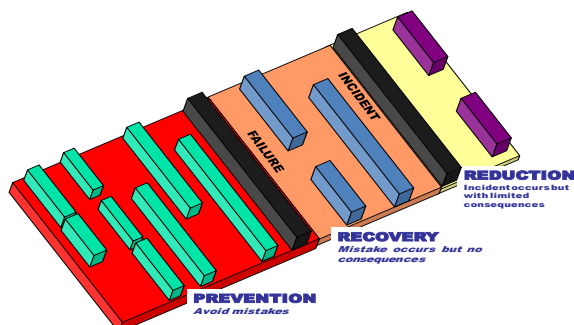
1. Why and when?
2. Basics
3. Which method to use?
4. Prospects



1. WHY AND WHEN?

WHY?

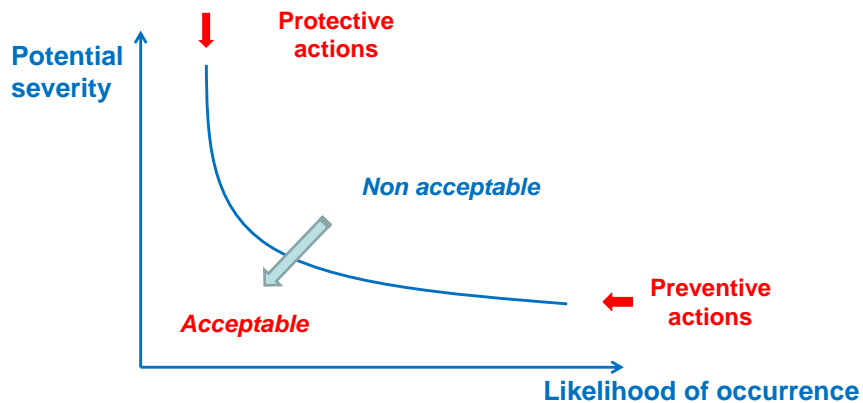
- Avoid an incident occurring
- Make a relevant risk reduction plan based on a reliable risk map



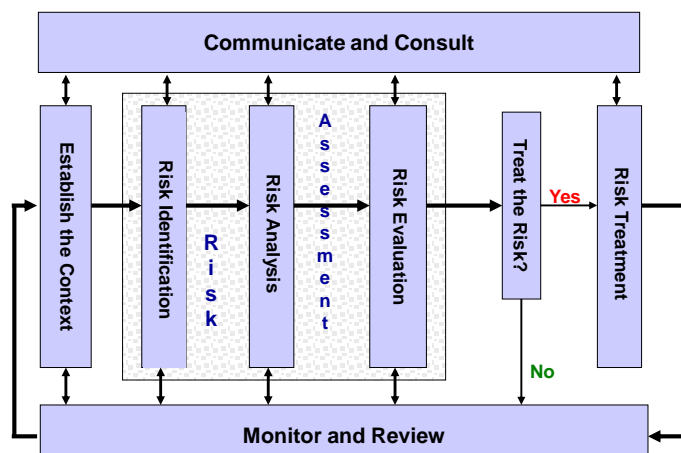
WHY?

Risk 0 doesn't exist

Make an acceptable level of risk



WHEN?



WHEN?

- Status of the current situation
- Significant operational changes
- Introduction of a new activity

WHEN?

Dynamic with time

- ✓ Assess risk reduction effect
- ✓ Identify new risks





2. BASICS

Participants

- Multidisciplinary team:
 - ✓ Healthcare professionals of the department
 - ✓ Environmental experts
 - ✓ Experts in risk management



Level of analysis

- Scope and size according to the objective



EARTH



CONGRESS IN HAMBURG

Evaluation of potential hazard

Criticality:

- Occurrence : are all the incidents reported?
- Severity : patient and process
- Detectability : linked to individual expertise?



Gross risk

Evaluation of potential hazard

- Level of control
 - Expertise: procedures, instructions
 - Knowledge and skills of staff
 - Compliance with rules
 - The management of an incident
 - The organization: existing structures
 - Relevance
 - The reliability of realization
 - Supervision
 - traceability



Net risk

Scoring system

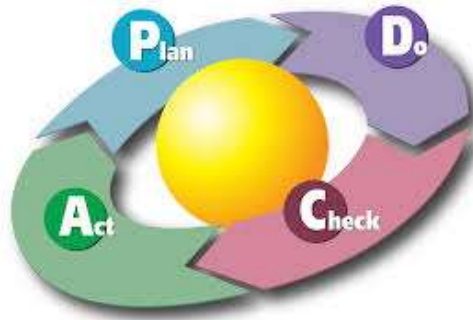
Scales scoring

Limits requiring different actions

Criticality	Rank risks	Decisions and corrective actions
C1	Acceptable	No action is required
C2	Tolerable under control	A follow-up in terms of risk management needs to be organized
C3	Unacceptable	The situation should be refused. Risk reduction measures must be in place or activity should be refused.

Ranking

Action plan according to the criticality score



3. WHICH METHOD TO USE?

Which method to use?

Many methods validated:

- HACCP (Hazard Analysis Critical Control Points) : chemotherapy compounding unit
- FMECA (Failure Modes, Effects And Criticality Analysis): surgery, emergency department, medical equipments or drug management process (prescription, pharmacist validation, delivery).

Which method to use?

Selection criteria:

- Scope
- Risk factors considered (technologic or organisationnels or human)
- Problem characteristics (+/-completeness)



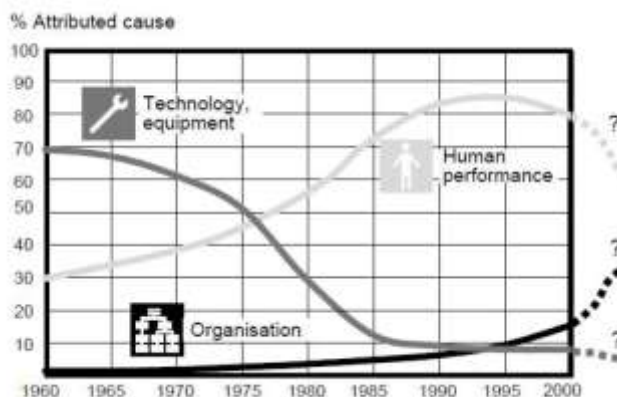
Which method to use?

Selection criteria:



- Adjustment method (static, dynamic)
- Use (punctual, regular)
- Necessary skills of participants
- Time, human and economic resources available

Limitations



Limitations

- Valid for technical failures
 - Low capacity to take into account the human factors
- Current hospital systems increasingly dynamic and complex
- Do not easily consider the evolution of the system over time, or external influences that may have an impact



4. PROSPECTS

New methods

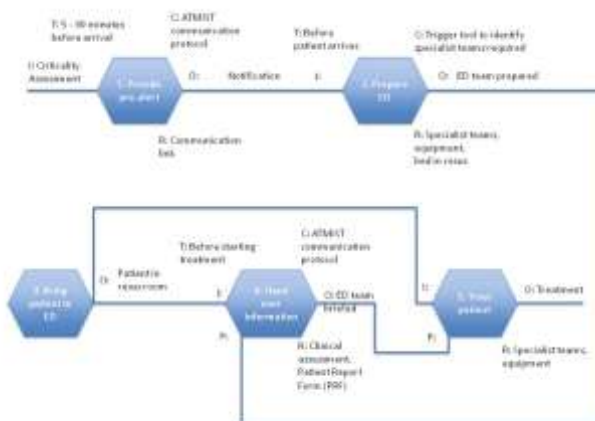
- FRAM (functional resonance analysis method)

Human factors at the individual level (training, aptitude)

Dynamic evolution of the system (modeling activity)

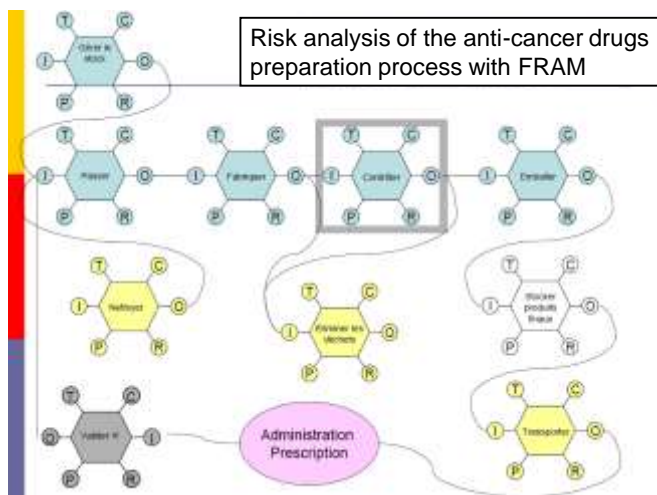
It combines the quantitative and qualitative aspects with respect to potential risks

New methods



FRAM representation in Emergency Department

New methods



New methods

- Individual level
 - Level of training
 - aptitude
 - knowledge of the software
- Activity in the departement
 - Number of prescriptions
 - Number of single/complex preparations
 - Complexity preparations:
 - Time required: number of bottle volume ...
 - Technical difficulty: foam, viscosity ...
- Proactive risk assessment
- Undergoing validation in compliance with the incidents measured


New approaches

The tracer patient:

Purpose :

- Evaluate care management of a patient through his course of care
- Risk Assessment : [Process and Organizations](#)

In addition to process audits or needs to achieve

 Not to assess the relevance of diagnostic or therapeutic strategies.

Healthcare simulation

- Create real scenario care without risk to patients
- Highlight new, possibly, unidentified risks resulting from the actual applications procedures, dysfunctions related to teamwork ...

Healthcare simulation

- Technical procedures
- Non technical acts
 - Teamwork
 - Organizational & human factors
- Common situations
- Rare situations but potentially hazardous

Healthcare simulation

Technical procedures



Teamwork



Summary

Proactive approach less intuitive than the analysis of incidents

Method extremely demanding on time and human resources

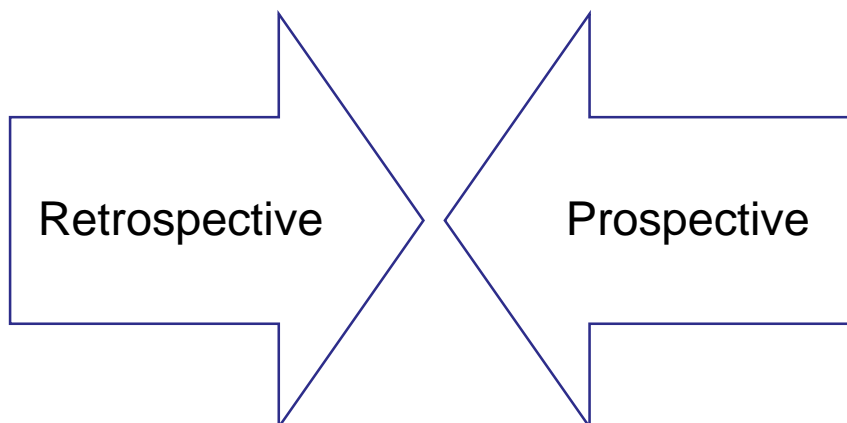
With multidisciplinary teams including process experts and experts in risk management

Mainly occasional use: measuring impact?

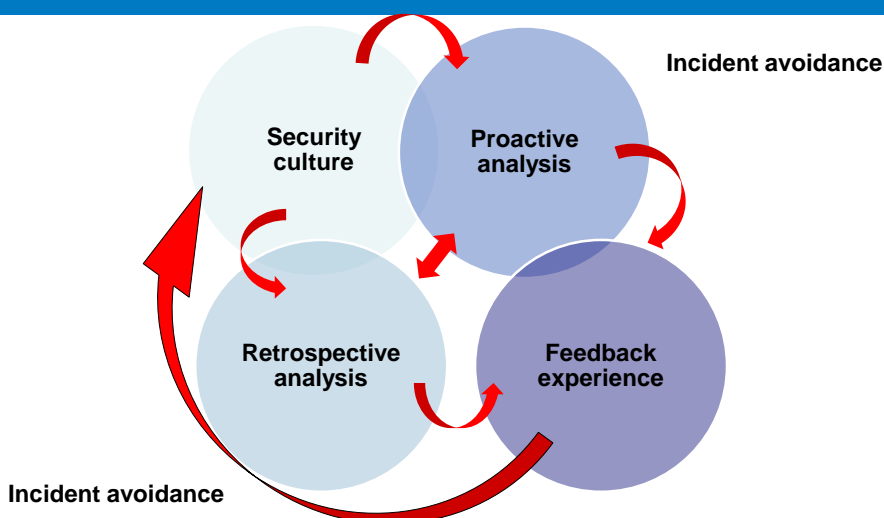
Learn from the literature but necessary adaptation

Mix methodological approaches and applications/simulation

Bringing the two approaches together



Bringing the two approaches together



Discussion

- Advantages and disadvantages of each approach
- Similarities and differences
- How they can be used together
 - Used in parallel
 - Used together eg use of retrospective data to populate prospective methods such as FMEA

Questions

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