



Anticoagulation therapy : improving processes using risk management tools

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Risk management tools and anticoagulation therapy

- The applicable processes
- Focus on Failure Mode Effects Analysis
- Key risks and findings in Anticoagulation therapy
- Using analytical tools for improvement



High Risk Drugs



High Risk Drugs

- Drugs that pose the most risk to the organization in terms of harm
- Represent the drugs with “low therapeutic index”—small changes in dose can have severe consequences



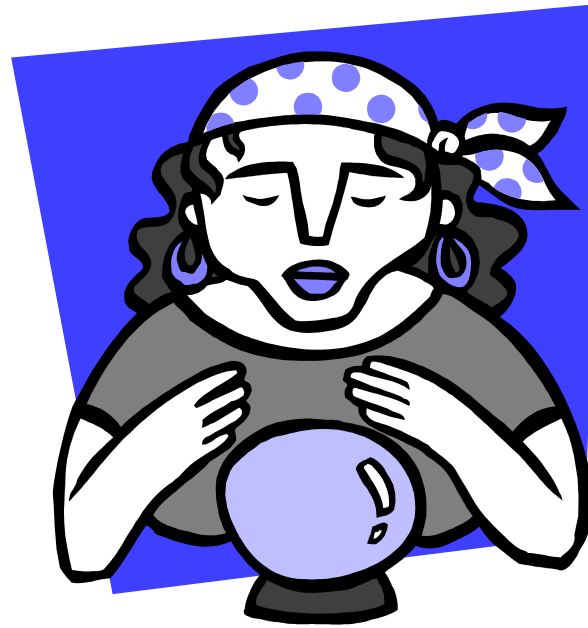
NPSA Patient Safety Observatory report 4

Medicines most frequently associated with severe harm were:

- Anticoagulants
- Antibiotics (allergy related)
- Injectable sedatives
- Chemotherapy
- Opiates
- Antipsychotics
- Insulin
- Infusion fluid



Using Analytical tools : prospective



Understanding why things go wrong

- Learning from experience
- Systems thinking
- Prospective and retrospective techniques
- Human reliability analysis : human factors
 - Assessing reliability through an understanding of human behaviours in the context of their environments

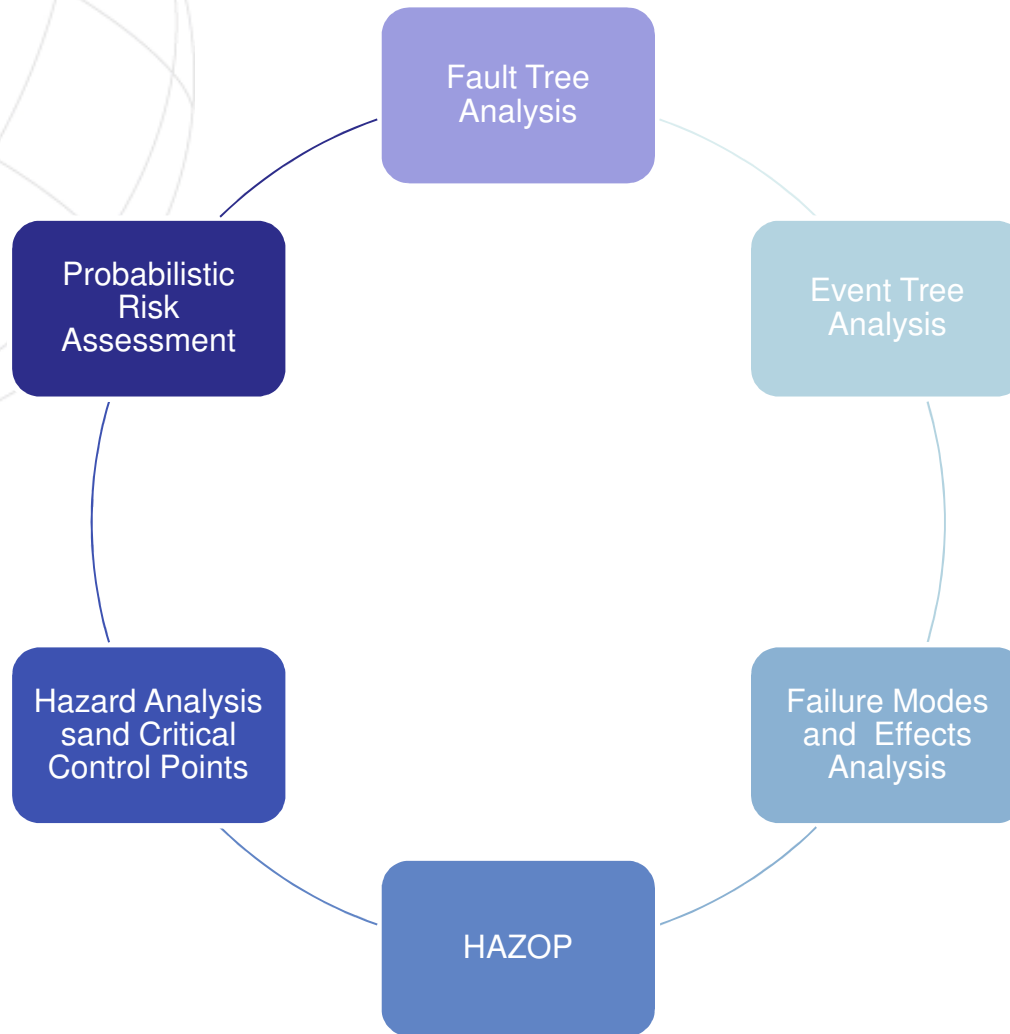


Human Reliability Analysis

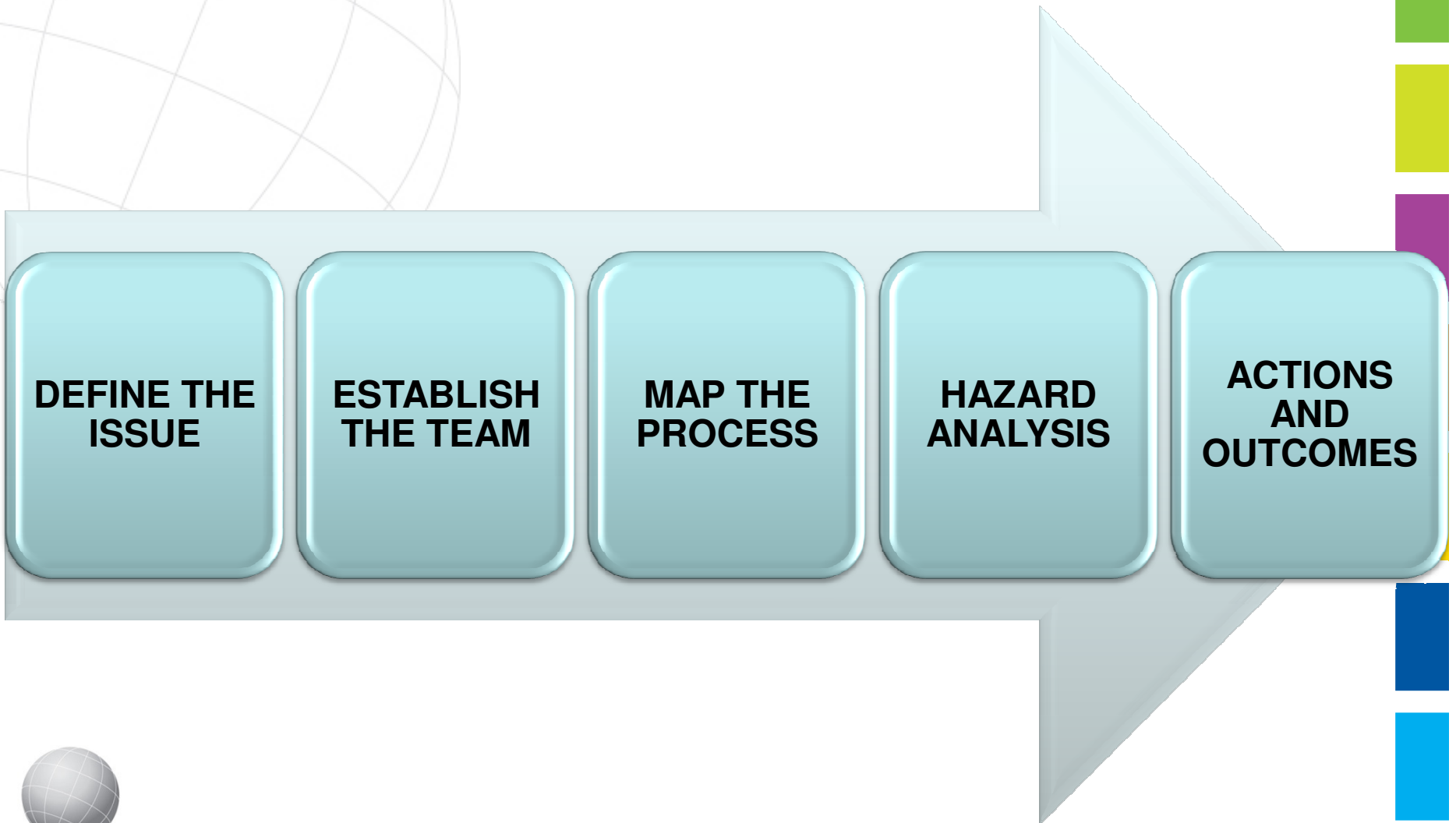
- Prospective approach
- Error probability – understanding likelihood
- Takes process of care, rather than single case or incident
- Developed in industries where you need to know *in advance* of operations eg nuclear.



Human Reliability Analysis



The FMEA process



FMEA process in a nutshell!



Each step – what could go wrong – failure mode – why could it go wrong – what could happen.

- Identify possible causes for each failure mode
- Identify possible effects
- Scoring of risk of each failure: product of 3 measures – occurrence / severity and detectability – Risk Priority Number
- Identifying highest scoring failures to prioritise for action



Choosing the team

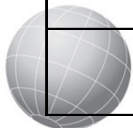
- Individuals closest to the event or issues involved
- Individuals critical to implementation of potential changes
- Leader with a broad knowledge base, who is respected and credible
- Someone with decision making authority
- Individuals with diverse knowledge bases
- Process experts to encourage development of functional processes



Examples in practice



Steps	Failure Mode	Failure causes	Failure Effects	Likelihood of Occurrence	Likelihood of Detection	Severity	Risk Priority	Actions to reduce occurrence of failure
1	Is Anticoagulation indicated?							
1A	Is diagnosis correct?	Diagnosis tests not performed	Anticoagulant administered when not indicated	1	5	4	20	All caregivers double check diagnosis
			No treatment given when indicated	1	1	8	8	
			Failure of test to diagnose	2	9	8	144	Use 2 tests to diagnosis when possible. Repeat inconclusive tests
		Doesn't meet standards of practice Clinicians unaware of standards	Inappropriate prescribing of anticoagulants	2	1	7	14	Pharmacists check indication Educate prescribers Establish treatment guidelines
1B	Are there contraindications of disease interactions?	No or incomplete patient information Not evaluated Diagnosis inconclusive Didn't know patient had a given contraindication (or epidural) Interpretation biases	Bleeding Death Thrombosis	2	2	10	40	Pharmacists double check Establish treatment guidelines that include information on contraindications.
1C	Are there drug or food interactions? Can they be managed?	Incomplete medication history No computer alerts Skipped alert Incomplete alert Herbal / supplement interactions Interactions not considered Didn't check	Bleeding Death Thrombosis	7	2	1	14	Use pharmacy computer system that screens for drug interactions take a complete medication history including herbal/supplement information
			Severity can range from 1 - 10	7	2	10	140	



Steps	Failure Mode	Failure causes	Failure Effects	Likelihood of Occurrence	Likelihood of Detection	Severity	Risk Priority	Actions to reduce occurrence of failure
2	Initiate therapy: Write order							
2A	Initiate policy, pre-printed orders or protocol if exists	Don't exist Not followed Outdated, inaccurate Providers use differently Unclear when to use Pre-printed order wrong Haven't standardised	Wrong drug Wrong dose	7	8	4	224	Establish guidelines. Use inpatient warfarin protocols Do not use sliding scale warfarin schemes
			Cause bleed	4	1	4	16	Use protocols
2B	Select drug	Not formulary Not available Wrong drug for this patient Drug specific contraindication exists	Increase bleeding risk	1	3	9	27	Check for allergies Diagnose heparin induced thrombocytopenia appropriately
2C	Select dose	Wrong dose Wrong route Age, size, renal function not considered Mixed up drug or strength Order of magnitude error in writing dose	Increase bleeding risk				0	Pick one drug for formulary for LMWH Pharmacist picks dose
			Dose too high: develop bleed	7	1	4	28	
			Dose too low: develop thrombosis	1	3	10	30	
2D	Write order	Illegible Inappropriate abbreviations Order unclear Key elements of order omitted Left out sections of pre-printed orders Transcription errors No read back on verbal Orders	Wrong dose or drug administered. Bleeding	7	1	6	42	Avoid verbal orders. If do need to use, use read back procedure. Follow do not use abbreviations use pre-printed order forms.



Going through the process

Steps in process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence	Likelihood of Detection	Severity	Risk Priority Number	Actions to reduce occurrence



Lessons from other settings

- Must have backing and involvement of senior management
- Is there anyone who understands the whole process?
- Improvements often about simplification and standardisation



Why use FMEA?

- Proactively prevents harm
- Analyses system for vulnerabilities
- Identifies ways to help prevent harm
- IHI methodology and templates exist
- Has been shown to reduce variances and number of serious harm incidents
- Helpful in complex processes
- Substantial investment of time and resource – high priority issues only therefore
- Butconsider retrospective analysis



Retrospective analysis





A Root Cause Mentality

An insatiable desire to understand why things go wrong, why people do what they do, and how things got into their present state.

A realistic awareness of WHY things go wrong – not just the physical reasons, but the human, latent, and root reasons also.

A Reluctance to Blame – A Desire to Understand

Robert Nelms





RCA approach: deconstructing “failure cause”

Key problems

Acts or omissions in care which led to the events (= failure mode)

Examples:

- Patient received wrong medication
- Conveying the wrong information
- Not following policy/protocol
- Working beyond competence



RCA approach: for each key problem - contributory factors



Case study

- Elderly gentleman admitted 22.10.08 - breathing difficulties
- COPD; epilepsy; type II diabetes ; renal and heart failure
- Previous DVT – on warfarin long term
- Injectable heparin prescribed on admissions instead
- No note of change of anticoagulation regime in notes
- Warfarin not included on discharge summary sent to GP 25.10.08
- 8.12.08 patient had breathing difficulties. Ambulance called
Could not be resuscitated
- PM showed cause of death 1) pulmonary embolism 2) DVT limb



Factors contributing to failure / problem

Problems/ Issues	Contributory Factors								
	(CDP / SDP)*	Patient	Task	Individual Staff	Team and Social	Education and training	Equipment / Resources	Communication	Working Condition
FAILURE TO REPREScribe WARFARIN		NO COMPUTER ALERT	LACK OF KNOWLEDGE	TOO MANY STAFF INVOLVED – NOONE TAKING RESPONSIBILIY	LACK OF TRAINING		INADEQUATE HANDOVER	STAFF SHORTAGES	CLINICAL GOVERNANCE STRUCTURES UNCLEAR

Improvement actions: strengthening controls

- Prospective and reactive barrier analysis
- Failsafe analysis
 - what has failed in the past
 - is it easy to follow guidelines?
 - do the guidelines always apply – are they out of hours proof?
 - will the right people get the right training?
 - will people be able to point up problems or potential problems?





Retrospective analysis or prospective?

Experience is a comb which nature gives us
when we are bald

