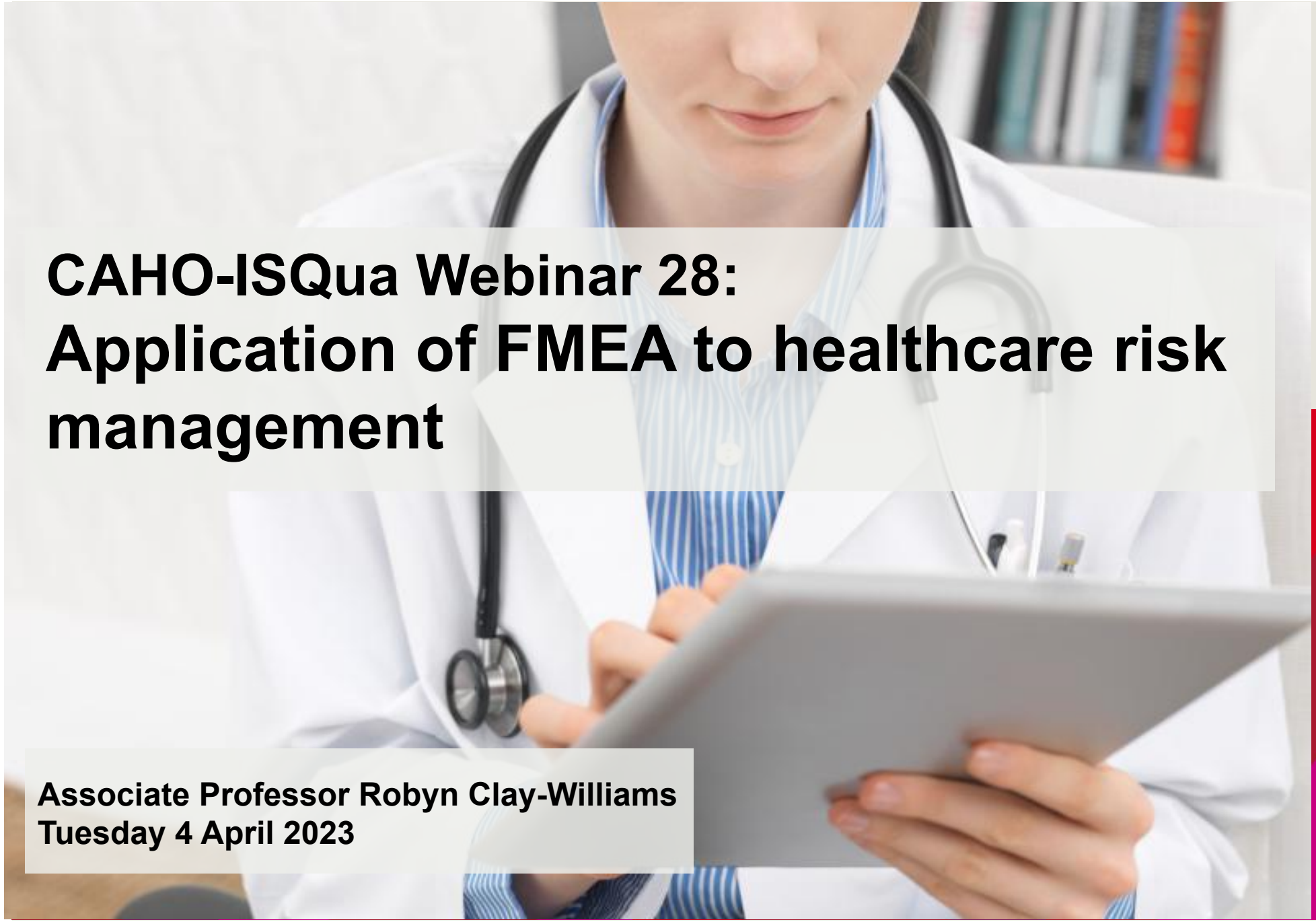


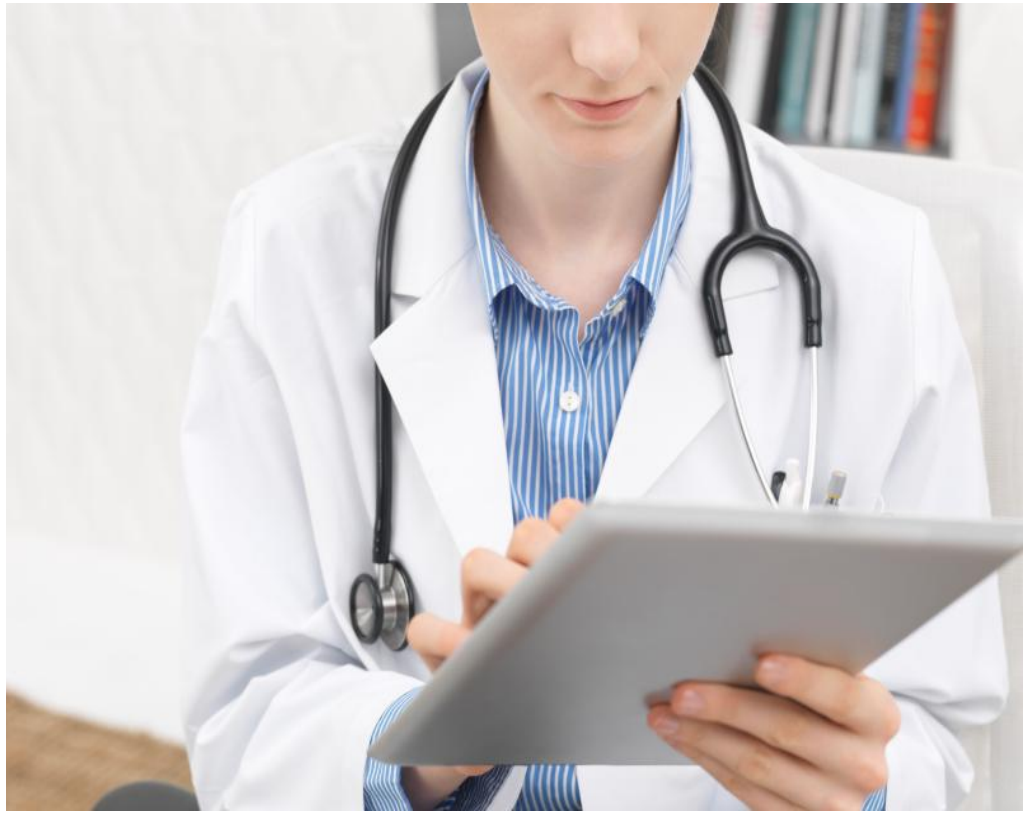
CAHO-ISQua Webinar 28: Application of FMEA to healthcare risk management

Associate Professor Robyn Clay-Williams
Tuesday 4 April 2023

Failure Mode and Effects Analysis (FMEA)

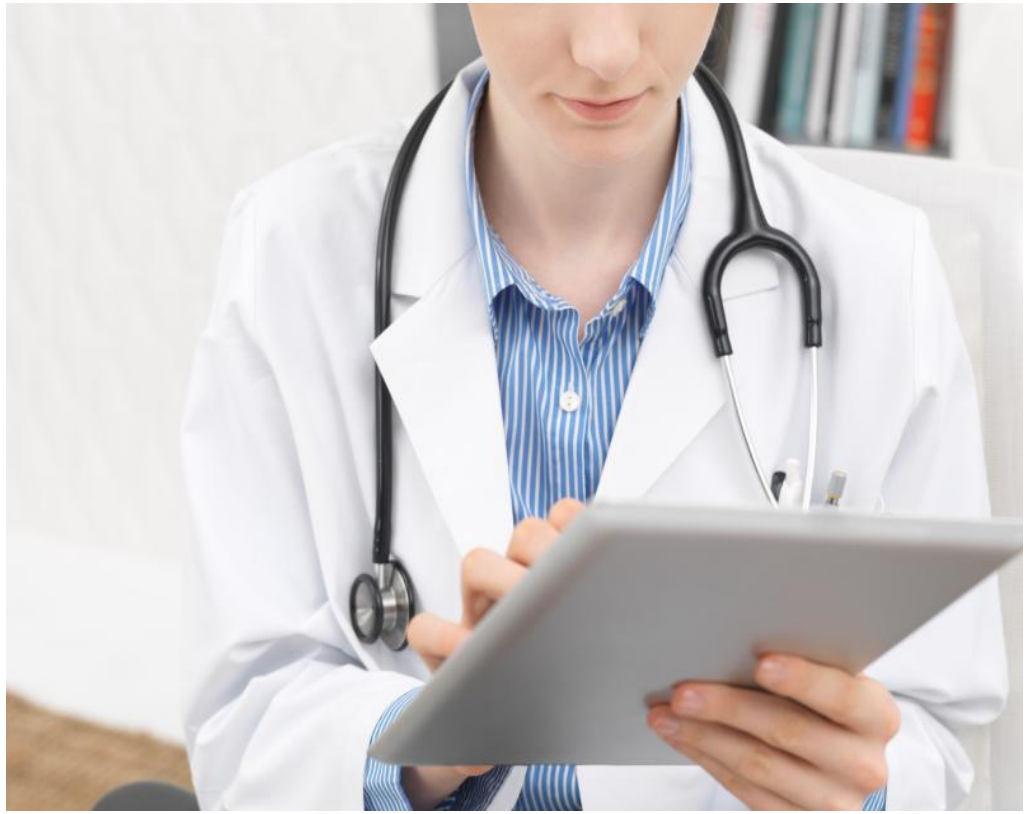
What is it?

- A method for ranking and managing risk
  - Identify risk
  - Analyse risk
  - Control risk
- Can be quantitative or qualitative



Failure Mode and Effects Analysis (FMEA)

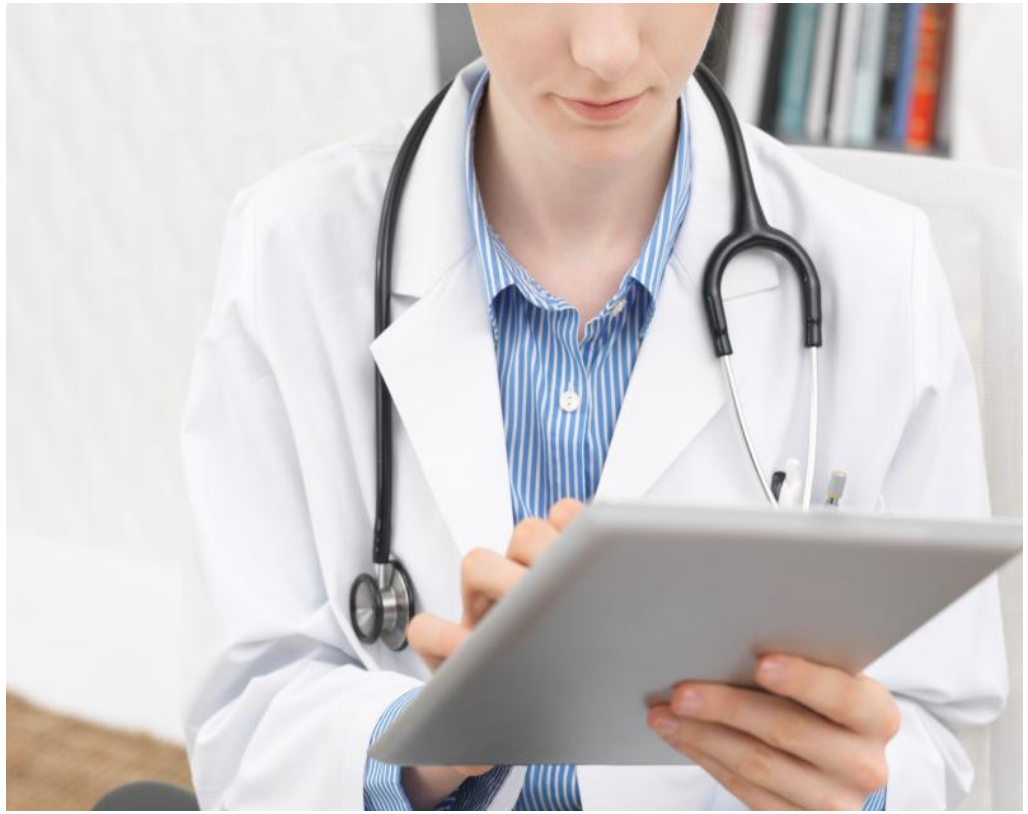
- **Failure modes** (What could go wrong?)
- **Failure causes** (Why would the failure happen?)
- **Failure effects** (What would be the consequences of each failure?)



Failure Mode and Effects Analysis (FMEA)

When might you use it?

- Analysing failures
  - what has a high impact or happens often?
- Process improvement
  - introducing or amending a work practice
- Workplace redesign
  - new location, new equipment, staffing changes



Basic risk management model

Impact	Probability: Low	Probability: Medium	Probability: High
Significant	Substantial management required	Must manage and monitor risks	Extensive management crucial
Moderate	May accept risks but monitor them	Management effort worthwhile	Management effort required
Limited/Minor	Accept risks	Accept but monitor risks	Manage and monitor risks

Failure Mode and Effects Analysis (FMEA)

FMEA tools - healthcare

https://www.patientsafety.va.gov/professionals/ontheob/HFMEA.asp

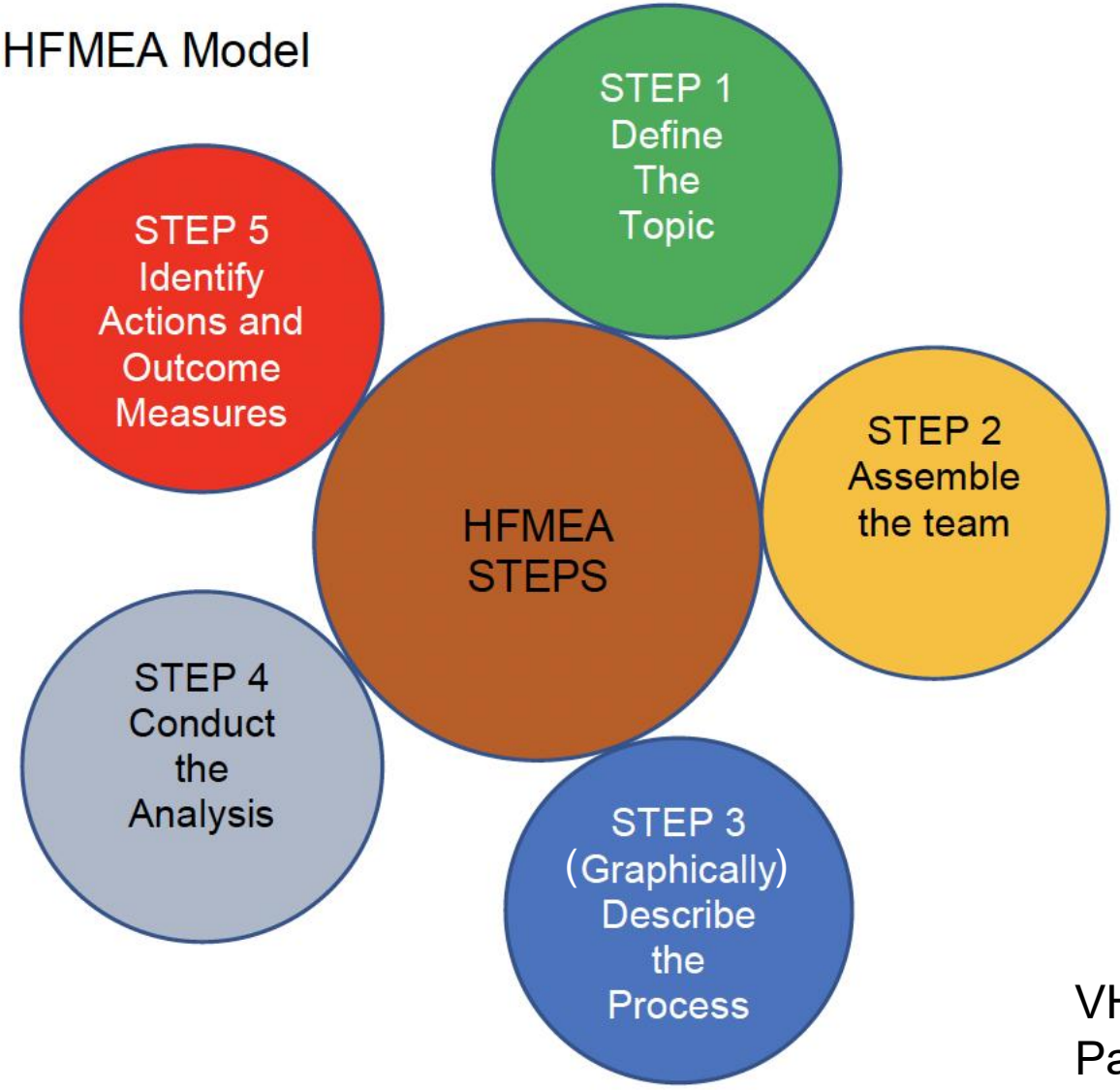
https://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx

FMEA tools - healthcare

https://www.patientsafety.va.gov/professionals/onthejob/HFMEA.asp

https://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx

HFMEA Model



VHA National Center for
Patient Safety ncps@va.gov

Step 1. Define the topic

- Must be able to define the system, process or problem
- Must not be overly complex or have too many subprocesses
  - If large or complex, pick the most critical subprocess:

e.g. instead of ‘medication management’, pick ‘medication ordering’, ‘dispensing’ or ‘administration processes’

Step 2. Assemble the team

- A safety, quality or risk management expert to lead
- Multidisciplinary team
- Subject Matter Experts (SMEs)
- Include everyone who is involved in the process
  - Core members will be part of the analysis and outcomes group
  - Ancillary members may only need to participate in ‘Step 3. Describing the process’

Step 3. (Graphically) describe the process

- Break the process or problem into specific steps, and number each step

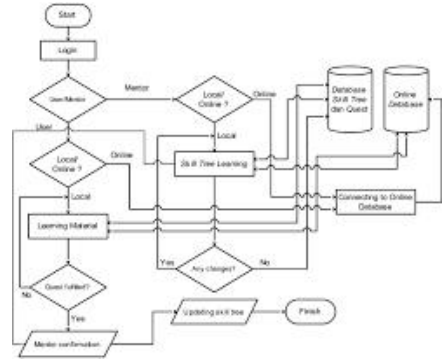
- Using a process mapping method your team is familiar with can help:

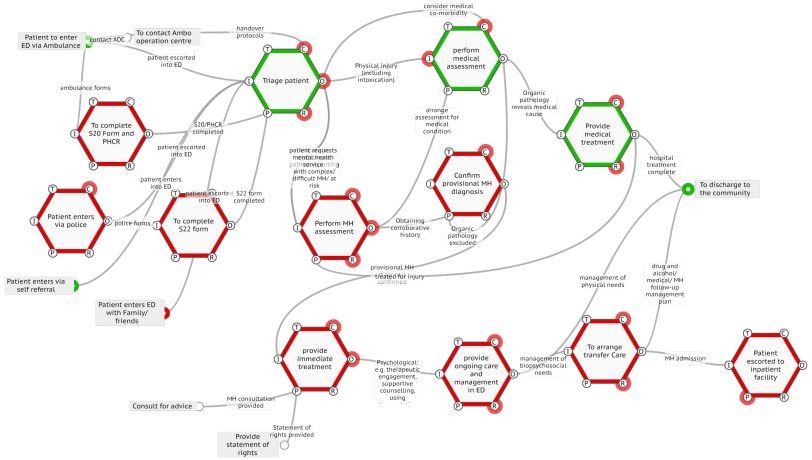
e.g. flowcharts, fishbone diagrams, swim lanes, Functional Resonance Analysis Method (FRAM), etc

- Map how the process is routinely done (Work-as-Done)

e.g. if working with an incident, describe the process as it should happen

- At the end of this step, you will have a numbered list of processes





Step 3. (Graphically) describe the process

- Working down the numbered list of processes, list all possible ‘failure modes’

e.g. anything that could go wrong, including minor or rare problems

- For each failure mode listed, identify all possible causes

e.g. why would the failure happen?

- Using an incident analysis method your team is familiar with can help:

e.g. Root Cause Analysis, fishbone diagrams, ACCIMAP, fault trees, etc

- For each failure mode listed, identify the failure effects

e.g. what would be the consequences of the failure?

Process	Failure	Cause	Effect
Step 1.	1.		
Step 1.	2.		
Step 1.	3.		
Step 1.	4.		
Step 1.	5.		
Step 2.	1.		
Step 2.	2.		
Step 2.	3.		
etc			

Step 4. Conduct the analysis

Step 4a. For each failure mode, estimate the likelihood of occurrence:

- How likely is it that this failure mode will occur?

Sometimes you will have data, but usually it is an estimate by your assembled experts (consensus is key!)

Assign a score between 1 and 10, with 1 meaning “very unlikely to occur” and 10 meaning “very likely to occur.”

Process	Failure	Cause	Effect	Likelihood of occurrence (1-10)	Likelihood of detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Actions to reduce occurrence
Step 1.	1.							
Step 1.	2.							
Step 2.	1.							

Step 4. Conduct the analysis

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Step 4b. For each failure mode, estimate the likelihood of detection:

- If this failure mode occurs, how likely is it that this failure will be detected?
- Assign a score between 1 and 10, with 1 meaning “very likely to be detected” and 10 meaning “very unlikely to be detected.”

Process	Failure	Cause	Effect	Likelihood of occurrence (1-10)	Likelihood of detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Actions to reduce occurrence
Step 1.	1.							
Step 1.	2.							
Step 2.	1.							

Step 4. Conduct the analysis

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Step 4c. For each failure mode, estimate the severity:

- If this failure mode occurs, how likely is it that harm will occur?
- Assign a score between 1 and 10, with 1 meaning “very unlikely harm will occur” and 10 meaning “very likely that sever harm will occur.”

e.g. for patient care, a score of 10 might mean the patient died

Process	Failure	Cause	Effect	Likelihood of occurrence (1-10)	Likelihood of detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Actions to reduce occurrence
Step 1.	1.							
Step 1.	2.							
Step 2.	1.							

Step 4. Conduct the analysis

Step 4d. Multiply the three scores to determine the Risk Priority Number (RPN):

- **RPN = O * D * S; Range: 0-1000**

Identify the top 10 RPNs:

- These should be considered first for improvement opportunities

To compare processes, a total RPN for each process can be obtained by adding all the RPNs for each failure mode together

Process	Failure	Cause	Effect	Likelihood of occurrence (1-10)	Likelihood of detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Actions to reduce occurrence
Step 1.	1.			8	5	8	320	
Step 1.	2.			8	10	8	640	
Step 2.	1.							

Step 5. Identify actions and outcome measures

Step 5a: Identify the type of action to take:

- Eliminate - prevent all future occurrences by removing the failure point.
- Control - minimize all future occurrences by implementing mitigating factors.
- Accept - acknowledge and accept known risks.
- If a failure is unlikely to be detected, consider putting Monitoring measures in place

Step 5b: Measure whether the action implemented was effective and if any unintended consequences occurred.

Process	Failure	Cause	Effect	Likelihood of occurrence (1-10)	Likelihood of detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Actions to reduce occurrence
Step 1.	1.							
Step 1.	2.							
Step 2.	1.							

Failure Mode and Effects Analysis (FMEA)

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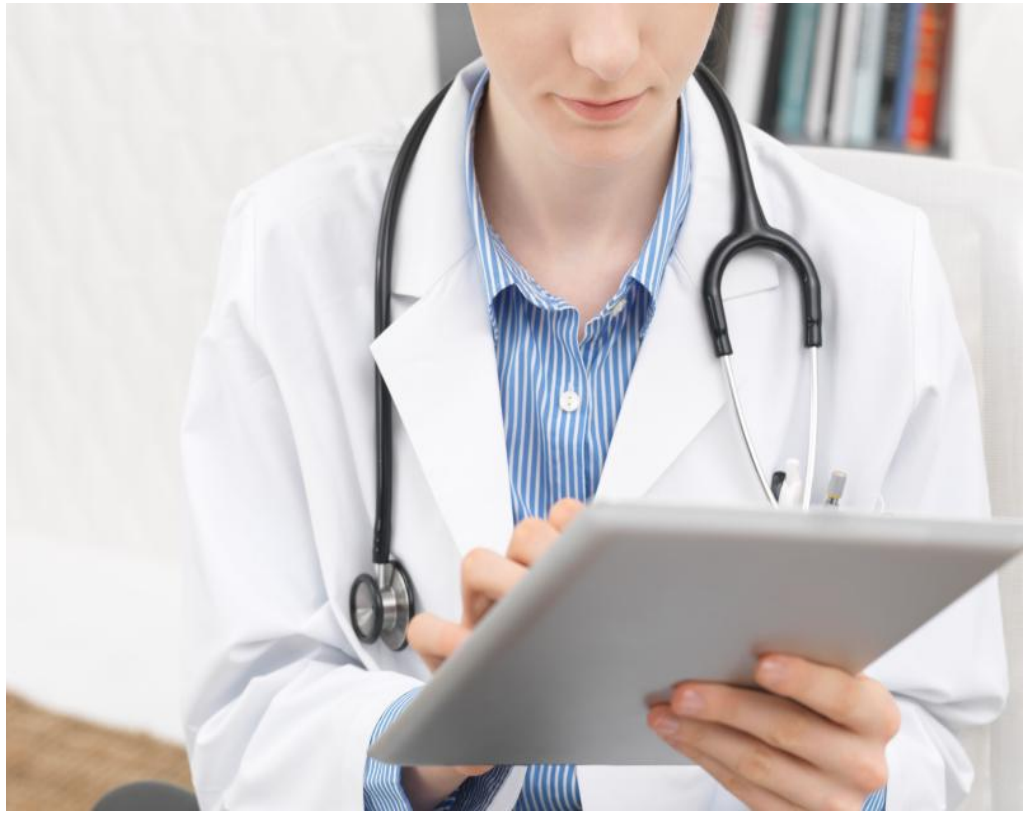
So, how does this work in practice?



Time taken

ID	Health care process	Health care setting	Facilitator[a]	Team size[b]	Number of meetings	Number of person-hours[c]	Number of failure modes	Number of actions
	MAASTRO clinic							
1	Documentation of treatment	Radiotherapy	PR	5	4	30.0	32	17
2	Electronic Portal Imaging	Radiotherapy	MH	8	6	72.0	109	33
3	Treatment on linear accelerator	Radiotherapy	JR	5	8	60.0	70	30
4	Release of accelerator after maintenance	Radiotherapy	PR	4	5	30.0	50	22
	UMC Utrecht							
5	Communication of unexpected findings	Radiology Cardiology	MH	7	5	52.5	19	7
6	Diet food process	Children's Hospital	MH	13	7	136.5	39	18
7	Physically restraining patients	Neurosurgery	MH	7	7	73.5	31	17
8	Ordering repeat prescriptions	Primary care	DZ	8	8	96.0	50	12
9	Patients with hip fractures	Emergency Room Radiology Ward Operating Room	MH	8	6	72.0	120	7
10	Medication administration (pumps)	Intensive Care Unit	MH	6	6	54.0	46	22
11	Admission of cardiac patients	Emergency Room Cardiac Cath Room Coronary Care Unit	CP	6	6	54.0	44	6
12	Use of a PICC line (catheter)	Neonatal Intensive Care Unit	MH	8	8	96.0	37	8
13	Administration of blood products	Laboratory Haematology ward	MH	8	6	72.0	27	11
			Mean	7.2	6.3	69.1	51.8	16.2
			SD	2.2	1.3	28.7	30.6	8.8

[a]M.H. and J.R. Eindhoven University of Technology; P.R. MAAS[illegible]

Habraken MM, Van der Schaaf TW, Leistikow IP, Reijnders-Thijssen PM. Prospective risk analysis of health care processes: a systematic evaluation of the use of HFMEA in Dutch health care. Ergonomics. 2009;52(7):809-19

Case 1. Radiation treatment

Veronese *et al. Radiation Oncology* (2015) 10:132
DOI 10.1186/s13014-015-0438-0

RADIATION ONCOLOGY

RESEARCH Open Access

Multi-institutional application of Failure Mode and Effects Analysis (FMEA) to CyberKnife Stereotactic Body Radiation Therapy (SBRT)

Ivan Veronese[1*], Elena De Martin[2], Anna Stefania Martinotti[3], Maria Luisa Fumagalli[2], Cristina Vite[3,7], Irene Redaelli[3], Tiziana Malatesta[4], Pietro Mancosu[5], Giancarlo Beltramo[3], Laura Fariselli[6] and Marie Claire Cantone[1]

Main processes

a) treatment planning following target delineation;

b) treatment delivery to liver tumours by using fiducial markers coupled with SRTS; and

c) treatment delivery to spine lesions (the analysis of this stage was carried out considering the process implemented at the Carlo Besta Neurological Institute Foundation).

Main processes

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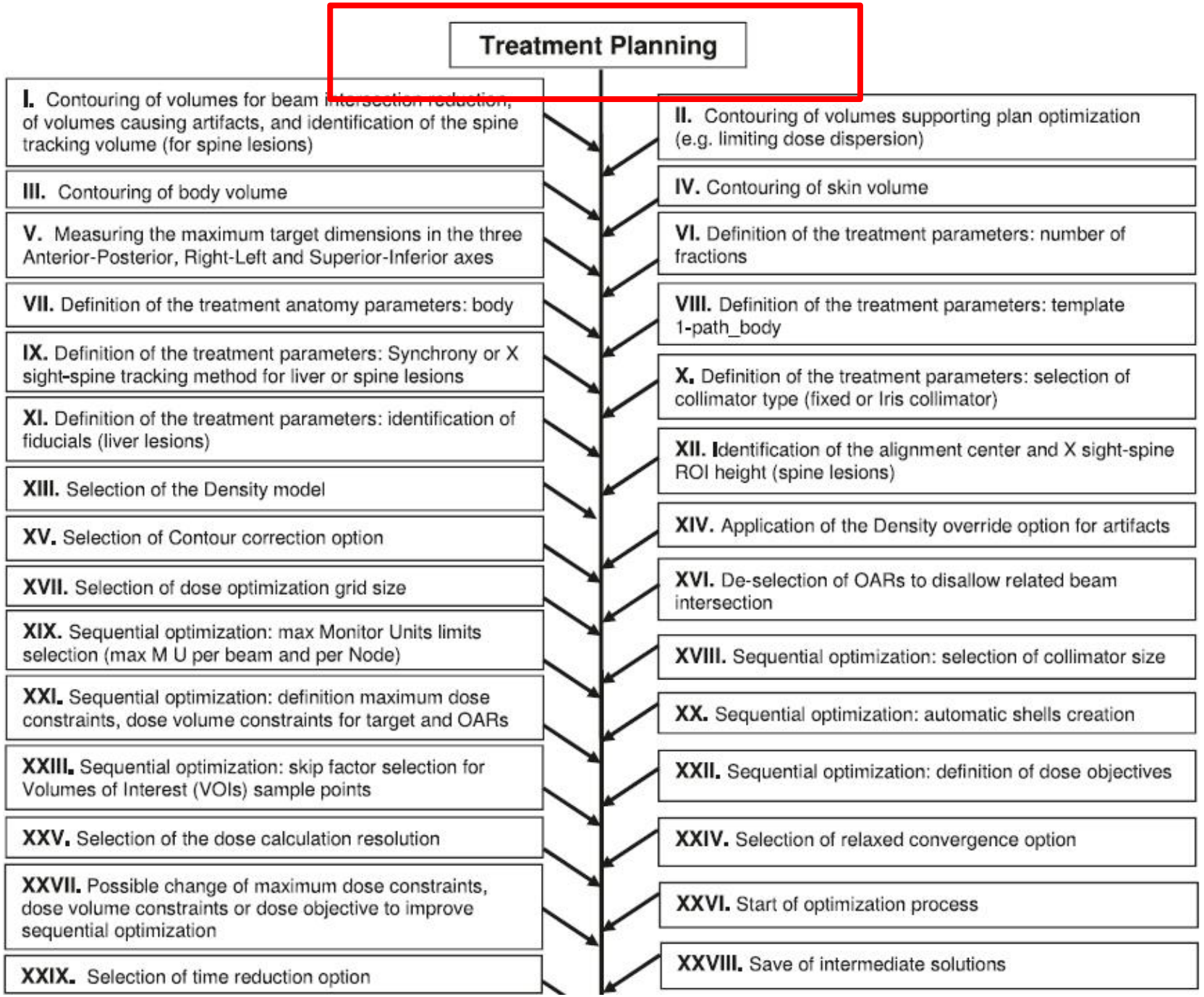
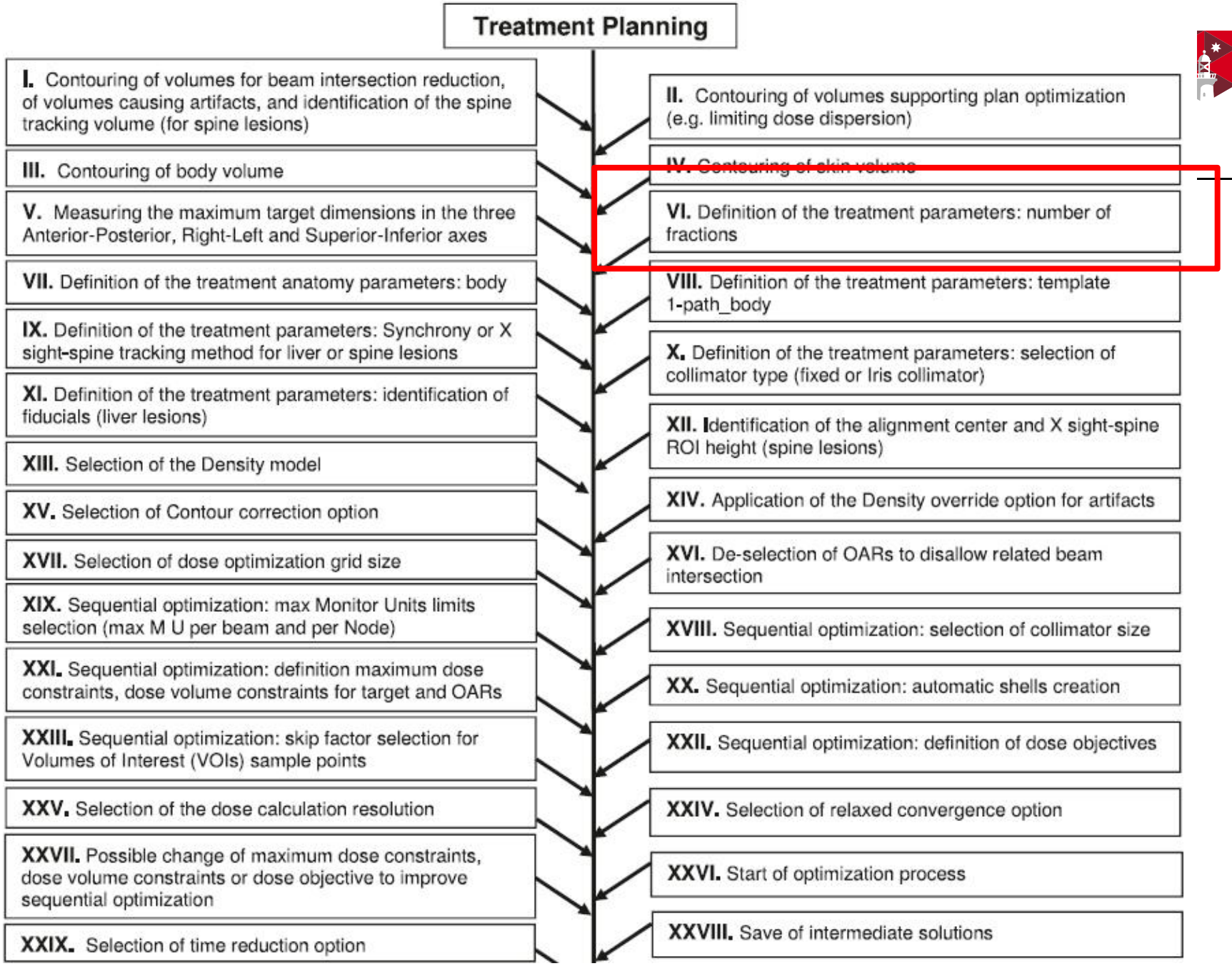
c) treatment delivery to spine lesions (the analysis of this stage was carried out considering the process implemented at the Carlo Besta Neurological Institute Foundation).


Treatment Planning
I. Contouring of volumes for beam intersection reduction, of volumes causing artifacts, and identification of the spine tracking volume (for spine lesions)
II. Contouring of volumes supporting plan optimization (e.g. limiting dose dispersion)
III. Contouring of body volume
IV. Contouring of skin volume
V. Measuring the maximum target dimensions in the three Anterior-Posterior, Right-Left and Superior-Inferior axes
VI. Definition of the treatment parameters: number of fractions
VII. Definition of the treatment anatomy parameters: body
VIII. Definition of the treatment parameters: template 1-path_body
IX. Definition of the treatment parameters: Synchrony or X sight-spine tracking method for liver or spine lesions
X. Definition of the treatment parameters: selection of collimator type (fixed or Iris collimator)
XI. Definition of the treatment parameters: identification of fiducials (liver lesions)
XII. Identification of the alignment center and X sight-spine ROI height (spine lesions)
XIII. Selection of the Density model
XIV. Application of the Density override option for artifacts
XV. Selection of Contour correction option
XVI. De-selection of OARs to disallow related beam intersection
XVII. Selection of dose optimization grid size
XVIII. Sequential optimization: selection of collimator size
XIX. Sequential optimization: max Monitor Units limits selection (max M U per beam and per Node)
XX. Sequential optimization: automatic shells creation
XXI. Sequential optimization: definition maximum dose constraints, dose volume constraints for target and OARs
XXII. Sequential optimization: definition of dose objectives
XXIII. Sequential optimization: skip factor selection for Volumes of Interest (VOIs) sample points
XXIV. Selection of relaxed convergence option
XXV. Selection of the dose calculation resolution
XXVI. Start of optimization process
XXVII. Possible change of maximum dose constraints, dose volume constraints or dose objective to improve sequential optimization
XXVIII. Save of intermediate solutions
XXIX. Selection of time reduction option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XXVIII. Save of intermediate solutions
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Table 1 FMEA of the treatment planning stage. Failures with RPN ≥ 80 or S ≥ 9 are listed

Sub-process	N	Potential failure mode	Potential causes of failure	Potential effects of failure	S	O	D	RPN
VI. Definition of the treatment parameters: number of fractions	1	Typing of a wrong number of fractions	Erroneous identification of the fractions number on the patient's record, wrong patient's record (coincidence of names), wrong typing	Wrong fraction dose administration	10	2	3	60
XII. Identification of the align centre and X sight-spine ROI height (in the case of spinal lesions)	2	Wrong positioning of the align centre and ROI height	Inexperience, presence of multiple lesions, damaged vertebrae	Tracking non-representative of the lesion's movement (underdosage of the PTV, overdosage of the OAR)	7	2	7	98
XXXIII. Enlargement of the calculation grid to all the CT volume in the three views	3	Missed enlargement of the calculation grid to all the CT volume	Inexperience, distraction, haste, activity interruption	Missed visualization of the hot spots in areas far from target and OARs, partial evaluation of the DVH	9	2	3	54
XXXVI. Physician's approval of the treatment plan, with eventual re-prescription of dose and number of fractions	4	Missed or wrong re-prescription of dose or number of fractions	Inexperience, distraction, haste, activity interruption, high workload, missed communication between physicist and physician	Erroneous dose delivery	10	2	4	80
XLII. Print of the report containing plan data, of the dose statistics table and of two images representative of the treatment plan (3D dose distribution, beams entry, DVH data and charts)	5	Missed or wrong printing of the plan report, of the table and images, printing of report, table and images not concerning the approved plan	Inexperience, distraction, haste, activity interruption, high workload, printing performed not contextually with the plan approval, missed communication among physicists	Missed check of the treatment plan, delivery of a sub-optimal plan or erroneous dose (in case there are other deliverable plans present)	10	1	4	40

Case 2. Medication management

Use of FMEA analysis to reduce risk of errors in prescribing and administering drugs in paediatric wards: a quality improvement report

Paola Lago,[1] Giancarlo Bizzarri,[2] Francesca Scalzotto,[1] Antonella Parpaiola,[1] Angela Amigoni,[1] Giovanni Putoto,[3] Giorgio Perilongo[1]

Table 1 Rating scales used to assign values to the occurrence (O), severity (S), and detection (D) scores in the failure mode and effect analysis of the drug administration process

Occurrence (O)l		Severity (S)		Detection (D)	
Score	Failure mode probability	Score	Description of injury	Score	Likelihood of detection
1	Remote: failure unlikely to occur (happening in 1 in 10000 episodes observed)	1	No injury or patient monitoring alone	1	Very high: detected 9/10 times
2	Low: relatively rare failure (happening in 1 in 1000 episodes observed)	2	Temporary injury needing additional intervention or treatment	2	High: detected 7/10 times
3	Moderate: occasional failure (happening in 200 episodes observed)	3	Temporary injury with longer hospital stay or increased level of care	3	Medium: detected 5/10 times
4	High: recurrent failure (happening in 1 in 100 episodes observed)	4	Permanent effects on body functions	4	Low: detected 2/10 times
5	Very high: common failure (happening in 1 in 20 episodes observed)	5	Death or permanent loss of major body functions	5	Remote: detected 0/10 times

The risk priority number (RPN) is calculated by multiplying the O, S and D scores.

Results

- 37 high-risk failures with 71 associated causes and effects.
- None of the steps in the drug administration process were free of potential failure modes
- Prescription and preparation of the drugs emerged as the most vulnerable steps (with RPNs over 48/125).
- The most critical element in the prescribing of drugs was the calculation of the doses required, especially for infusion drugs (RPN 60/125). This high-risk failure mode was found in all the paediatric units, and was believed to be related to doctors and nurses not having reference material available with all the pertinent information on the methods for preparing and administering the drugs, and the proportions and formulas for adapting the drugs' dosage to a given patient.

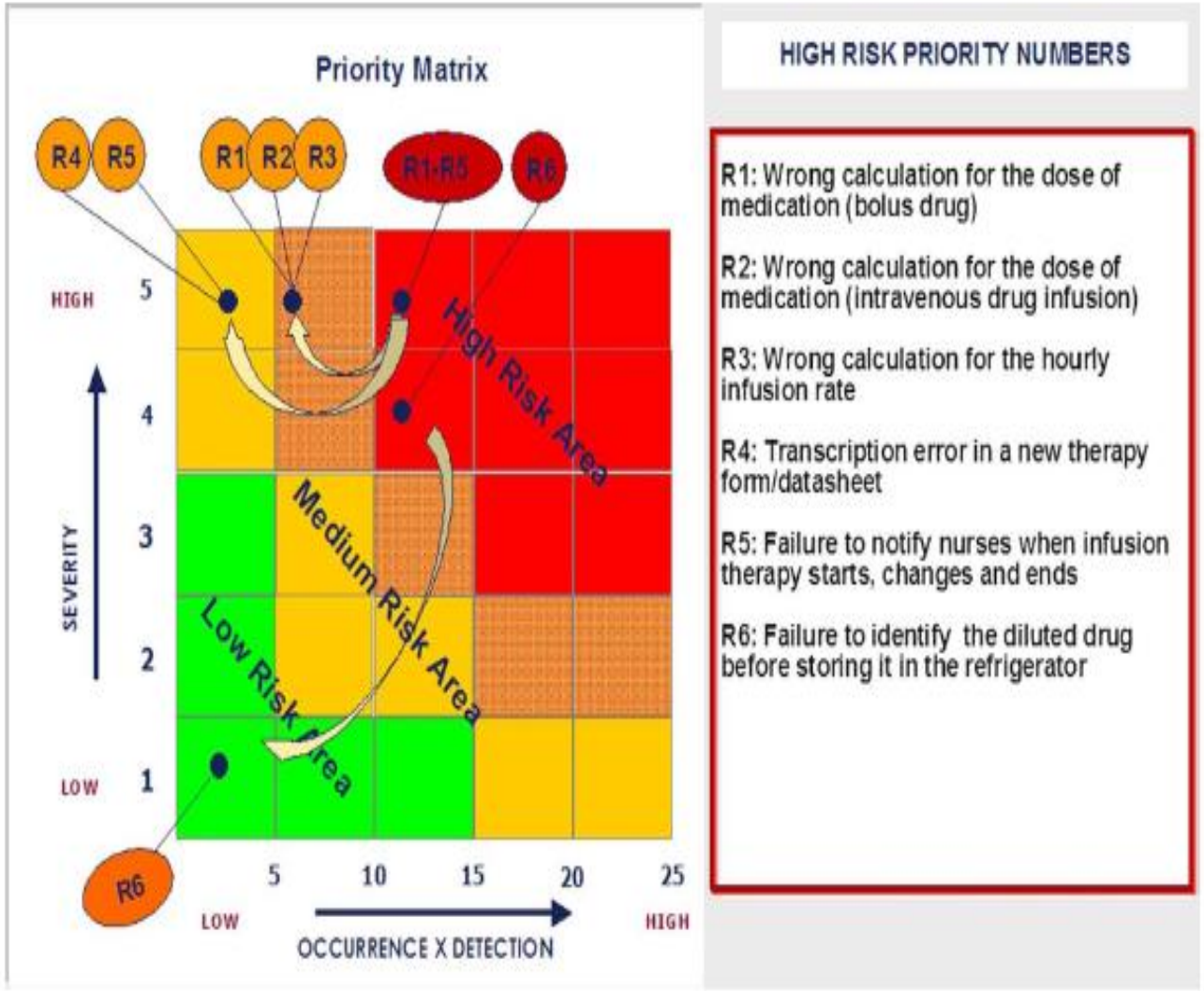


Figure 1 Priority matrix, plotting severity against probability (the product of O×D) before and after applying failure mode and effect analysis.

Differing contexts:

- NICU
- PICU
- Acute Care
- Onco-haematology
- General paediatrics

Table 3 High-risk failure-modes identified across multiple medication use failure mode and effect analysis

High-risk failure modes	Process phases	NICU	PICU	Acute care	Onco-haematology	General Ped	N° High-Risk Failure Modes
Error in using the Kanban system for re-order drugs	Supplying					■	1
Failure to check pharmacy supplies (to cross-check drugs ordered against drugs delivered and to correlate the drug package with the patient)	Supplying					■	3
Error in calculating the dosage of medication (Failure to measure patient's weight and height, failure to correctly prescribe bolus and continuous infusion drugs, 'high-risk' intravenous drugs, dilutions, infusion rate, frequency of administration)	Prescription	■	■	■	■	■	8
Failure to check dose and frequency of administration	Prescription	■	■	■	■		4
Erroneous prescription of therapy on the order form (writing error and transcription error on a new therapy form, oral prescription over the phone during the night)	Prescription		■	■	■		3
Incomplete reassessment of the daily clinical status and lack of written notes and/or spoken information on changes in clinical situation	Prescription	■					2
Failure to notify to the nurse a new medication order (either for bolus or and infusion, for changes and end of infusion)	Prescription	■	■				4
Failure to check chemotherapy components	Prescription				■		1
Unavailability of drugs at the time of patient's transfer owing to lack of medication reconciliation, and urgent need for drugs from the pharmacy	Prescription				■		1
Misinterpretation of prescription by the nurse owing to illegible handwriting or shortcuts	Prescription			■	■	■	3
Failure to consult handbook to check proper dilution, concentration, compatibility, rate of administration, photosensitivity and method of administration	Preparation	■					2
Erroneous calculation of the prescribed dose of medication (incorrect choice of proportions to obtain the right dose in ml, or of the proportions needed to reach the maximum concentration of the drug)	Preparation	■		■			1
Failure to identify type of drug in syringe during infusion and before storing it in the refrigerator	Preparation	■	■				2
Failure to explain to parents how to monitor the drug's administration	Administering					■	2
Inadequate monitoring of potential adverse effects	Monitoring			■			1
Total high-risk failure modes		8	8	9	6	6	37

General Ped, general paediatric ward; NICU, neonatal intensive care unit; PICU, paediatric intensive care unit.
■, Error was found in the unit selected

Actions to reduce occurrence

Table 4 Selected new activities to address high-risk failure modes affecting the five paediatric drug-delivery processes

Process phase	New activities of improvement plans	Unit
Supplying	Change the collection point for Kanban card*	General Ped
Supplying	Check consistency and sign delivery note. Preprinted label to identified patient with barcode. New form for re-ordering galenic drugs	General Ped
Prescription	Quiet place for preparing prescriptions without distraction. Single formulary. Prescription of active ingredient, in mg. Tables for standard doses and dilutions. Healthcare worker involved to get daily weight of patients	NICU, PICU, PED.Acute Care, Onco-haematology
Prescription	Doctors doublecheck and double-sign	NICU, PICU, PED.Acute Care, Onco-haematology, General Ped
Prescription	Clearly understandable written prescription. Preventive written prescription necessary or written prescription by doctor on duty	PICU, PED. Acute Care, Onco-haematology
Prescription	Daily discussion of clinical situation and ongoing therapy between resident and attending physicians. Daily notes by attending physician	NICU
Prescription	Yellow Post-it on therapy folder. Nurse signs	NICU, PICU
Prescription	Green label for chemotherapy. Nurse doublechecks and doublesigns for preparation; and nurse signs for drug administration	Onco-haematology
Prescription	List of medication available prior to patient's transfer. (medication reconciliation)	Onco-haematology
Preparation	Write clearly and comprehensibly. Nurse doublechecks and doublesigns. Easy-to-read therapy form. Pre-printed label with barcode	PED. Acute Care, General Ped, Onco-haematology
Preparation	Pre-printed label briefly reports the essential notes for correct dilution, compatibility, rate of administration and the sign of the nurse who prepared the medication	NICU, PED. Acute Care
Preparation	Facsimile of the proportions required on hand in the room	NICU
Preparation	All diluted drugs are discarded once used	NICU, PICU
Administering	Written instructions for parents involved in drug administration	General Ped
Monitoring	Check vital signs and site of infusion for certain drugs	PED. Acute Care

*The Kanban card is a message that alerts to the depletion of product stocks and triggers their replenishment.
General Ped, general paediatric ward; NICU, neonatal intensive care unit; PICU, paediatric intensive care unit.

Corrective Actions

- Each unit independently developed plans for new corrective actions focussing only on the higher risk failure modes. Some were common to all five units.
- After corrective action implementation, no steps in the revised drug administration process had an RPN>32/125.
- The reduction in the RPNs for the higher risks was around 60% at almost all units, and 23 of 37 higher risk failure modes now plotted in the low-risk area (yellow and green area of the priority matrix).
- Clinical audits conducted by the team leader 3 and 6 months later confirmed that the main clinical changes and innovations introduced were still firmly in place.

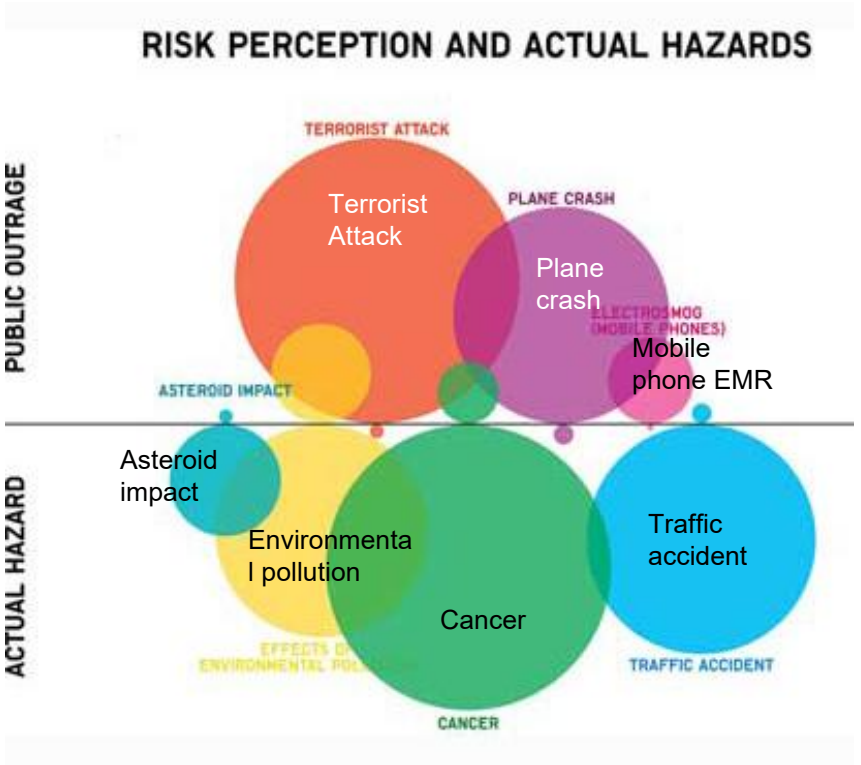
Patient view of risk:

- May differ significantly from the actual evidence-based risk
  - Patient experience
  - Patient fears
  - Patient preferences
- Where patients are involved, consider the patient's perception of risk, in addition to any evidence-based risk, when deciding on risk management strategies

Patient view of risk; Hazard vs. Outrage[1]

Underestimate low outrage hazards, Overestimate high outrage hazards

- Voluntary/involuntary
- Familiar/exotic
- Natural/industrial
- Memorable/not memorable
- Dreaded/not dreaded
- Chronic/catastrophic
- Knowable/not knowable
- Fair/unfair
- Morally irrelevant/relevant
- Trust/no trust
- Responsive process/unresponsive



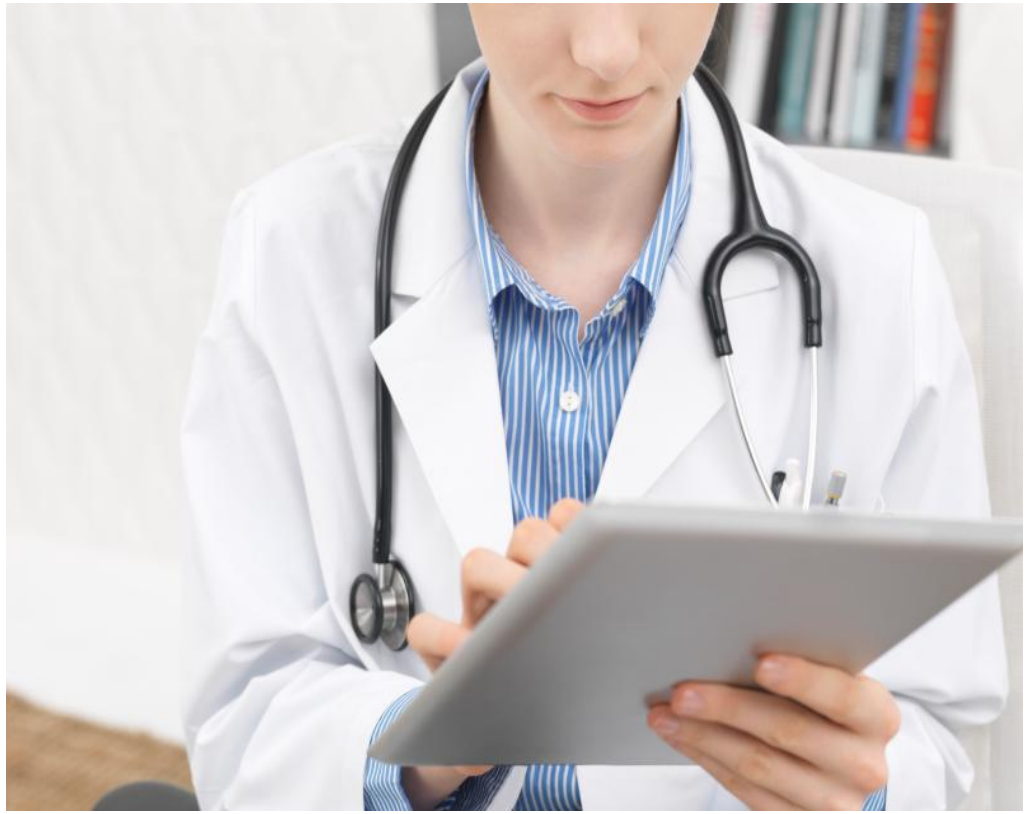
Susanna Hertrich, RISK, 2010

1. Peter Sandman, 1993 & 2012

Failure Mode and Effects Analysis (FMEA)

In summary, FMEA is:

- A useful tool for analysing:
  - high impact failures
  - critical changes to workplace practice
  - large scale workplace redesign
- Can be costly:
  - takes time, resources
  - need a (large) multidisciplinary team who have expert knowledge of the process you are analysing
  - need a safety & quality professional to lead and direct
- Most of the risks you will encounter in healthcare involve behaviours:
  - ratings may not be obvious (but *relative* ratings are OK)
  - ratings require consensus among the team
  - the consensus process will build teamwork



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Thank you

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