

Setting up a hospital-wide patient safety programme

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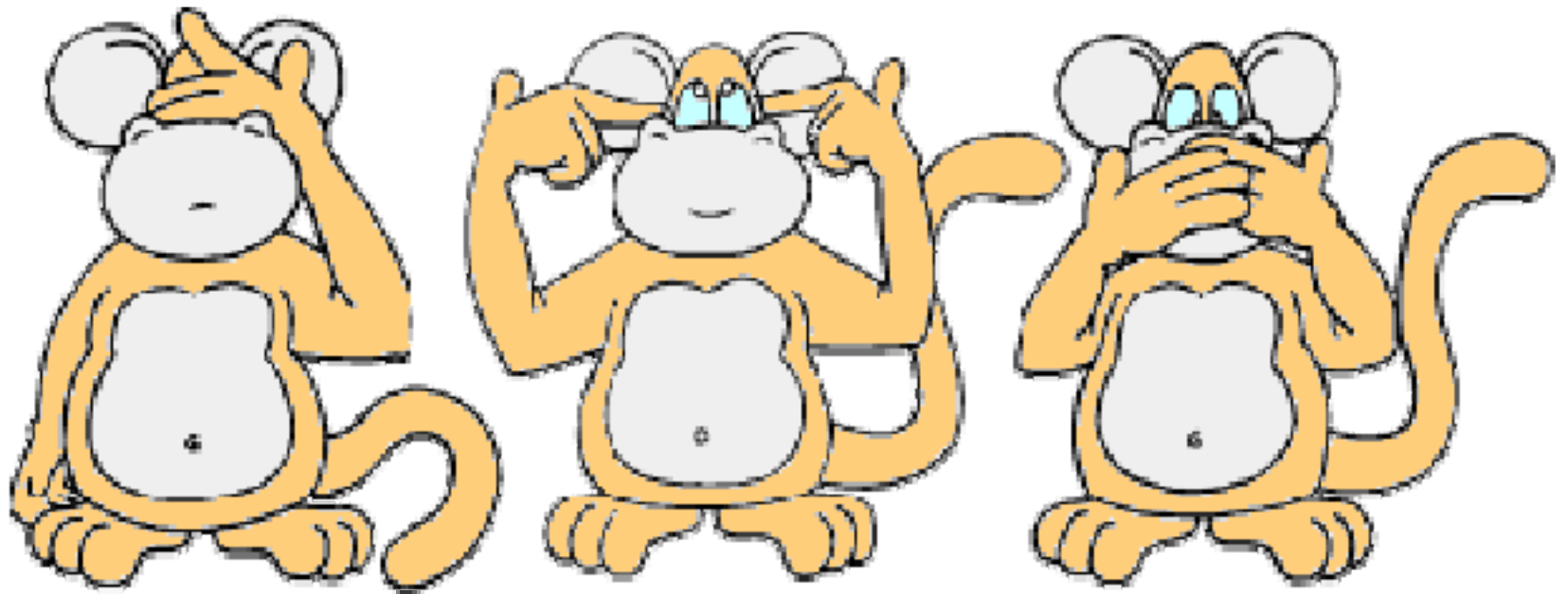
Risk Analysis



Risk analysis

- **Reactive**
 - Incident reports
 - Root Cause Analysis

- **Proactive**
 - “black pistes”
 - Healthcare Failure Mode and Effect Analysis





What is Root Cause Analysis?

- The root causes are the fundamental issues which have led to an incident occurring
- What?
- How?
- Why?
- It's not about: who

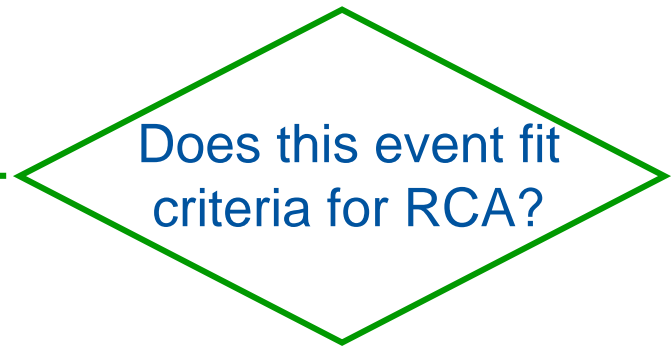


An event occurs

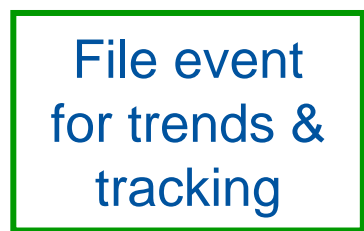
CIRC: Central Incident Reporting Committee



Event reported to CIRC for initial screening



Does this event fit criteria for RCA?



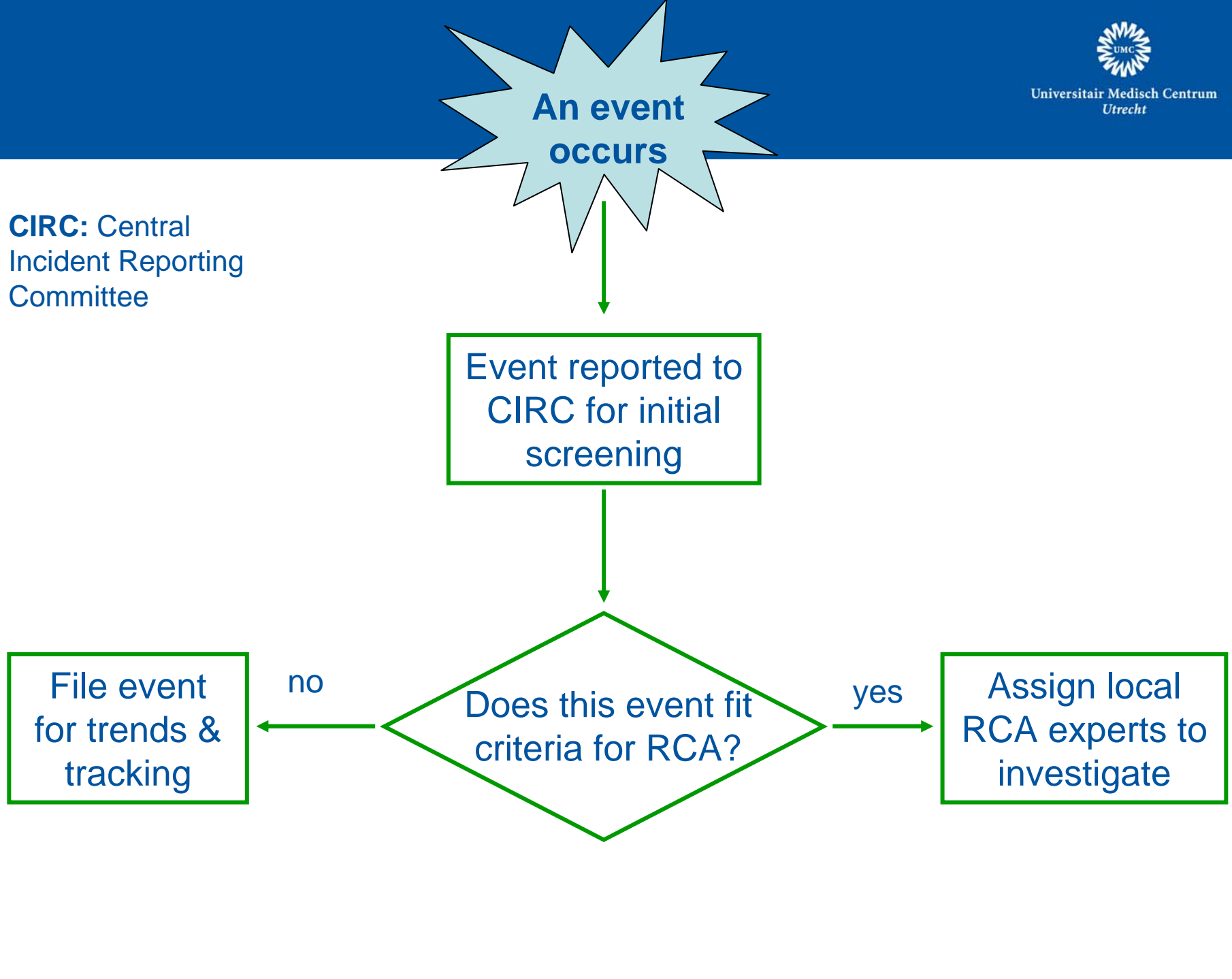
File event for trends & tracking

no

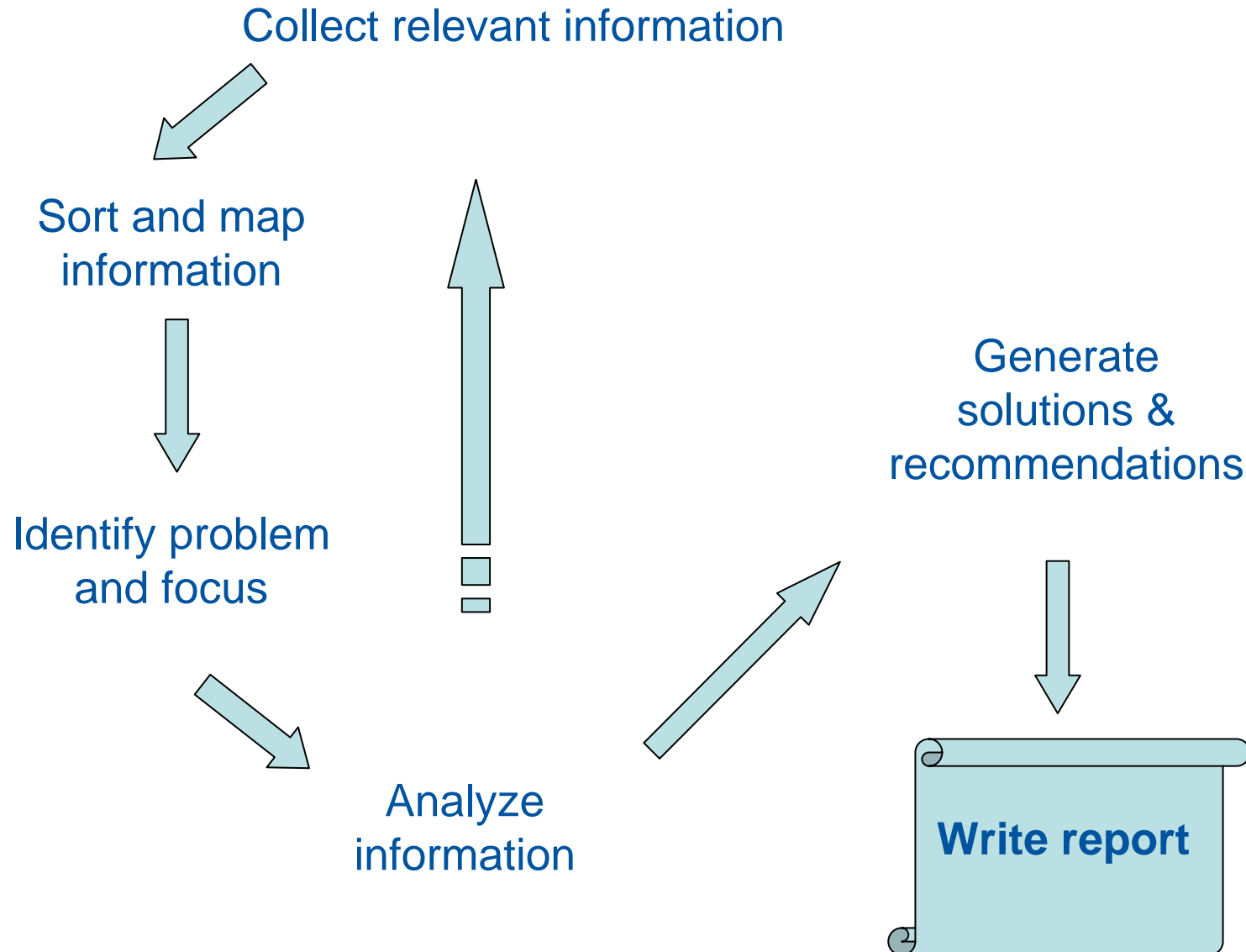


Assign local RCA experts to investigate

yes



Root Cause Analysis - Steps





Collect relevant information - Question

- A nurse administers adrenaline instead of heparin through an IV line

How would you collect appropriate information?



Collect relevant information

- Patient chart,
- Interview
 - Nurse
 - Head of the ward
 - Attending physician
- Visit the room
- See the vials
- ...

Collect relevant information



Collect relevant information

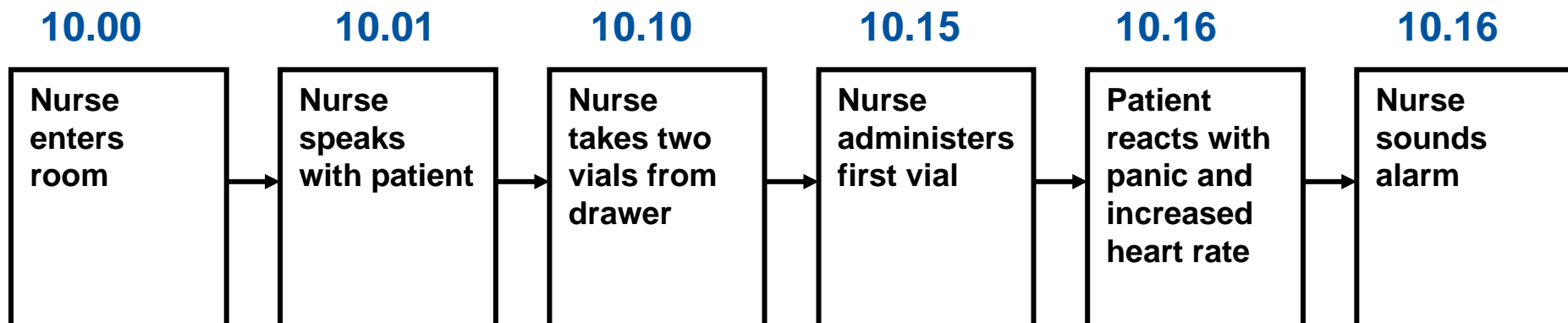


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Sort and map information

- Time line
- Time-person grid
- What do we miss?



Identify problem and focus



- Don't try to save the world
- Focus on the event at hand

- 5 whys
- Barrier analysis
- Fishbone
- Brainstorming
- Brain writing
- Identify root causes



Analyze information - WHYs

Why did nurse administer adrenalin?

→ she flushes the IV line and expected the vial to contain heparin

Why did she confuse adrenalin with heparin?

→ there should only have been heparin in the drawer

→ vials are identical

→ she didn't do a double check

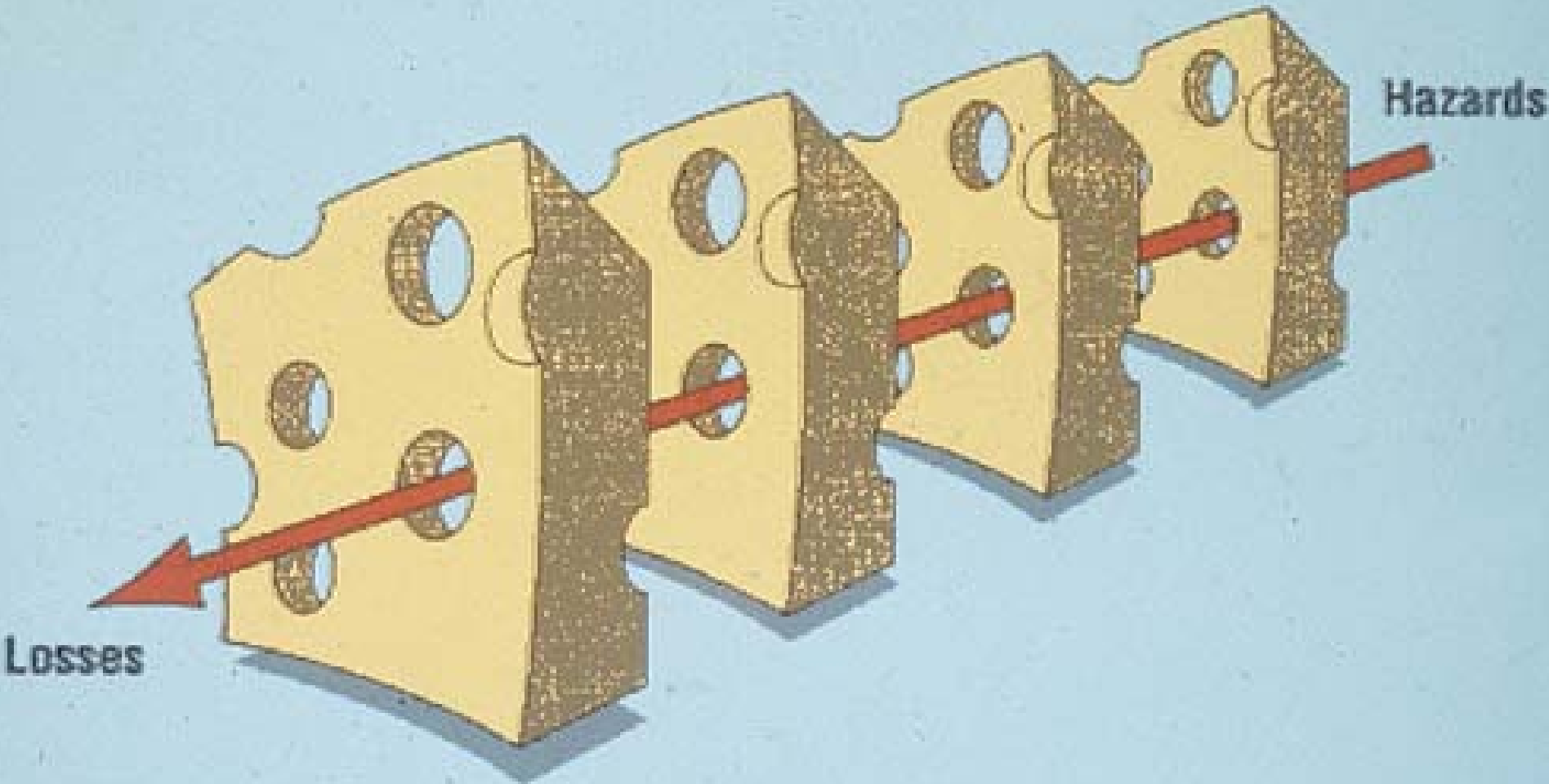
Why was adrenalin in the drawer?

→ etc

Barrier analysis - Reason's model



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Barrier analysis



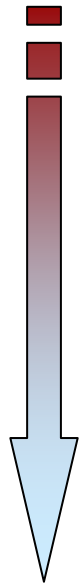
| Existing barrier | Did it work? | Why not? |
|--|--------------|---|
| Room only contains vials for flushing IV lines | NO | Adrenaline vial had been placed between heparin vials |
| Before administering medication, nurse should perform a double check | NO | 1) Heparin administration for keeping an IV line open isn't seen as medication 2) Patient was in isolation room, this makes double check difficult |
| | ... | ... |

Generate solutions - Question

Please place the following solutions in order of strength:

- new policy on flushing lines
- remove all vials from patient room
- fire the nurse
- double-check
- replace one vial with pre-filled syringe
- redesign labels of vials
- hold a meeting and tell everybody this happened

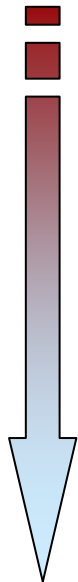
strong



weak

Generate solutions & recommendations

strong



Physical

- e.g. introduce pre-filled syringe

Natural

- e.g. remove vials, change labels

Human action

- e.g. double-check

Administrative

- e.g. new policy on flushing,
hold a meeting

weak

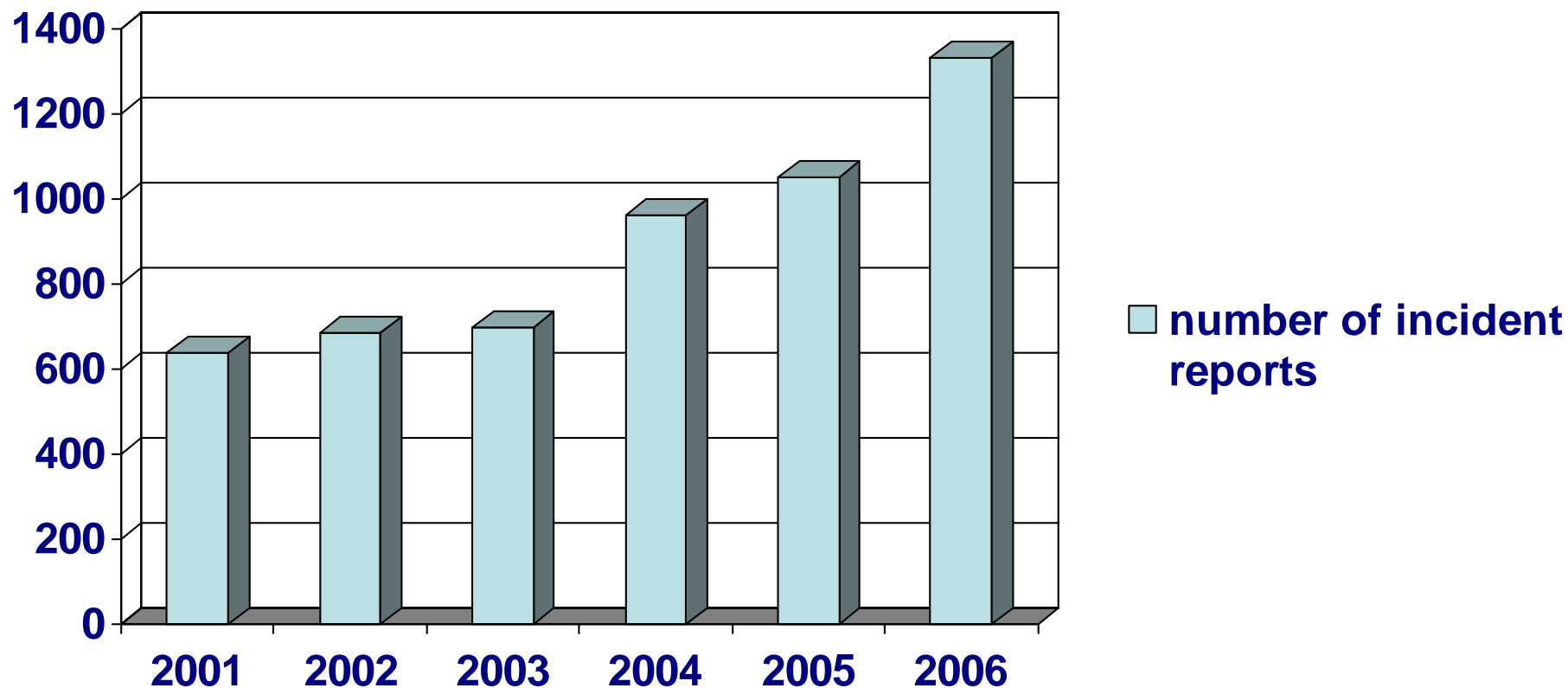


Write the report



- structure
- be objective
- write for a layman

Effect of safety program on incident reporting









Start patient safety program

CATINAT 2106

Vers le lac de ROUE
et SOULIERS



Vers le col d'IZOARD 2340

- | | |
|--|--|
|  Très facile 8,5 km |  Difficile 4,5 km |
|  Facile 2 km |  Très difficile 0,5 km |
|  piste en projet |  enneigement artificiel |
|  enneigement artificiel en projet | |

Proactive – “black pistes”



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Healthcare Failure Mode and Effect Analysis

- A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome.
- A systematic approach to identify and prevent product and process problems before they occur.



HFMEA

- Pro-active
- Process
- Occurrence
- \pm 140 hours

- Multidisciplinary
- Blame-free

RCA

- Retrospective
- Incident
- Recurrence
- \pm 30 hours

- Multidisciplinary
- Blame-free

What is a Failure Mode?



Different ways that a process or sub-process can fail to provide the anticipated result.

General Electric
GE 90-115B Turbofan
for Boeing 777-300ER

FMEA terminology:
MTBF
*(mean time
between failures)*





GE90-115 high bypass turbofan

- ...must demonstrate an **in-flight shutdown rate** of less than 0.02 per thousand flight hours to gain *Extended Twin Operations* certification
- ~ one shutdown per 50,000 hours of flight, or in normal commercial service, once every 10 yr

Hazard Matrix



| | | Severity | | | |
|-------------|------------|--------------|-------|----------|-------|
| | | Catastrophic | Major | Moderate | Minor |
| Probability | Frequent | 16 | 12 | 8 | 4 |
| | Occasional | 12 | 9 | 6 | 3 |
| | Uncommon | 8 | 6 | 4 | 2 |
| | Remote | 4 | 3 | 2 | 1 |
| | | | | | |

- Hip fracture from ER to theatre
- Blood transfusion
- Medication in ICU
- Fixation of restless patients
- Acute heart patients from ER to CCU
- Perioperative continuity of medication
- Special diets for patients with metabolic disorder

Step 1 - Define the topic

Step 2 - Assemble the team

Step 3 - Graphically describe the process

Step 4 - Conduct the analysis

Step 5 - Identify actions and outcome measures

Step 1



Define the scope of the HFMEA along with a clear definition of the process to be studied.

Patients with hip fracture

Starting point: Emergency Room admission

End point: incision in the operating theatre

Step 2



Assemble the team

multidisciplinary team with subject matter expert(s)
plus advisor

Step 2 - Question



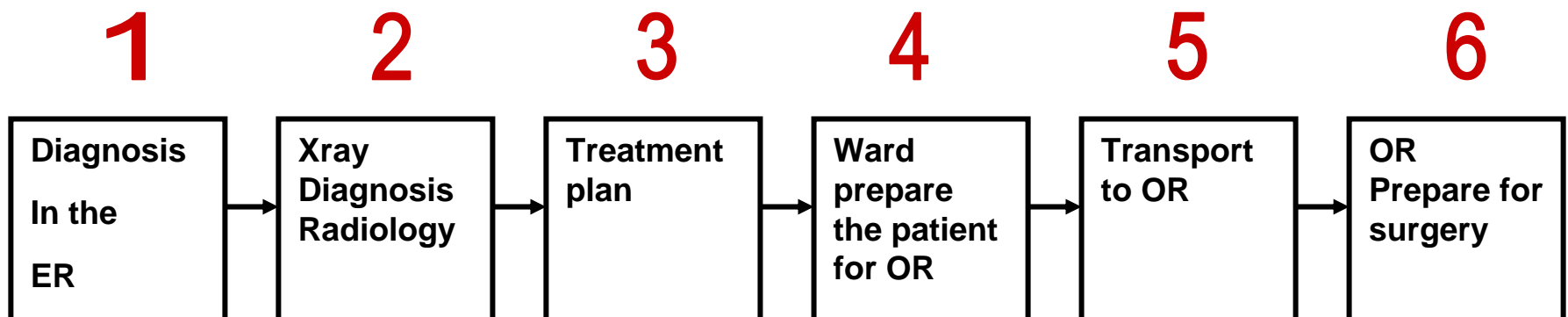
Hip fracture from ER to theatre

- **Who should be on the team?**

Step 3



- A. Develop and verify the flow diagram
- B. Consecutively number each process step
- C. If the process is complex identify the area of the process to focus on (manageable bite)



Step 3



- D. Identify all sub processes under each block of this flow diagram. Consecutively letter these sub-steps.
- E. Create a flow diagram composed of the sub processes.

Step 3



1

2

3

4

5

6

Diagnosis
In the
ER

Xray
Diagnosis
Radiology

Treatment
plan

Ward
prepare
the patient
for OR

Transport
to OR

OR
Prepare for
surgery

5A. Choose medication

5B. Calculate dose

5C. Adjust machine

5D. Gently apply mask

5E. Distract & reassure patient

Step 4



- A. List potential failure modes of each (sub)step
- B. Determine severity & probability
- C. List all failure mode causes

Step 4 A



| | | | | |
|--------|----|------------------------|---------------------------------------|----------------------------------|
| Step 4 | 1 | Process Step | 5.B Calculate dose | |
| | 2 | Failure Mode | 5.B (1) Wrong calculation made | 5.B (2) Wrong weight used |
| | 3 | Cause | | |
| | 4 | Severity | | |
| | 5 | Probability | | |
| | 6 | Hazard Score | | |
| | 7 | Decision | | |
| Step 5 | 8 | Action | | |
| | 9 | Description of Action | | |
| | 10 | Outcome Measure | | |
| | 11 | Person Responsible | | |
| | 12 | Management Concurrence | | |

Step 4 B



| | Severity | | | | |
|-------------|--------------|-------|----------|-------|---|
| | Catastrophic | Major | Moderate | Minor | |
| Probability | Frequent | 16 | 12 | 8 | 4 |
| | Occasional | 12 | 9 | 6 | 3 |
| | Uncommon | 8 | 6 | 4 | 2 |
| | Remote | 4 | 3 | 2 | 1 |
| | | | | | |

Severity rating



| Catastrophic Event | Major Event |
|---|---|
| <p><u>Patient Outcome:</u> Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family</p> <p><u>Visitor Outcome:</u> Death; or hospitalization of 3 or more.</p> <p><u>Staff Outcome:</u> * A death or hospitalization of 3 or more staff</p> <p><u>Equipment or facility:</u> **Damage equal to or more than \$250,000</p> <p><u>Fire:</u> Any fire that grows larger than an incipient</p> | <p><u>Patient Outcome:</u> Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients</p> <p><u>Visitor Outcome:</u> Hospitalization of 1 or 2 visitors</p> <p><u>Staff Outcome:</u> Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses</p> <p><u>Equipment or facility:</u> **Damage equal to or more than \$100,000</p> <p><u>Fire:</u> Not Applicable – See Moderate and Catastrophic</p> |

HFMEA - step 4



| | | | | |
|--------|----|------------------------|--------------------------------|--|
| Step 4 | 1 | Process Step | 5.B Calculate dose | |
| | 2 | Failure Mode | 5.B (1) Wrong calculation made | |
| | 3 | Cause | | |
| | 4 | Severity | Major | |
| | 5 | Probability | Occasional | |
| | 6 | Hazard Score | 9 | |
| | 7 | Decision | | |
| Step 5 | 8 | Action | | |
| | 9 | Description of Action | | |
| | 10 | Outcome Measure | | |
| | 11 | Person Responsible | | |
| | 12 | Management Concurrence | | |

HFMEA - step 4 D



| | | | | |
|--------|----|-----------------------|--------------------------------|---------------------------------|
| Step 4 | 1 | Process Step | 5.B Calculate dose | |
| | 2 | Failure Mode | 5.B (1) Wrong calculation made | |
| | 3 | Cause | | Trainee can't calculate by head |
| | 4 | Severity | Major | |
| | 5 | Probability | Occasional | |
| | 6 | Hazard Score | 9 | |
| | 7 | Decision | | |
| Step 5 | 8 | Action | | |
| | 9 | Description of Action | | |
| | 10 | Outcome Measure | | |
| | 11 | Person Responsible | | |
| | 12 | Management concur | | |

STEP 5 - Actions and outcome measures

- A. Decide to “Eliminate,” “Control,” or “Accept” the failure mode cause.
- B. Describe an action for each failure mode cause that will eliminate or control it.
- C. Identify outcome measures that will be used to analyze and test the re-designed process.

STEP 5 - Actions and outcome measures

- D. Identify a single, responsible individual by title to complete the recommended action.
- E. Indicate whether top management has concurred with the recommended actions.

HFMEA - step 5



| | | | | |
|--------|----|-----------------------|--------------------------------|---------------------------------|
| Step 4 | 1 | Process Step | 5.B Calculate dose | |
| | 2 | Failure Mode | 5.B (1) Wrong calculation made | |
| | 3 | Cause | | Trainee can't calculate by head |
| | 4 | Severity | Major | Major |
| | 5 | Probability | Occasional | Occasional |
| | 6 | Hazard Score | 9 | 9 |
| | 7 | Decision | | proceed |
| Step 5 | 8 | Action | | Control |
| | 9 | Description of Action | | Use calculator |
| | 10 | Outcome Measure | | Calculator present |
| | 11 | Person Responsible | | John |
| | 12 | Management concur | | Yes |