Patient Safety Support Service &
Medication Safety Support Service
Workshop

Failure Modes and Effects Analysis

Supported by the Ontario Ministry of Health and Long Term Care

Please silence your communication leashes

Objectives – FMEA Session

- To introduce the OHA Patient Safety Support Service and ISMP Canada Medication Safety Support Service
- To Describe the origin and utility of FMEA
- To Involve participants in an abbreviated FMEA

ISMP CANADA Vision

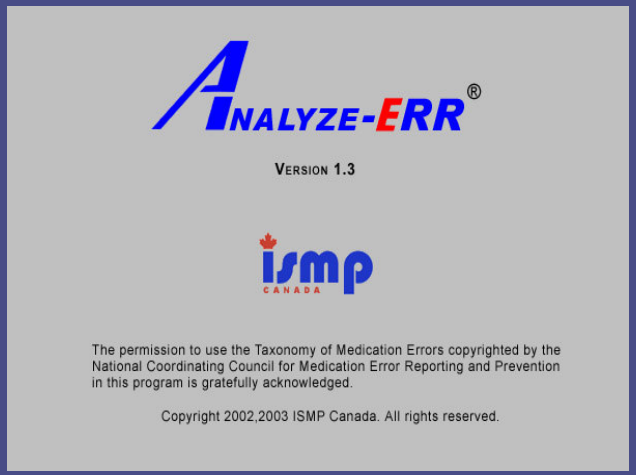
- Independent nonprofit Canadian organization
- Established for:
  - the collection and analysis of medication error reports and
  - the development of recommendations for the enhancement of patient safety.
- Serves as a national resource for promoting safe medication practices throughout the health care community in Canada.

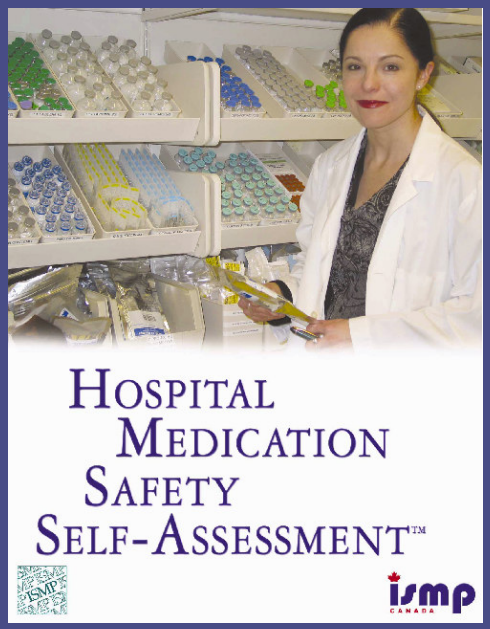
ISMP Canada Programs

- CMIRPS (Canadian Medication Incident Reporting and Prevention System)
  - 3 partners:
    - ISMP Canada,
    - Canadian Institute for Health Information (CIHI)
    - Health Canada

ISMP Canada Programs

- Medication Safety Support Service
  - Concentrated Potassium Chloride
  - Opioids (narcotics)
- Analyze-ERR





Medication Safety Self-Assessment (MSSA)

Outline

- Introduction
- Brief Overview of Human Factors
- Overview of the Origins of FMEA
- FMEA steps
- Practice Sessions
- Discussion and Wrap Up

Human Factors Engineering 101

HFE: a discipline concerned with design of systems, tools, processes, machines that take into account human capabilities, limitations, and characteristics

HFE = Ergonomics = usability

engineering = user centered design

Human Factors Engineering Principles

- Simplify key processes
- Standardize work processes
- Improve verbal communication
- Create a learning environment
- Promote effective team functioning
- Anticipate that human make errors

Human Factors – Guiding Principle

Fit the task or tool to the human, not the other way around.

FMEA definition

- FMEA is a team-based systematic and proactive approach for identifying the ways that a process or design can fail, why it might fail, the effects of that failure and how it can be made safer.
- FMEA focuses on how and when a system will fail, not IF it will fail.

Why me ? Why you?

- Practitioners in the systems know the vulnerabilities and failure points
- Professional and moral obligation to “first do no harm”
- Increased expectation that we create safe systems

FMEA Origins

- FMEA in use more than 40 years beginning in aerospace in the 1960s
- 1970s and 1980s used in other fields such as nuclear power, aviation, chemical, electronics and food processing fields (High Reliability Organizations)
- Automotive industry requires it from suppliers, reducing the after-the-fact corrective actions

FMEA is a tool to:

- Analyze a process to see where it is likely to fail.
- See how changes you are considering might affect the safety of the process.

JCAHO Position

- JCAHO's safety standards now includes requirements for the prospective analysis and redesign of systems identified as having the potential to contribute to the occurrence of a sentinel event (FMEA)
- JCAHO expects healthcare facilities to set FMEA priorities based on their own risk management experiences or external sources

CCHSA Patient Safety Goals

Carry out one patient safety-related prospective analysis process per year (e.g. FMEA), and implement appropriate improvements / changes.

FMEA versus RCA - when to use

FMEA = Future (preventative)

RCA = Retrospective (after the event or close call)

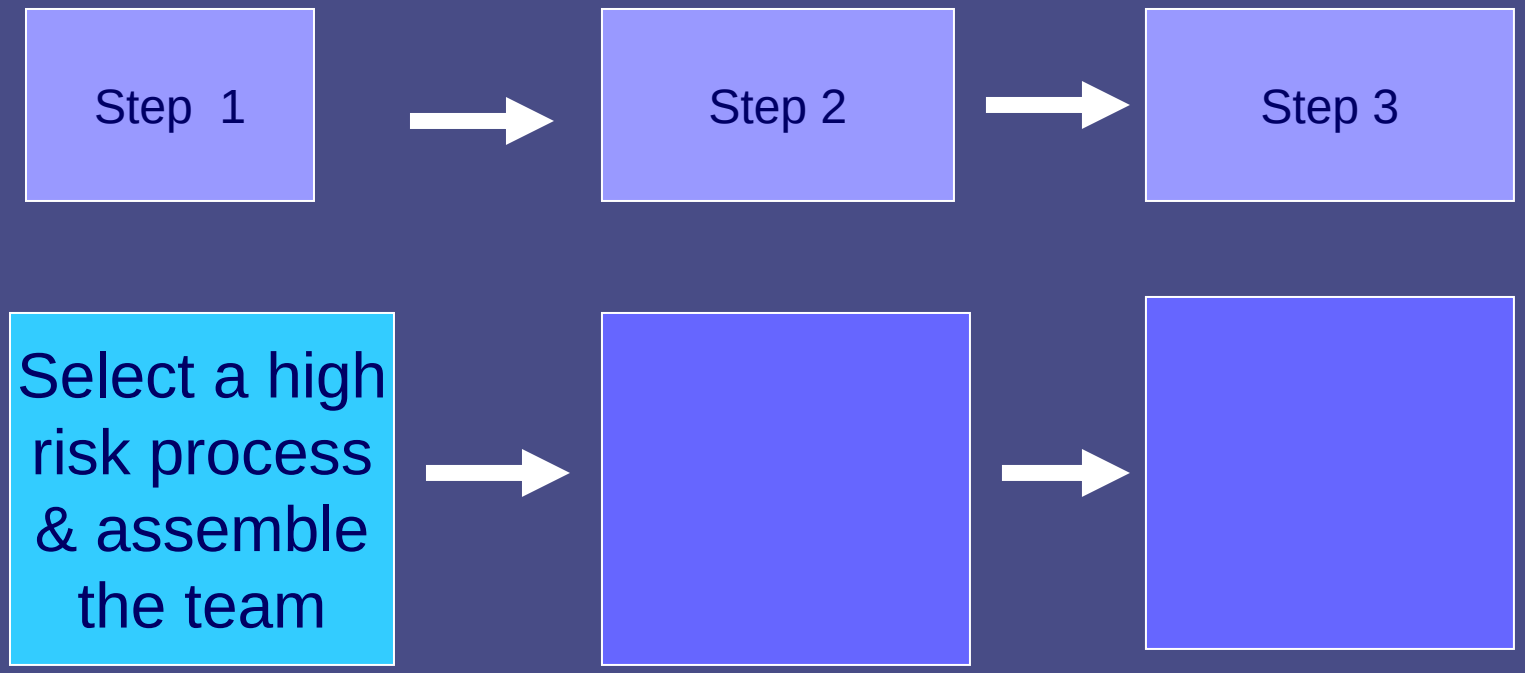
FMEA Steps

Step 1	Select process and assemble the team
Step 2	Diagram the process
Step 3	Brainstorm potential failure modes and determine their effects
Step 4	Identify the causes of failure modes

FMEA Steps (cont)

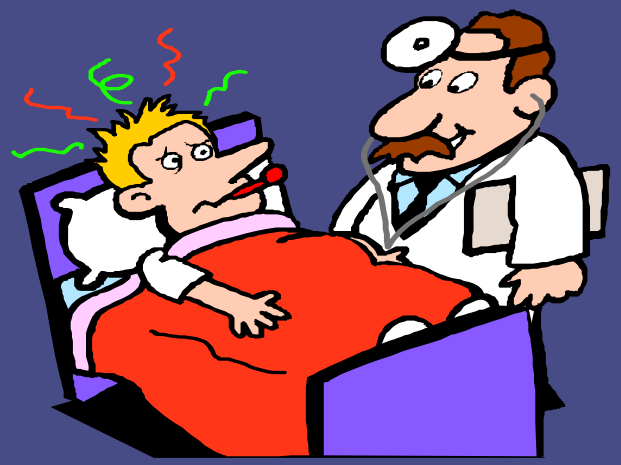
Step 5	Prioritize failure modes
Step 6	Redesign the processes
Step 7	Analyze and test the changes
Step 8	Implement and monitor the redesigned processes

FMEA Process Steps - 1



Select a high-risk process

- Internal data – aggregate data, significant individual events
- Sentinel Events
- CCHSA Patient Safety Goals
- ISMP Canada
- Executive buy-in



Select processes with high potential for having an adverse impact on the safety of individuals served.

High Risk Processes - Definition

Those processes in which a failure of some type is most likely to jeopardize the safety of the individuals served by the health care organization. Such process failures may result in a sentinel event.

High Risk Processes - Examples

- Medication Use
- Operative and other procedures
- Blood use and blood components
- Restraints
- Seclusion
- Care provided to high-risk population
- Emergency or resuscitation care

Typical FMEA topics in Health Care

- Blood administration
- Admission / discharge / transfer processes
- Patient Identification
- Outpatient Pharmacy Dispensing
- Allergy Information Processing
- Specimen Collection

Typical Medication Use FMEAs

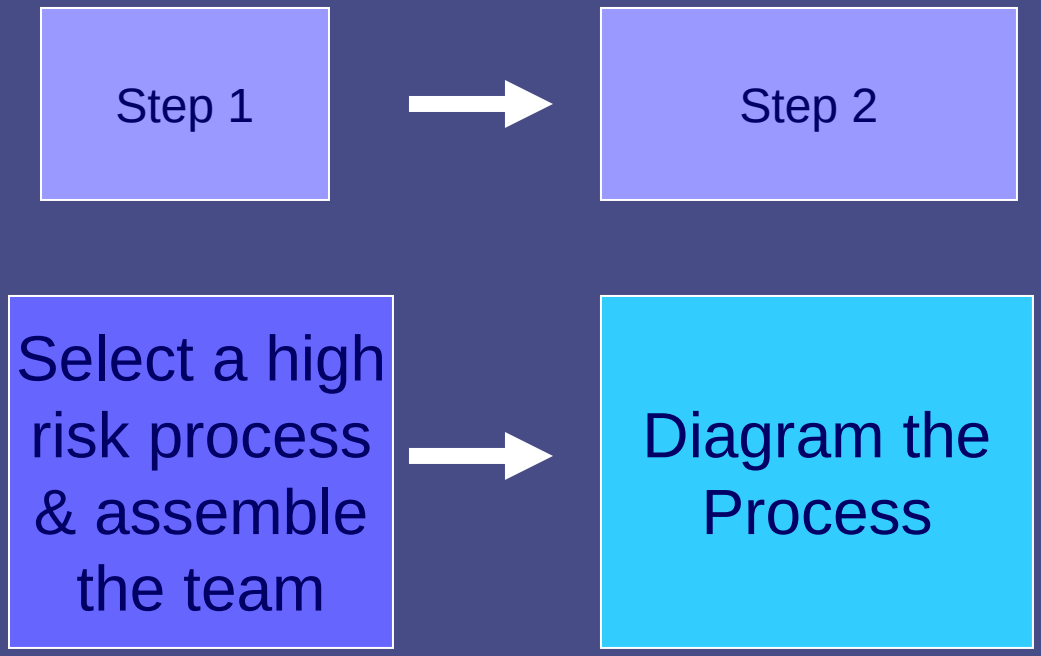
- Narcotic use
- Anticoagulation
- Insulin or other diabetes drug use
- Chemotherapy processing
- Parenteral Electrolyte use
- Neonatal or pediatric drug use

It is no coincidence that many are high alert drug use processes

Assemble a team

- Leader
- Facilitator
- Scribe / Recorder
- Process experts
  - Include all areas involved in the process
- “Outsider” /Naïve person
- 6-10 optimal number

FMEA Process Steps - 2



Handy Hints:

- ✓ Pick a manageable portion of the the process
- ✓ Make sure the topic is narrow enough of a focus (don't try to cure world hunger)
- ✓ FMEA should focus on larger high profile, safety critical areas
  - ➢ Resource intense to analyze and fix
  - ➢ Can apply methodology on other projects without a super team

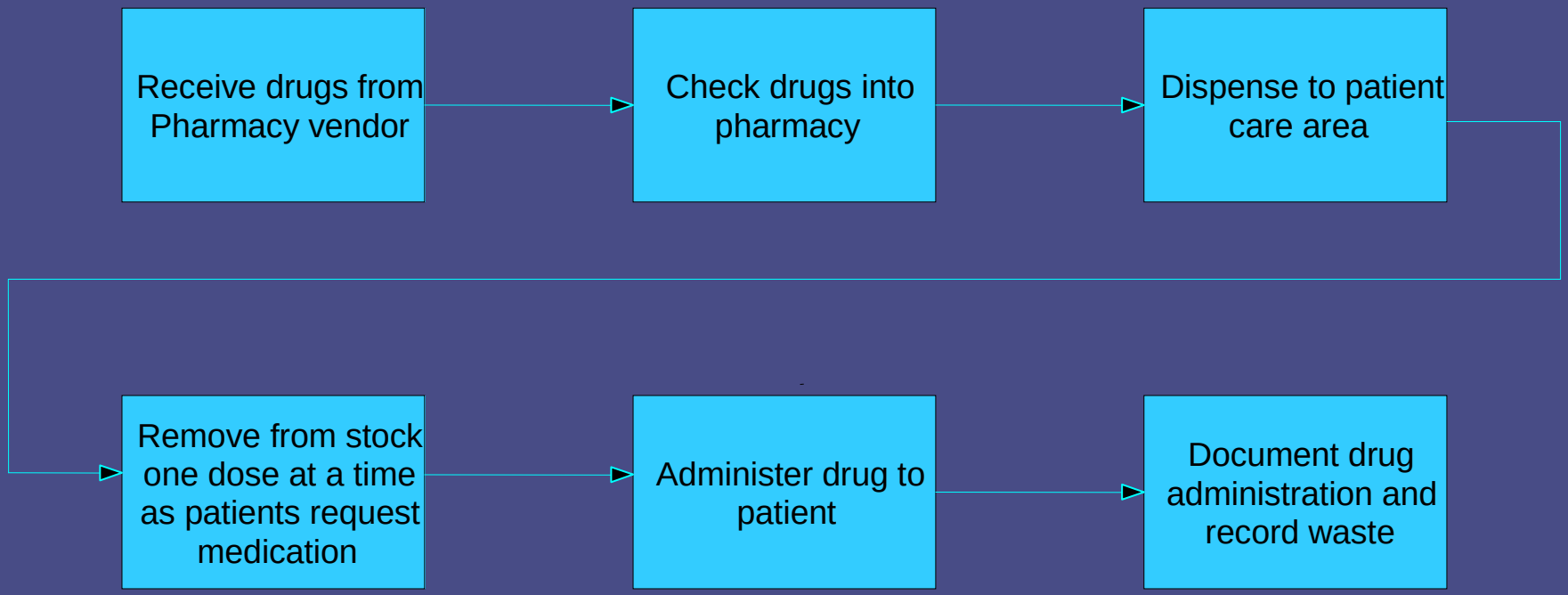
Diagram (flow chart) the process

- Define beginning and end of process under analysis
- Chart the process as it is normally done
- Using the collective process knowledge of the team, a flow chart is sketched.

Why diagram the process?

- Diagrams clarify things between members
- Narrows the topic – goes from broad topic e.g. narcotic use process to narrow topic e.g. morphine removed from narcotic drawer

Narcotic Drug Use Process
Diagram Basic Steps

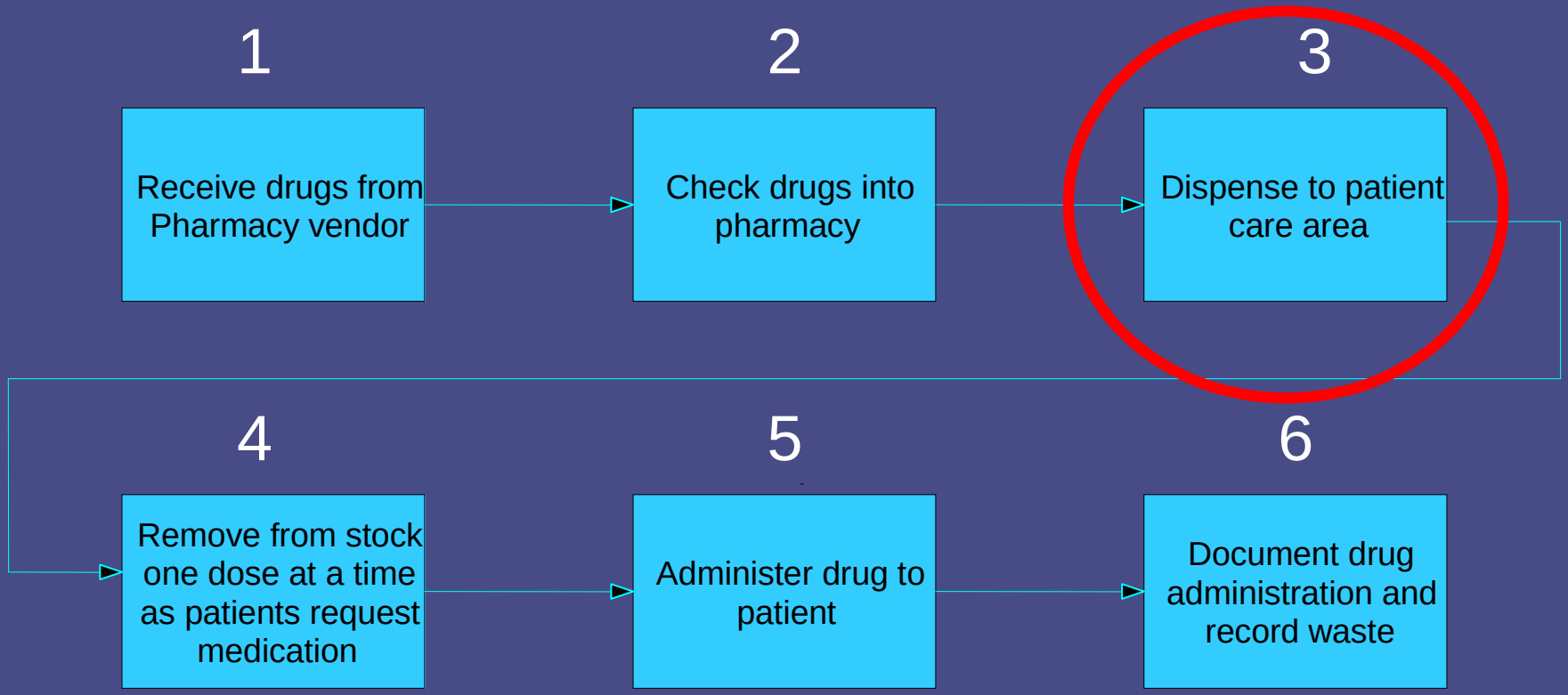


Narcotic Drug Use Process

Number Basic Steps

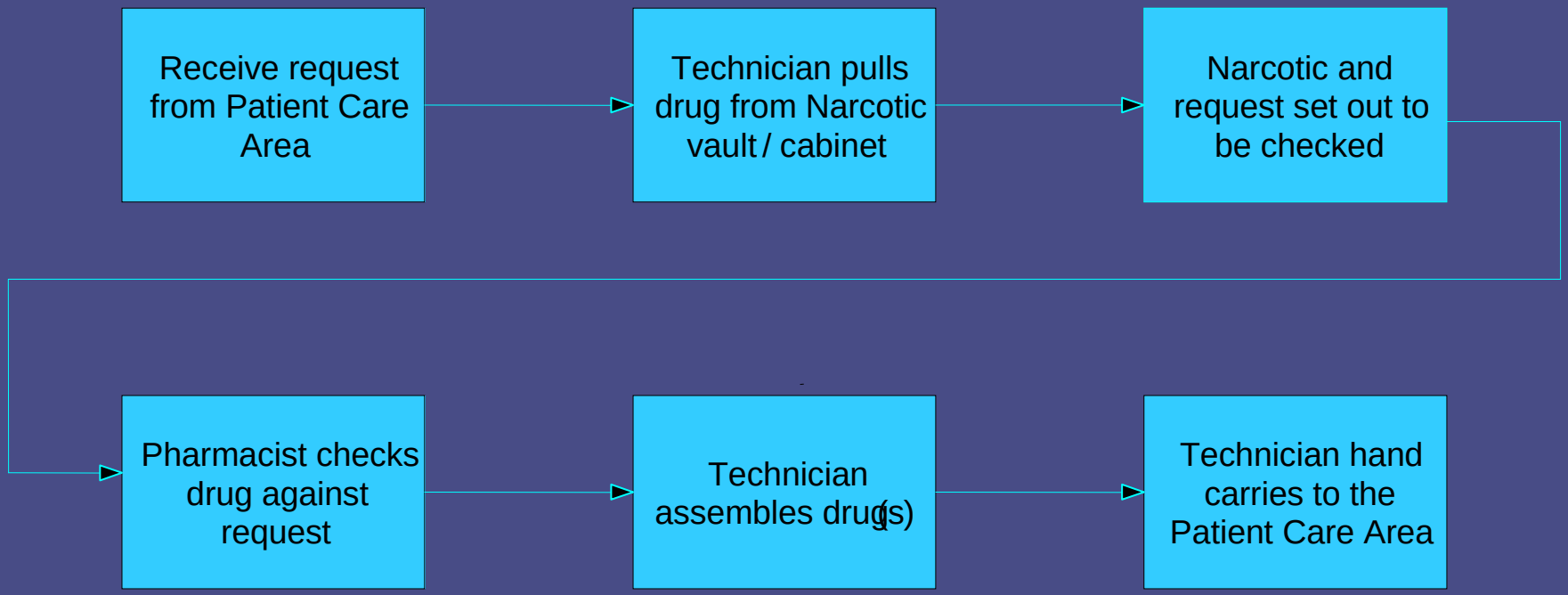
Narcotic Drug Use Process

Select One Portion of Process at a Time to Diagram



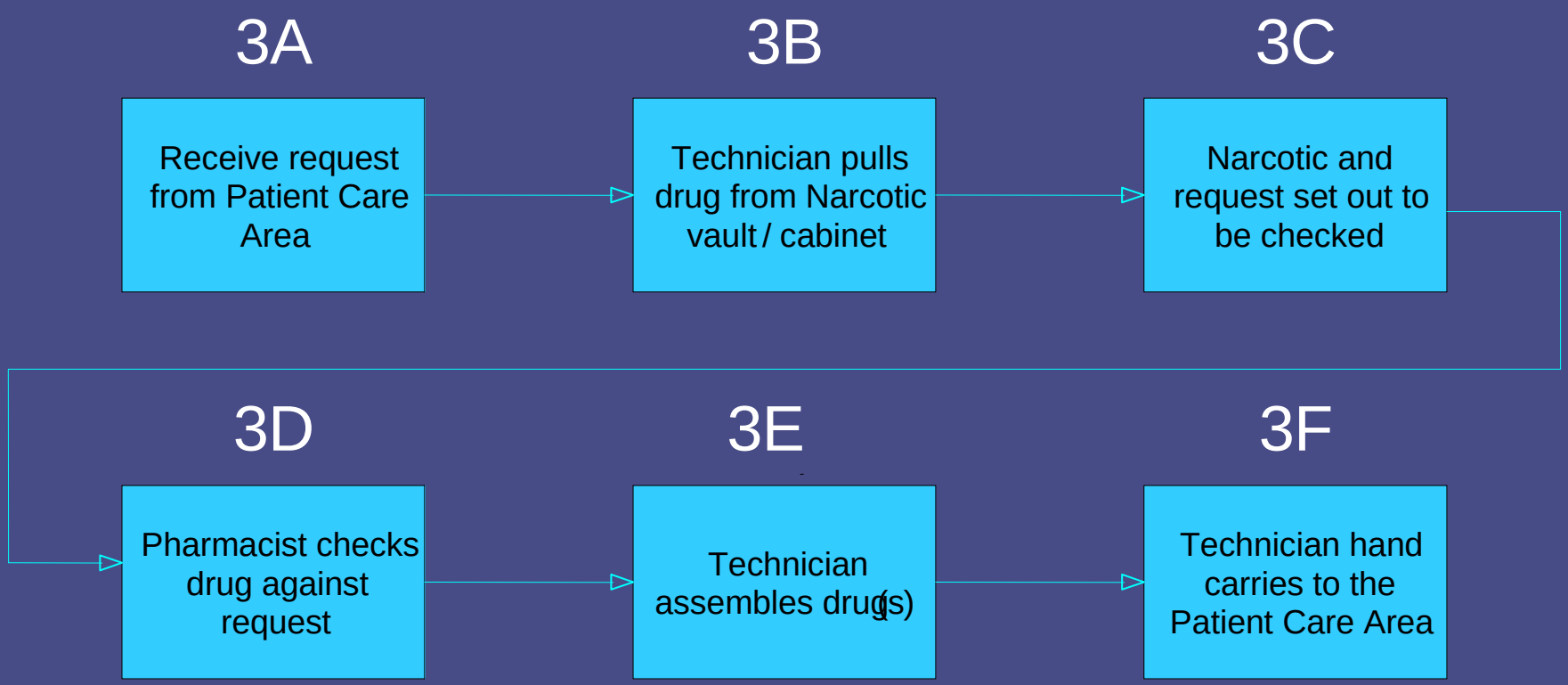
Narcotic Drug Use Process

Diagram the Sub-Process Steps



Narcotic Drug Use Process

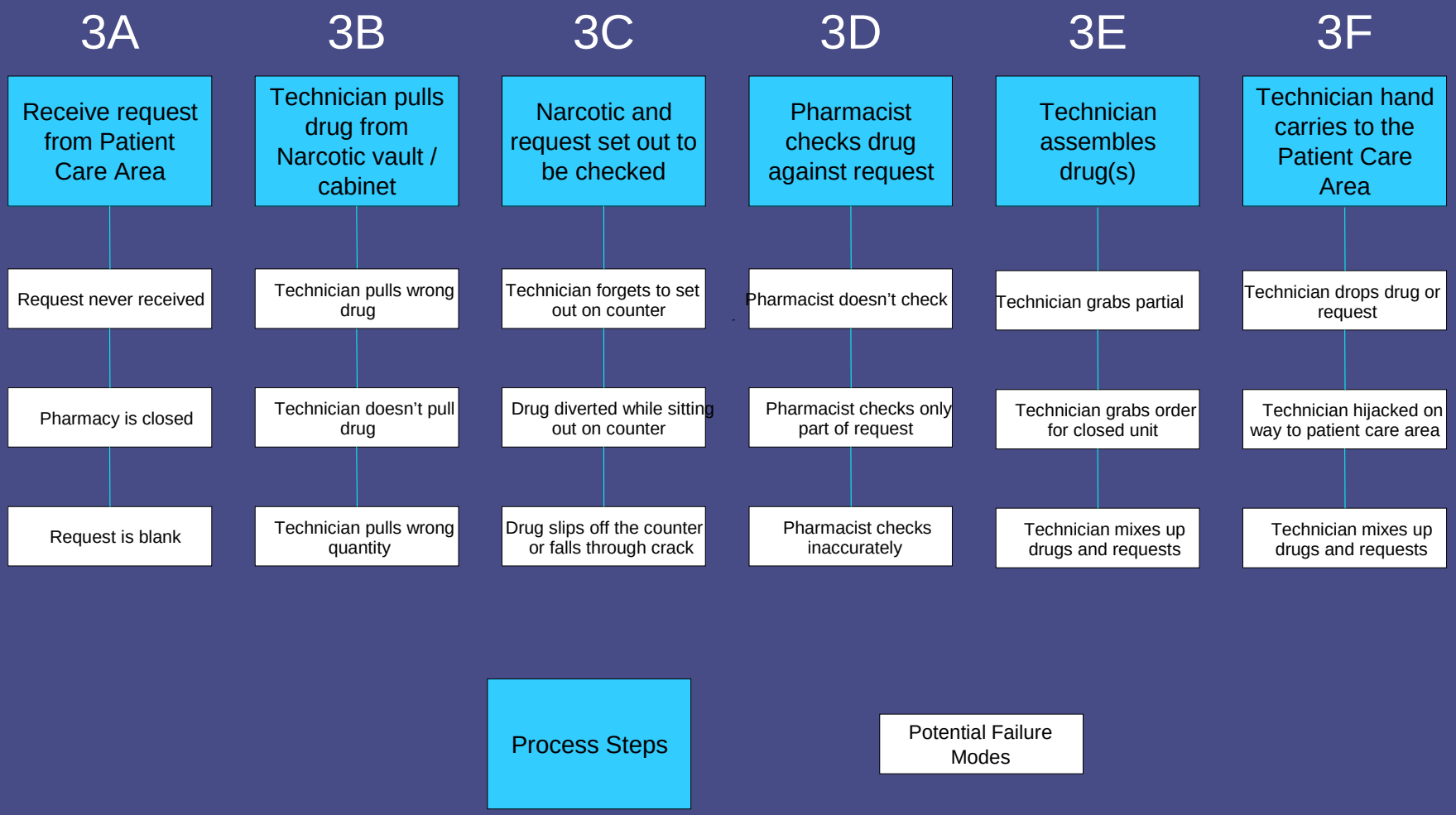
Number the Sub-Process Steps



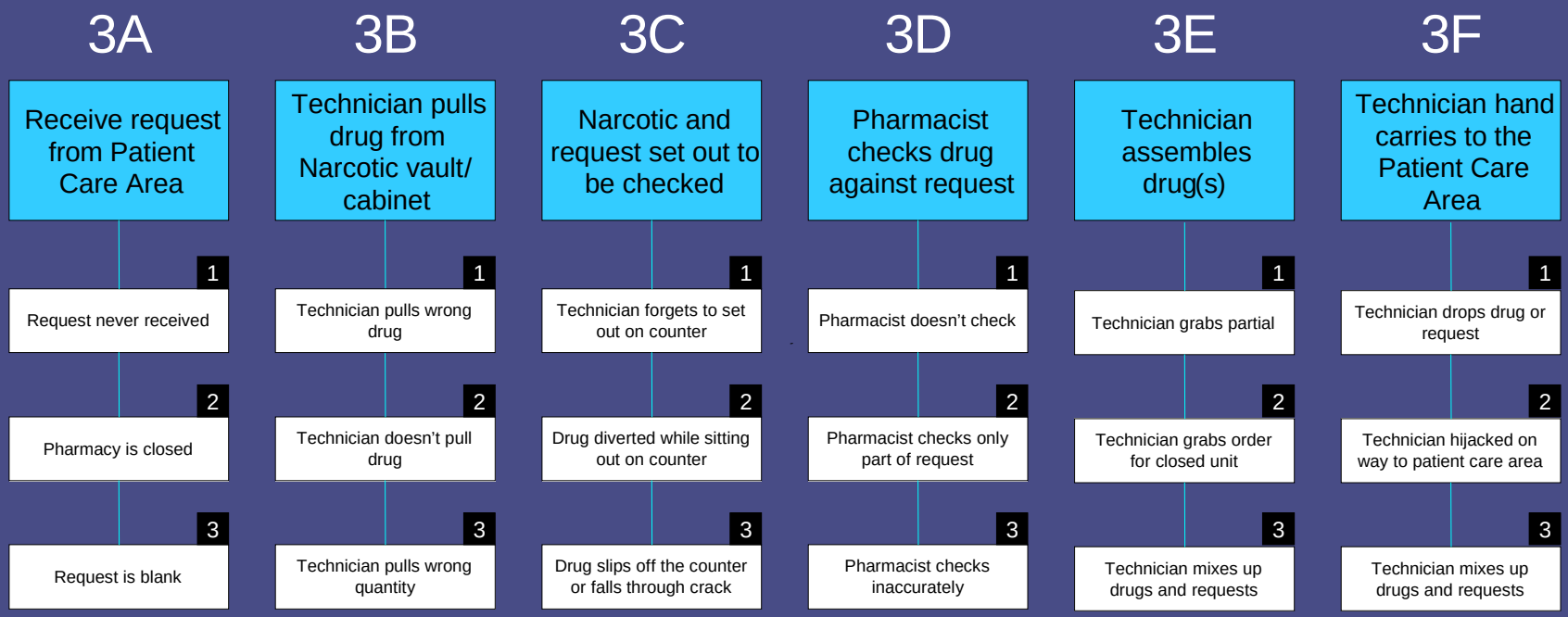
Notes about Diagramming

- Once the diagramming is done, the team may realize that the topic is TOO LARGE
- The team may want to re-define the topic to a more manageable portion of the subject, but the larger diagram will be useful to “see” the interrelation between different parts of the process
- It is not uncommon for the diagrams to be more complex and branched than in our examples here (organization is the key)

Narcotic Drug Use Process
Brainstorm Failure Modes



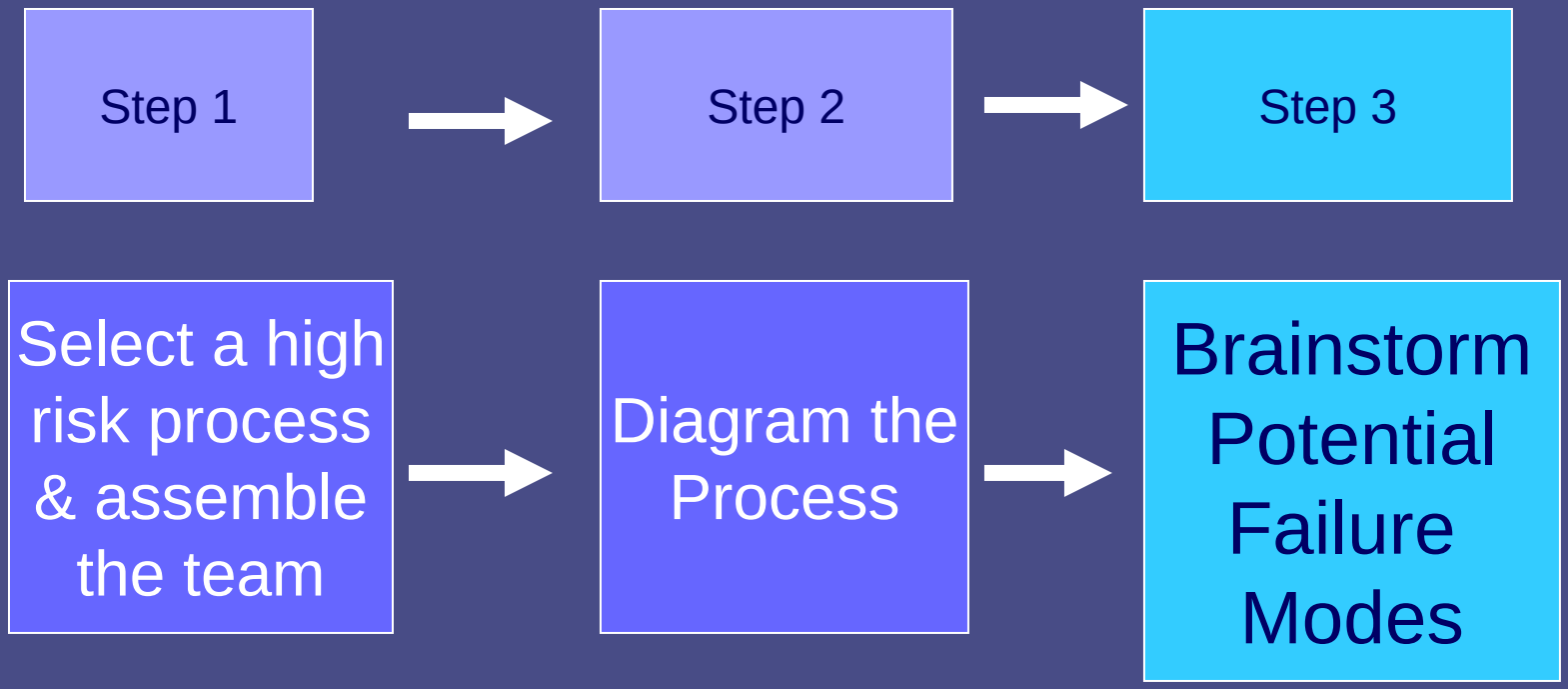
Narcotic Drug Use Process
Number Failure Modes



Process Steps

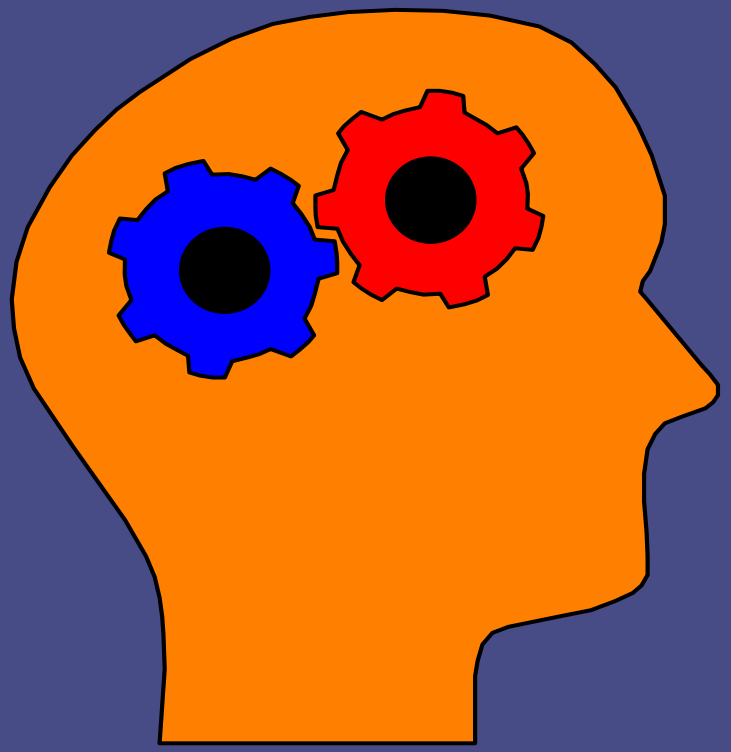
Potential Failure Modes

FMEA Process Steps - 3



Brainstorm potential failure modes

1. People
2. Materials
3. Equipment
4. Methods
5. Environment

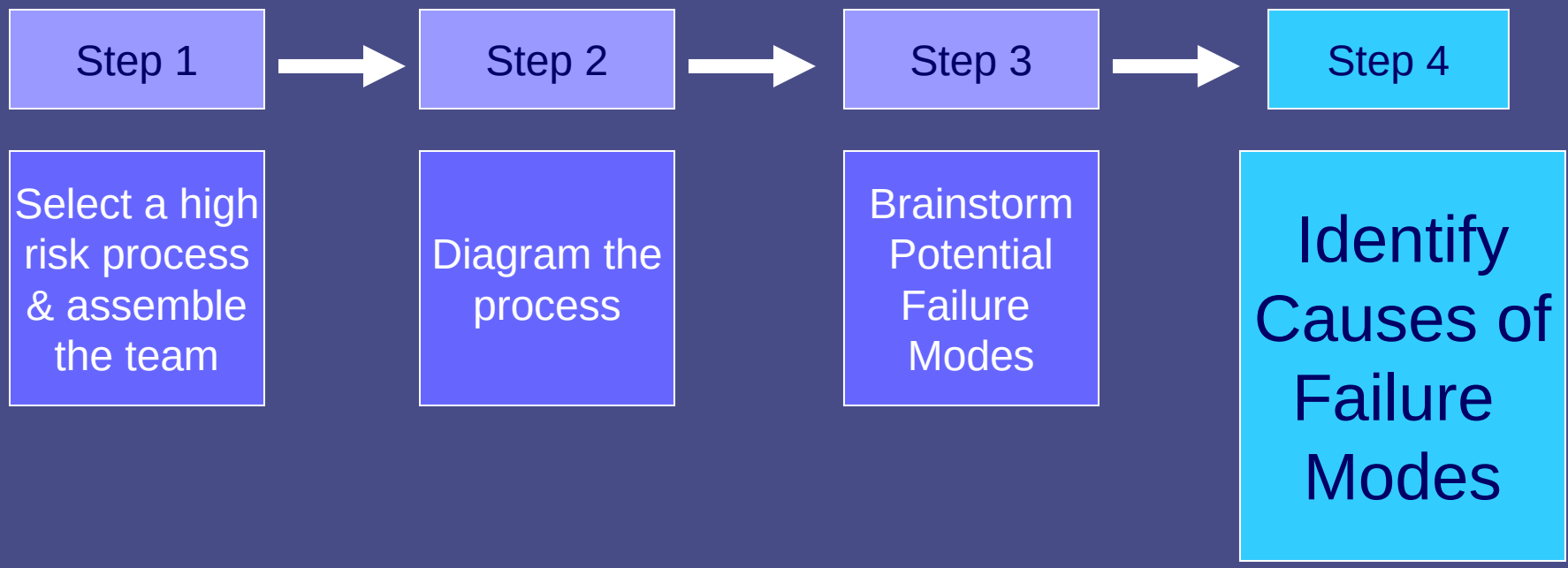


Failure modes answer the <u>WHAT</u> could go wrong question

Handy Hints

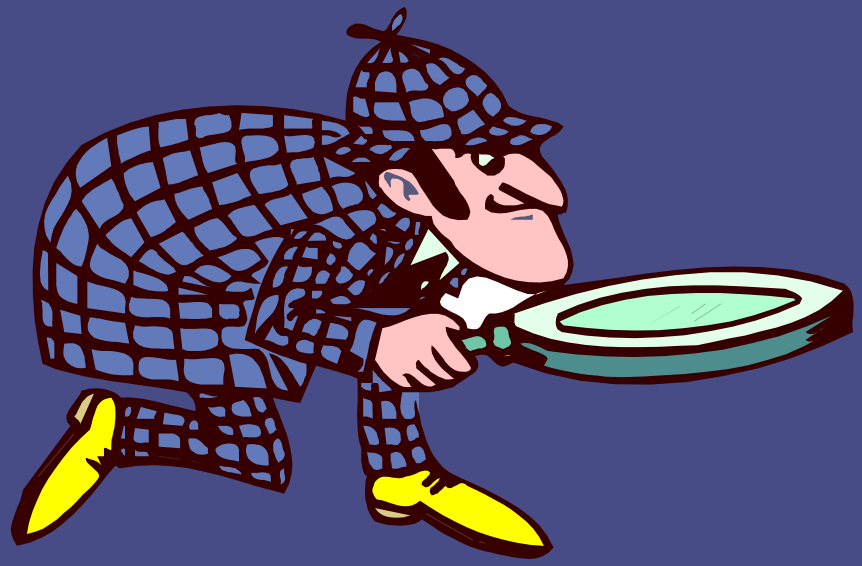
- ✓ Failure Modes are the WHATs that could go wrong
- ✓ ***Failure Mode Causes are the "WHY"s***
  - ✓ ***May be more than one cause for each failure***

FMEA Process Steps - 4



Identify root causes of failure modes

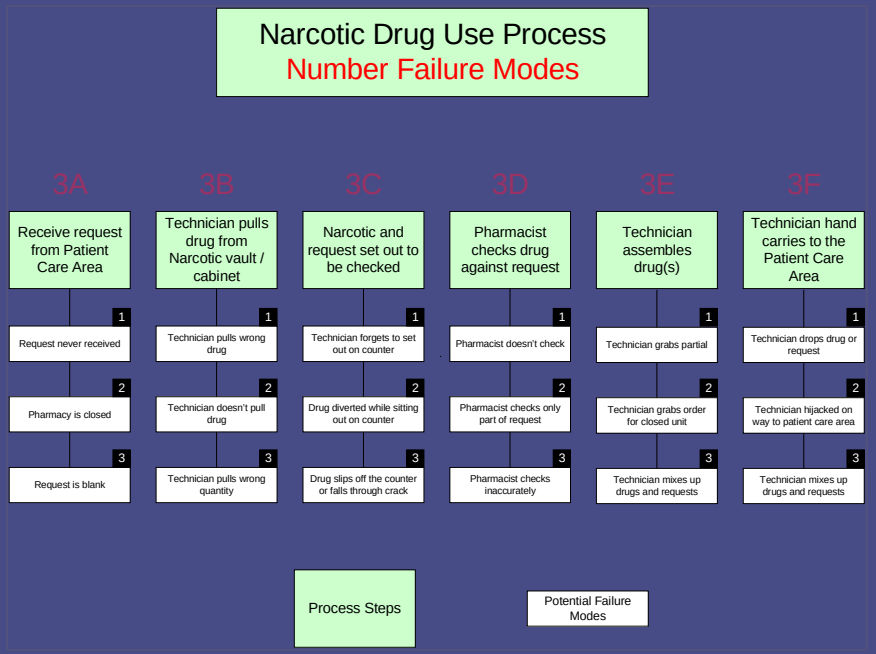
- Focus on systems & processes, not individuals
- Asks why?, not who?
- Prospective application of RCA
- Critical to identify ***all*** root causes and their interactions



Practice Session ONE

- For your sub-process brainstorm the potential failure modes of at least one step
- Finish one process step before moving on to the next process step
  - Use sticky notes for failure modes
- Next brainstorm the causes of the failure modes
  - Use different coloured sticky notes for the causes
- Be ready to de-brief the results to the other groups

Transfer the Failure Modes from the diagram to the spreadsheet



Failure Mode Number	Potential Failure Mode Description	Single Point Weakness?	Potential Cause(s) of Failure	Potential Effect(s) of Failure
1	Technician pulls wrong drug			
2	Technician doesn't pull drug			
3	Technician pulls wrong quantity			

Hint: be careful to keep the numbering!

Transfer Failure Modes on to Spreadsheet

Process Step Number: 3 B Technician pulls drug from Narcotic vault / cabinet				
Failure Mode Number	Potential Failure Mode Description	Single Point Weakness?	Potential Cause(s) of Failure	Potential Effect(s) of Failure
1	Technician pulls wrong drug			
2	Technician doesn't pull drug			
3	Technician pulls wrong quantity			

Single Point Weakness

- A step so critical that it's failure will result in a system failure or adverse event
- Single point weaknesses and existing control measures "modify" the scoring
  - Single point weaknesses should all be acted upon
  - IF effective control measures are in place, it would cancel the need to take further action (risk is mitigated)

Evaluate if the failure modes are single point weaknesses

Process Step Number: 3 B Technician pulls drug from Narcotic vault / cabinet				
Failure Mode Number	Potential Failure Mode Description	Single Point Weakness?	Potential Cause(s) of Failure	Potential Effect(s) of Failure
1	Technician pulls wrong drug	N		
2	Technician doesn't pull drug	N		
3	Technician pulls wrong quantity	N		

Single Point Weakness: ***A step so critical that it's failure will result in a system failure or adverse event***

Evaluate the CAUSE(S) of the failure

Process Step Number: 3 B Technician pulls drug from Narcotic vault / cabinet

Failure Mode Number	Potential Failure Mode Description	Single Point Weaknes	Potential Cause(s) of Failure	Potential Effect(s) of Failure
1	Technician pulls wrong drug	N	Look alike packaging	
			Storage location too proximal	
2	Technician doesn't pull drug	N	Form is hand written and not very legible	
			Technician is distracted	
3	Technician pulls wrong quantity	N	packages are in random order	

Effects of the Failure Modes

- Review each failure mode and identify the effects of the failure should it occur
- May be 1 effect or > 1
- Must be thorough because it feeds into the risk rating
- ***If*** failure occurs, ***then what*** are the consequences

Evaluate the EFFECT(S) of the failure

Process Step Number: 3 B Technician pulls drug from Narcotic vault / cabinet				
Failure Mode Number	Potential Failure Mode Description	Single Point Weakness?	Potential Cause(s) of Failure	Potential Effect(s) of Failure
1	Technician pulls wrong drug	N	Look alike packaging	Patient receives wrong drug
2	Technician doesn't pull drug	N	Storage location too proximal	Nursing unit runs out of drug
3	Technician pulls wrong quantity	N	Form is hand written and not very legible	Nursing unit is over or under stocked
			Technician is distracted	
			packages are in random order	

FMEA Process Steps - 5

Step 1	Step 2	Step 3	Step 4
Select a high risk process & assemble the team	Diagram the process	Brainstorm Potential Failure Modes	Identify Causes of Failure Modes

Step 5
Brainstorm Effects & Prioritize Failure Modes Calculate RPN

Prioritize failure modes

- Score frequency of failure mode
- Score detectability of failure prior to the impact of the effect being realized
- Score severity of effect of failure mode

Frequency

- Also known as occurrence – it is the likelihood or number of times a specific failure (mode) could occur

Frequency Description	Score
Yearly	1
Monthly	2
Weekly	3
Daily	4
Hourly	5

Detectability

The likelihood of detecting a failure or the effect of a failure BEFORE it occurs

Detectability Description	Score
Always	1
Likely	2
Unlikely	3
Never	4

Many events are detectable or obvious after they occur but that is not a FMEA detectable event by definition.

Examples of Detectability

- Break away locks
- Emergency drug boxes with pop up pin
- Ampoules
- Low battery alarm

Severity

The seriousness and severity of the effect (to the process or system or patient) of a failure if it should occur.

Severity Description	Score
No effect	1
Slight	2
Moderate	3
Major	4
Severe / Catastrophic	5

Score based upon a "reasonable worst case scenario"

If severity = 5 … always address it

e.g. Potassium Chloride (KCl)

The severity = 5 but the frequency = 1

Calculate the Risk Priority Number

- Determine the impact of the failure on the patient or the system using the severity, frequency and detectability parameters
- Multiply three scores to obtain a Risk Priority Number (RPN) or Criticality Index (CI)
- Also assign priority to those with a high severity score even though the RPN may be relatively low

RPN = Severity x Frequency x Detectability

Handy Hints

- ✓ Use group discussion and the expertise of the team members
- ✓ Since ratings are multiplied, one or two points can have a significant impact on RPN. Don't agree just to keep the process going
- ✓ Talk things out
- ✓ If no consensus is reached, the team should use the higher rating. (better to have more work than to miss a severe failure mode)
- ✓ Use a "reasonable worst case" scenario

Practice Session –TWO

1. Brainstorm potential failure effects
2. Assign a number to:
   - Frequency,
   - Detectability
   - Severity,
3. Determine the RPN number for the failures you identified
   - Use the flipchart or form
   - Be prepared to debrief

RPN

- FREQUENCY → 1 ~ Yearly, 5 ~ Hourly
- DETECTABILITY → 1 ~ Always, 4 ~ Never
- SEVERITY → 1 ~ No Effect, 5 ~ Severe

Assess current controls, determine the impact of the failure and prioritize them

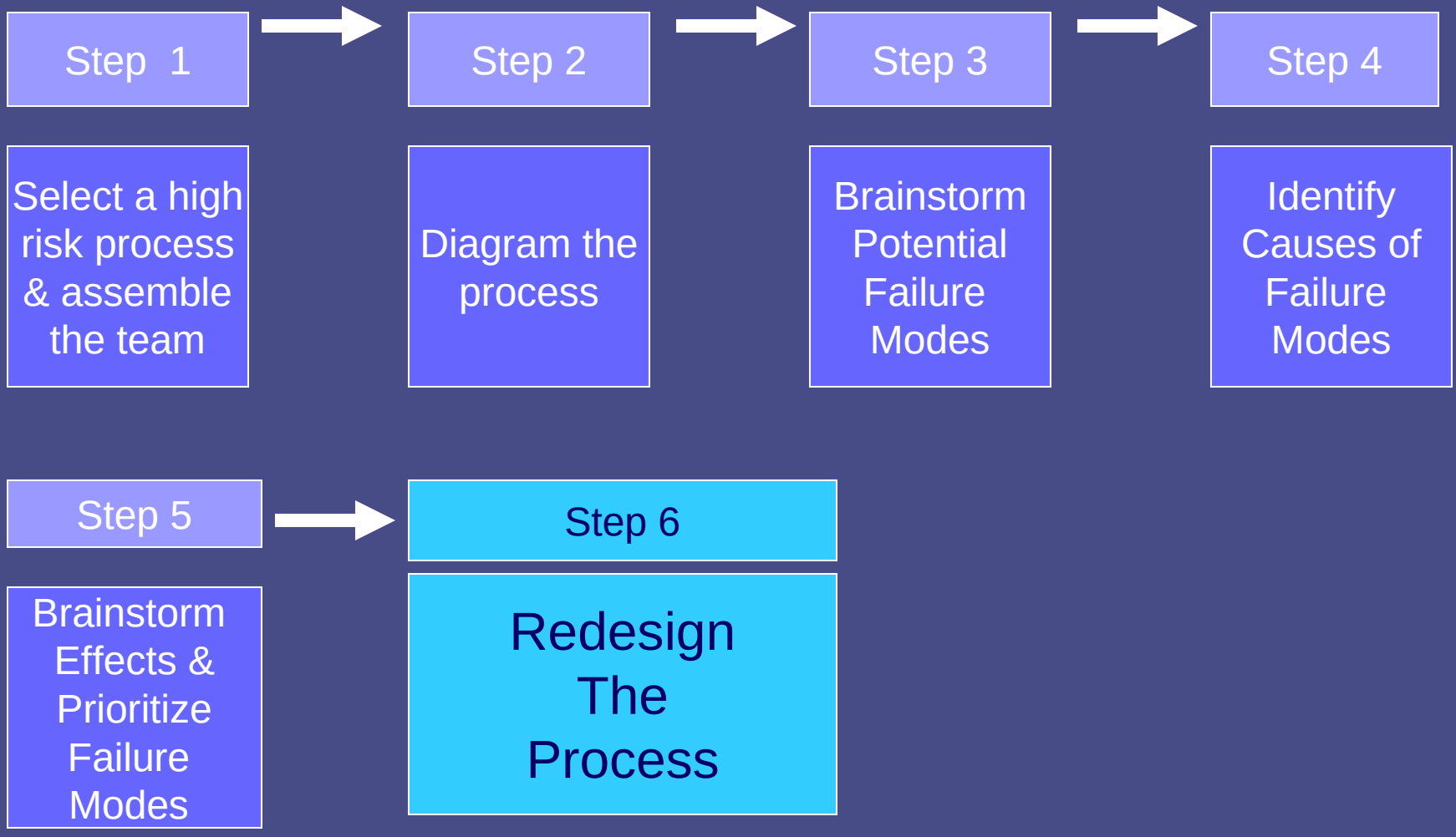
FMEA Subject: Narcotic Drug Distribution

Process Step Number: 3 B Technician pulls drug from Narcotic vault / cab | Process Step Description:

Failure Mode Number	Potential Failure Mode Description	Single Point Weakness	Potential Effect(s) of Failure	Potential Cause(s) of Failure	Effective Control Measure in Place	Severity	Frequency	Detection	RPN	Action / OR reason for not acting	Who is responsible?
1a	Technician pulls wrong drug	N	patient receives wrong drug	Look alike packaging	N	5	3	4	60		
1b				Storage location too proximal	N	5	2	2	20		
2a	Technician doesn't pull drug	N	nursing unit runs out of drug	Form is hand written and not very legible	N	2	4	2	16		
2b				Technician is distracted	N	2	4	3	24		
3a	Technician pulls wrong quantity	N	over or under stocked	packages are in random order	N	2	4	3	24		

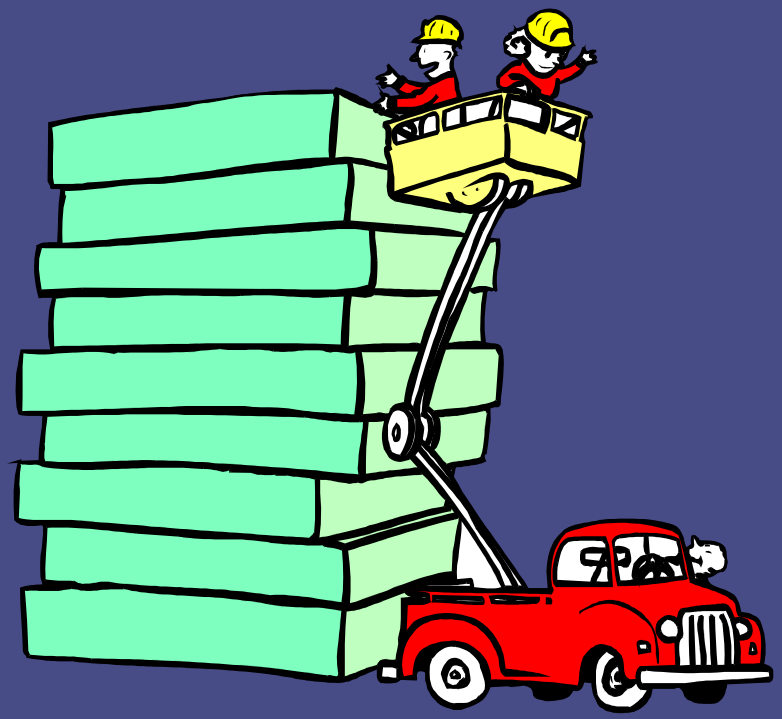
In a real FMEA, a spreadsheet can be sorted in numerical order by RPN

FMEA Process Steps - 6



Redesign the process

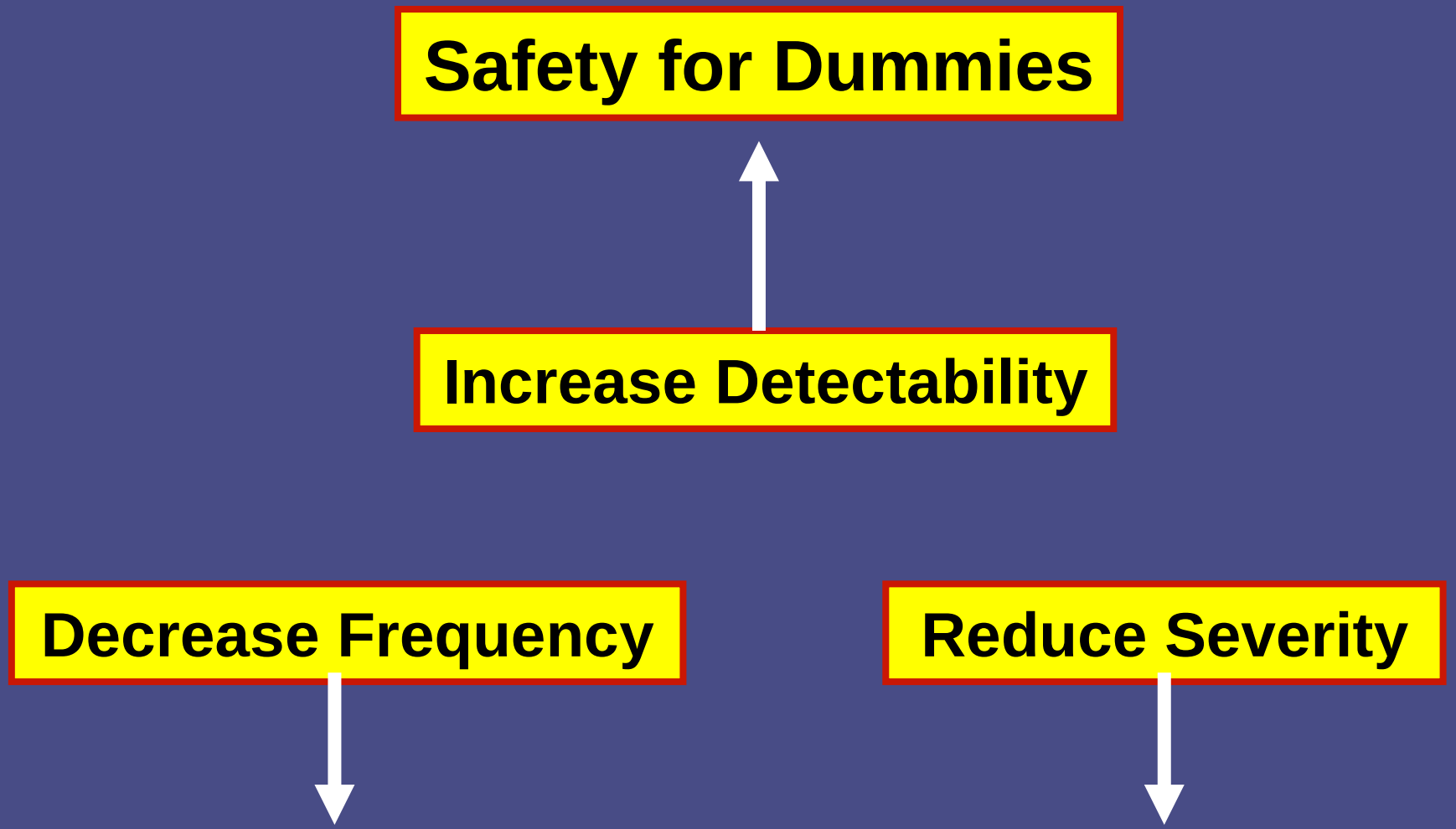
- Apply strategies to decrease frequency, decrease severity, or increase detection
- Goal: prevent harm to the patient
- Simplification, automation, standardization, fail-safe mechanisms, forcing functions, redundancy



Evaluating Redesign Options

- Don’t just pick training and policy development. They are basic actions but not very strong or long lasting.
- Go for the permanent fixes when possible.
- Elimination of the step or the function is a very strong action.
- Most actions are really controls on the system.
- Sometimes your team might have to accept some of the failure modes as “un-fixable”.

Three ways to improve safety



HFE Strength of possible actions

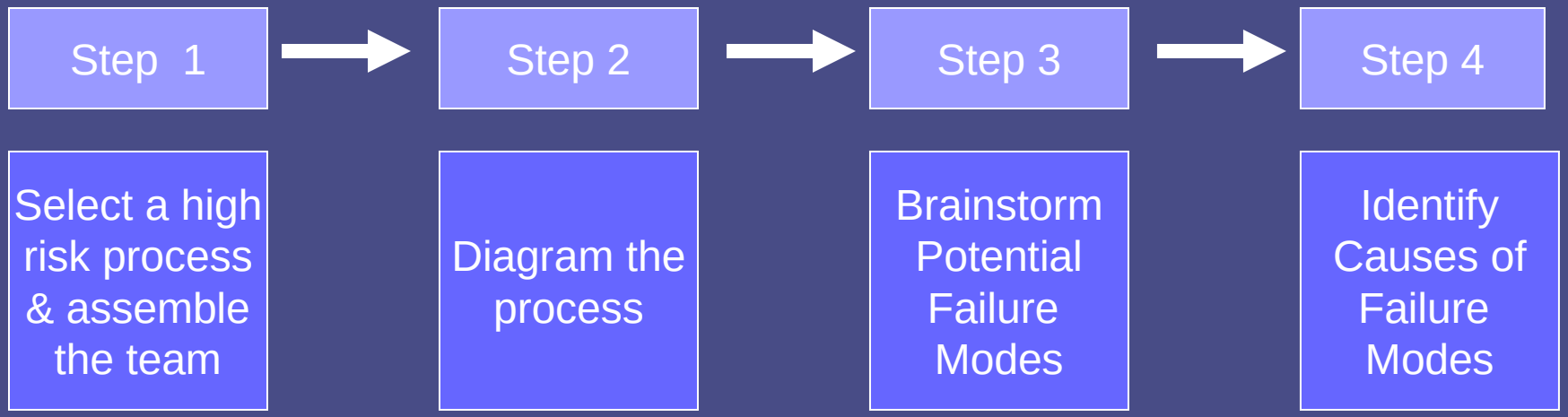
- Use stronger actions where possible
  - Physical and architectural over policy and training
  - Check lists, forcing functions
  - Standardization, simplification
  - Cognitive aids, usability testing

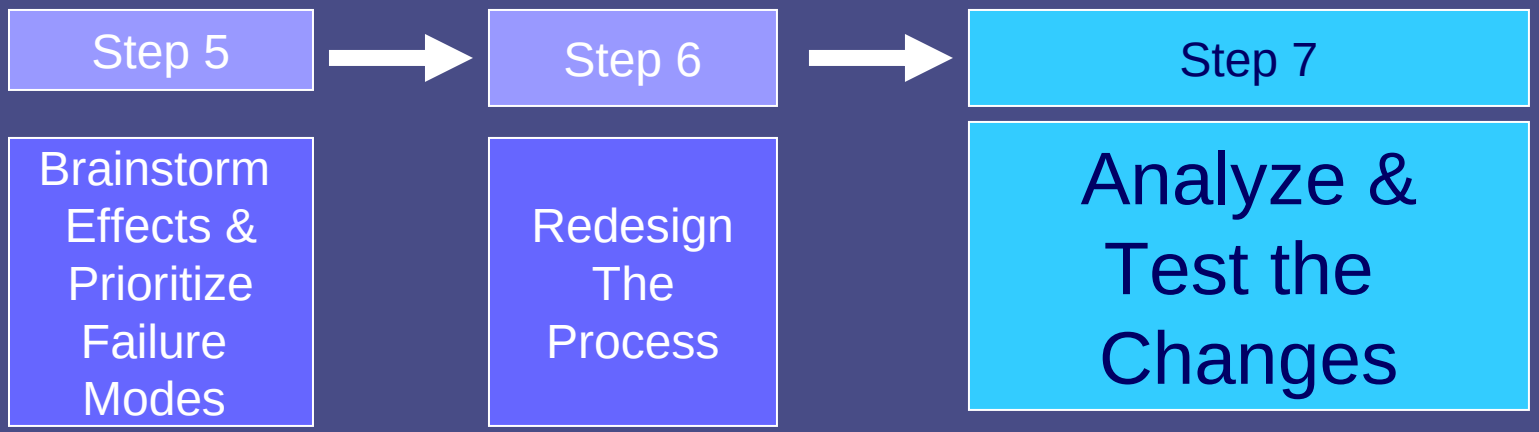
FMEA Subject: Narcotic Drug Distribution

Process Step Number: 3 B Technician pulls drug from Narcotic Vault Process Step Description:

Failure Mode Number	Potential Failure Mode Description	Single Point Weakness?	Potential Effect(s) of Failure	Potential Cause(s) of Failure	Effective Control Measure in Place	Severity	Frequency	Detection	RPN	Action / Date OR reason for not acting	Who is responsible?
	Technician pulls wrong drug	N	patient receives wrong drug	Look alike packaging	N	5					CS Pharmacist
1				Storage location too proximal	N	5	2	2	20	As above	CS Pharmacist
2	Technician doesn't pull drug	N	nursing unit runs out of drug	Form is hand written and not very legible	N	2	4	2	16	Implement pre-printed par level order form by 7/31/04	CS Pharmacist
2				Technician is distracted	N	2	4	3	24	Implement balance sheet (order lines = dispense lines) by 7/31/04 Par level process	CS Pharmacist
3	Technician pulls wrong quantity	N	nursing unit is over or under stocked	packages are in random order	N	2	4	3	24	will solve this (ordering in standard quant)	CS Pharmacist

FMEA Process Steps - 7



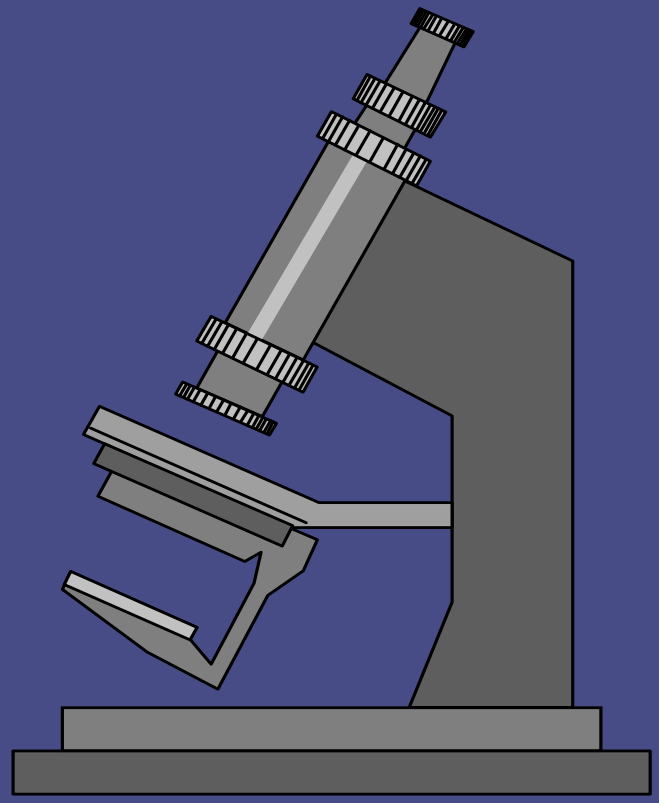


Practice Session –THREE

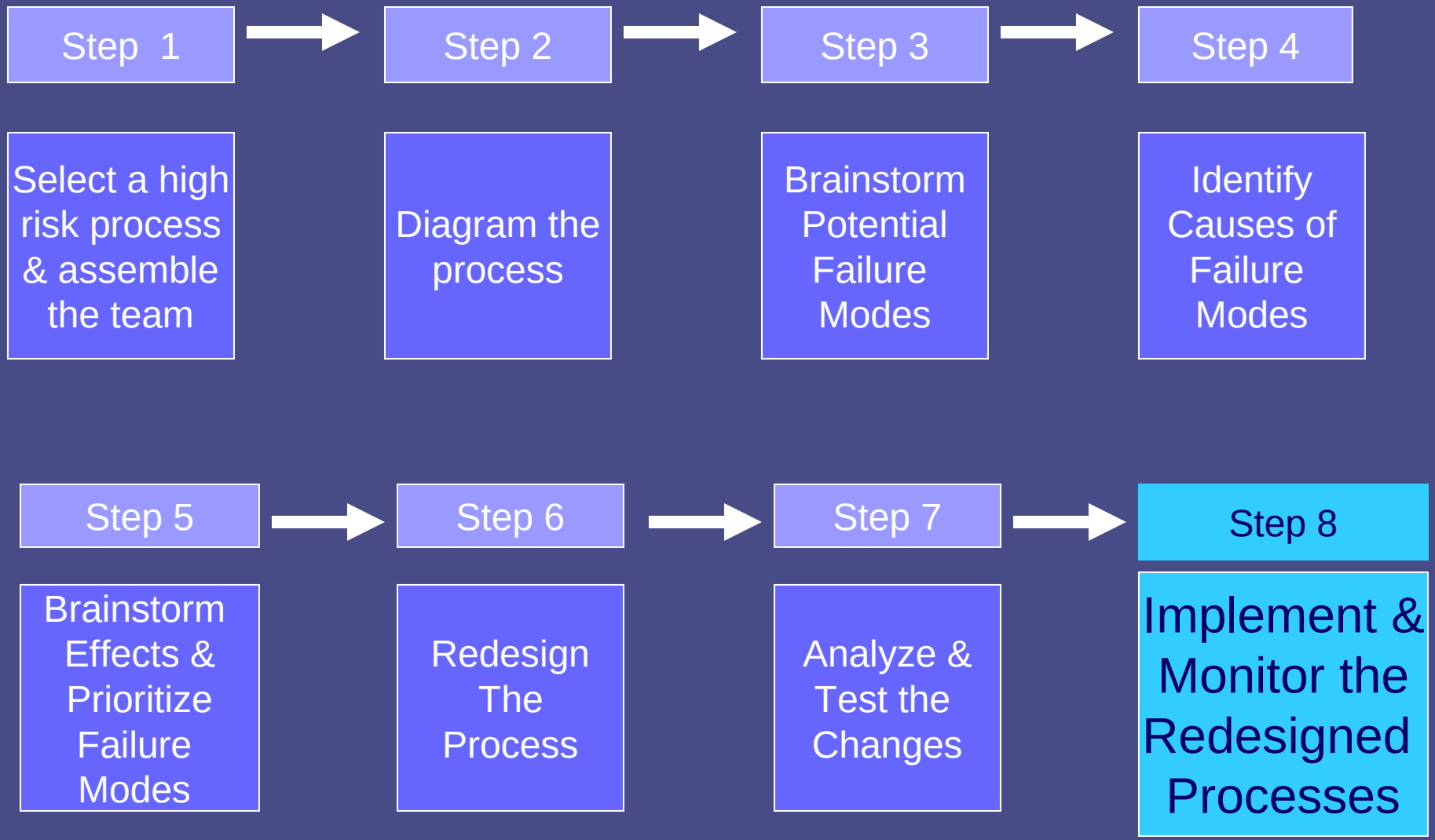
- For the highest RPN's identified, brainstorm actions for change
- Use high leverage strategies as much as possible
- Identify responsibility for action

Analyze and test the changes

- Conduct FMEA of re-designed process
- Use simulation testing whenever possible
- Conduct pilot testing in one area or one section

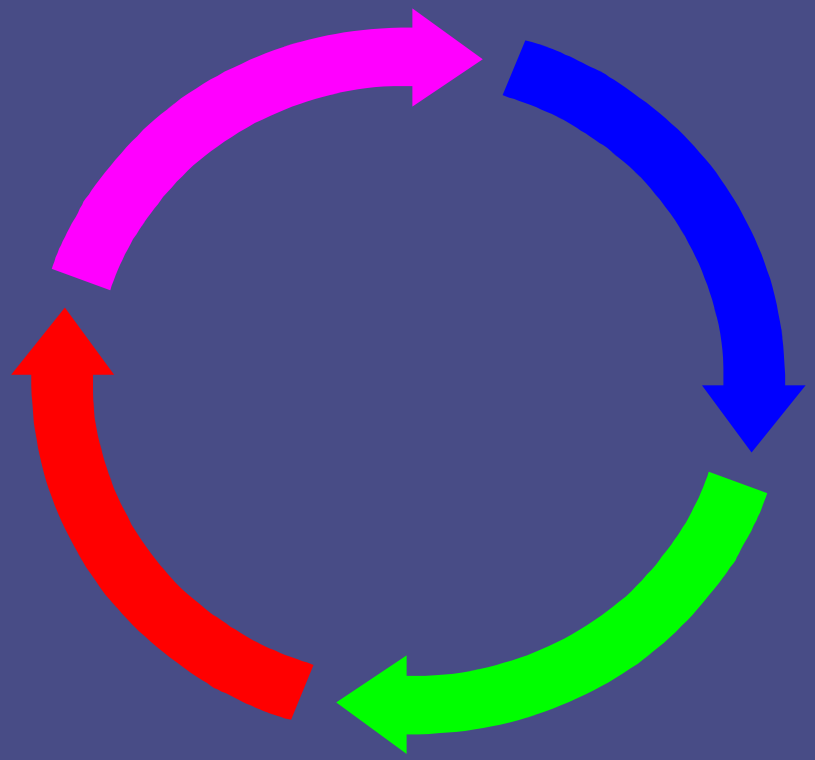


FMEA Process Steps - 8



Implement and monitor the redesigned process

- Communicate reasons for process changes
- Find change agents
- Define process and outcome measures
- Share results
- Monitor over time



Tips (gold nuggets)

- Start small and get success early on
- Narrow Narrow Narrow
- Can use different team members from the same department for different parts of the process (substitution of team players) versus RCA not able to do that

Beware of Stagnation

- Reasons FMEA projects might stagnate:
  - We have never done it that way
  - We are not ready for that yet
  - We are doing all right without it
  - We tried it once and it did not work
  - It costs too much
  - That is not our responsibility
  - It would not work around here anyway

Gains using FMEA

- Safety minded culture
- Proactive problem resolution
- Robust systems
- Fault tolerant systems
- Lower waste and higher quality

‘Emphasis on prevention may reduce risk of harm to both patients and staff.’

Failure Modes and Effects Analysis (FMEA), IHI and Quality Health Care.org, 2003

References

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