



Toronto Rehab

*Advancing Rehabilitation
Enhancing Quality of Life*

Failure Modes Effects Analysis (FMEA)

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September 26, 2005

Agenda

- Introduction to FMEA
 - History
 - Applications in health care
- Creating an FMEA
 - Map a process
 - Break the process apart
 - Review each section of the process for failures
 - Assign Values



What is FMEA?

- Failure Modes Effect Analysis is a method for analyzing any process to:
 - see where it is likely to fail
 - see how changes you are considering might affect the safety of the process
 - track impact of changes to risk over time



What does an FMEA Provide?

- a structured method to review and confirm processes
- a structured risk analysis
- is proactive
- helps prioritize and identify areas requiring increased attention



Failure Modes Effects Analysis

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



Questions Raised

- Can we make the process better?
- Is there a systematic method of evaluating our current system?
- Is there a way that we can evaluate a new system before implementation?



History of FMEA

- Used for aerospace development in 1940s - 1960s
- Ford Motor Company reintroduced FMEA in late 1970s
 - Safety and regulatory consideration after “Pinto” affair
 - Ford also used FMEAs effectively for production improvement as well as design improvement



Applicability of FMEA to Health Care

- Accreditation Requirements
- Medication Safety
 - Physician Ordering
 - Pharmacy Dispensing
 - Nursing Administration
- Falls prevention
- Computerized Physician Order Entry
- Compliance with Best Practice Guidelines



Applicability of FMEA to Health Care

- Patient registration and scheduling
- Reduce risk of delayed or missed treatment due to missing lab report
- Possible outcomes of decreased staffing
- Equipment evaluation and usage
 - IV pumps
 - Surgical Equipment



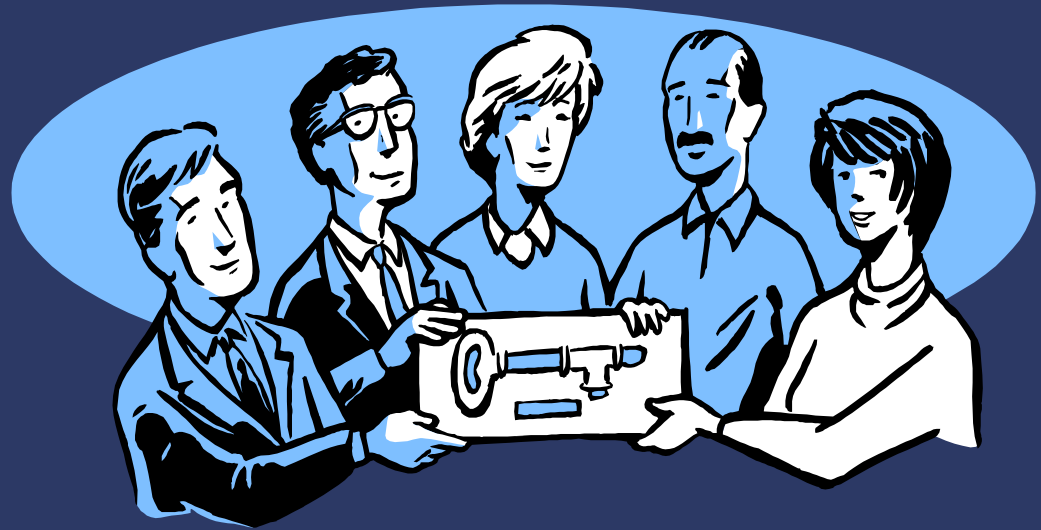
Creating your own FMEA Multi-Disciplinary Team

- Select a process to evaluate with FMEA
- Recruit a multidisciplinary team
- Critical to have the right people on the team
- Front line vs. Management
- Set aside time in 1.5hour increments
- Tedious hard to remain focused

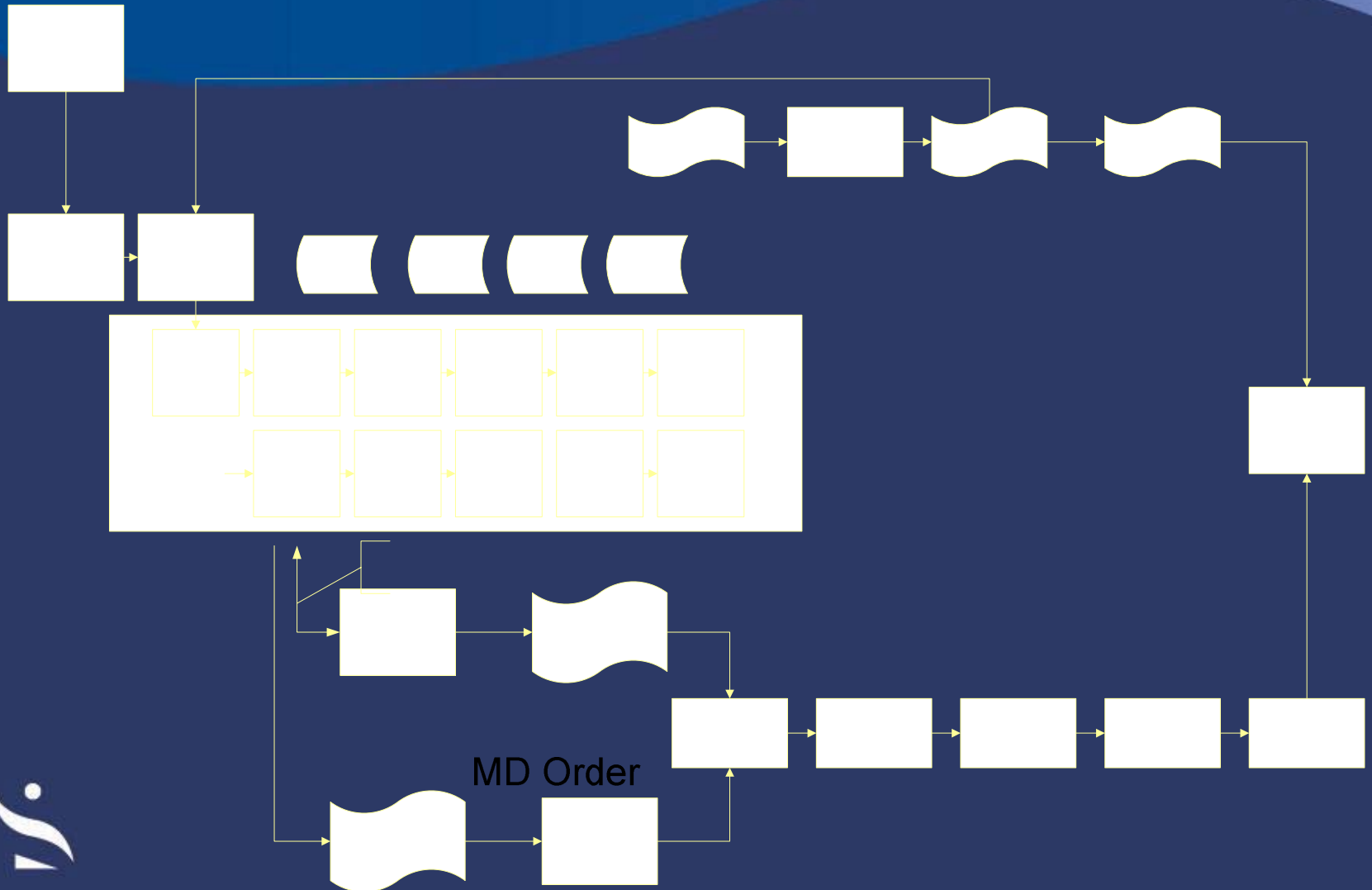


Team Activity

- Meet together to map all the steps in the process

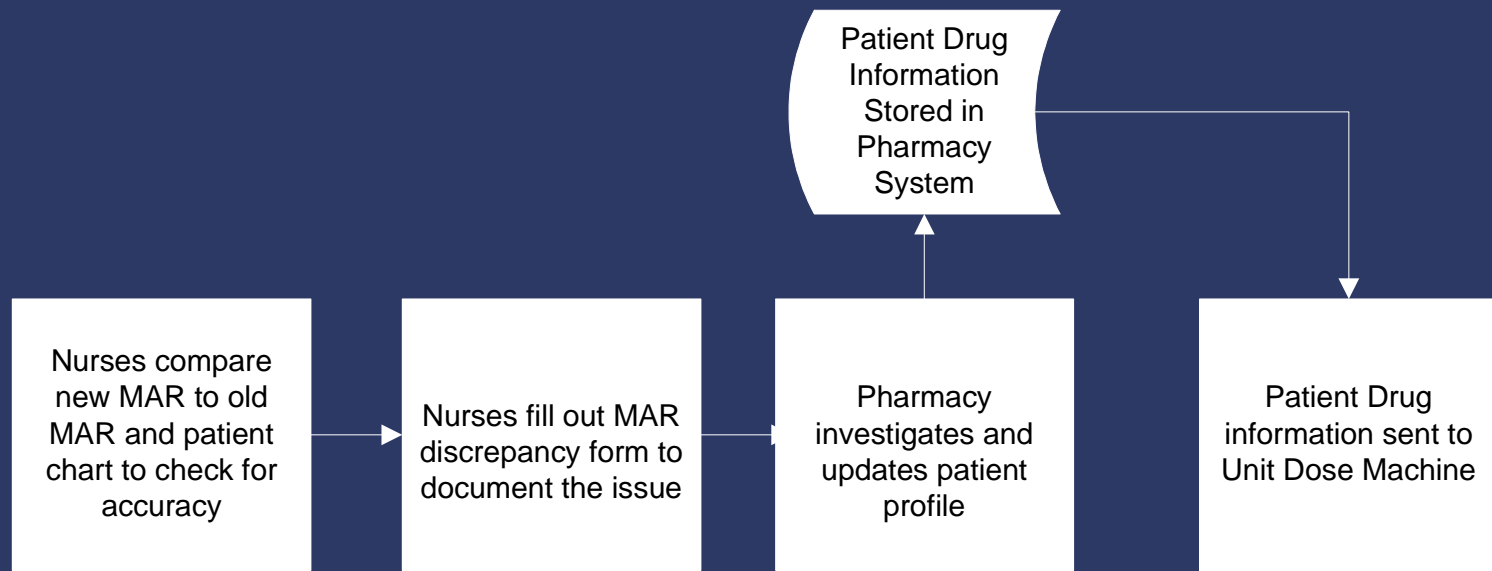


Map a Process



Take a Process Excerpt

MAR PROCESS: 'To Be'



Team Activity

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



FMEA Process MAR

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Priority Number	Actions to Reduce Occurrence of Failure

Failure Mode: What could go wrong
Failure Cause: Why would the failure happen
Failure Effects: What would be the consequences of the failure
Likelihood of Occurrence: 1-10, 10=very likely to occur
Likelihood of Detection: 1- 10, 10= very unlikely to detect
Severity: 1-10, 10 most sever effect



Creating your own FMEA

- For each failure mode, assign a number for:
 - Likelihood of occurrence (1-10)
 - 10=very likely to occur
 - Likelihood of detection (1-10)
 - 10= very UNlikely to detect
 - Severity (1-10)
 - 10=most severe effect



FMEA

- Takes 3 dimensions:
 - Likelihood (probability)
 - Severity (impact)
 - Detection

And assigns a value (RPN)

= Likelihood X Severity X Detection



Creating your own FMEA

- Evaluate the results
 - Multiply numbers to get a Risk Priority Number (RPN)
 - Total RPN is the sum of all steps and failure mode RPNs



FMEA Process MAR

Nurses fill out MAR discrepancy form to document the issue

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
MAR Discrepancy sheet completed and returned to pharmacy								
Complete sheet	Failure to complete sheet accurately	human error, no form	ADE, Increased LOS, Death	9	2	7	126	
	Failure to complete sufficiently, incomplete	human error, no form, lack of resources	ADE, Increased LOS, Death	9	6	7	378	

Failure Mode: What could go wrong
 Failure Cause: Why would the failure happen
 Failure Effects: What would be the consequences of the failure
 Likelihood of Occurrence: 1-10, 10=very likely to occur
 Likelihood of Detection: 1- 10, 10= very unlikely to detect
 Severity: 1-10, 10 most sever effect

Process that may require increased attention



Targeting Areas for Improvement

- Prioritize improvement efforts based on RPN
 - Focus on failure modes with high RPNs

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
MAR Discrepancy sheet completed and returned to pharmacy								
Complete sheet	Failure to complete sheet accurately	human error, no form	ADE, Increased LOS, Death	9	2	7	126	
	Failure to complete sufficiently, incomplete	human error, no form, lack of resources	ADE, Increased LOS, Death	9	6	7	378	



Targeting Areas for Improvement

- Consider individual RPN components as well
 - Reduce severity first –most important component
 - Pay special attention to 9 and 10 regardless of total RPN
 - Then occurrence – has greatest overall benefit
 - Then detection – be sure to test effectiveness

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
MAR Discrepancy sheet completed and returned to pharmacy								
Complete sheet	Failure to complete sheet accurately	human error, no form	ADE, Increased LOS, Death	9	2	7	126	
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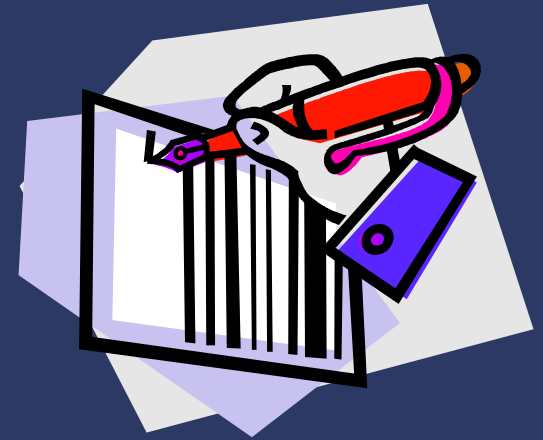
Plan Actions to Reduce Harm from Failure Modes

- If the failure is likely to cause severe harm
 - Identify early warning signs that a failure mode has occurred, and train staff to recognize them for early intervention
 - Provide information and resources at points of care for events that may require immediate action



Plan Actions to Reduce Harm from Failure Modes

- If the failure mode is likely to occur:
 - Can cause be eliminated
 - Can a forcing function be added
 - Add a verification step (e.g. bar coding medications)
 - Modify other processes that contribute to causes

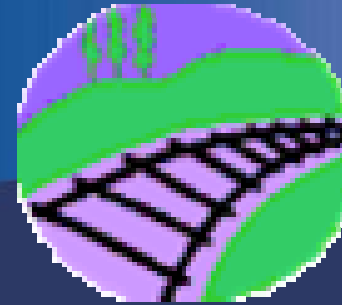


Plan Actions to Reduce Harm from Failure Modes

- If the failure is unlikely to be detected
 - Can previous events serve as “flags” to indicate likely occurrence”?
 - Add an intervention step earlier in the process (e.g. add pharmacy rounds to remove discontinued medications with 1 hour)
 - Consider device alerts when values are approaching unsafe limits



Tracking Progress



- Your process probably changes; so should your FMEA
- Periodically (a few times a year) revisit your process
 - Update your FMEA based on changes you have made
 - Track your RPN over time to see progress
- Be sure to make changes
- Focus on continuous improvement

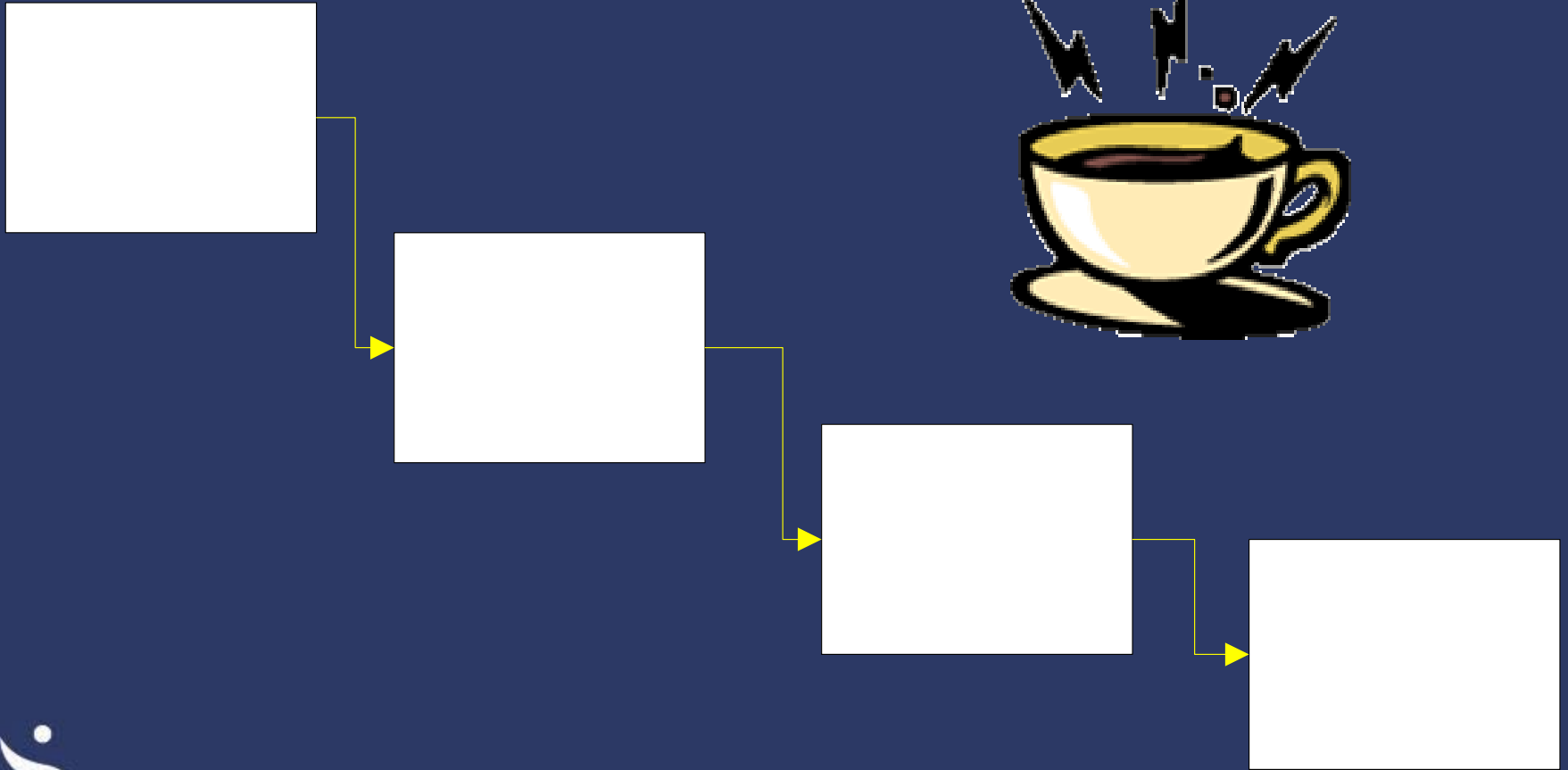


Summary of FMEA Steps

- Step 1: Map a process
- Step 2: Break the process apart
- Step 3: Review each section of the process for failures
- Step 4: Assign Values



Coffee Making Process (Step 1 Map a process)



Step 3 of FMEA Process 1

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level							

Failure Mode:	What could go wrong	Likelihood of Occurrence:	1-10, 10=very likely to occur
Failure Cause:	Why would the failure happen	Likelihood of Detection:	1-10, 10=very unlikely to detect
Failure Effects:	What would be the consequences of the failure	Severity:	1-10, 10=most severe effect



Step 3 of FMEA Process 1

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well					

Failure Mode:	What could go wrong	Likelihood of Occurrence:	1-10, 10=very likely to occur
Failure Cause:	Why would the failure happen	Likelihood of Detection:	1-10, 10=very unlikely to detect
Failure Effects:	What would be the consequences of the failure	Severity:	1-10, 10=most severe effect



Step 4 of FMEA Process 1

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	2*8*3 = 48	

Failure Mode:	What could go wrong	Likelihood of Occurrence:	1-10, 10=very likely to occur
Failure Cause:	Why would the failure happen	Likelihood of Detection:	1-10, 10=very unlikely to detect
Failure Effects:	What would be the consequences of the failure	Severity:	1-10, 10=most severe effect



Step 3 of FMEA Process 2

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	48	
Insert a filter into the basket	Filter not available							
	Filter not the right size							

Failure Mode: What could go wrong

Failure Cause: Why would the failure happen

Failure Effects: What would be the consequences of the failure

Likelihood of

Occurrence: 1-10, 10=very likely to occur

Likelihood of

Detection: 1-10, 10=very unlikely to detect

Severity: 1-10, 10=most severe effect



Step 3 of FMEA Process 2

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	48	
Insert a filter into the basket	Filter not available	Forgot to buy	Can't make coffee					
		Ran out	Can't make coffee					
	Filter not the right size		Need to rework filter to fit					



Failure Mode: What could go wrong

Failure Cause: Why would the failure happen

Failure Effects: What would be the consequences of the failure

Likelihood of

Occurrence: 1-10, 10=very likely to occur

Likelihood of

Detection: 1-10, 10=very unlikely to detect

Severity: 1-10, 10=most severe effect

Step 4 of FMEA Process 2

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	48	
Insert a filter into the basket	Filter not available	Forgot to buy	Can't make coffee	1	1	10	10	
		Ran out	Can't make coffee	1	1	10	10	
	Filter not the right size		Need to rework filter to fit	1	1	2	2	



Failure Mode: What could go wrong

Failure Cause: Why would the failure happen

Failure Effects: What would be the consequences of the failure

Likelihood of

Occurrence: 1-10, 10=very likely to occur

Likelihood of

Detection: 1-10, 10=very unlikely to detect

Severity: 1-10, 10=most severe effect

Step 3 of FMEA Process 3

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	48	
Insert a filter into the basket	Filter not available	Forgot to buy	Can't make coffee	1	1	10	10	
		Ran out	Can't make coffee	1	1	10	10	
	Filter not the right size		Need to rework filter to fit	1	1	2	2	
Place 1 scoop of coffee in the filter for every cup of coffee required	Wrong number of scoops placed in filter							



Failure Mode: What could go wrong

Failure Cause: Why would the failure happen

Failure Effects: What would be the consequences of the failure

Likelihood of

Occurrence: 1-10, 10=very likely to occur

Likelihood of

Detection: 1-10, 10=very unlikely to detect

Severity: 1-10, 10=most severe effect

Step 3 of FMEA Process 3

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	48	
Insert a filter into the basket	Filter not available	Forgot to buy	Can't make coffee	1	1	10	10	
		Ran out	Can't make coffee	1	1	10	10	
	Filter not the right size		Need to rework filter to fit	1	1	2	2	
Place 1 scoop of coffee in the filter for every cup of coffee required	Wrong number of scoops placed in filter	Forgot to count	Distracted					
		Miscounted	Distracted					



Failure Mode:	What could go wrong	Likelihood of Occurrence:	1-10, 10=very likely to occur
Failure Cause:	Why would the failure happen	Likelihood of Detection:	1-10, 10=very unlikely to detect
Failure Effects:	What would be the consequences of the failure	Severity:	1-10, 10=most severe effect

Step 4 of FMEA Process 3

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	48	
Insert a filter into the basket	Filter not available	Forgot to buy	Can't make coffee	1	1	10	10	
		Ran out	Can't make coffee	1	1	10	10	
	Filter not the right size		Need to rework filter to fit	1	1	2	2	
Place 1 scoop of coffee in the filter for every cup of coffee required	Wrong number of scoops placed in filter	Forgot to count	Distracted	2	3	3	18	
		Miscounted	Distracted	2	6	3	36	



Failure Mode: What could go wrong

Failure Cause: Why would the failure happen

Failure Effects: What would be the consequences of the failure

Likelihood of

Occurrence: 1-10, 10=very likely to occur

Likelihood of

Detection: 1-10, 10=very unlikely to detect

Severity: 1-10, 10=most severe effect

Step 3 and 4 Process 4

Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	48	
Insert a filter into the basket	Filter not available	Forgot to buy	Can't make coffee	1	1	10	10	
		Ran out	Can't make coffee	1	1	10	10	
	Filter not the right size		Need to rework filter to fit	1	1	2	2	
Place 1 scoop of coffee in the filter for every cup of coffee required	Wrong number of scoops placed in filter	Forgot to count	Distracted	2	3	3	18	
		Miscounted	Distracted	2	6	3	36	
Turn on the coffee maker	Coffee maker not turned on	Forgot	No coffee made	1	1	10	10	
Total RPN for process							134	



New Coffee Process

Fill carafe with water to the number of cups mark required

Insert filter containing coffee

Turn on the coffee maker

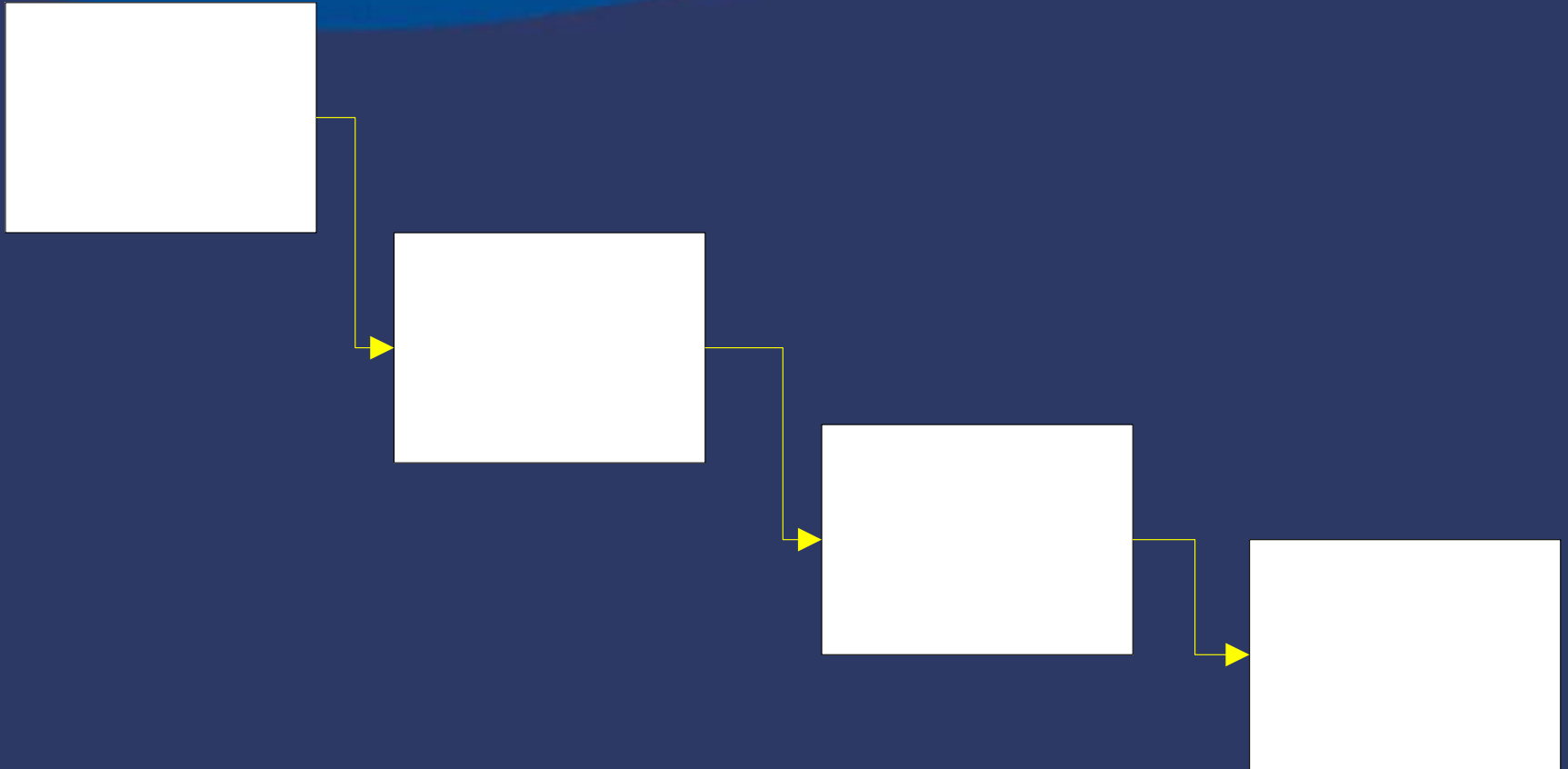


New Coffee Process FMEA

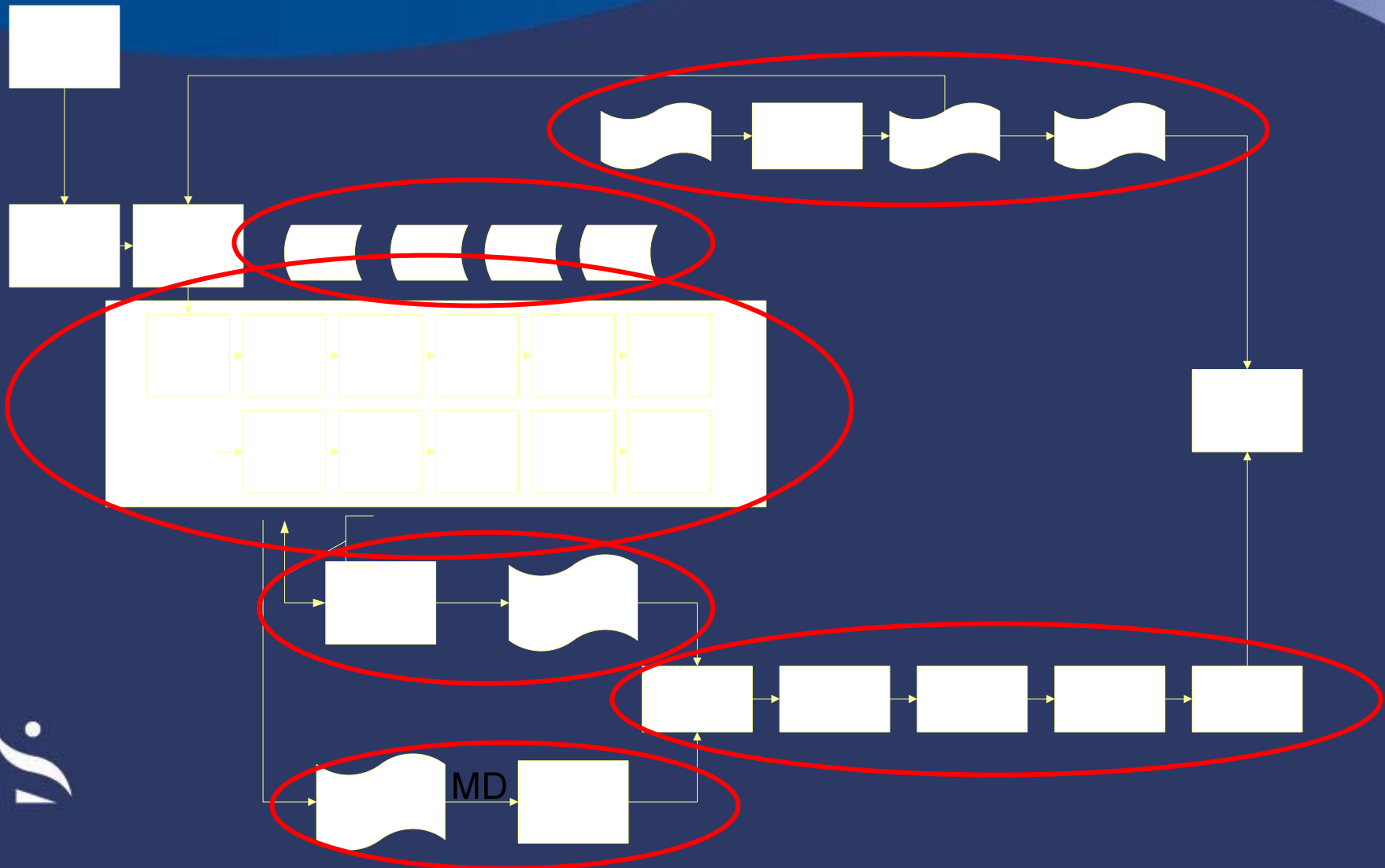
Steps in Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1 - 10)	Likelihood of Detection (1 - 10)	Severity (1 - 10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Fill carafe with water to the number of cups mark required	Water filled to the wrong level	Difficult to Read	Coffee not taste very well	2	8	3	48	
Insert filter containing coffee	Not available	Forgot to buy	Can't make coffee	1	1	10	10	
		Ran out	Can't make coffee	1	1	10	10	
	Filter not the right size		Need to rework filter to fit	1	1	2	2	
Place 1 scoop of coffee in the filter for every cup of coffee required	Wrong number of scoops placed in filter	Forgot to count	Distracted	2	3	3	18	delete step by using prepackaged filters
		Miscounted	Distracted	2	6	3	36	
Turn on the coffee maker	Coffee maker not turned on	Forgot	No coffee made	1	1	10	10	
Total RPN for process							78	



FMEA Case Study



Map a Process



Resources and Credits

- Institute for Healthcare Improvement www.ihc.com
- QualityHealthCare.org www.qualityhealthcare.org
- Quality Associates International www.quality-one.com
- FMEA Info Centre www.fmeainfocentre.com
- FMECA.COM www.fmeca.com
- American Society for Quality www.asq.org
- Society of Automotive Engineers www.sae.org

