

# The Basics of Healthcare Failure Mode and Effect Analysis

Videoconference Course

presented by

VA National Center for Patient Safety



# What is Failure Mode and Effect Analysis?

Failure Mode and Effect Analysis (FMEA) is a systematic method of identifying and preventing product and process problems before they occur.



# Why Use FMEA?

- Aimed at prevention of tragedy
- Doesn't require previous bad experience or close call
- Makes system more robust
- Fault tolerant



# **Course Objectives**

By the end of the course, participants will:

- Understand the purpose of Healthcare FMEA
- Have a conceptual understanding of the steps of the Healthcare FMEA process
- Know how to choose an appropriate topic for analysis
- Be able to successfully address the JCAHO
   2001 proactive risk assessment standard



# Failure Mode & Effect Analysis

- Do you take actions to prevent yourself from being late to work? Yes or No
- Do you "take the shortcut" when you see traffic building up in a familiar place? Yes or No
- Do you try to distinguish "big problems" from "little problems"? Yes or No
- Do you see the possibility of eliminating some problems, but need a better way to show that to people? Yes or No



# Failure Mode & Effect Analysis

Your answers indicate that you are already applying some of the principles of Failure Mode and Effect Analysis (FMEA) to prevent problems in day-to-day life.



#### Who uses FMEA?

- Engineers worldwide in:
  - **≻**Aviation
  - ➤ Nuclear power
  - ➤ Aerospace
  - > Chemical process industries
  - > Automotive industries
- Has been around for over 30 years
- Goal has been, and remains today, to prevent accidents from occurring



# Rationale for FMEA in Healthcare

# Historically...

- Accident prevention has not been a primary focus of hospital medicine
- Misguided reliance on "faultless" performance by healthcare professionals
- Hospital systems were not designed to prevent or absorb errors; they just reactively changed and were not typically proactive



# Rationale for FMEA in Healthcare

If FMEA were utilized, the following vulnerabilities might have been recognized and prevented:

- Major medical center power failure
- MRI Incident ferromagnetic objects
- Bed rail and vail bed entrapment
- Medical gas usage



# JCAHO Standard LD.5.2 Effective July 2001

Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.



#### Intent of LD.5.2

The organization seeks to reduce the risk of sentinel events and medical/health care system error-related occurrences by conducting its own proactive risk assessment activities and by using available information about sentinel events known to occur in health care organizations that provide similar care and services. This effort is undertaken so that processes, functions and services can be designed or redesigned to prevent such occurrences in the organization.



# Intent of LD.5.2 (continued)

Proactive identification and management of potential risks to patient safety have the obvious advantage of preventing adverse occurrences, rather than simply reacting when they occur. This approach also avoids the barriers to understanding created by hindsight bias and the fear of disclosure, embarrassment, blame, and punishment that can arise in the wake of an actual event.



#### **JCAHO Standard LD.5.2**

- Identify and prioritize high-risk processes
- Annually, select at least one high-risk process
- Identify potential "failure modes"
- For each "failure mode," identify the possible effects
- For the most critical effects, conduct a root cause analysis



#### **JCAHO Standard LD.5.2**

- Redesign the process to minimize the risk of that failure mode or to protect patients from its effects
- Test and implement the redesigned process
- Identify and implement measures of effectiveness
- Implement a strategy for maintaining the effectiveness of the redesigned process over time



# Healthcare Failure Mode & Effect Analysis (HFMEA):

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



#### **Effective Control Measure:**

A barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.



# **Hazard Analysis:**

The process of collecting and evaluating information on hazards associated with the selected process. The purpose of the hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled.



#### **Failure Mode:**

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



# **HFMEA** and the RCA Process

#### **Similarities**

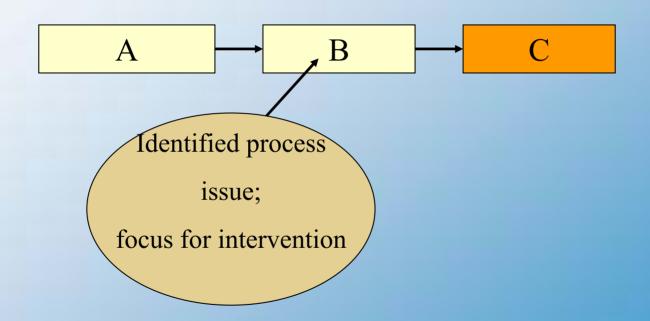
- Interdisciplinary Team
- Develop Flow Diagram
- Focus on systems issues
- Actions and outcome measures developed
- Scoring matrix (severity/probability)
- Use of Triage/Triggering questions, cause & effect diagram, brainstorming

#### **Differences**

- Process vs. chronological flow diagram
- Prospective (what if) analysis
- Choose topic for evaluation
- Include detectability and criticality in evaluation
- Emphasis on testing intervention

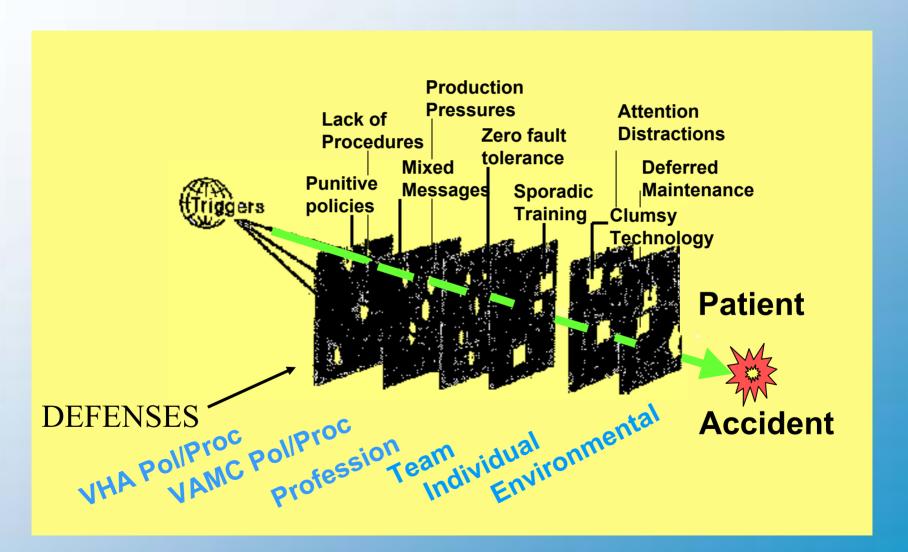


# HFMEA Points Out System/Process Vulnerabilities





#### Reason's Model of Accidents





# Process Design & Organizational Change

#### Process Re-Design

- Redundancy
- Usability Testing
- Simplification
- Fail-safe designs
- Reduce Reliance on Memory & Vigilance
- Simplify
- Standardize
- Checklists
- Forcing Functions
- Eliminate Look and Soundalikes
- Simulate
- Looser coupling of systems

#### Organizational

- Increase Constructive Feedback and Direct Communication
- Teamwork
- Drive Out Fear
- Leadership Commitment



# The Healthcare Failure Modes and Effects Process

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.



#### STEP 2

Assemble the Team –

Multidisciplinary team with Subject

Matter Expert(s) plus advisor



### **STEP 3 - Graphically Describe the Process**

- A. Develop and Verify the Flow Diagram (this is a process vs. chronological diagram)
- B. Consecutively number each process step identified in the process flow diagram.
- C. If the process is complex identify the area of the process to focus on (manageable bite)



### **STEP 3 - Graphically Describe the Process**

- 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 4 - Conduct a Hazard Analysis**

- A. List Failure Modes
- B. Determine Severity & Probability
- C. Use the Decision Tree
- D. List all Failure Mode <u>Causes</u>



#### **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.



# Forms & Tools

- **Forms**
- **≻** Worksheets
- **≻**Hazard Scoring Matrix
- > Decision Tree



Step 1. Select the process you want to examine.
Define the scope (Be specific and include a clear
definition of the process or product to be studied).

This HFMEA is focused on		



#### Step 2. Assemble the Team

FMEA Number_		
Date Started	Date Cor	npleted
Team Members	1	4.
	2	<u>5.</u>
	3	<u>6.</u>
Team Leader		
Are all affected	areas represented? YE	S / NO
Are different lev	vels and types of knowled	ge represented on the team? YES / NO
Who will take m	inutes and maintain reco	ds?



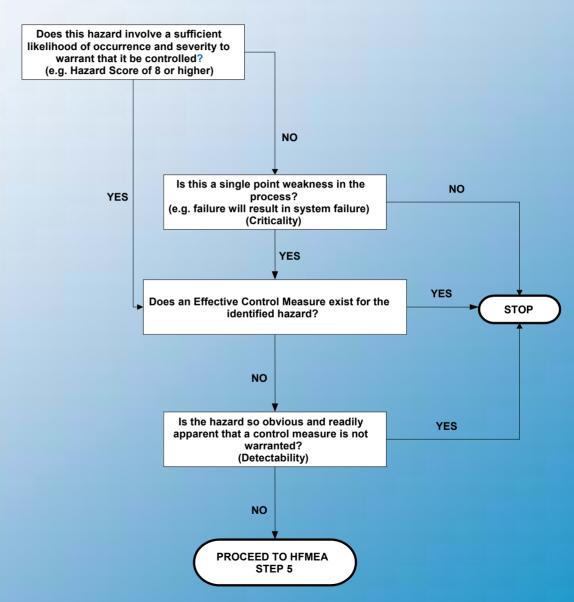
## **HFMEA Worksheet**

HFMEA Subprocess step name and title													
HFMEA Step 4 - Hazard Analysis HFMEA Step 5 - Identify Actions and Outcomes													
Scorin		ıg	<b>Decision Tree Analysis</b>			lysis							
Failure Mode: First Evaluate failure mode before determining potential causes  Potential Causes	Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?	Action Type (Control, Accept, Eliminate)	for Stopping	Outcome Measure	Person Responsible	Management Concurrence	
	-												



#### **HFMEA Decision Tree**

The HFMEA Decision Tree...





#### **HFMEA Decision Tree**

Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled?
 (e.g. Hazard Score of 8 or higher)

YES |

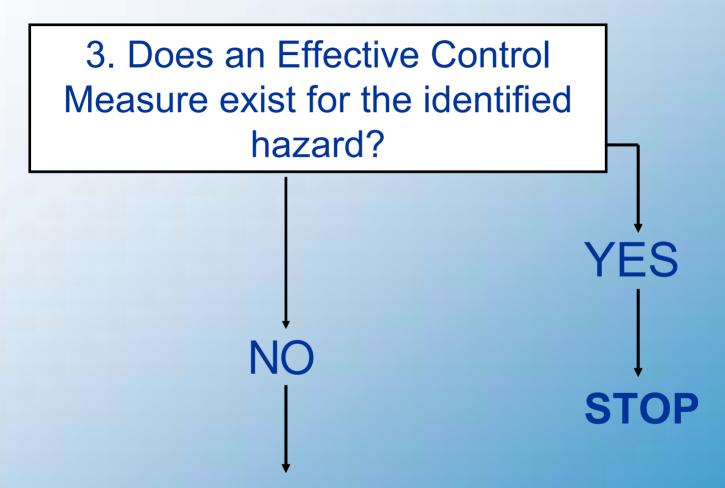


### **HFMEA Decision Tree**

2. Is this a single point weakness in the process? (e.g. failure will result in system failure) (Criticality) YFS

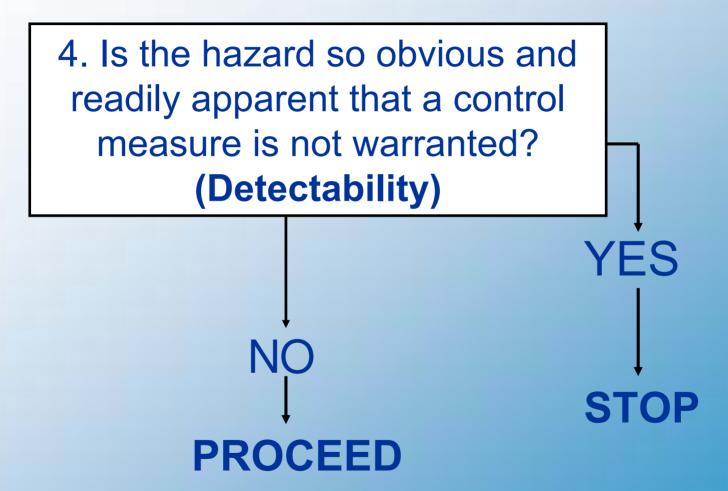


### **HFMEA Decision Tree**





### **HFMEA Decision Tree**





## **Hazard Analysis**

#### **SEVERITY RATING:**

	Cata	stro	phic	<b>Event</b>
--	------	------	------	--------------

(Traditional FMEA Rating of 10 - Failure could cause death or injury)

Patient Outcome: 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

<u>Visitor Outcome:</u> Death; **or** hospitalization of 3 or more.

**Staff Outcome:** \* A death or hospitalization of 3 or more staff

**Equipment or facility:** \*\*Damage equal to or more than \$250,000

Fire: Any fire that grows larger than an incipient

#### **Major Event**

(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)

<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

<u>Visitor Outcome:</u> Hospitalization of 1 or 2 visitors <u>Staff Outcome:</u> Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses

**Equipment or facility:** \*\*Damage equal to or more than \$100,000

<u>Fire:</u> Not Applicable – See Moderate and Catastrophic



## **Hazard Analysis**

#### **SEVERITY RATING:**

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п	٧I	v	u	┖	ı a	LC	_	VC	7 I I	ı

(Traditional FMEA Rating of "4" – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)

<u>Patient Outcome:</u> Increased length of stay or increased level of care for 1 or 2 patients

<u>Visitor Outcome:</u> Evaluation **and** treatment for 1 or 2 visitors (less than hospitalization)

<u>Staff Outcome:</u> Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff

Equipment or facility: \*\*Damage more than \$10.000 but less than \$100.000

Fire: Incipient stage<sup>‡</sup> or smaller

#### **Minor Event**

(Traditional FMEA Rating of "1" – Failure would not be noticeable to the customer and would not affect delivery of the service or product.)

<u>Patients Outcome:</u> No injury, nor increased length of stay nor increased level of care

<u>Visitor Outcome:</u> Evaluated and no treatment required **or** refused treatment

<u>Staff Outcome:</u> First aid treatment only with no lost time, nor restricted duty injuries nor illnesses

Equipment or facility: \*\*Damage less than \$10,000 or loss of any utility\* without adverse patient outcome (e.g. power, natural gas, electricity, water, communications, transport, heat/air conditioning).

<u>Fire:</u> Not Applicable – See Moderate and Catastrophic



## **Hazard Analysis**

### **PROBABILITY RATING:**

- Frequent Likely to occur immediately or within a short period (may happen several times in one year)
- Occasional Probably will occur (may happen several times in 1 to 2 years)
- **Uncommon -** Possible to occur (may happen sometime in 2 to 5 years)
- Remote Unlikely to occur (may happen sometime in 5 to 30 years)



# **HFMEA Hazard Scoring Matrix**

		Se	verity		
7		Catastrophic	Major	Moderate	Minor
Probability	Frequent	16	12	8	4
abilit	Occasional	12	9	6	3
יל	Uncommon	8	6	4	2
	Remote	4	3	2	1



## **Example - Driving to Work**

- Decided to perform FMEA on driving to work.
- Want to include the processes associated with this activity.
- Meant as an illustrative example by walking through the steps.



### **Healthcare FMEA Process**

Step 1. Select the process you want to examine.	
Define the scope (Be specific and include a clear	
definition of the process or product to be studied	).

This HFMEA is focused on		



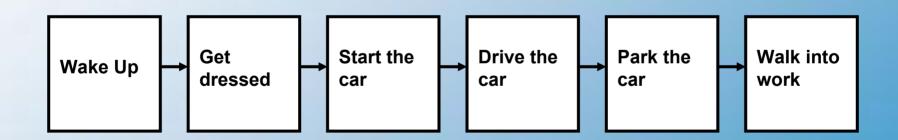
## **Healthcare FMEA Process**

### Step 2. Assemble the Team

FMEA Number_		
Date Started	Date Con	npleted
Team Members	1	4
	2	<u>5.</u>
	3	<u>6.</u>
Team Leader		
Are all affected	areas represented? YES	S / NO
Are different lev	vels and types of knowled	ge represented on the team? YES / NO
Who will take m	inutes and maintain recor	ds?

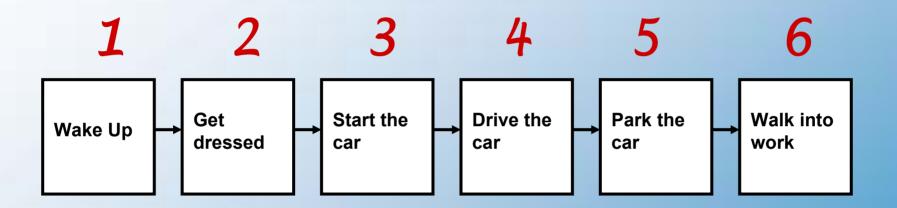


Step 3A. Gather information about how the process works – describe it graphically.



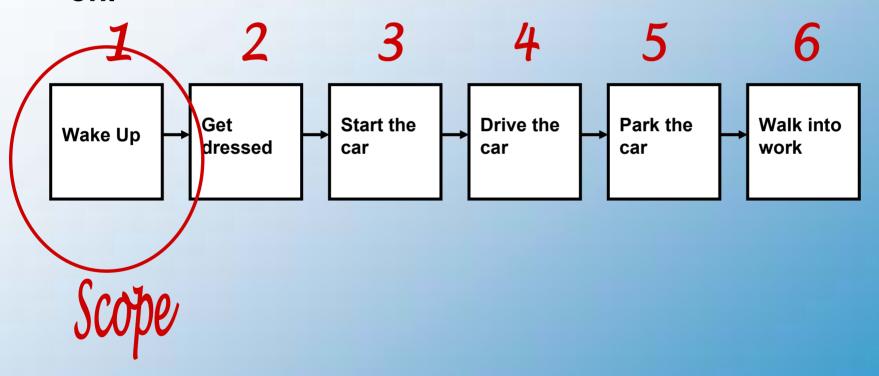


### Step 3B. Consecutively number each process





Step 3C. If process is complex, choose area to focus on.



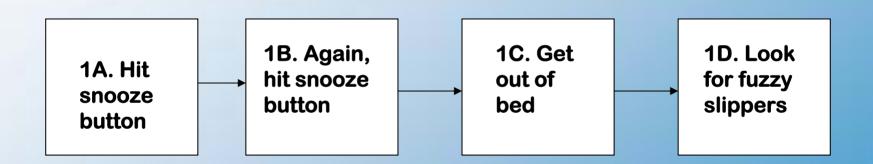


Step 3D. If necessary, list sub-process steps and consecutively number.



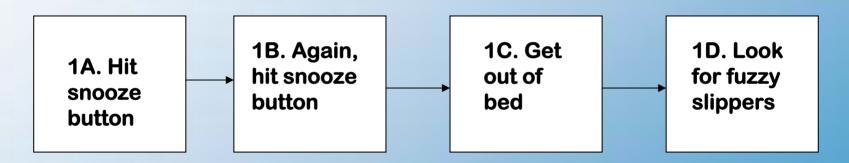


Step 3D. Wake up (Sub-process flow diagram)





### Step 4A. List all failure modes.



**Failure Modes** 

1A(1) Turn off alarm

1A(2) Unplug Alarm

1A(3) Break alarm clock



# HFMEA Worksheet, Step 4A

						Hit S	Snoo	ze B	utto	n - 1A				
	HFMEA Step 4 - Hazard Analysis HFMEA Step 5 - Identify Actions and Outcomes													
			S	corin	g	Decis	ion Tre	e Ana	lysis				0	
Fail	ure Mode:						rol			Action			b le	nt ce
m	Evaluate failure ode before nining potential causes	Potential Causes	Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?	Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsib	Management Concurrence
1A(1)	Turn off alarm													



# S\* HFMEA Worksheet

						Hit S	Snoo	ze B	utto	n - 1A				
		HFMEA Step 4 - Ha	zard Ar	nalysis	s						HFMEA Step 5 - Identi	fy Actions and Outco	mes	
First I	lure Mode: Evaluate failure ode before mining potential causes	Potential Causes		Probability Euro	ore	Single Point Weakness?	Existing Control us Measure?	Detectability au	Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
1A(1)	Turn off alarm													



## **Step 4: Hazard Analysis**

Step 4B. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

#### **SEVERITY RATING:**

Catastrophic Event (Traditional FMEA Rating of 10 - Failure could cause death or injury)	Major Event (Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)
Patient Outcome: 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  Visitor Outcome: Death; or hospitalization of 3	Patient Outcome: 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  Visitor Outcome: Hospitalization of 1 or 2 visitors
Staff Outcome: * A death or hospitalization of 3 or more staff  Equipment or facility: **Damage equal to or more than \$250,000  Fire: Any fire that grows larger than an incipient	Staff Outcome: Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses  Equipment or facility: **Damage equal to or more than \$100,000  Fire: Not Applicable – See Moderate and Catastrophic



## **Step 4: Hazard Analysis**

Step 4. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

#### **PROBABILITY RATING:**

- Frequent Likely to occur immediately or within a short period (may happen several times in one year)
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# **HFMEA Hazard Scoring Matrix**

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	Remote	4	3	2	1

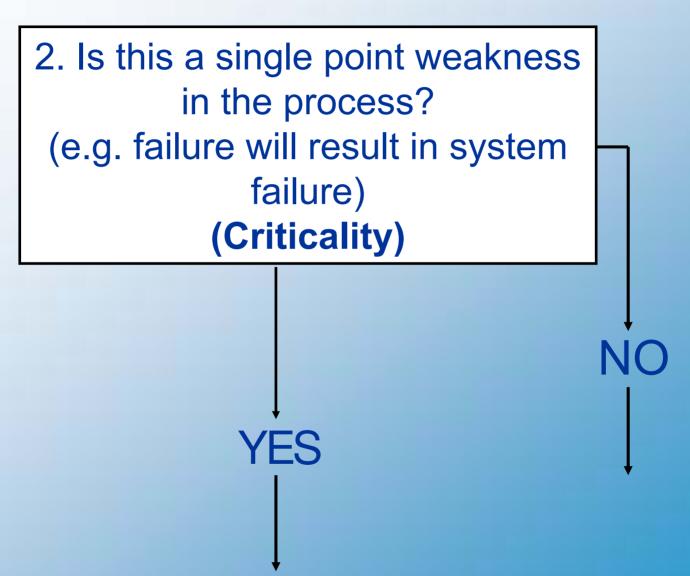


1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled? (e.g. Hazard Score of 8 or higher)

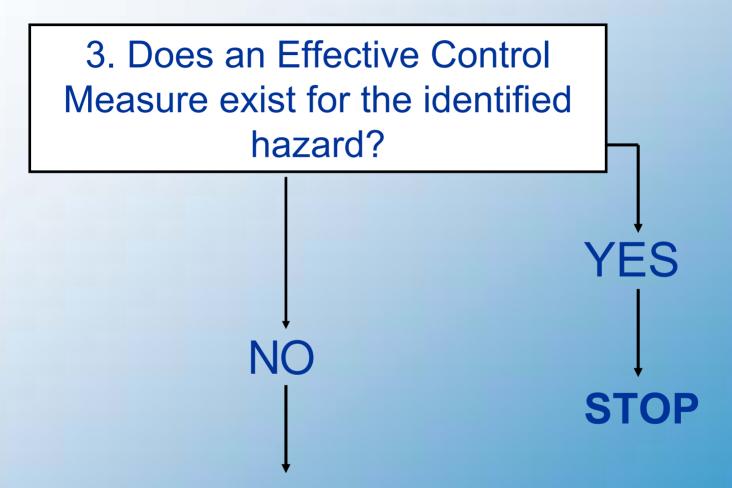
YES

58

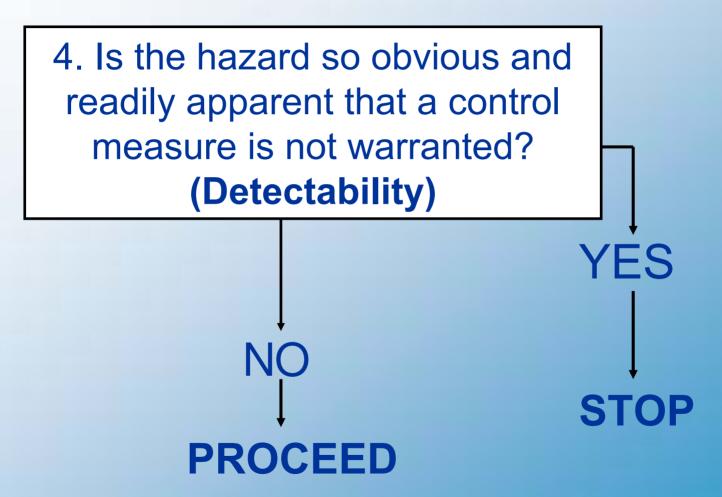














# NCPS HFMEA Worksheet, Steps 4B & 4C

						Hit S	Snoo	ze B	utto	n - 1A				
		HFMEA Step 4 - Ha	zard A	nalys	sis						HFMEA Step 5 - Identi	fy Actions and Outco	mes	
First Eval mode determini	e Mode: uate failure before ng potential uses	Potential Causes	Severity 00	Probability is	ت Haz Score	Single Point ad Weakness?	Existing Control uo Measure ?	Detectability au	Proceed? sign	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
` '	urn off arm		Major	Occasional	0	>	N	N	<b>Y</b>					

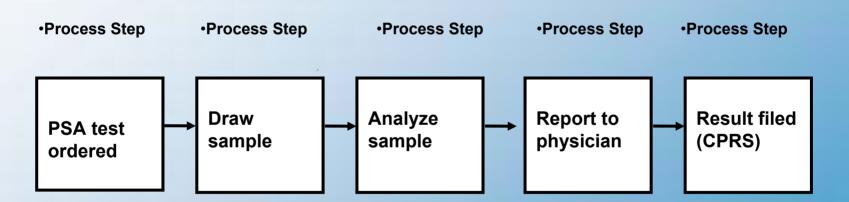


# **HFMEA Worksheet, Step 5**

						Hit S	Snoo	ze B	utto	n - 1A				
		HFMEA Step 4 - Ha	zard A	naly	sis						HFMEA Step 5 - Identi	fy Actions and Outco	mes	
			S	corin	ıg	Decis		on Tree Analy					O)	
First I	ure Mode: Evaluate failure ode before nining potential causes	Potential Causes	Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
1A(1)	Turn off alarm	-	major	occasional	9	>	N	N	Υ					
		1A(1)a Missed snooze button	major	occasional	9	>	N	N	Y	Eliminate	Purchase new clock	Purchase by certain date xx/xx/xx	YOU	Yes

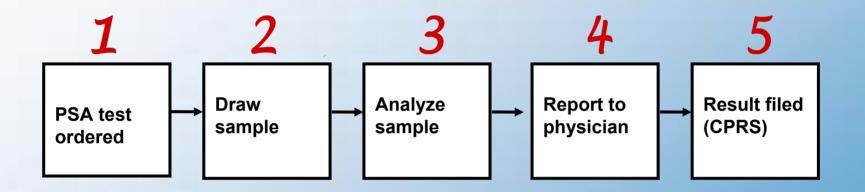


Step 3A. Gather information about how the process works – describe it graphically.



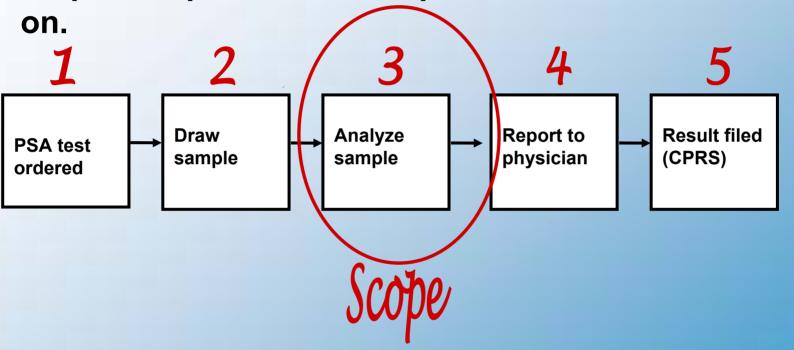


Step 3B. Consecutively number each process step.



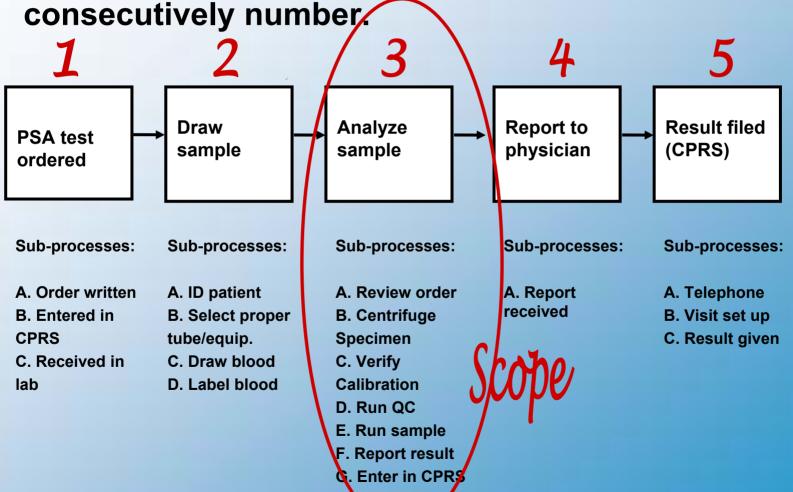


Step 3C. If process is complex, choose area to focus



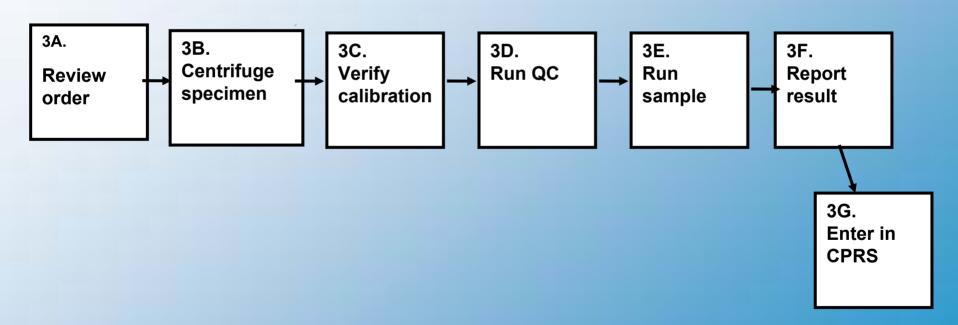


Step 3D. If necessary, list sub-process steps and





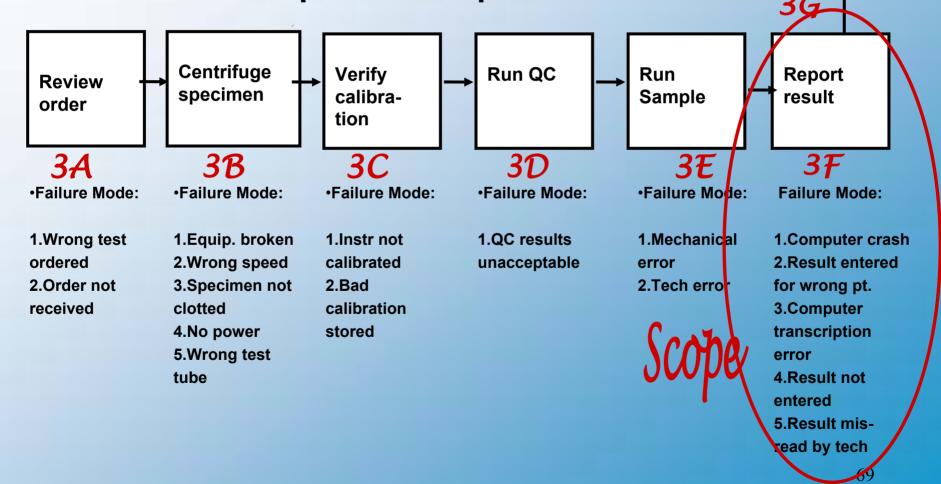
Step 3E. Analyze Sample (Sub-process flow diagram)





Step 4A. Hazard Analysis: List potential failure modes for each process step.

Enter result (CPRS)





Step 4B,C, D. Determine hazard score and list all the potential causes for each potential failure mode.

HFMEA Step 4 - Hazard Analysis										HFMEA Step 5 - Identify Actions and Outcomes					
Failure Mode: First Evaluate failure mode before determining potential causes		Potential Causes		Severity	Probability 2	ت Haz Score	Single Point and Weakness?	Existing Control u Measure?	Detectability but be	Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
3F(1)	Computer Crash	-		Major	Occasional	9	>	N	N	Υ					
		3F(1)a	Virus	Major	Occasional	9	>	N	N	Υ	Control	Purchase and install virus procection software	Software installed	Chief IRM	Y
		3F(1)b	Old equipment	Moderate	Remote	2	Υ	Υ	>	N	N/A	Ongoing/continuous program to replace existing equipment			
		3F(1)c	Software license expired	Moderate	Occasional	6	Y	Υ	>	N	N/A	All software licenses are review annually			

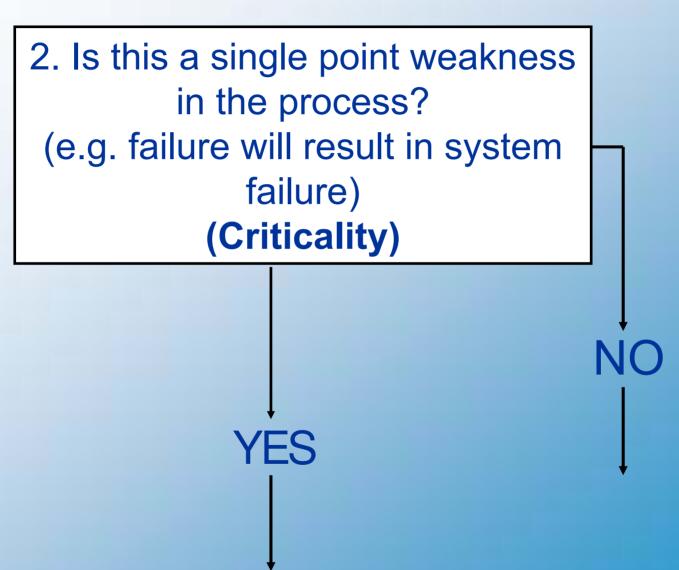


1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled?

(e.g. Hazard Score of 8 or higher)

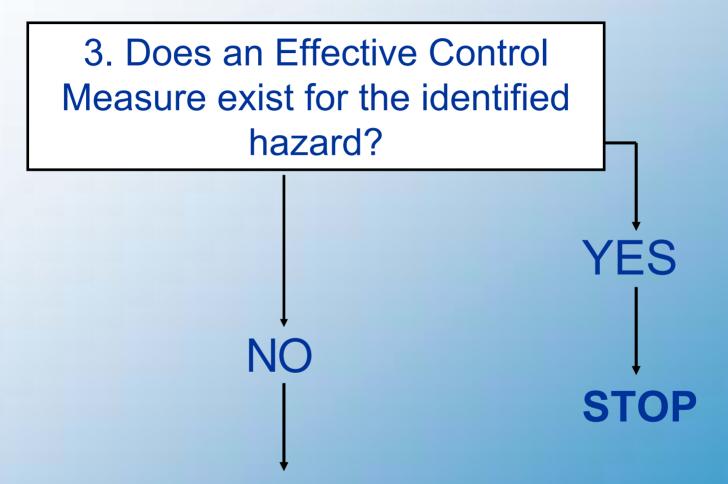
YES





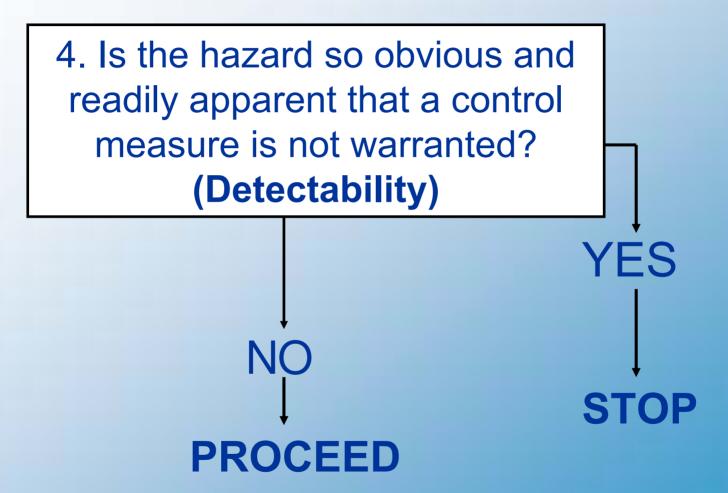


# **Step 4: HFMEA Decision Tree**





#### **Step 4: HFMEA Decision Tree**





## **HFMEA PSA Example**

Step 4B,C, D. Determine hazard score and list all the potential causes for each potential failure mode.

													fy Actions and Outco	mes	
	Failure Mode: First Evaluate failure mode before determining potential causes		Potential Causes		corir	ng	Decision Tree Ar			alysis				Ø)	
First					Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
3F(1)	Computer Crash		<b>•</b>	Major	Occasional	9	>	N	N	Υ					
		3F(1)a	Virus	Major	Occasional	9	>	N	N	Y	Control	Purchase and install virus procection software	Software installed	Chief IRM	Y
		3F(1)b	Old equipment	Moderate	Remote	2	Υ	Υ	>	N	N/A	Ongoing/continuous program to replace existing equipment			
		3F(1)c	Software license expired	Moderate	Occasional	6	Y	Υ	>	N	N/A	All software licenses are review annually			



# **HFMEA PSA Example**

							R	epor	t Re	sult	- 3F										
		Н	IFMEA Step 4 - Ha	zard A	naly	sis						HFMEA Step 5 - Identify Actions and Outcomes									
First m	Failure Mode: First Evaluate failure mode before determining potential causes		Potential Causes		Potential Causes		Potential Causes		Potential Causes		Potential Causes		Potential Causes		ity billity be Point ness? ng Contr ness? tability bed?		Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	// // // // // // // // // // // // //
3F(5)	Tech mis- reads results		-	Moderate S	frequent P	8	<u>∞</u> ×	N N	N	Υ				Person Responsible Management Concurrence							
		3F(5)a	Tech fatigue	Moderate	frequent	8	>	Υ	>	N	N/A	Techs working second continuous shift will not perform this task									
		3F(5)b	Too busy	Moderate	frequent	8	>	N	N	Υ	Control	Hire Tech	Staff increased								
		3F(5)c	Poor lighting	Moderate	remote	2	N	>	Υ	N	N/A	Low light level due to faded bulb is dectectable									
		3F(5)d	Confusing readout on PSA instrument	Moderate	frequent	8	>	N	N	Υ	Eliminate	New equipment	New equipment on site	Chief PALMS	Y						

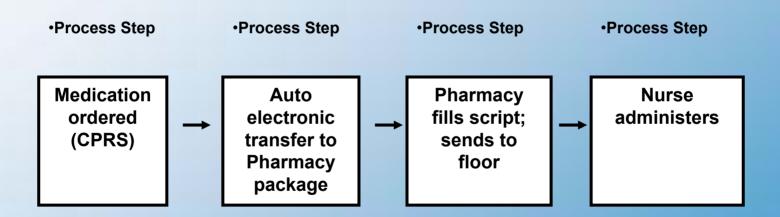


#### **Healthcare FMEA Process**

Let's work on another example that takes place in a healthcare setting using the Healthcare FMEA Process...

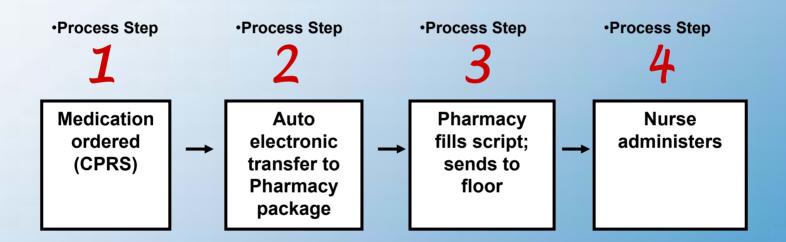


Step 3A. Gather information about how the process works – describe it graphically.



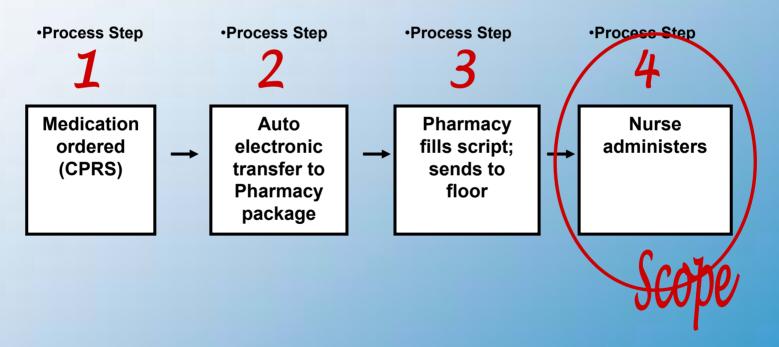


#### Step 3B. Consecutively number each process step.





Step 3C. If the process is complex, choose an area to focus on.





Steps 3D. Identify all sub-processes under each block. Consecutively letter these sub-steps.

Medication ordered (CPRS)

Auto electronic transfer to Pharmacy package

Pharmacy fills script; sends to floor

Nurse administers

Sub-processes:

A-Dummy terminal B-PC's Sub-processes:

A-Check drug

allergies

**B-Check drug** 

interactions

C-Check proper

dosages

**D--Orders Labs** 

E-order sent to

auto dispensing

Sub-processes:

**A-Automatically** 

fills orders

checked

**B-Drugs pulled** 

and script filled

**C-Med cart filled** 

**D-Cart sent to** 

floor

Sub-processes:

A-Log on to laptop

**B-Medcart** 

**C-Medications** 

scanned

**D-Patient band** 

scanned

E-Medication given to

patient

F-Patient record updated



Steps 3D. Identify all sub-processes under each block. Consecutively letter these sub-steps,

Medication ordered (CPRS)

Auto
electronic
transfer to
Pharmacy
package

Pharmacy fills script; sends to floor Nurse administers

**Sub-processes:** 

A-Dummy terminal B-PC's

Sub-processes:

A-Check drug

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**B-Check drug** 

interactions

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**Sub-processes:** 

A-Log on to laptop

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**C-Medications** 

scanned

**D-Patient band** 

scanned

E-Medication given to

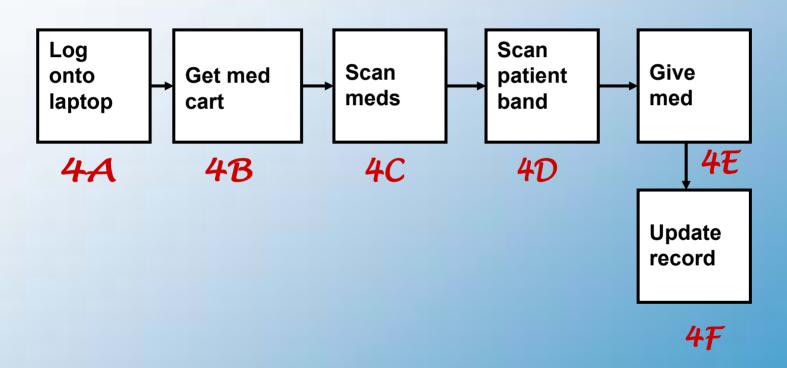
patient

F-Patient record

updated

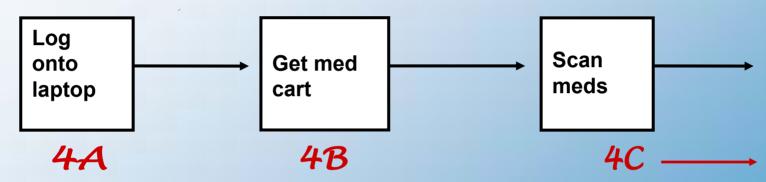


Steps 3E. Create a flow diagram composed of the sub-processes.





# Step 4. Hazard Analysis: List potential failure modes for each process step.



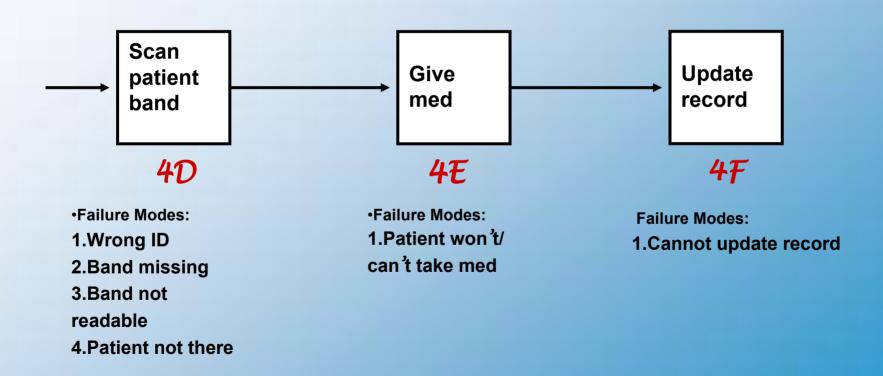
- •Failure Modes:
- 1.laptop missing
- 2.network down
- 3. No battery power
- 4.CPRS not functioning
- 5.forget password
- 6.Pharmacy pkg down
- 7.RF system not working
- 8. Server off line/down

- ·Failure Modes:
- 1.Med cart not there
- 2. Filled incorrectly
- 3.Expired meds
- 4. Wrong cart

- •Failure Modes:
- 1.medication missing from cart
- 2.Scanner/laptop missing
- 3.No power for laptop
- 4.Barcode label missing
- 5.Barcode label not readable
- 6.No power for scanner

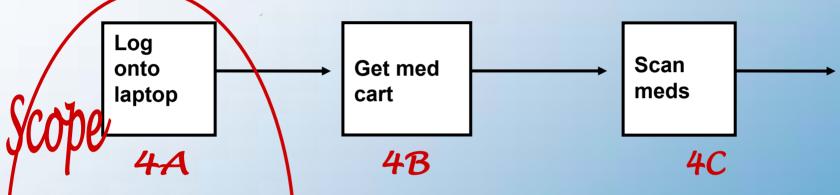


Step 4. Hazard Analysis: List potential failure modes for each process step.





Step 4. Hazard Analysis: List potential failure modes for each process step.



- •Failure Modes:
- 1.laptop unavailable
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- 3. network down
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- 6.Pharmacy pkg down
- 7.RF system not working
- 8.Server off line/down

- •Failure Modes:
- 1.Med cart not there
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- 4. Wrong cart

- ·Failure Modes:
- 1.medication missing from cart
- 2.Scanner/laptop missing
- 3.No power for laptop
- 4.Barcode label
- missing
- 5.Barcode label not
- readable
- **6.No power for scanner**



#### Step 4. List all the potential causes for each potential failure mode.

	Log onto Laptop - 4A																
	HFMEA Step 4 - Hazard Analysis											HFMEA Step 5 - Identify Actions and Outcomes					
						ıg	Decision Tree Analysis			lysis				Ф			
Failure Mode: First Evaluate failure mode before determining potential causes		Potential Causes		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence		
4A(1)	Laptop unavailable	-	-	Moderate	Occasional	6	Y	N	N	Υ							
		4A(1)a	Theft	Moderate	Occasional	6	Y	N	N	Υ	Control	Buy backup	Total downtime is less than or equal to 15 minutes	Chief IRM	Y		
		4A(2)b	Locked in an office	Moderate	Occasional	6	Υ	N	N	Υ	Control	Call for IRM help	Total downtime is less than or equal to 15 minutes	Chief IRM	Y		



#### Step 4. List all the potential causes for each potential failure mode.

	Log onto Laptop - 4A													
	HFMEA Step 4 - Hazard Analysis HFMEA Step 5 - Identify Actions and Outcomes													
Failure Mode: First Evaluate failure mode before determining potential causes		Potential Causes		Probability is	ق Haz Score	Single Point ad Weakness?	Existing Control uo Measure?	Detectability as	Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
4A(2)	No power		Moderate	Occasional	6	Υ	N	N	Υ					
		4A(2)a Battery failure	Moderate	Occasional	6	Y	N	N	Υ	Control	Backup battery	Total downtime is less than or equal to 15 minutes	Chief IRM	Y
		4A(2)b Battery not charged up	Moderate	Occasional	6	Y	N	N	Y	Control	Add 120v receptacles	Power available	Chief ENG	Y



# **Summarize Today's Discussion**

- Extension of what we're currently doing
- Fully complies with JCAHO 2001 standards
- VHA NCPS providing training and forms
- Additional examples in Fall
- Need to do only one in fiscal year 2002
- Request feedback and suggestions