Healthcare Failure Mode Effect Analysis
A PROACTIVE Approach in identifying & preventing problems

What is a Healthcare Failure Mode Effect Analysis (HFMEA)?
A failure mode effect analysis (FMEA) may be defined as a "systematic method of identifying and preventing process and product problems before they occur."
Healthcare FMEAs focus on preventing defects, enhancing safety, increasing positive outcomes and increasing patient satisfaction.

The objective of the HFMEA is to look for all ways a process or product can fail. The famous question is **"What <u>Could</u> happen?"** not "What does happen?"

Steps to Conducting a HFMEA

STEP 1: Gather a team and define the topic and scope if complex

STEP 2: Graphically Describe the Process (Use your current policy/procedure as your guide)

STEP 3: List the Failure Modes, their effects & severity for each process step (What could go wrong)

STEP 4: Identify causes for selected (highest scoring) Failure Modes - Why it went wrong

STEP 5: Conduct Effects Analysis for Failure Modes & their causes to score, prioritize, & select

STEP 6: Design the interventions for the selected high risk Failure Modes & Causes, assign the responsible staff, timeframes and obtain management support.

STEP 7: Identify outcome measures for the interventions

STEP 8: Implement and monitor

STEP 1: GATHER A TEAM & DEFINE THE SCOPE

- Make sure that all represented parties are on the team that is affected by the process
- Identify a team leader
- Identify a recorder

DEFINE THE SCOPE

- Keep it well-defined
- Specific and clear definition of the process should be written and understood by everyone on the team
- Keep it simple! Break up into sub-processes when possible

STEP 2: GRAPHICALLY DESCRIBE THE PROCESS

There are several actions that need to be completed with Step 2. They are:
Action 1: Have a detailed flow sheet of the process

- Walk through the process *(Remember not what currently happens!)*
- Keep the focus narrow
- Break process into sub-processes

STEP 3: LIST THE FAILURE MODES

List the Failure Modes for each process step (What could go wrong)

STEP 4: CONDUCT THE FAILURE MODE EFFECTS ANALYSIS

Step 4 looks at the probability, severity and detectability of the failure mode. Please note that you can use different definitions appropriate to your organization and failure mode analysis. You can also use a 1- 10 rating scale as defined in some of the FMEA literature.

Ranking the Probability:

Ranks the failure mode on the projected frequency of the occurrence using a scale from 1 – 4:

1 = Remote – Unlikely to occur in 5 – 30 years
2 = Uncommon – Possible to occur in sometime in 1 years
3 = Occasional – Likely to occur several times in 1 – 2 months
4 = Frequent – Likely to occur several times within a short period 1day -1 week

Ranking the Severity:

Rank the seriousness of the failure mode using a scale from 1 - 4: Similar to NCCMERP Severity Index

1 = No harm - Does not affect patient
2 = Temporary Harm - Intervention and/or monitoring required
3 = Permanent Harm - Lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, or increased length of stay
4 = Death or major loss of function (sensory, motor, physiologic, or intellectual),- Rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family

Ranking the Ability to Detect a Failure Mode:

The question is asked, "Are any controls in place that detect a failure mode?" Using a scale from 1 – 4 the ability to identify a failure mode is ranked:

1 = Very likely to be detected – there are checks and balances in place that exposes the failure mode (more than 5 steps in the process)
2 = Likely to be detected – With the use of the checks and balances in place the failure mode is likely to be detected (more than 3- 5 steps in the process)
3 = Unlikely to be detected – detection of a failure mode not likely to be detected (1 - 2 steps in the process)
4 = Very unlikely to be detected – There are no checks and balances in place to detect of a failure mode – only a one step process

STEP 5: LIST THE FAILURE MODE CAUSES AND CONDUCT THE FAILURE MODE EFFECTS ANALYSIS FOR THE CAUSES (Why the failure occurs)

STEP 6-8: DESIGN INTERVENTIONS, DESCRIBE OUTCOME MEASURES, IMPLEMENT & MONITOR

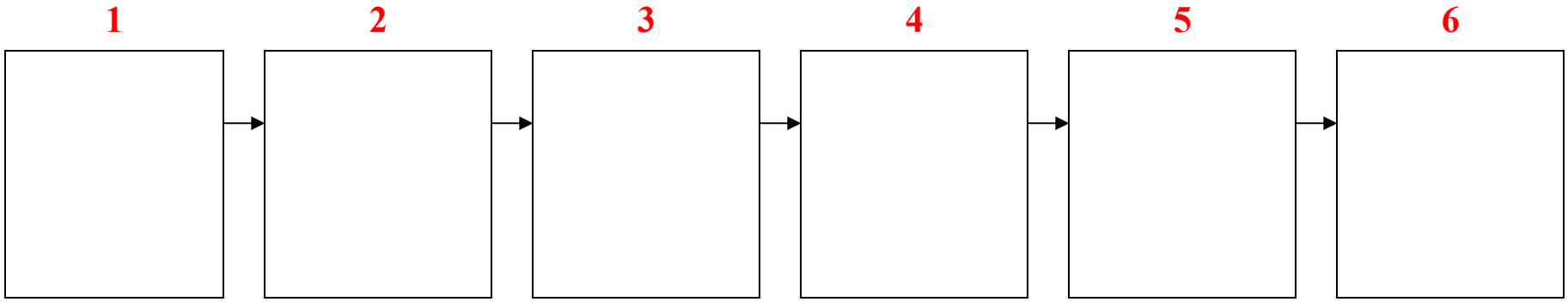
REFERENCES & RESOURCES

The Basics of FMEA, McDermott, Robin, Mikulak, Raymond, Beauregard, Michael, Resource Engineering, Inc., 1996
Interactive FMEA Tools, www.qualityhealthcare.org
Step-by-Step Guide to Failure Modes and Effects Analysis, Marder, Robert & John Sheff, HcPRO, Inc., http://www.hcmarketplace.com/prod.cfm?id=1152
JCAHO, http://www.jcrinc.com/generic.asp?durki=405
Bongiorno, Jim, "Improving FMEAs", Quality Digest, 20 (10) October 2000, p. 37-4

FAILURE MODE EFFECTS ANALYSIS

PROCESS STEPS: Describe the process graphically, according to your policy and procedure for the activity, and number each one

If the process is complex you may want to select one process step or sub-process to work on



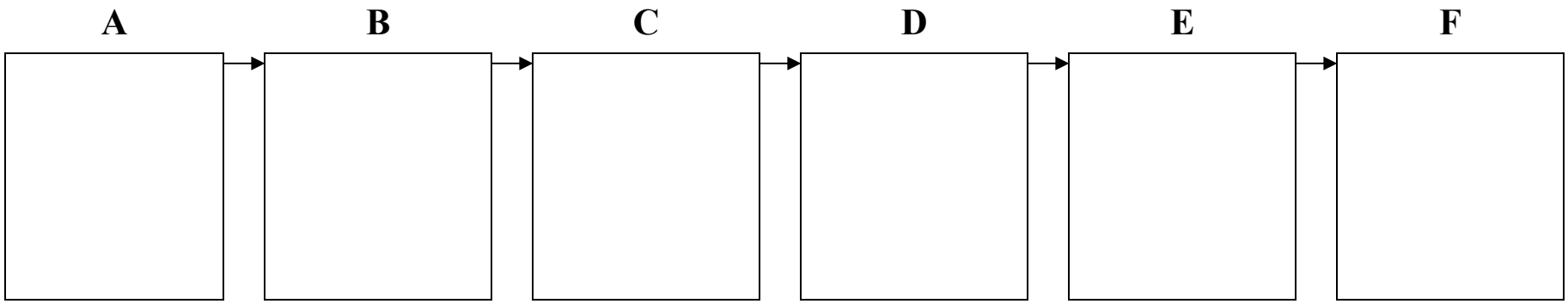
List the sub-processes for each process step and letter

Sub Process Steps	Sub Process Steps	Sub Process Steps	Sub Process Steps	Sub Process Steps	Sub Process Steps
A. _____	A. _____	A. _____	A. _____	A. _____	A. _____
B. _____	B. _____	B. _____	B. _____	B. _____	B. _____
C. _____	C. _____	C. _____	C. _____	C. _____	C. _____
D. _____	D. _____	D. _____	D. _____	D. _____	D. _____
E. _____	E. _____	E. _____	E. _____	E. _____	E. _____
F. _____	F. _____	F. _____	F. _____	F. _____	F. _____

FAILURE MODE EFFECTS ANALYSIS

SUB-PROCESS STEPS: Graphically describe the sub processes for each process step and then list the possible failure modes for each one

If the process is complex you may want to select sub-process to work on



Failure Modes	Failure Modes	Failure Modes	Failure Modes	Failure Modes	Failure Modes
1 _____	1 _____	1 _____	1 _____	1 _____	1 _____
2 _____	2 _____	2 _____	2 _____	2 _____	2 _____
3 _____	3 _____	3 _____	3 _____	3 _____	3 _____
4 _____	4 _____	4 _____	4 _____	4 _____	4 _____
5 _____	5 _____	5 _____	5 _____	5 _____	5 _____
6 _____	6 _____	6 _____	6 _____	6 _____	6 _____

Healthcare Failure Mode Effects Analysis Worksheet

Analysis Steps	**PROCESS STEP**				
	POTENTIAL FAILURE MODE (What could go wrong – go to step 3 to analyze the failure mode, then proceed to list &analyze the causes for each failure mode)				
	EFFECT (What could happen)				
	SEVERITY: 1= No Harm; 2 = Temporary Harm; 3= Permanent Harm; 4 = Death/major loss of function)				
	POTENTIAL CAUSE(s) (Why the failure could occur – list all possibilities for each failure mode and conduct analysis for all failure modes within the scope of this FMEA)				
	PROBABILITY: 1= Remote; 2 = Uncommon 3 = Occasional; 4 = Frequent				
	CURRENT CONTROL MEASURE				
	DETECTABILITY: 1 = Very Likely; 2 = Likely; 3 = Unlikely; 4 = Very Unlikely				
	HAZARD SCORE (RPN* = Severity x Probability x Detectability)				
	DECISION: Proceed or Rationale for Stopping based on score or explanation				
Intervention Steps	**ACTION (Eliminate, Control, or Accept)**				
	DESCRIPTION OF INTERVENTION				
	OUTCOME MEASURE				
	PERSON RESPONSIBLE				
	MANAGEMENT CONCURRENCE (Yes or No)				
	IMPLEMENTATION TIME FRAME/DATE DUE				