

# Failure Mode and Effects Analysis (FMEA)

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# What is Failure Mode and Effects Analysis (FMEA)?

Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process.

# What is Failure Mode and Effects Analysis (FMEA)?

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.

‘FMEA can be employed before new services, processes, or products are purchased or implemented, to identify potential failure modes and so steps can be taken to avoid errors before they occur.’

*‘Failure Mode and Effects Analysis Can Help Guide Error-Prevention Efforts’, Matthew Grissinger, RPh, P&T, January 2003 – Vol 28 No. 1*


# FMEA includes a review of:

## Steps in the process

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

‘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



Failure Modes and Effects  
Analysis (FMEA) was  
developed outside of  
healthcare.





# Step One:

Select a process to evaluate  
with FMEA

## Step Two:

Recruit a multi-disciplinary team

(Be sure to include everyone who is involved at any point in the process)

## Step Three:

Have the team meet together to list all the steps in the process

- Number every step in the process, and be as specific as possible.

## Step Four:

Have the team list failure modes and causes

- List anything that could go wrong including minor and rare problems.
- Identify all possible causes for each failure mode.



University Health Network

## Doctor's Order Sheet

### Anesthesia/Acute Pain Service Patient Controlled Analgesia (PCA) Orders

PLEASE USE BLACK  
OR BLUE BALLPOINT  
PEN. PRESS HARDLY.

ALLERGIES:  
NO KNOWN ALLERGIES  
KNOWN ALLERGIES (Specify)

PHYSICIAN'S ORDER AND SIGNATURE

While on PCA device, patient is to receive no further supplemental Narcotics unless approved by the Anesthesia/Acute Pain Service.

#### 1. PCADRUG:

- Morphine 2 mg/mL
- Meperidine 10 mg/mL
- Hydromorphone 0.4 mg/mL
- Other: \_\_\_\_\_

#### 2. PUMP SETTINGS:

- Dose \_\_\_\_\_ mg to \_\_\_\_\_ mg
- Initial Lockout Interval \_\_\_\_\_ min
- Four hour limit \_\_\_\_\_ mg

#### 3. MONITORING:

Respiratory Rate, Sedation Score q 2 h x 24hr, then q 4 h. Record on PCA Flow Sheet.

#### 4. TREATMENT OF SIDE EFFECTS:

Have Naloxone (Narcan®) 0.4 mg/mL. Ampoule readily available at Nursing Station.

(Check  appropriate box(es) and complete orders as required)

- Dimenhydrinate (Gravol®) \_\_\_\_\_ mg IV/IM q 3 h prn for nausea/vomiting  
IV dose to be infused in 15 - 30 minutes.
- If Dimenhydrinate (Gravol®) ineffective, then give Granisetron (Kytril®) 1mg IV q 24 h  
x \_\_\_\_\_ doses for nausea/vomiting.
- Diphenhydramine (Benadryl®) \_\_\_\_\_ mg IV/IM q 3 h prn for pruritis  
IV dose to be infused in 15 - 30 minutes.

If patient confused or loses IV access - HOLD PCA and Treat Pain with \_\_\_\_\_ mg IV / SC q \_\_\_\_\_ h prn.

PLEASE USE BLACK  
OR BLUE BALLPOINT  
PEN. PRESS HARDLY.

ALLERGIES:  
NO KNOWN ALLERGIES  
KNOWN ALLERGIES (Specify)

PHYSICIAN'S ORDER AND SIGNATURE

#### 6. NSAIDs:

(Choose one of the following only)

- Toradol (Ketorolac®) 15 mg IV q \_\_\_\_\_ h x \_\_\_\_\_ doses
- Celecoxib (Celebrex®) \_\_\_\_\_ mg po bid x \_\_\_\_\_ doses
- Rofecoxib (Vioxx®) \_\_\_\_\_ mg po q 24 h x \_\_\_\_\_ doses

#### Call Acute Pain Service (APS) if:

- a) Respiratory Rate less than 10/minutes
- b) Blood Pressure Systolic less than 90 mmHg
- c) Pulse less than 50 beats per minute
- d) Sedation Score of 3 (somnolent, difficult to rouse)
- e) Inadequate pain control (eg. NRS greater than 4)
- f) If four hour limit of drug dose is reached before 4 hours has elapsed.

7. If side effects of slow respiratory rate, hypotension or somnolence occur, STOP PCA Pump immediately and inform attending service as well as Acute Pain Service.

8. Two RN's will check and verify the initial PCA settings and document on PCA Flowsheet.

9. RN will check and verify PCA setting every shift and document on PCA Flowsheet.

10. (For TGH only) When tolerating fluids well, discontinue PCA then start:

- a) Analgesia \_\_\_\_\_
- b) Bowel Medications:
  - Colace 100 mg po bid
  - Seroquel \_\_\_\_\_ tablets po q \_\_\_\_\_
  - Other: \_\_\_\_\_

In an emergency, if NO response after calling the APS pager #, call Anesthesia Resident or Staff Anesthesia on call through locating.

PAGER NUMBERS:	TGH	TWH
APS Staff	416) 667-6285	416) 667-3557
ACHP	416) 667-6035	416) 667-3765
Anesthesia Resident	416) 664-3490	416) 589-3618
	PMB	
APS Staff	416) 664-6620	
HN	416) 664-6685	



University Health Network

Toronto General Hospital Toronto Western Hospital Prince Margaret Hospital

Doctor's Order Sheet

Cardiac Investigation Unit

Post Cardiac Catheterization Orders

Addressograph

PLEASE USE BLACK OR BLUE BALLPOINT PEN, PRESS FIRMLY

ALLERGIES:

NO KNOWN ALLERGIES

KNOWN ALLERGIES (Specify)

PHYSICIAN'S ORDER AND SIGNATURE

ROUTE/ROUTE AND POSITION	ACTION TAKEN	PHARMACY

(Please check  appropriate box(es) and complete orders as required)

1. MEDICATION GIVEN DURING CARDIAC CATHETERIZATION

- Heparin \_\_\_\_\_ units IV.
- Protamine \_\_\_\_\_ mg IV.
- Atropine \_\_\_\_\_ mg IV.
- Nitroglycerin \_\_\_\_\_ mg IC/ \_\_\_\_\_ mg SL.
- Diazepam (Valium®) \_\_\_\_\_ mg IV.
- Fentanyl \_\_\_\_\_ mcg IV.
- Midazolam \_\_\_\_\_ mg IV.
- Verapamil \_\_\_\_\_ mg IV.

2. POST CARDIAC CATHETERIZATION ORDERS:

Activity Level Bed rest for \_\_\_\_\_ hours with \_\_\_\_\_ leg/arm straight then ambulate.

3. OBSERVATION:

Observe \_\_\_\_\_ groin/arm for bleeding, check Vital Signs and palpate pedal/dorsal pulses in both feet/arms:

- q 15 min x 1 hour then,
- q 30 min x 2 hours then,
- q 1 h x 2 hours until discharge.

4. IV THERAPY:

- Start IV:  D5W to keep vein open (TKVO)
- OR
- Other (specify solution): \_\_\_\_\_ mL, infused at (specify rate) \_\_\_\_\_ mL/h.
- Discontinue IV as per criteria in policy 3.50.013 \_\_\_\_\_ hours after procedure.

5. TREATMENT:

- a) May have head of bed up 30 degrees.
- b) Sandbag for \_\_\_\_\_ hours.
- c) Remove dressing 24 hours after the procedure.

6. RADIAL ARTERY APPROACH:

- a) Clamp time:  Hemoband® 90 minutes.
- Radial Artery Clamp 90 minutes.
- b) Elevate arm on pillow.
- c) May sit up.
- d) Blood pressure on opposite arm.
- e) Vital Signs q 15 minutes while clamp on arm (Blood Pressure, Colour sensation movement and warmth and Oxygen Saturation).
- f) Release clamp as per units protocol (check with department)
- g) Discharge patient with dressing and sling as per units protocol (check with department)

7. POST CARDIAC CATHETERIZATION MEDICATIONS:

Resume pre-catheterization medication except: \_\_\_\_\_

New Medications:

- a) Acetaminophen (Tylenol®) (325-650 mg) \_\_\_\_\_ mg po q 4 h prn
- b) Other: \_\_\_\_\_

8. Discharge...

Physician's Signature \_\_\_\_\_ Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_ Time \_\_\_\_\_









# Step Six:

## Determine which failures to work on

- Calculate the Risk Priority Number (RPN)
  - Multiply the three scores obtained for likelihood of occurrences, detection, and severity
  - Identify the failure modes with the the top 10 RPNs

## Step Seven:

Use RPNs to plan  
improvement efforts

Failure modes with high RPNs are usually the most important parts of the process to concentrate improvement efforts.

## If the failure mode is likely to occur:

- Evaluate causes to determine if any can be eliminated.
  - What safeguards are in place?
  - Do the safeguards work?
  - What would have to go wrong for this failure to occur?
  - Why wouldn't the failure be caught and corrected before it reached to patient?

## If the failure mode is likely to occur (cont.):

- Consider using a force function.
  - Discontinue medications
- Add a verification step.
- Modify other processes that contribute to causes.

## Design and Implement Improvement Strategies to Prevent Failures.

- Eliminate the chance for errors.
- Make it easier for people to do the right thing.
- Identify errors quickly and take appropriate action.

# How to use the FMEA tool

- To evaluate the potential impact of changes under consideration.
  - Teams can 'verbally simulate' a change before implementing in patient care areas
- To monitor and track improvement over time.
  - Use total RPN to set a goal for improvement (i.e. improve by 50%)



# Case Study

# Case Study Worksheet

Steps in the Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrences (1-5)	Likelihood of detection (1-5)	Severity (1-5)	Risk Profile Number (RPN)	Actions to Reduce
1								
2								
3								
							TOTAL RPN (Sum of all RPNs):	





**Questions?**