TG 100 Workshop

(Session 7 of the TG100 Certificate Course)
Failure Modes and Effects Analysis – emergency treatment

Exercise

Learning Objective

To illustrate Failure Modes and Effects Analysis for one process step and using the TG100 methodology

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What is FMEA?

- A risk assessment tool

- It is used to identify weaknesses or deficiencies in processes

- A step-by-step approach for assessing postulated failure modes in a clinical process

- FMEA helps us to prioritize postulated failure modes for further analysis
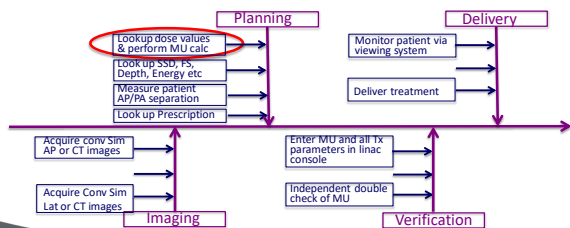
FMEA exercise – emergency treatment

We will complete the first few steps of an FMEA i.e. identify potential failure modes, error pathways and the effects of failure during a **generic** emergency treatment.

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FMEA exercise – emergency treatment

Let's look at this step in a **generic** emergency treatment

FMEA exercise – emergency treatment

Consider this step in the process:

• Lookup dose values and perform MU calculation

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FMEA exercise – emergency treatment

- Think of 1-3 things that could go wrong

- What might cause these things to go wrong?

- How bad would it be if these things happened?

- What is currently in place to stop this FM happening?

- How likely are these causes to happen?

- How likely is it that the failure pathway **not** to be interrupted?

- What would you do to minimize the RPN?

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Exercise 8: FMEA, emergency

Sub-process	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN
Look up dose values and perform MU calculations							

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O, S, and D values

Rank	Occurrence (O) of Cause		Severity (S) of Effect		Detectability (D) of Failure Mode	
	Qualitative description	Frequency in %	Qualitative description	Descriptive	Qualitative description (likelihood of detection)	Probability of going undetected in %
1	Remote probability	0.01	No effect	No effect	Detection almost assured	0.01
2	Failure unlikely	0.02	Inconvenience	Inconvenience	Very high likelihood	0.2
3	Low probability – few failures	0.05	Minor effect	Effect only seen when reviewing large populations	High likelihood	0.4
4	Moderate probability	0.1	Noticeable effect	Suboptimal care for a patient	Moderate likelihood	1.0
5	Intermediate probability	<0.2	Limited toxicity	Minor undertreatment or small overtreatment	Intermediate likelihood	2.0
6	Occasional failures	<0.5	Undesired effect	Care that worsens the patient's life	Some likelihood	5.0
7	High probability	<1	Serious effect	Treatment or diagnostic failures that affect patient function	Low likelihood	10
8	Very high probability	<2	Possible very serious toxicity	Very negative effects on patient	Very low likelihood	15
9	Repeated failures	<5	Sentinel failure	Serious injury	Serious detection problem	20
10	Failure inevitable	>5	Catastrophic effect	Death or very serious injury	Detection unlikely	>20

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FMEA exercise – emergency treatment

- Think of 1-3 things that could go wrong in this step
  - Failure Modes
- What might cause these things to go wrong?
  - Causes
- How bad would it be if these things happened?
  - Effects and severity
- What is currently in place to stop this FM from happening?
  - Current controls

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FMEA exercise – emergency treatment

- How likely are these causes to happen?
  - Occurrence
- Hoe likely is the failure pathway not to be interrupted?
  - Detectability
- What would you do to minimize the RPN?
  - Preventive Actions (Quality management)

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Summary

We have:

- Learned how to perform an FMEA e.g. identify failure modes, error pathways and determine effects of failure on patient treatment

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