TG100 Implementation Guide - FMEA

FMEA

In this section, we are going to learn about Failure Modes and Effects Analysis (FMEA).

"What is FMEA?"

- It is a risk assessment tool. It is used to identify weaknesses or deficiencies in processes. It is a step-by-step approach for assessing postulated failure modes in a clinical process.

"What are failure modes?"

- They are simply the ways that something can go wrong. A failure mode happens when a process step does not produce the desired outcome.

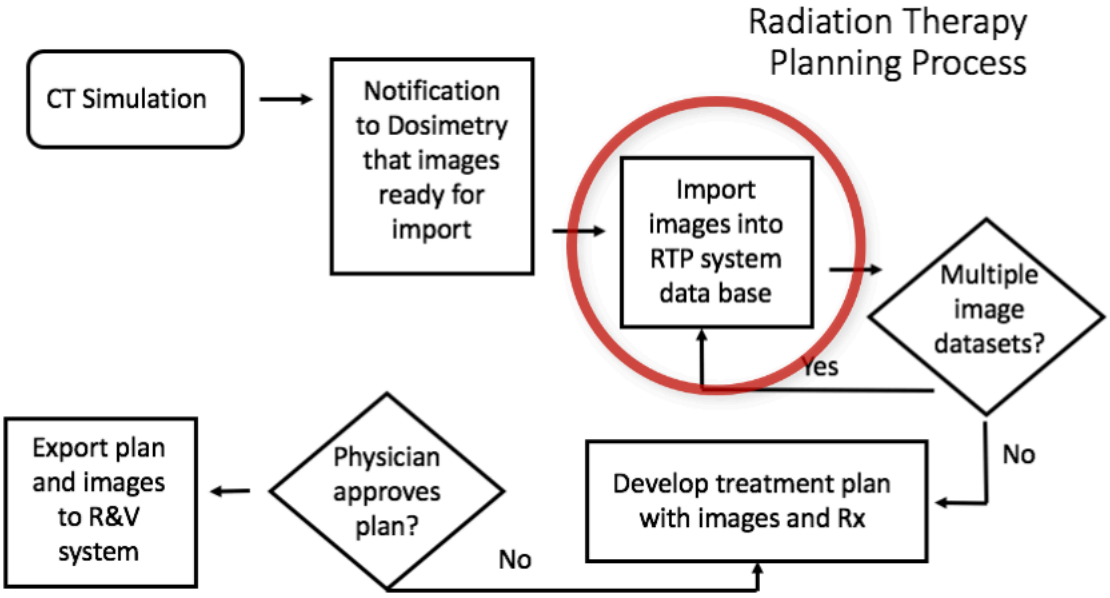
"What is the purpose of FMEA?"

- We want to identify any weaknesses in a process. In order to do that, we identify failure modes in a process and ask a number of questions about how these failure modes came to be and how they might affect the patient.
- Because all failure modes are NOT created equally, we also want to assess the risk associated with each type of failure. FMEA allows us to do just that.

"How do I conduct this analysis in my clinic?"

- Start with a process map. Carefully consider each step in the process and try to think of failure modes or ways that something could go wrong with each step. Next comes the task of scoring the failure modes.

Let's discuss more details of FMEA via an example. Consider this simple process for radiation therapy planning, starting with CT simulation and ending with the export of plan and images to the R&V system. We will conduct an FMEA for the process step involving the importing of images into the planning system database.



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We will use this process step and build a table. In the table, consider including the following information. First, we will make a column for the potential failure modes. Next, it is useful to think of the potential causes for each failure. You'll ask the question: "Why did this failure mode ultimately occur"? In addition, you'll want to make note of the potential effects of failure modes. This will be helpful in scoring failure modes. Now start recording failure modes. Ask yourself: "How can this step go wrong"? In this example, when importing images, we could import the wrong patient's images or import the wrong imaging study (i.e., the wrong phases of a 4D or a wrong MR sequence). Or perhaps we could import corrupt data. These are three failure modes we have thought of for this step.

Process Step	Potential Failure Modes	Potential Causes	Potential Effects				
Import images into RTP system database	Wrong patient's images						
	Wrong imaging study (i.e., wrong phases of 4D, wrong MR sequence)						
	Corruption during import						

Now let's record the potential causes of each failure. A list of common causes includes: types of human errors like distraction or lack of attention, software and hardware errors, miscommunication, or inadequate training or skill. These are just a few to get you thinking. For this example, the wrong patient's images being imported could simply be due to the manual selection of the incorrect patient. The wrong imaging study being imported could be due to a couple of things: inadequate training of the appropriate imaging studies to acquire or miscommunication among the team about which study is appropriate. Corrupt data would ultimately be the result of a software error.

Process Step	Potential Failure Modes	Potential Causes	Potential Effects				
Import images into RTP system database	Wrong patient's images	Manual selection of incorrect patient					
	Wrong imaging study (i.e., wrong phases of 4D, wrong MR sequence)	Inadequate training of appropriate imaging studies					
		Miscommunication					
	Corruption during import	Software Error					

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Let's go through the potential effect of each failure. Ask the question: "How will this failure effect the patient"? If we import the wrong patient images, we could end up with the wrong dose distribution or the wrong target volume. If we import the wrong imaging study, we could again end up with the wrong dose distribution or the wrong target volume. Let's split the next failure mode up into having two effects: one effect could be the loss of patient images or the other, more severe type of data corruption, could also result in the wrong dose distribution or the wrong target volume.

Process Step	Potential Failure Modes	Potential Causes	Potential Effects				
Import images into RTP system database	Wrong patient's images	Manual selection of incorrect patient	Wrong dose distribution; Wrong volume				
	Wrong imaging study (i.e., wrong phases of 4D, wrong MR sequence)	Inadequate training of appropriate imaging studies	Wrong dose distribution; Wrong volume				
		Miscommunication					
	Corruption during import	Software Error	Lost images				
			Wrong dose distribution; Wrong volume				

Now we will score each failure mode, taking into account the information we have just recorded. If we are going to come up with a score, we need a scoring system. The following table is from TG100 and it describes three parameters which we will use to characterize and prioritize each failure. Please note that this scale is from 1-10 though other scales have been used. The first parameter, occurrence or *O*, describes the likelihood that a particular cause for the specified failure mode exists. *O* ranges from 1 (probability that particular cause exists is low) to 10 (highly likely the particular cause exists). Severity or *S* describes the severity of the effect on the final outcome if the failure is not detected or corrected. Ask yourself: "How severe is the effect on the patient if this failure were to reach the patient"? *S* ranges from 1 (no danger or minimal clinical disturbance) to 10 with a catastrophic outcome. Detectability or *D*, describes the likelihood that the failure would not be detected in time to prevent an error. *D* ranges from 1 (very detectable) to 10 (very hard to detect).

TABLE II. Descriptions of the *O*, *S*, and *D* values used in the TG-100 FMEA.

Rank	Occurrence (*O*)		Severity (*S*)		Detectability (*D*)
	Qualitative	Frequency in %	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01	No effect		0.01
2		0.02	Inconvenience	Inconvenience	0.2
3	Relatively few failures	0.05			0.5
4		0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	2.0
6	Occasional failures	<0.5			5.0
7		<1	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2			15
9		<5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location, or volume	20
10	Failures inevitable	>5	Catastrophic		>20

Use your knowledge and experience with this process to determine these values. You'll note in this example that different potential causes may occur at different frequencies and are therefore scored separately. In constrast, different causes with the same effect on the patient will end up with the same severity score.
These three parameters are multiplied together to obtain a single metric called a risk priority number, or RPN. These tables are often sorted by RPN AND Severity rankings to recognize both the most hazardous and the most severe failure pathways.

A few tips to get started on FMEA:

- Form a team. Make it multidisciplinary and cross-functional with representatives from various groups in your department.
- Start with a small, simple process to analyze and work up.
- The power of an FMEA is to try and think of as many failure modes as possible. Refer to your Incident Learning System as a starting point and then think outside the box for failures that you may not have experienced yet.
- Consult each team member. Everyone brings a different perspective on what can go wrong.
- Don't get hung up on the perfect score! It does not exist. It is all relative to the department's practice and each team member's experiences.

You will find that in practice, two different groups may come up with two different FMEAs and that is OK because every department is different and everyone has a unique radiotherapy process. Trust that each risk assessment will highlight the parts of the process and the failure pathways in need of attention.