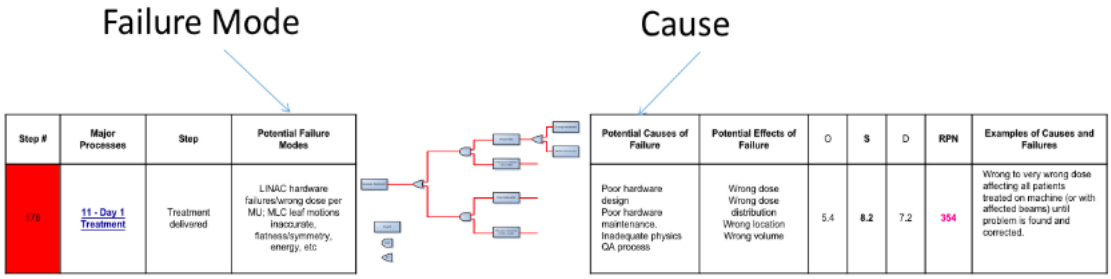
TG100 Implementation Guide - FTA

FTA

In this section, we will talk about Fault Tree Analysis (FTA).

"What is a fault tree?"

- It is a tool used to trace failure pathways back to the causes and contributing factors. A fault tree analysis starts with the FMEA. Imagine that we have identified a failure mode and its potential cause but it is likely that there are many steps in between these two. With fault tree analysis, we are taking a closer look at the failure pathway. In the analysis, we will ask the questions: "How could this failure mode propagate into an error"? and "What happens in between the underlying cause and the failure"?



It is possible that some pathways are stronger or weaker than others at catching and preventing failures. Thus, we are able to identify systemic program weaknesses, if present. It is also likely that we have quality checks along the way and we have the opportunity to realize whether they are effective. Do we have the quality checks in the most effective spot in the process to catch or prevent an error?

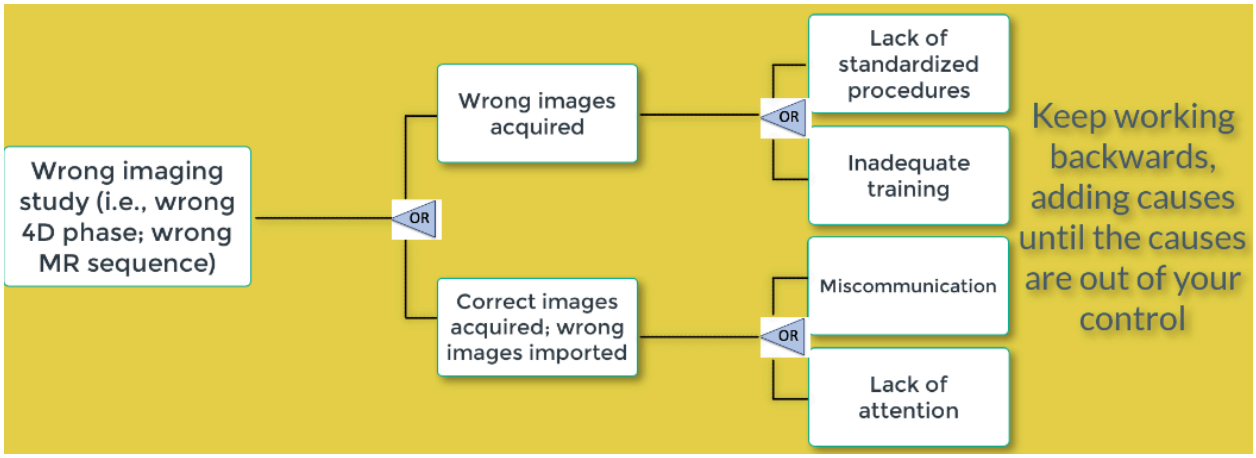
"How do I build my own fault tree?"

- Start with the FMEA. Identify a failure mode in need of a quality management plan.

Let's take the failure of importing the wrong imaging study such as the wrong 4D phase or the wrong MR sequence and place it on the left side of the fault tree. What could have led to the wrong study being imported? It could be that the wrong images were acquired in the first place. Or it could be that the correct images were acquired but the wrong images were exported.

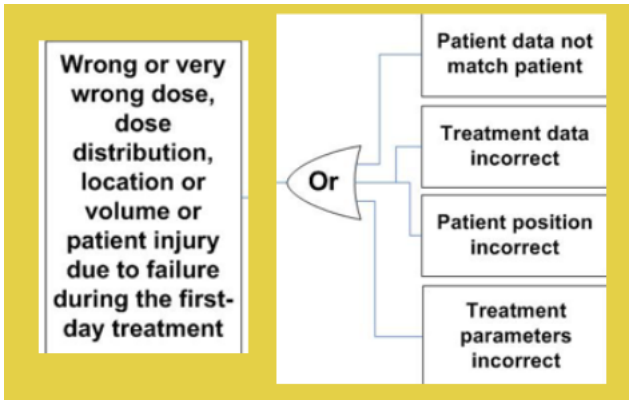
We have the option in a fault tree to choose from an OR gate or an AND gate. When two or more separate events can lead to a failure, we use an OR gate. This means that either pathway would lead to this failure. When two or more events must occur for the failure to propagate, we use an AND gate. In this example, either circumstance could lead to this failure so we use an OR gate. Each of these causes we have identified are also failure modes themselves, with causes of their own. So we keep going in

building the fault tree, adding more causes. At this point we ask: “What could have caused the wrong images to be acquired”? It could be that the technologist did not have the knowledge of the appropriate imaging studies to acquire due to lack of standard operating procedures. Or perhaps there is some standard in the department but there is inadequate training. Both of these could independently lead to this failure so we use an OR gate. Next, what could have caused the correct images to be acquired but the wrong images are imported? In this case, miscommunication between team members could have occurred or perhaps lack of attention on the part of the team member. Either of these could lead to the failure. At this point, we can keep adding causes until the causes are out of our control.



Let’s look at another example.

Depending on the goal of your project, it may be useful to start an FTA with the overall failure mode. A generalized failure mode that we are all ultimately trying to prevent. In this example, it is the wrong or very wrong dose distribution, location or volume or patient injury due to failure on the first treatment day. Potential causes are: patient data did not match, treatment data incorrect, patient position incorrect, or treatment parameters incorrect.



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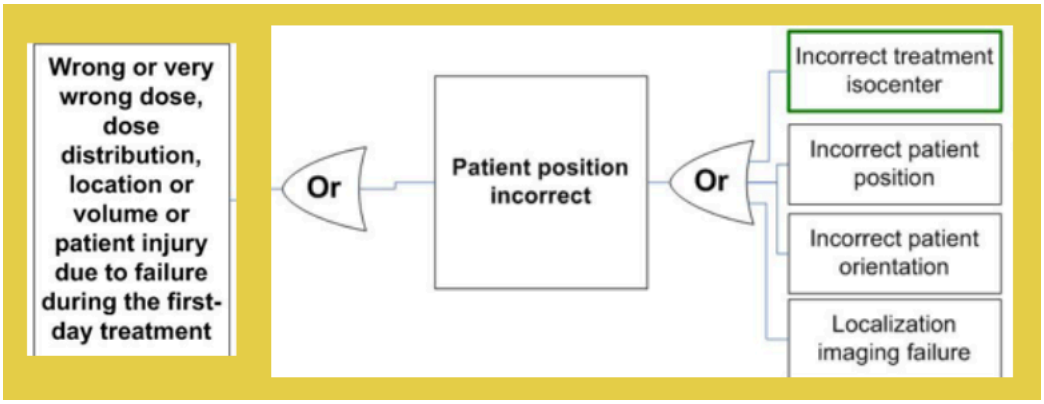
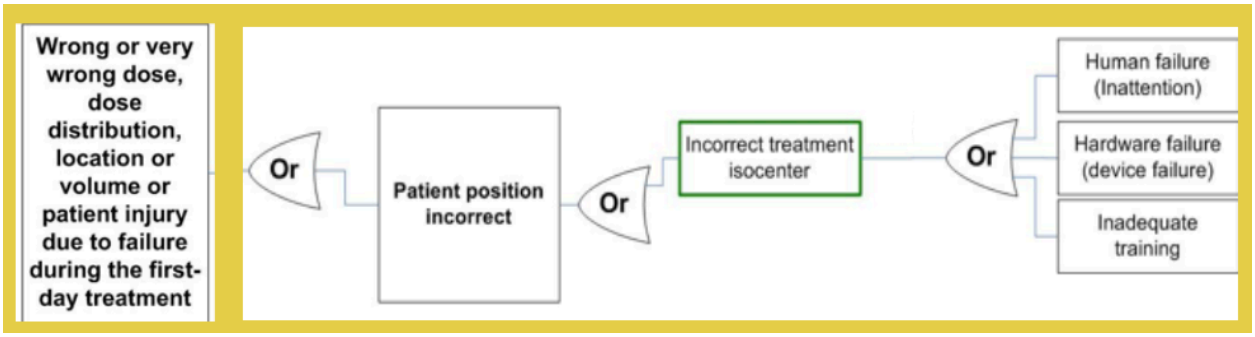
Let's look a bit further at patient position incorrect. Potential causes of this are: incorrect treatment isocenter, incorrect patient position, incorrect patient orientation or localization imaging failure.



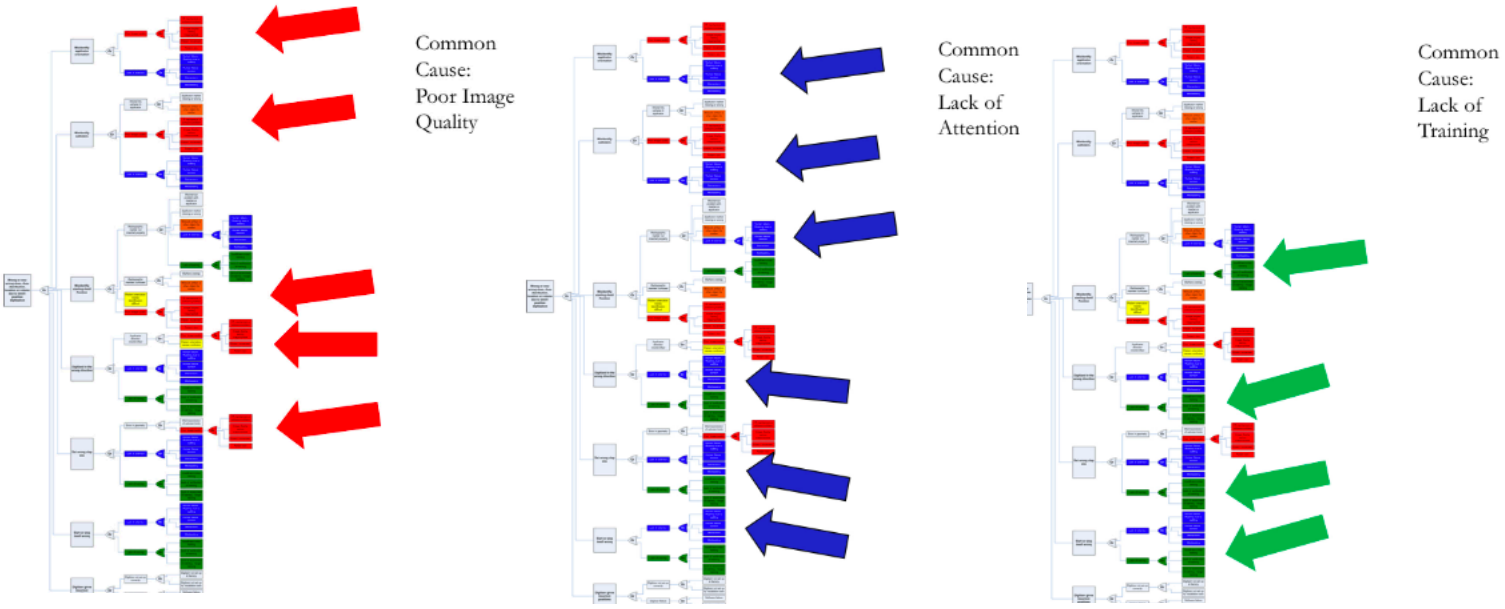
If we look further at incorrect treatment isocenter, causes of this could be: inattention, device failure or inadequate training. This is where we can stop. We have the ability to work on and potentially mitigate problems rooting from these causes but causes beyond this would be out of our control.



Now that we know how failures can find their way through our processes, we can think about:
"How do I design my system to prevent errors?"

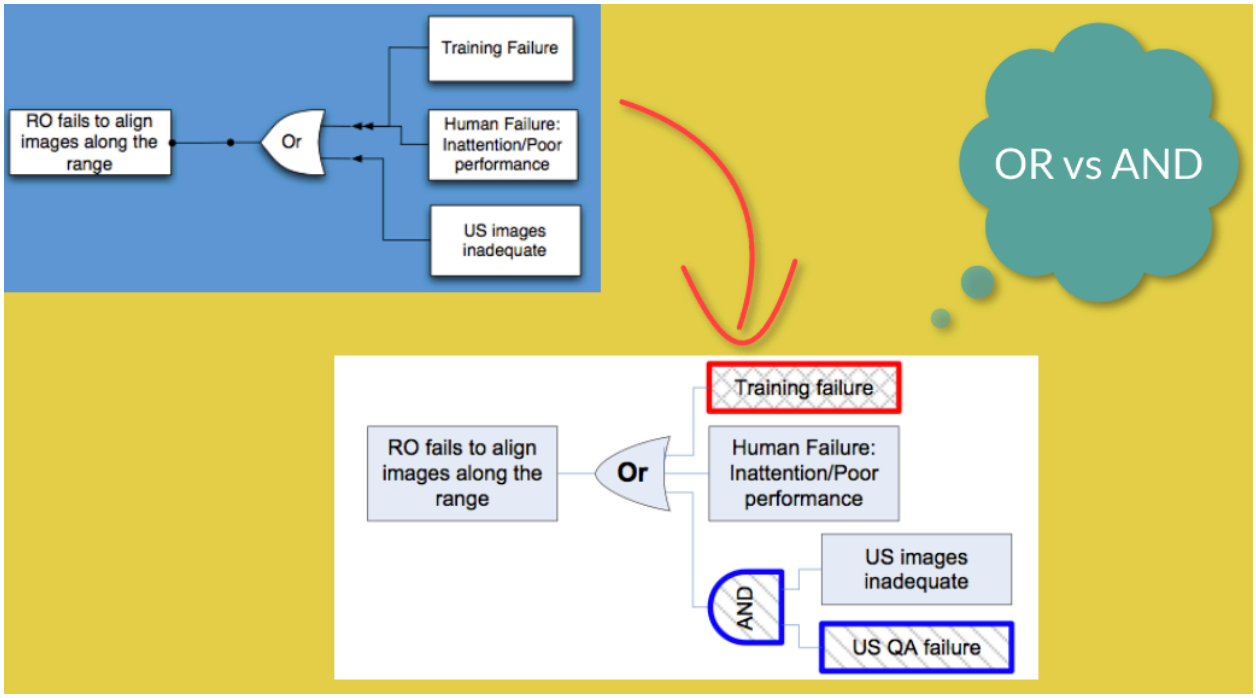
- With fault tree analysis, we can look at a few things to make our processes more robust: Common causes, OR versus AND gates and quality checks.

Common causes are those that pop up frequently as underlying causes in the fault tree. In this example, the causes are color coded by type. We find that there are several common causes: poor image quality, lack of attention, and lack of training. This can be extremely helpful to identify as we may choose to focus our resources on causes that affect multiple failure pathways.



OR vs AND Gates

Recognize that when OR gates are present, they represent increased hazard in that multiple, independent causes could lead to an error. AND gates represent increased protection because two or more causes would have to be present for the failure to occur. Let's look at an example where three separate causes could lead to a failure: training failure, inattention/poor performance, and ultrasound images are inadequate. If we redesign the system, adding QA of ultrasound images, we have added a layer of protection to the system. Now both the US images would have to be of poor quality AND the QA of them would have to fail for an error to propagate along this route. This makes the propagation of a failure more unlikely.



Quality Activities

It is difficult to know where along the pathway to insert a quality activity such as a checklist or a timeout. Instituting a quality step that prevents multiple failure pathways at once can be an effective use of resources. For example, instituting annual training. However, for high severity failure modes, it may be appropriate to insert a quality step immediately before the failure mode, like an additional timeout.

A few tips for doing FTA:

- Form a team. Make it multidisciplinary and cross-functional with personnel from various disciplines in your department.
- Start with branches of the fault tree with the highest risk and go from there.
- Be open to new approaches such as redesigning the system.

More tips for general quality management are provided in the next section.