

Diagnosis of Clinical Process Failures

Remember, Hippocrates "light". We're going to try to place the clinical process failures "in the light" and, at the same time, try not to stand in the light.

– You are the experts on the clinical processes we're examining, but you have a distinct disadvantage: you know so much about the current system that it's difficult to capture what you know and to bring it into the light for examination and improvement. In addition, different team members may have different perspectives on how processes work and how they can fail. Many of our improvement techniques are limited in their capacity to surface these different perspectives, to create a common and shared representation of our processes.

– To address this, we're going to try a method we've borrowed from other high-risk industries – fault tree analysis. We'll go through some background on this because we hope that you'll find this a useful method and will be interested in applying it to the improvement efforts you undertake.

Covenants:

I'm not advocating that this is a method that should or must be applied to every problem. There are plenty of situations where this is simply more analysis horsepower than you will need. (It can be used in combination with other methods.)

We're going to spend about an hour on this today – you will not be experts at the end of that hour! Developing effective fault tree analyses is a skill, a skill worth developing, but you have to invest in it.

Overview

- Fault tree analysis: principles and methods
- Review draft pressure ulcer fault tree
- Revise/expand fault tree
- (Later) identify critical failure paths

The purpose of this session is to introduce you to a techniques to determine the nature of the process failures we observe in our quality indicators – a process for diagnosing the sources of failure in care systems and processes. The focus of this activity is on diagnosis, not on solutions (although I expect that with a more explicit diagnosis, effective, and ineffective, solutions will become more evident). We'll talk about linking diagnoses with solutions (or treatments) in the next session.

We're going to review fault tree analysis methods

Together, as a group, we'll review some preliminary and draft fault trees that we've put together as a starting point

We'll give you a chance to revise, correct, and comment on these draft fault trees, and identify critical failure paths (prioritize for your improvement efforts)

Fault Tree Analysis (FTA)

A top-down approach to failure analysis that begins with an undesirable event, the top level event and then identifies the failures or combination of failures that can produce this event.

Fault tree analysis is a "top down" approach. We begin with the outcome, the "undesirable event" that we would like to prevent. We then identify the different failures or combination of failures that can produce this event.

Fault trees, in conjunction with other analyses and data, can help us:

Predict the reliability and safety of systems or processes.

Identify the most likely failure paths so we know where to focus our efforts.

Understand the influence of the configuration of work processes and design features on reliability.

Prioritize areas for further review, analysis, and investigation.

Determine expected impact of proposed interventions or system redesign efforts.

Increase the effectiveness of team interactions – a communication tool.

I'll mention in passing that fault tree analysis is different from Failure Modes and Effects Analysis (FMEA), which we'll be talking about later on today. Neither method should be thought of as uniformly "superior" to the other – they have similar purposes, but are applied in different circumstances. With fault tree analysis, we begin by specifying the outcome we're trying, through redesign, to avoid, with failure modes and effects analysis, we begin with individual component or process step failures and ask what would be the impact of these failures.

This is different also from "cause and effect" analysis (or fishbone diagrams) in that the combinations of failures required to produce the undesirable event can be represented. It is fairly labor intensive, but working together, and for the purposes of the pilot, I think it's worth it in this case.

FTA Structure

- Top level event or failure
- Failure paths:
 - Context, operator, and tasks
 - Defenses breached

A useful way to think of Fault Tree Analysis is in terms of the following components:

We begin with our top-level event or failure.

Then we develop a tree representation of the various failure paths that can produce this top-level event. These failure paths will specify both the context, operators, and tasks where the failure was initiated and the defenses that have to be breached (the other system breakdowns that have to occur) in order to produce the top level event.

Top Level Event

- Patient outcomes
 - Adverse event
 - Quality measure failure
- Process failures
 - Quality indicator failures
 - Undesired/unsafe system state

Top level event or failure can include:

Adverse patient outcomes

Quality measure failures

Quality indicator failures

Undesired/unsafe system states

So, any of our CMS indicators or measures are suitable. But it's important to be specific about the top level event – especially whether we're talking about processes or outcomes, whether measurement or documentation failures are possible contributors and whether "unavoidable" outcomes are included.

Context, Operator, and Tasks

- *For quality indicator failures, consider:*
 - Measurement
 - Documentation
- Modes of patient entry into process
- Procedures/processes used for different patient types
- Provider/operator type
- Process step
- Task step
- Perceptual and cognitive stages within a task

The failure paths will describe different failure modes in terms of the work context, operator(s), and tasks they are performing. For our purposes, it may be useful to think of describing failures in terms of the following (although it won't be necessary to include all of these dimensions in every fault tree and there may be additional important factors to be considered):

Limitations in clinical science – for undesired patient outcomes (not for our indicators)

Measurement and documentation – for quality indicator failures

Modes of patient entry into process

Procedures/processes used for different patient types

Provider/operator type

Process step

Task step

Perceptual and cognitive stages within a task

We'll explore these further in the examples.

One of the things that will come out early on is that we can't develop a branch on our fault tree for every conceivable failure type or for every shade of variability. In the course of the process there's some heuristic prioritization.

Defenses Breached

- Intentional redundancy
- System reminders/prompts
- Forcing or limiting functions
- Team work
- Patient and/or family

One of the most powerful features of fault tree analysis is the ability to visualize the redundancy and defenses designed into a system (in fact, if there are no such redundancies, FTA may not provide much insight), and, more important, where there are no redundancies (the "open nets" in our systems). The idea here is that system performance, system reliability, is only partially determined by the reliability of the basic tasks (not all errors or violations result in unhappy outcomes) – it's also determined by how those tasks are configured. FTA allows us to see the effects of this configuration,

The redundancies we've specifically designed into the system

The reminders or prompts that are encountered

Whether the work is designed such that you can't proceed without completing a task correctly (those forcing or limiting functions)

Prompts from other team members

Prompts from the patient or their family

Example Review

- Incident pressure ulcer

Analysis procedures:

Pressure ulcer:

Me and informant (clinical topic expertise) – 1 to 1½ hours

Feedback from other clinical topic experts

2) Acute care hospitalization:

Me, other analysts, and team of clinical topic experts – 6 hours

Focus groups (iterative – 8 hours)

Feedback from other experts

Possibly 5 major revisions overall

Team Activities

- Review working fault trees
 - Clarify understanding of structures
- Begin development of fault tree for your topic(s)
 - *If we don't have enough information*, develop information collection plan
 - Identify dominant/key/important branches



Fault Tree Analysis

A completed fault tree will include basic events and a description of the configuration of defenses. The next analysis step would be to predict failure rates so that we can identify vulnerable features of our system and process design.

Data sources for failure rate prediction:

- **Review of actual cases**
- **Human reliability analysis (task analysis) for basic events**
- **Expert (your) opinion**



A Note on Basic Events

A basic event can describe:

- The operator type responsible for performing the task (someone)
- A specific task or operation within a specific process (doing something)
- The context in which the task is performed (somewhere)

These can be further analyzed to predict the likelihood and nature of failure



The elements the fault tree provides are a description of relevant basic events. Basic events can describe:

The operator type responsible for performing the task (someone)

A specific task or operation within a specific process (doing something)

The context in which the task is performed (somewhere)

As it turns out, this is the type of information we use to understand the likelihood and nature of failure. These are the kinds of things human factors practitioners ascertain.

Putting It All Together

- Thoughts
 - Insights: did this provide a new/useful perspective on the clinical process?
 - Development and applications: how can we apply this to other improvement efforts?
 - Applications to guideline implementation efforts?

