Inside Medical Liability

The Genetic Test That Wasn’t Done

And

Annual ‘Industry Update’
Proactive Blindness: The Allure (and Costs) of Reaction

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The allure of an effective reaction to an adverse event derives from the fact that when it happens, there is adrenaline pumping and, eventually, recognition for a job well done.

Lives could have been lost, as well as significant financial losses via claims and other related costs. However, a paradigm shift is necessary to recognize the greater benefits of “proaction,” a new approach that obviates the need to react in the first place. To make this happen, proaction must become a priority, and incentives will be needed to persuade people to become part of this new type of culture.

Figure 1 indicates how the candidates for root cause analysis (RCA) are selected in the reactive, versus the proactive, paradigm. There are two proactive, analytical tools discussed here: (1)

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failure modes and effects analysis (FMEA) and (2) opportunity analysis (OA). Clinicians on the front lines can use these to make a business case for proaction.

FMEA and OA are field-tested tools, in essence, two approaches to risk assessment and prioritization. They identify things that could go wrong, and they assign quantitative values to those potentials. This will be a measure of risk. At some point in this type of analysis, we will draw a line and say everything above that point is an unacceptable risk, and below it, is a risk we are willing to live with and mitigate if possible.

**FMEA vs OA: What’s the Difference?**

FMEA is not a foreign concept to high-hazard industries; it has been a regulatory requirement to formally assess risk for more than five decades. The requirements are quite rigid in the high-hazard industries and a critical step in any reliability and environment, health, and safety strategy.

While variations of FMEA exist, Figure 2 is intended to express the basic concept. The universal measure of Risk is Severity (S) x Probability (P) = Criticality (or Risk Prioritization Number [RPN] in healthcare). Different industries use different value tables to measure these parameters. Regardless, they end up quantifying risk.

An FMEA is a tool that puts a magnifying glass on a “process flow” (either new or already in place) and analyzes what could go wrong within each process step. It lets us determine the impact on the overall process if a given failure mode were to occur. After that, it becomes a subjective evaluation on the Probability (P) the failure mode will occur and its Severity (S) if it were to occur. As Figure 2 indicates, it lets us look into a crystal ball and predict what might happen in the future. Certainly, our experiences in the past will play into that subjective evaluation of the future.

An FMEA can be applied to any business in any industry; the framework is applied in the same way. Every organization is a “system” (inputs > transformation > outputs), so where FMEA is applied is not of significance.

When such an analysis is completed, the analyst can sort the items in the “criticality” column from highest to lowest. One way of “drawing the line” between acceptable versus unacceptable risk, is to figure the sum for the criticality column, and multiply it by .80. Then, we can add up how many of the top failure modes (rows) it takes to equal or exceed the 80% number totaled in the “criticality” column.

Wherever this point falls, the identified risks above the line are deemed “unacceptable” and will require further, deep-drill analysis using tools like RCA to determine why the risks are so high. This is truly a proactive application of RCA: no failure has yet occurred. We are using the RCA to minimize the risk that such potential failures will actually occur.

Let’s contrast this procedure to an OA, as seen in Figure 3. While an OA is typically not a regulatory requirement, it may be deemed a recommended best practice. This is the reason why most people likely have never heard of this tool. It is a sister analysis to the FMEA, but instead of predicting the future, it relies on looking in the rearview mirror to see what has happened, not what might happen.

Notice that the calculation in this case is...
based on failures that have occurred (usually in the past 12 months) that have met some predetermined definition of failure. Samples of these include:

- Any event or condition that has resulted in a claim paid due to a surgical misadventure
- Any event or condition that has resulted in an adverse drug event (ADE)
- Any event or condition that has resulted in a blood redraw in the ER.

Defining what constitutes a “failure” in the process analyzed establishes the scope for the entire analysis. This is necessary in order to maintain our focus on what is important to us, at the time.

In these cases, the analysis teams (usually made up of those closest to the work) identify events they have encountered in their daily work that have met the definition of failure in each process step. The facilitator will simply ask, “How often does that happen in a year?” And then, every time it does happen, “How long does it take to get back to normal operations and what costs are incurred during this interval?”

Notice in these examples how the frequency factor sheds new light on the true cost of seemingly insignificant chronic failures. When these happen one at a time, no one usually cares because personnel were not hurt and the costs of each event were minor. They are hidden in plain sight in our budgets. The blood redraw line item is a classic case of a chronic failure that is perceived as a normal cost of doing business and therefore considered acceptable.

This type of analysis will provide the raw data to be able to determine the cost of inefficient labor (because they had to react and could not be doing more productive work), the costs of extended lengths of stay (or what we call “lost profit opportunities”), and the costs of any materials that were used to get back to where we were before. If claims were paid in such cases, they were paid in addition to the costs just described, which normally go unnoticed. The simple calculation here is Frequency/Yr x Sum of the Impacts/Occurrence = Total Annual Loss (TAL).

Then the lead analyst does the same sorting as he did with the FMEA, summing up the TAL column in this case, and arriving at the 80% number. Usually 20% or less of the Failure Modes (rows) will equal or be greater than 80% or more of the TAL (the Pareto Split in Figure 4). In an OA (and FMEA), these are now the quantified and qualified candidates for a thorough RCA.

### OA case study results

In the explanation of the OA tool shown in Figure 3, we cited a few line items to demonstrate how to fill in the blanks with relevant data. The blood redraw line item was actually the subject of a published case study that is quite persuasive in demonstrating the OAs’ capacity to express astounding returns on investment (ROIs) that result from the identification of chronic failures in a process.

Figure 5 shows the summarized results of this case study: blood redraws in the ER were costing more than $3 million annually. Here, the OA was done because they wanted to do it, not because a regulation compelled them to do it. After this analysis, redraws became a candidate for RCA; before, they were not.

To me, the OA is the more valuable tool, because it makes it easy
to determine ROI rapidly. The “Frequency/Year” column is what allows the chronic failures to bubble up to the top and catch the eye of CFO types (and other Cs). These chronic failures are eating our lunch and are typically contributing factors/root causes in more serious events that occur, ones that frequently result in claims (and claims paid). So conducting this sort of proactive analysis is indeed an effective approach to preventing unnecessary liability, and thus claims as well, in the future.

Summary
To summarize (Figure 6), the OA is historical and deals with factual evidence (because these events have occurred). The reason we still call it “proactive” is because the chronic nature of the failures it identifies are failures that are generally viewed as acceptable because we have learned to compensate for them.

The FMEA on the other hand is truly proactive as it looks to tomorrow and seeks to identify unacceptable risks before they materialize.

Using both of these tools together, as part of an overall reliability strategy, is key to shifting from a reactive culture to a proactive one. This will allow us to “control the fix, instead of the fix controlling us.”

High reliability organizations have an obsession with “failure,” whether they are sporadic/acute in nature or repetitive and chronic.

Business case tools like these make it easier to correlate the impact of failures in our work flows to our financials. Since we are usually seeking funds from our budgets to pursue these opportunities, we need to speak the language of finance so they can see the potential returns. These tools also allow us to show the cost of inaction.

Tools like OA and FMEA help us view healthcare as a system and a science. They also allow us to see that now, in order to make a quantum difference not only in patient safety, but on our bottom lines as well.

Dr. Peter Pronovost says that the fundamental problem with the quality of American medicine is that we’ve failed to view the delivery of healthcare as a science.1

Unfortunately, if we don’t use these types of analytical tools, it is nearly impossible to find and quantify these opportunities. There is no line item on our balance sheet or income statements for the specific annual costs of chronic failures or the cost of not acting on a high risk.

Remember, “We NEVER seem to have the time and budget to do things right, but we ALWAYS seem to have the time and budget to do them again.” Together, using these basic tools, we can defeat this paradigm and make a difference to our patients now.

For related information, see www.reliability.com.

References