Detection to the Rescue

FDA Medical device recalls hit an all-time high again. Hidden faults make hidden defects.

Richard L. Bollinger

Back in 2016 MDDI published a paper titled "What's Behind MetTech's Recall Epidemic?" by Joshua R. Dix, Suraj Ramachandran, and Darin S. Oppenheimer.[1] They reported that FDA recalls hit an all-time high in 2014.

Figure 1 shows it has happened again in 2017. This most recent fiscal year now holds the record.

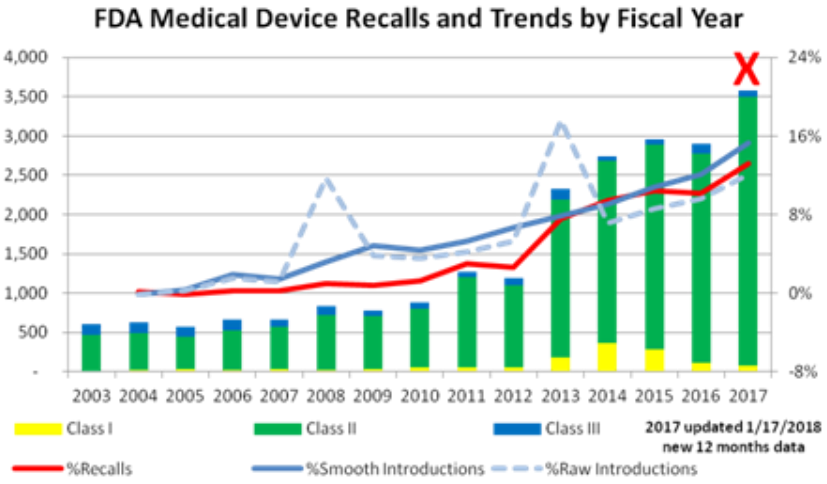

Figure 1 Recalls by Fiscal Year and Class

MANUFACTURERS ARE GETTING A BAD RAP

The 2016 paper blamed risk management: the culture, the shallow understanding industry-wide, the inability to tie risk management into quality management systems. A valid claim, but, only a symptom.

There was never an epidemic. Only economics. More devices means more recalls. New companies are no better at risk management. And, older companies are not improving, either. At least, not for the last 10 years. The data speaks loudly. Growth of recalls correlates 95% with growth in new device introductions (blue lines). The solid blue line has two spikes averaged out. The dashed line shows the raw values. And, the result is the same. The problem here is complacence.

The industry needs to have higher risk management standards, yes. Add Detectability to make your risk management more rich and robust. Find tools and methods to implement it and make full use of it.

There seems to be a lot of confusion about Detectability. Some articles say it should not be used because it is flawed and unnecessary[2], or it does not meet ISO standards[3]. Others say FMEA requires it, but then present a rote and shallow understanding of why and how it should be used.[4] Who says ISO can discount many decades of rich engineering tradition?

DO THE BEST YOU CAN

Always do what's right. The medical device industry needs to debate the use of Detectability. You should use it until you know for certain you don't need it. Or, an official auditor cites you for it. Detectability will win in the end. You should never be cited for doing more than regula-

tions require. ISO and other agencies should learn and observe this principle. Otherwise to make products safe and reliable, an organization could be faced with a terrible choice. Doing the best it can, or following regulations to the letter and doing less. How do you want your next medical device made?

HIDDEN FAULTS MAKE HIDDEN DEFECTS

> "Detection is a numeric ranking that reflects the likelihood your current controls in their current configuration will detect a failure mode, assuming the failure mode is present, and regardless of the severity. A low value indicates detection is easy and likely. A large value indicates it is difficult and perhaps impossible. It is a relative ranking within the scope of the specific FMEA, product or project, as needed."

Detection rank is not all that complicated. It just rates how hard it is to detect risks before products reach a user. (See sidebar for a more complete working definition.) A higher Detection rating does its job by raising the overall priority (RPN) of a risk so that it receives more appropriate attention and resources to mitigate severity and likelihood of harm. This protects your RPN calculations from mistakenly being low by not identifying and mitigating a hidden fault. The results of unmitigated hidden faults are hidden defects that leave the factory to cause harm. These give rise to FDA recalls and official pronouncements that speak poorly of your product quality.

Detection is never a mitigation of risk. However, Detection-based controls can be used as mitigation. Mitigation will increase the probability that a risk will be caught before it reaches a user. Mitigation is always the action taken to reduce a risk's impact or probability. Like adding a test or inspection that makes failure modes present more easy or more likely to notice.

Figure 2 shows a simple model with processes in stages from Design to Use. The product has two components. One goes inside the other during manufacturing. The components have separate designs. In this model a fictitious potential problem arises when assembled. The red dot indicates where it is introduced. But, when it is introduced is uncertain. It could be during any stage of development or manufacture.

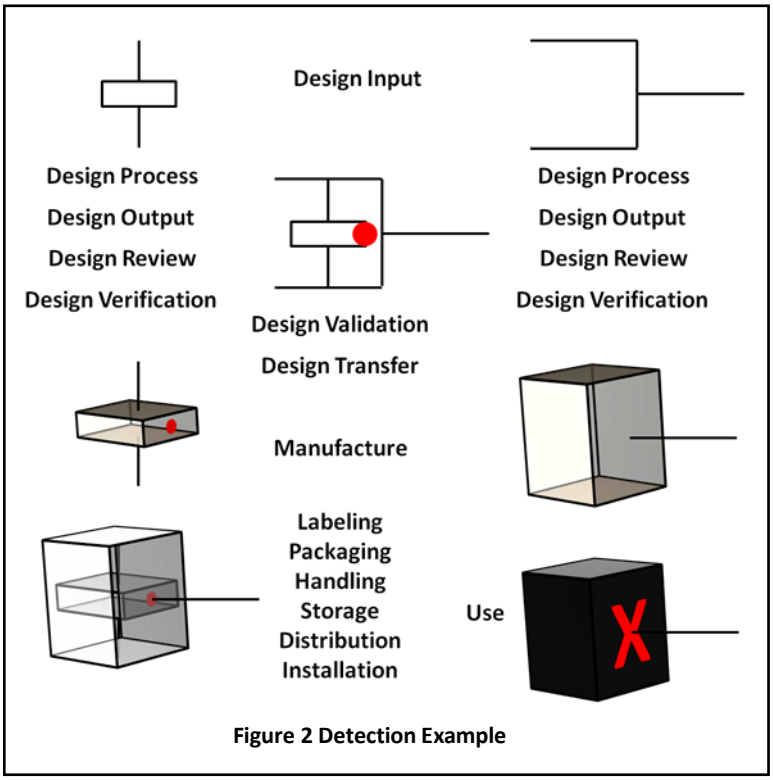

Figure 2 Detection Example

Detection to the Rescue

The failure mode could be any kind of problem: material, dimensional, electrical, a software bug. (Big jet manufacturers combine all their system models, like electrical, signal, hydraulic, air and water to avoid dangerous conflicts.)

From Design Input, our model splits into multiple paths like done for many actual devices. Using Design Controls, paths combine for Design Validation and Design Transfer. If the problem was dimensional, the designs could be inspected to make sure tolerances were correctly observed. And, in manufacture, components could be measured for the same.

Every process is a chance to introduce risks. Every process is a chance to detect risks. Build it into their definitions. The earlier a risk is detected, the easier and cheaper it is to remedy.

Manufacturers that have been in business a while should have a proprietary risk vault of past risks detected and, better yet, not detected, before reaching a user. This is a learning process. It creates a precious resource for future risk management. For future detection.

Your risk vault should help drive planning and process design. Any past problem is a potential future problem. This resource should gradually improve the safety and quality of your products. Every project should have a post-mortem where its history is mined for project risks, product faults, and lessons learned.

Once a product is in the hands or use by a customer or patient, there is no chance of prevention. The opportunity of detection is gone. Detectability is never about discovering harm from a failure after it occurred. It was always about discovering the failure mode before it failed. Mitigation is doing something to prevent or reduce the harm. Like adding a requirement for software. Maybe changing a process. Adding an inspection. Tacking on new tests.

Detectability gets the best results when used in a comprehensive program that employs Fault Tree Analysis and Failure Mode and Effects Analysis. When more easily mitigated risks have been accepted, the more uncertain ones loom larger in their quest for priority. And, when one has been revealed the rest may become more apparent.

Figure 3 Red Hot Stove Burner Example

DETECTABILITY MISUNDERSTANDINGS

Some experts claim Detectability is unnecessary. They say it is covered by Occurrence/Likelihood.

Jon Speer has an article[2] with lots of good advice. But, he has picked a bad example

and it corrupts his recommendation to exclude Detectability.

Detectability never reduces probability of occurrence in medical devices. Let's examine Jon's example of a red hot stove burner. His intentions may have been good, but his example leads to misunderstanding. Human examples can be misleading. Let's follow it again and go further.

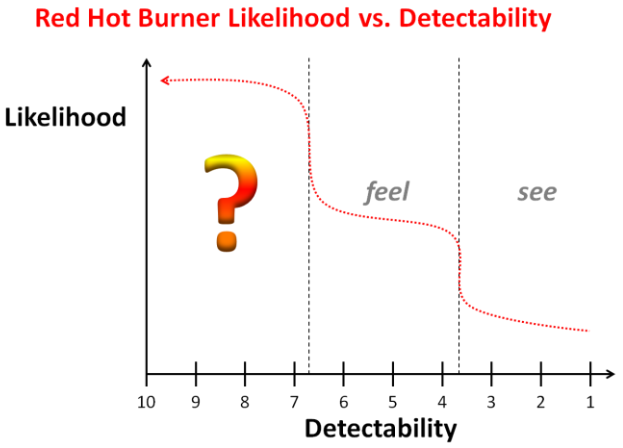

Figure 4 Electric Stove Burner Relationship

The dynamic relationship between detectability and likelihood for a person to be harmed by a hot burner on a stove might look like Figure 4. The vertical axis represents Likelihood, the probability that a person would touch the burner and be burned.

The horizontal axis represents Detectability, the probability that the hazard would be known before harm occurs. Note that this axis looks backwards. The smaller the probability, the larger is the numeric ranking. This is because the more likely we are to perceive a hazard, the less danger it presents. Think of a ninja. They dress in black at night to be undetectable. This makes them dangerous so their Detection Rank would be high.

Follow the dotted red line starting at the right. If someone can see a burner is red hot, then, yes, they are less likely to touch it. In that region, Detectability is high. This pushes Likelihood lower. That makes them related. So, they are not independent in this third of the example.

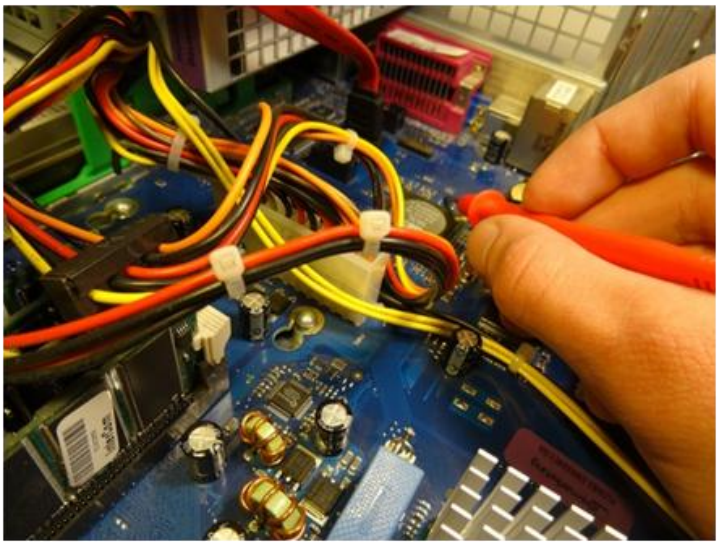

Figure 5 High Voltage Wire Example

When the burner does not glow red they might still feel the warmth and be less likely to touch it. In that region Detectability is moderate and Likelihood is moved lower. Still not independent.

If they don't feel any heat for some reason then Detectability is low. In this region the Detectability makes no contribution to Likelihood. It is uncertain. The dotted red line is horizontal. There is no way to push Likelihood down. Now they are independent. Note that the Detection Rating is high. That makes more

mitigation deserved. More mitigation could mean, for example, post-build testing of all wires for dangerous voltages, adding an access screen with a warning, or adding a Ground-Fault-Interrupter to the circuit. So, even within Jon's example we find the situation that medical devices are always in: that Detectability and Likelihood are independent.

In the medical device industry, and certainly others, situations analogous to red hot stove burners are extremely remote. Detectability is not a matter of a user seeing or feeling that something is wrong. The devices are complex systems where failure can be catastrophic. Let's try a human, but more realistic, example where a potentially high voltage wire is exposed.

Figure 5 shows a situation where a person's hand is operating in close proximity to wires. In manufacture of this circuit any one of the wires could be misconnected and made hot when the device is live with a dangerous voltage.

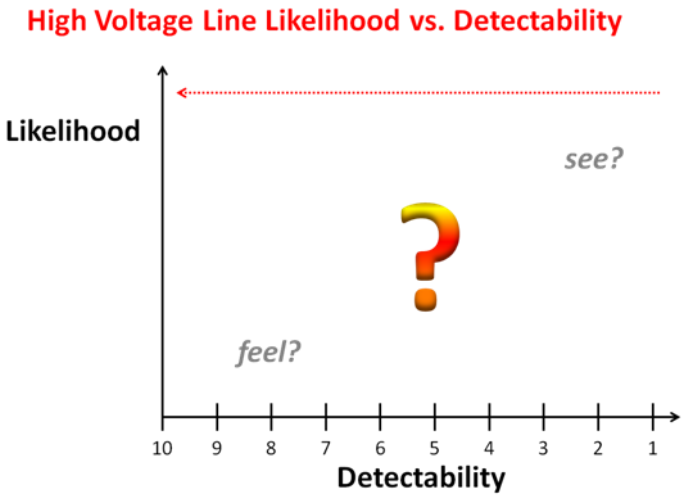

Figure 6 High Voltage Example

The person operates a probe which could protect them. But, if circuits are live, there is still chance in tight spaces that a finger could contact a hot wire. Note the red dotted line in Figure 6. Likelihood is fixed at whatever value it would have naturally. A finger touches a hot wire or not. Detectability has no opportunity to move Likelihood lower. They are completely independent.

They have been completely independent in Failure Mode and Effects Analysis done since the 1940's. It is a rich and solid engineering tradition.

DETECTION TO THE RESCUE

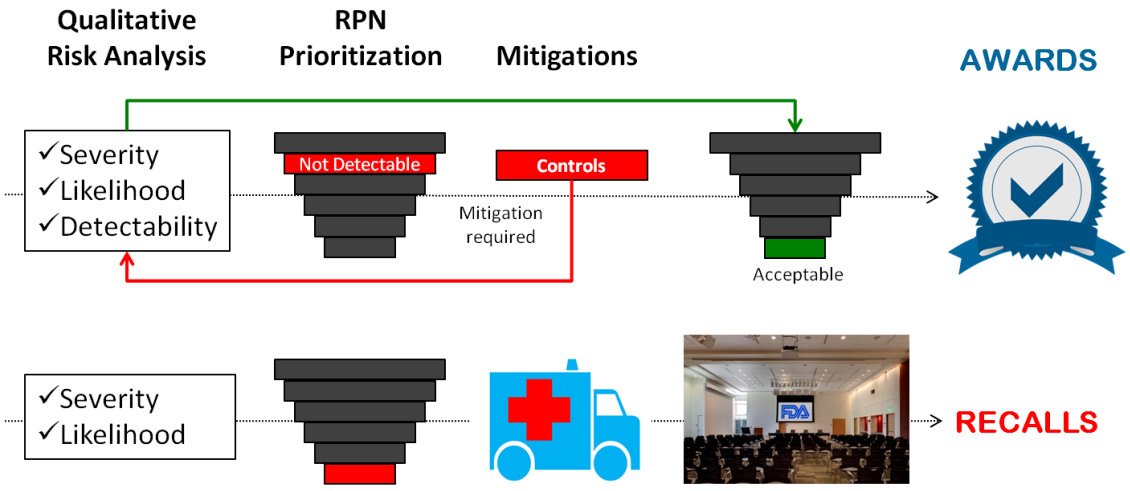

Figure 7 Two Paths of Detection

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Figure 7 shows the two paths you can take with Detection. One that leads to safety. The other leads to harm. Detection ranking protects your Risk Priority Numbers (RPN). They are raised so that hidden risks receive more appropriate attention and resources to mitigate severity and likelihood of harm. This motivates development of better controls that have a higher likelihood of detecting faults before they leave the factory.

The top path shows a high ranked risk due to detectability difficulty. Note that the red risk that is "Not Detectable" is above the line for "Mitigation required." It is prioritized such that it receives appropriate attention and resources for its mitigation. In this example, controls are applied. After that, the residual risk is such that the risk now becomes acceptable. Recalls are prevented and quality is the result.

The bottom path shows the same hidden risk. Trusting only severity and likelihood, the red risk is mistakenly given a low RPN such that mitigation is not required. Hidden faults that go unmitigated become hidden defects that leave the factory to cause harm. This gives rise to FDA recalls and official pronouncements that speak poorly of your product quality.

Examples involving human analogs for medical devices can lead to incorrect reasoning. They should be avoided. Especially, if they involve weird objects like hand grenades. These turn reasoning upside-down, like devices causing harm when operating correctly. These create untrustworthy conclusions and make no common sense.

DETECTION TO THE RESCUE

You are, of course, free to choose you own way forward. But, now you know the power and utility of Detection ratings. Done correctly, these ratings should help you do mature and competent risk management and prevent FDA recalls.

In addition to consulting, I teach risk management. And all my students leave my classes knowing that risk management is special and powerful. This is because it can change anything: a product, a design, a plan, a project, a process and an organization. And, if more people understood the power of risk management, it could change the world.

Your risk vault has great economical value for your organization as well. In contract bidding, you only want to win when it would be profitable. Risk management plays a big part in this. Knowing your costs is a great asset.

If you found this article useful, or otherwise, I would appreciate some feedback. Also, I am currently interviewing practitioners from medical device manufacturers about industry problems and how they are affected. You are welcome to join the group of 100 people diagnosing, and prognosticating a larger solution.

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MY VISION AND THE TRANSACTIONS INVOLVED.

I was in the medical device industry some years ago. The world has changed. The survey and interview are to characterize the current problems and solutions in the industry from your point of view.

For this, I am willing to give you a method I have developed that should be helpful today. It is very important to get a diversity of views. They will form the basis of needs in other new methods and tools.

You will also get to influence the design of new methods and tools. To make sure your needs are addressed exactly. To ensure your enterprise profits from the close match to features and practices.

New methods and tools need to be spread all over the world to improve medical device safety and reliability globally. Your role is to be a champion for quality. To discover new ways and means.

YOU ARE WELCOME TO JOIN ME IN THIS QUEST.

REFERENCES

[1] "What's Behind MetTech's Recall Epidemic?" by Joshua R. Dix, Suraj Ramachandran, and Darin S. Oppenheimer.
[2] "Detectability and Medical Device Risk Management" (https://www.linkedin.com/pulse/detectability-medical-device-risk-management-jon-speer/)
[3] "ISO 14971:2007(en)" (https://www.iso.org/obp/ui/#iso:std:iso:14971:ed-2:v2:en)
[4] Carlson, C. S. (2012). *Effective FMEAs: achieving safe, reliable, and economical products and processes using failure mode and effects analysis, p.145*. Hoboken, N.J: Wiley.

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