

Detection to the Rescue

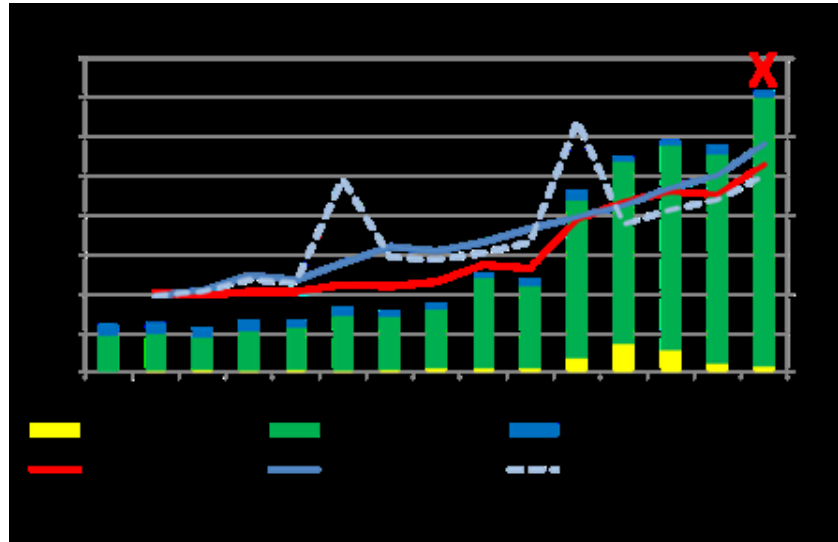
FDA Medical device recalls hit an all-time high again. Start using Detectability. OK?

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.

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. The %Recalls trend line says what many will believe:



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. More devices, more recalls. New companies are no better at risk management. And, older companies are not improving, either. At least, not for the last 14 years.

The problem here is complacency. The industry needs to have higher risk management standards. Detectability will make your risk management more rich and robust. You need to 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 unnecessary², or it does not meet ISO standards³. 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 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 regulations 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,

Detection to the Rescue

or following regulations to the letter and doing less. How do you want your next medical device made?

UNDERSTANDING DETECTABILITY

“Detection is a numeric ranking that reflects the likelihood your current best controls in their best 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, 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.

The failure mode could be any kind of problem: material, dimen-

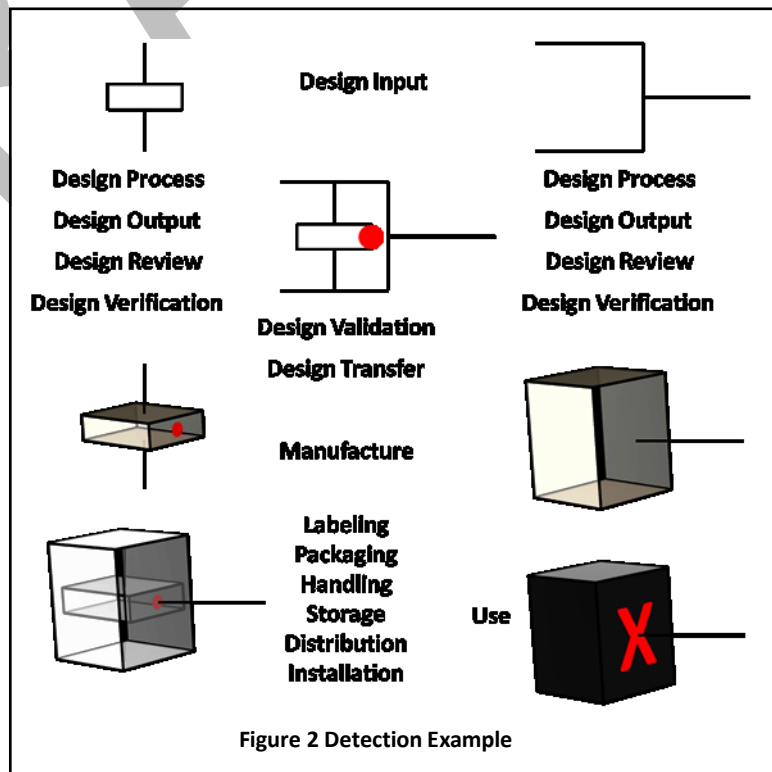


Figure 2 Detection Example

Detection to the Rescue

sional, 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 with lots of good advice. But, he has picked a bad example and it discolours his recommendation to exclude Detectability.

Detection to the Rescue

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

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.

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.



Figure 5 High Voltage Wire Example

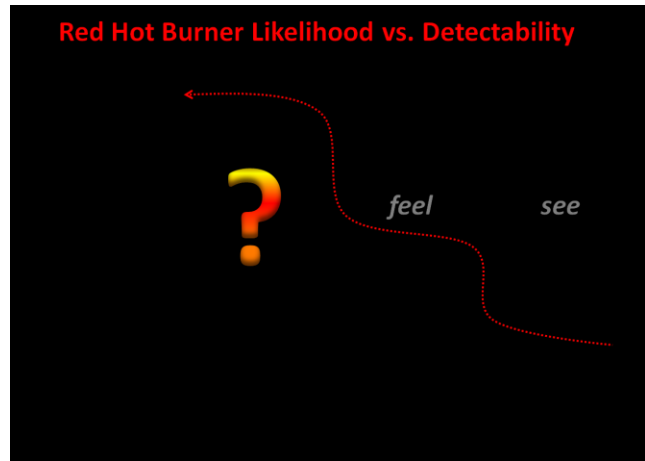


Figure 4 Electric Stove Burner Relationship

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

Detection to the Rescue

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.

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.

High Voltage Line Likelihood vs. Detectability

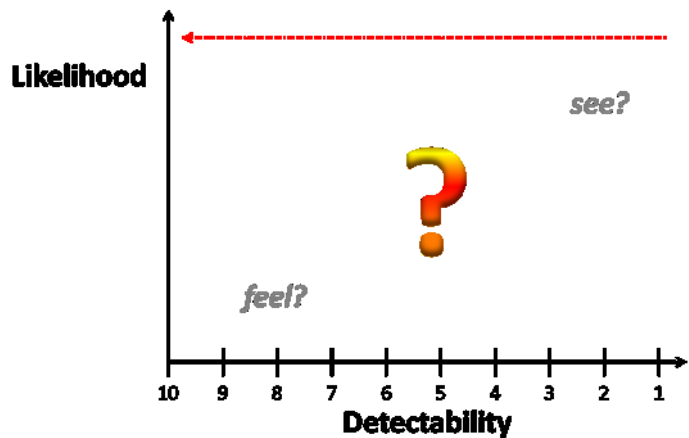


Figure 6 High Voltage Example

TWO PATHS OF DETECTION

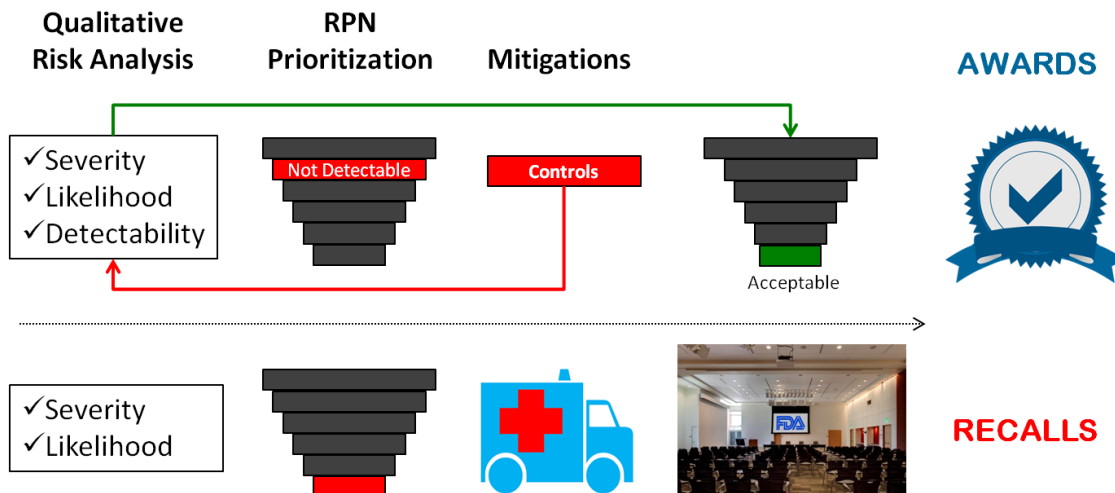


Figure 7 Two Paths of Detection

Detection to the Rescue

Figure 7 shows the two paths you can take with Detection. Detection protects your Risk Priority Number (RPN) by raising it so that hidden risks receive more appropriate attention and resources to mitigate severity and likelihood of harm.

The top path shows a high ranked risk due to detectability difficulty. As consequence, it is prioritized such that mitigation is required. In this example, controls are applied. 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, it is mistakenly given a low RPN such that mitigation is not required. The results of unmitigated hidden faults are 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.

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 interviewing medical device practitioners about industry problems and how they are affected. You are welcome to join the group of 100 people diagnosing, and prognosticating a larger solution.

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.

Richard L. Bollinger is CEO of Menlo Park Associates, a management consulting firm based in Ann Arbor, MI. Contact him at rick@menloparkassociates.com.

Detection to the Rescue

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