Residual risk analysis of user interaction problems

Determining whether safety-related use errors observed in a human factors validation test are acceptable

Human Factors Research & Design

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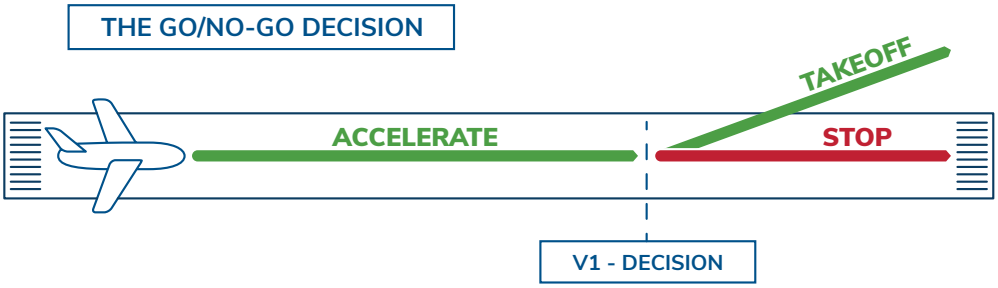
Executive Summary

Residual risk analysis is an important part of the process of developing medical devices, and its use is expected by medical device regulators. Rather than being a professional discipline per se, residual risk analysis is an analytical method that may and should be practiced by people from many disciplines.

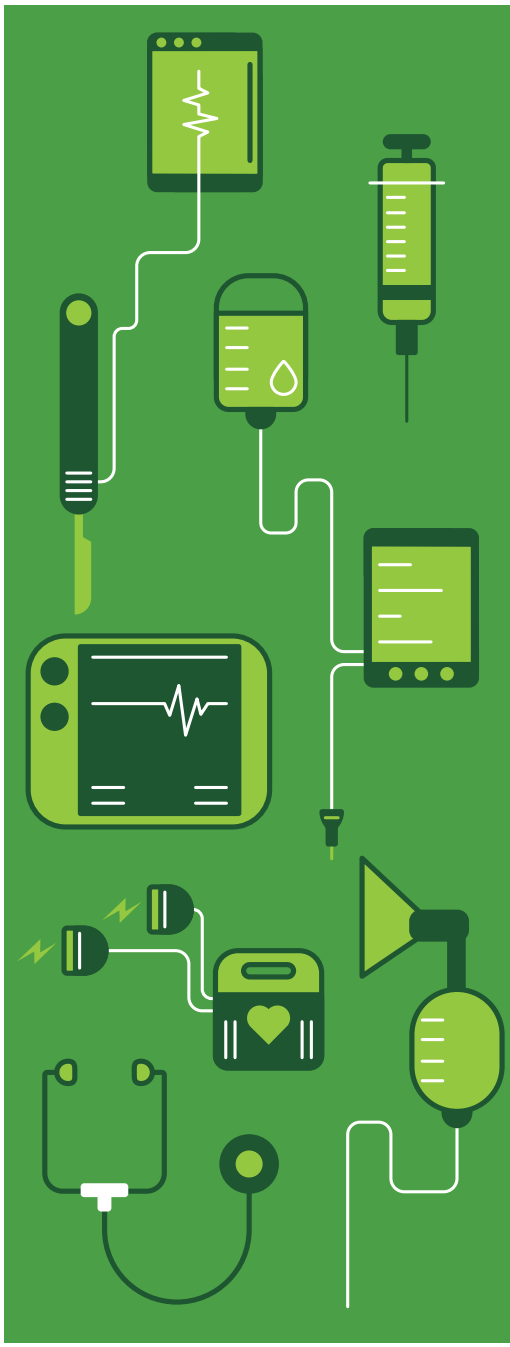
The practice might seem dry compared to some aspects of product development, such as designing the user interface. After all, user interface design promises the opportunity for creative exploration, conceptual design sketching, appearance model development, and the excitement that comes from producing a working prototype.

By comparison, a vigorous residual risk analysis, and one specifically focused on user interaction problems, might indeed seem dry, but it is far from it. It is an essential step in the product development process and a prerequisite for commercialization. It calls upon a cross-disciplinary team to consider a wide variety of factors in the course of making a “go” or “no-go” decision regarding a regulatory submission. In this sense, the residual risk analysts collectively act like the airplane pilot deciding to proceed with takeoff. Accordingly, residual risk analysis is usually an intense and pivotal activity. A company’s future might ride on the successful launch of the product, so analysts might feel under high pressure.



Residual risk analysis generates the insights and supporting data necessary to decide if a product is a “go” for launch.

An important step in the human factors engineering process



If you send a flawed medical device to market, it might harm or even kill people. Therefore, residual risk analysis is closely tied to protecting people from harm. This is particularly true when it comes to shielding people from the consequences of use errors such as pressing the wrong button, connecting the wrong tubes, or entering incorrect data. That is why it is a critical step in the human factors engineering (HFE) process, as delineated in textbooks on the subject and HFE guidance from regulators such as the FDA and an IEC standard (IEC 62366-1) on the topic of usability engineering.

The HFE process involves the following steps:

- Learning about a medical device's users and use environments as a preamble to writing user interface design requirements for a product that will serve the users well.
- Identifying tasks and hazards in the use environment that pose risks to a product's safe and effective use.
- Deciding if those risks are appropriately mitigated through good user interface design, instructions, and training.
- Designing a user interface that ensures safety, enables people to perform tasks as intended, and satisfies users in meaningful ways (e.g., a tool that feels good in the hand, a software user interface that seems intuitive and is visually pleasing).
- Conducting various types of user interface design evaluations, in particular usability testing, to identify a product's strengths and opportunities for improvement leading to a final, validated solution that is ready for submission to regulators for their clearance or approval.
- Analyzing the residual risk associated with potential use-related issues and determining whether it is acceptable or not, and including the analysis as part of a submission's HFE documentation.

Sample residual risk analysis (hypothetical)

Assume the following:

- An HF validation test of a pen-injector that a patient uses to deliver a weekly injection of medication has been completed.
- One use scenario called for the user to press the pen-injector needle into the skin, press a button to start the injection, and after hearing a "click," continue to hold the needle in place for 10 seconds before removing it.
- Use error description: 4 out of 15 test participants removed the needle prematurely after durations of only 3, 5, 6, and 9 seconds rather than after a full 10 seconds.
- Human factors specialists who ran the usability test and reported the results determined that the possible root causes of the use errors included: (1) reliance on the user to accurately count to 10, (2) misinterpretation of the "click" sound as indicating the injection was complete and the needle should be removed from the skin, and (3) that a graphic in the instructions for use – indicating to wait 10 seconds after the "click" to remove the needle – was confusing.

In this case, the residual risk analysis could focus on the consequences of premature needle removal from the skin, which might result in an underdose because some of the injected drug could flow backward from the injection site rather than infusing into the skin. Analysts could access the results of studies about how much fluid actually leaks out of the injection site, or conduct such studies if they were not already done. The results could show that there is no appreciable leakage after 2 seconds, suggesting that the original direction to keep the needle in place for 10 seconds was overly conservative. Or, they might determine that only 10% is likely to leak out after 3 seconds and that virtually none leaks out after 4 seconds. The second finding might lead medical specialists to conclude that the risk of such leakage is low in view of adult-size doses and the body's insensitivity to small differences in a delivered dose.

Accordingly, the product developer might assert that the residual risk associated with premature needle removal is acceptably low. Or, on the contrary, the product developer might decide that there is low residual risk to adults but a comparatively high risk to children who receive small doses and might have a negative reaction to an underdose.

FDA's guidance on residual risk analysis of interaction problems

FDA expects manufacturers to determine the root causes of use errors that occur during simulated device use (i.e., during an HFE validation test) with the mindset that something about the user interface caused the problem. Such an analysis should determine whether design modifications are needed, would be possible, and are likely to reduce the associated risks to an acceptably low level.

Residual risk analysis comes after what product developers hope will be their last usability test: a test alternately called a human factors validation test or a summative usability test. This involves a sample of intended users engaging in use scenarios that put the product of interest through its paces, including scenarios involving so-called critical tasks. A critical task is one that, if performed incorrectly (i.e., there are one or more use errors) or if not performed at all, could lead to harm and/or compromise medical care. For example, setting the correct dose on an insulin pen-injector is a critical task. So is placing an AED's electrode pads in the correct position on a victim's torso, or inhaling deeply when taking asthma medication through a metered dose inhaler.

These pivotal tests usually show that a medical device is designed well, but not always perfectly. Perfection requires that none of the test participants make a mistake. Accordingly, because few if any devices are perfect, there are usually use errors that require a root cause analysis and assessment of residual risk.

Use errors or problems associated with high levels of residual risk should be described in the human factors validation report. This description should include how the use problems were related to the design of the device user interface. If your analysis shows that design modifications are needed but would be impossible or impractical to implement, you should explain this and describe how the overall benefits of using the device outweigh the residual risks.

Residual risk analysts should be shielded from pressure to reach any particular outcome. The outcome should not be consciously or unconsciously biased by considerations such as the cost of making a product design change. Rather, the outcome should be a logical conclusion drawn from an examination of HF validation test results, keen root cause analysis of persisting user interaction problems, intensive consideration of potential risk control measures, and realistic assessment of the residual risk of patient or user harm posed by an unchanged product.

Asking why a use error occurred and what residual risk it poses

Root cause analysis of use errors calls for analysts to determine the reason(s) why someone was not able to perform a task correctly.[1] One operating principle that guides such analyses is to avoid blaming the user for a given use error, even though you might think that such factors as forgetfulness, carelessness, distraction, and fatigue played a role. It is better to assume that users have predictable shortcomings and that the conditions of use can conspire to induce a use error. Moreover, it is better to aim for a user interface design that anticipates human shortcomings and suboptimal use environment conditions. Following this logic path, it is then reasonable to assume that a use error indicates a design shortcoming. Here are some examples of user interface design shortcomings that could, in some situations, trigger a use error.

- Text on a patient monitor that is too small, thereby causing a user to misread a vital sign.
- Pushbuttons on an intravenous infusion pump that are so close together that a user inadvertently presses the wrong one.
- An alarm tone generated by a ventilator that is too quiet to hear over background (ambient) noise, causing a user to miss it.

Root cause analysis of a use error involves a triangulation of a sort. An analyst can base their conclusion on (1) feedback from the user who committed a use error, (2) inspection of the user interface in view of established user interface design principles, and (3) consideration of environmental factors that might have made conditions ripe for a use error.

Upon completing the root cause analysis, the team must then perform a residual risk analysis. Notably, residual risk is a discomforting concept in many ways. It requires acceptance that a product will not be perfectly safe. And how can anybody be comfortable with the idea of using a product that stands a chance of causing significant harm?

The answer is that few things in life are truly risk-free, and people accept many kinds of risks every day. They pour piping hot coffee into cups even though spills could burn them. They drive cars despite the risk of a serious, injurious accident. They handle power tools that are double insulated but still, in highly unlikely circumstances involving damage to the product, could cause a shock.

Therefore, it should be no surprise that medical devices pose a residual level of risk, and everyone who plans to receive medical care must come to terms with this reality. That said, people hope and expect that the residual risk is extremely low. In fact, they have a right to expect this, particularly in view of regulations that require it.

Residual risk analysis takes a team

The people who conduct HF validation tests – usually they are human factors specialists – are trained to lead the residual risk analysis (RRA) of use errors, but they cannot do their work without the support of people representing other disciplines, such as:

- Clinical (e.g., medical specialists)
- Engineering (general)
- Design
- Risk management
- Regulatory affairs
- Quality assurance

RRA takes a team, and here are the things they can do together.

1. Review the consequences of the given use error, confirming that the severity of harm described in the risk analysis – performed before detailed user interface design and then updated afterward – remains correct (i.e., not under- or over-estimated). If unable to make this confirmation, perform the next step.

2. Seek clinical input or perhaps even conduct studies to clarify the nature of the harm that might arise from the observed use error.

3. Consider the likelihood of the use error occurring during actual use, noting that likelihood should not be a major consideration early in the risk management process when every use error that could cause significant harm should be evaluated for potential risk mitigation. Keep in mind that FDA and other regulators are likely to advocate design changes to reduce risk when the value of the changes is relatively self-evident, even in view of a use error being judged as highly unlikely. Also note that use errors judged to be unlikely might be more common than expected, thereby increasing the importance of mitigating their risk.

4. Determine if the risk mitigations are sufficient in view of user interaction problems observed during the HF validation test. In view of borderline or poor results (i.e., disconcerting problems), determine if there are any additional, practical ways to make the product inherently safe through design, or perhaps less prone to use error by virtue of warnings, improved instructions for use, or training, for example. (Note that regulators favor design enhancements over improved instructions and training as a risk mitigation.)

5. If the previous step identifies practical ways to make a product safer, the rework should proceed. Here, the word “practical” pertains to engineering and design feasibility and does not consider economic or schedule concerns. When residual risk remains, identify the key benefits affecting the clinical outcomes and the patient’s quality of life.[2] Describe why the benefits outweigh the risk.

6. Ensure that benefits of use are described fully, noting that the “benefit” part of the benefit/risk ratio helps justify residual risk. Note that the latest version of ISO 14971 (Medical devices — Application of risk management to medical devices) encourages manufacturers to define the benefits of a product.

No product is truly risk-free.

This is something that the FDA recognizes and reflects in the following passage in its HF guidance. "It is practically impossible to make any device error-proof or risk-free; some residual risk will remain, even if best practices were followed in the design of the user interface."[3]

Possible outcomes

Ultimately, a device developer will take into consideration the results of the analyses listed above and perhaps arrive at one of these three decisions:

1. The product is adequately safe and effective in its current form. Making it safer is not feasible, which could be due to the limits of science and technology.

2. The product is reasonably safe and effective in its current form. Making it safer is not feasible due to any number of factors, such as high costs that would make the product unaffordable, prohibitive negative impact on other important factors (e.g., portability), or perhaps a radical departure from accepted practice and public expectations regarding what constitutes acceptable risk.

3. The product is **not** reasonably safe and effective in its current form and requires a rework.

In the first two cases, a product developer would proceed on a path toward submission to a regulator for an approval or clearance to market the given device. In the latter case, it's back to the workshop, so to speak.

Regarding the FDA, the agency expects submissions to explain the developer's analysis of residual risks. The following information must be integrated into the submission:

- An assertion that the residual risk posed by an interaction problem is not cause for significant concern. This essentially means that the product is acceptable "as is."
- The use scenario, particular task, use error, and type of participant(s) who made the error (e.g., physician, nurse, patient).
- The root cause(s) of the use error, stated in either a factual or strong hypothesis form depending on how certainly you can state your conclusion.
- Results of any analysis that changed your view of the type and severity of harm that might arise from the use error.
- Clarification about why there is no available means to reduce the chance of the use error occurring or reduce the harm that might ensue.
- Commentary on the presumably low likelihood of the use error occurring; a factor that is dismissed when initially considering how to mitigate the chance of significant harms due to use error, but may come back into play when considering residual risk analysis.

In essence, your residual risk analysis is making the case for "exoneration," much as one might make a closing argument in a trial.

You are saying that a use error (or multiple ones) occurred and was originally considered to be significant because it happened in conjunction with a critical task, but that the regulator should accept the product's performance as acceptable in view of its benefits and the impracticality of producing a better one noting present-day technology and science.

Summary + Conclusion

It behooves medical device developers to fully understand the nuances of residual risk analysis and provide regulators, including the FDA, with the information they need to be comfortable approving or clearing a device with a (claimed) low level of residual risk. Again, keep in mind that practically all medical devices pose a degree of residual risk. This is reality in a world full of medical products that do great things for us, but also pose – to some degree – a small risk to the people who use the devices and the patients receiving or self-administering care.

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End Notes

1. Michael Wiklund, Andrea Dwyer, Erin Davis. *Medical Device Use Error: Root Cause Analysis*. Boca Raton, FL: CRC Press. 2016.

2. Section 3.1 How can patient input impact decision making? Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling. FDA. Document issued on August 24, 2016. Available at **https://www.fda.gov/media/92593/download**.

3. Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, Section 8.1.7 Residual Risk, Document issued on: February 3, 2016. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluation. Available at **https://www.fda.gov/media/80481/download**.

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About the author

Michael Wiklund serves as General Manager of the Human Factors Research & Design (HFR&D) practice at Emergo by UL. Previously, he founded Wiklund Research & Design, a human factors consulting firm that UL acquired in 2012. He has over 30 years of experience in human factors engineering, much of which has focused on medical technology development – optimizing hardware and software user interfaces as well as user documentation. He is a Certified Human Factors Specialist and Licensed Professional Engineer. He is author, co-author, or editor of several books on human factors, including Writing Human Factors Test Plans and Reports for Medical Technology Development, Usability Testing of Medical Devices, Handbook of Human Factors in Medical Device Design, Medical Device Use Error – Root Cause Analysis, and Writing Human Factors Plans and Reports for Medical Technology Development. He is one of the primary authors of today's most pertinent standards and guidelines on human factors engineering of medical devices: AAMI HE75, IEC 62366-1, and IEC 62366-2. In addition to leading Emergo by UL's human factors engineering practice that now includes over 70 HFE and user interface design specialists, he is a Professor of the Practice at Tufts University where he teaches graduate courses on HFE, including applying HFE in medical technology development.

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