MEDICAL DEVICE USE ERROR

ROOT CAUSE ANALYSIS

Michael Wiklund
Andrea Dwyer
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Illustrations by Jonathan Kendler

CRC Press
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Foreword

This is the latest book in a series of usability-related texts from Michael Wiklund and colleagues that has focused on human factors engineering of medical devices. In this newest contribution to the series, titled *Medical Device Use Error: Root Cause Analysis,* Michael Wiklund, Andrea Dwyer, and Erin Davis address the very important safety topic of analyzing use errors. They provide excellent, practical guidance on how to methodically discover and explain the root cause of a use error—a mistake—that occurs when someone uses a medical device.

This newest book complements Michael Wiklund and colleagues' previous books: *Usability Testing of Medical Devices, Handbook of Human Factors in Medical Device Design, Designing Usability into Medical Products, Medical Device and Equipment Design*, and *Usability in Practice*.

Readers familiar with the application of human factors engineering ("HFE," also called usability engineering) to medical devices will no doubt appreciate that regulators of medical products have for the last 10 years used the term "use error," as opposed to the more common, but somewhat inaccurate, terms "human error" or "user error." The contemporary term "use error" is neutral regarding the cause. It does not automatically blame the user, as implied by the previously used term "user error." Philosophically consistent with using the contemporary term, root cause analyses should assess all possible causes of use error, and doing so is what this book prescribes. It calls on readers to view and access use errors with the same attitude and rigor that they would apply to an electrical defect, such as a short circuit producing a leakage current, that could shock a user. Note that device developers do not blame users for shocks due to poor electrical insulation or grounding, and

neither should they blame users for pressing the wrong button because it is poorly labeled or an array of buttons are too closely spaced, for example.

In the broader scheme, manufacturers and medical product designers should strive to design a device that does not induce usability-related errors during interaction with the device's user interface, now widely known as use errors. The designer should not blame the user for failing to read the instructions or not learning to use the device during training. Instead, as described in this book, the designer should focus on whether the root cause of the problems might be due to user interface design flaws or other usability defects, such as poor navigation, misleading function labels, confusing symbols, difficult-to-use controls, illegible displays, or poorly communicated error messages. Thus, the term "use error," by its very nature, calls for an investigation of why the use problem exists, and this is best done through root cause analysis. As director of human factors engineering at AbbVie (formerly part of Abbott Laboratories), I have considered it very important to make sure that product developers understand and support such analyses because it is the path toward essential insights into optimizing user interactions with medical devices as well as other equipment, such as laboratory instruments.

After working for three decades in the human factors engineering business, I have a deepening appreciation for the history behind our current methods, so indulge me as I share some history related to the book's topic. The method of root cause analysis has been around for a long time and has been a major component in business excellence tool kits, such as Six Sigma and Lean. In the 1950s, Sakichi Toyoda introduced the term in Japan at what is now the Toyota automobile company. Toyoda-san promoted the concept of "Five Whys," which called on investigators to ask "why" five times to get to the heart of a problem. This is how one might start with a car problem, such as a seized engine, and trace it back to inadequate oil, a difficult-to-access dip stick, and the lack of an oil pressure gauge.

I am sure that root cause analyses, including asking a lot of "whys," have helped Toyota isolate and remedy many design and manufacturing problems during the ensuing 60+ years. In parallel, root cause analysis techniques have helped in the investigation of spectacular failures, including the accident at the Three Mile Island Nuclear Power Plant and two space shuttle accidents. Fortunately—and for the betterment of the medical device industry, health providers, and patients alike—root cause analysis has been enthusiastically applied in the healthcare field for many problems, including adverse event analysis, customer complaint analysis of both single events and trending of multiple events, and CAPA (corrective and preventive action), as well as events related to product liability (Figure 0.1).

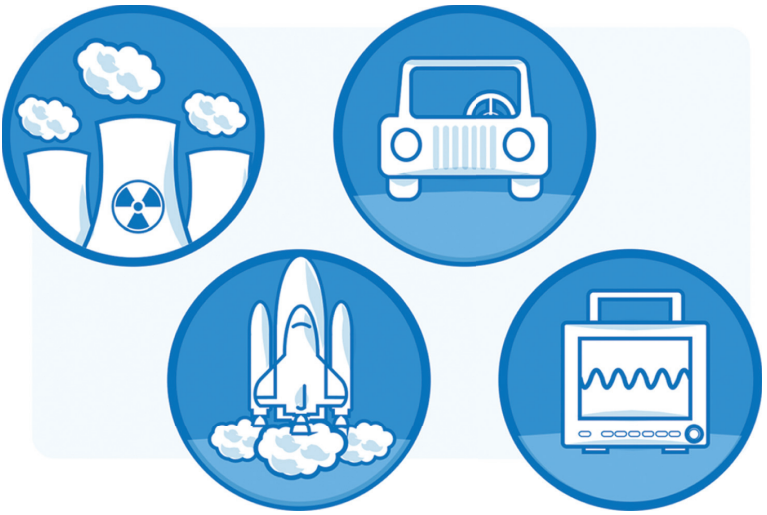


FIGURE 0.1 Clockwise from upper left: Symbols of a nuclear power plant, an automobile, a medical device, and a space shuttle. Official death toll resulting from accidents are: Three Mile Island = 0 (long-term health effects uncertain); space shuttle: 14 astronauts; car accidents in USA in 2014: 32,719; medical errors in USA in 2014: >200,000. (Adapted from James, J. T. 2013. A new, evidence-based estimate of patient harms associated with hospital care. *Journal of Patient Safety*, 9(3), 122–128.)

Let's talk more about this book now. I think you will find it to be well organized, taking you through a logical order of pertinent root cause analysis subject matter. The book educates readers on valuable topics such as the fundamentals of root cause analysis, the language of risk and root cause analysis, and regulatory expectations for the analysis of use errors. Additionally, several chapters provide practical instruction regarding identifying use errors, interviewing users about use errors, and user interface design flaws that might induce use errors.

Such design flaws are further exemplified through some very informative case studies in Chapter 12. These 30 examples graphically illustrate the issues that may be explored in a thorough analysis and the presentation style is very compelling. The examples cover a wide range of devices, including home-use products used by laypeople and highly complex devices used in clinical environments. I like the fact that each example concludes with suggestions on how to fix the problem that causes the use error. The simple illustrations are a great complement to the narrative explanations, in some cases clarifying design flaws that are difficult to appreciate just by reading words.

The examples are solid exemplars of the rigor with which the root cause analysis process should be applied. They show how root cause analysis leads

from an understanding of the use error, its consequences, potential causes, and ultimately to mitigations and a range of solutions. In my view, these examples alone make the book a significant value.

The book also includes a discussion of the FDA mandates for application of best practice in human factors engineering. It is fairly well known that the FDA human factors product reviewers now require what is fundamentally a qualitative methodology for conducting usability tests, both formative and summative (validation). Unlike other regulated submissions to the FDA, such as clinical effectiveness, product stability, bioavailability, etc., human factors engineering is unique in not requiring inferential statistical evidence for medical device usability related to safety. This is because usability testing studies with proper statistical power would, to some manufacturers, be burdensome and impractical. Furthermore, the best way to understand the inevitable use errors that you are likely to observe in the final summative test is to do thorough root cause analysis. Then, designers must make the case that further redesign of the user interface is not practicable and that the remaining residual risk is acceptable because the clinical benefit of the device convincingly outweighs the residual risk. I know of no other way to justify the final design when you observe use errors in the summative test other than through root cause analysis. FDA guidance from both the Center for Devices and Radiological Health (CDRH) and Center for Drug Evaluation Research (CDER) reinforce the concept of risk/benefit trade-off.

To conclude this Foreword, I encourage readers to view root cause analysis as the sine qua non or the essence of good human factors. Industrial and user interface design is challenging, elusive, and a very creative part of usability engineering. However, due to limitations in the knowledge we have about human capabilities and limitations from the applied behavioral sciences, it is not easy to get early designs to be completely self-evident and intuitive. It takes hard work and a kind of brute force iterative process of design, testing, redesign, and retesting over multiple cycles to achieve a high-quality user interface. It would be almost impossible to learn from iterative cycles of design and testing without rigorous root cause analysis. This book makes a significant contribution to the literature on how to conduct root cause analysis as it applies to user interfaces.

Ed Israelski

Acknowledgments

We thank our colleagues at UL (Underwriters Laboratory)-Wiklund (a human factors engineering consulting firm) for their support. Our book cites many use errors related to those that occurred during usability tests conducted at UL-Wiklund. It also draws upon root cause analyses that we performed in close collaboration with our colleagues.

We particularly thank our professional family members Jonathan Kendler (our illustrator), Allison Strochlic, and Jon Tilliss, who energetically helped make Wiklund Research & Design a success, taking it to the point that it transitioned into the human factors engineering practice within UL.

We acknowledge other professionals who pioneered root cause analysis methods and wrote the papers and books cited in footnotes and listed in the book's list of resources. Our practical insights on root cause analysis stand on their original work.

Thanks go to Edmond Israelski, director of human factors at AbbVie, for writing the book's Foreword in which he shares his perspective on root cause analysis of medical device errors.

We thank our workmates Rachel Aronchick, Laura Birmingham, Stephanie Demarco Bartlett, Cory Costantino, Kelly Desharnais, Sami Durrani, Michael Geller, Limor Hochberg, Stephanie Larsen, and Frauke Schuurkamp-van Beek for their peer reviews of the book's draft content.

Merrick Kossack, manager of human factors engineering at Intuitive Surgical, Inc. (Sunnyvale, CA), was also generous to review our root cause analysis examples from a medical device developer's perspective and provided us with excellent advice.

Michael thanks his wife Amy for encouraging him to energetically pursue his interests, including writing about human factors engineering.

Finally, we collectively thank Taylor & Francis's Michael Slaughter for his enthusiastic response to our initial book proposal and steady support during its development and production, and Kathryn Everett for bringing the book swiftly from the manuscript stage to publication.

The authors thank the International Electrotechnical Commission (IEC) for permission to reproduce Information from its International Standards IEC 60601-1-6 ed.3.0 (2010) and IEC 62366-1 ed. 1.0 (2015).

Who Should Read This Book

Determining the root cause of use errors that people make when interacting with medical devices is key to design improvement and protecting people from harm. As such, this book's content should be of interest to a wide array of product development professionals and others who become involved in making healthcare delivery as safe and effective as possible, including the following:

- **Human factors specialists**—Individuals who are responsible for executing human factors engineering tasks, which include analyzing root causes of use errors detected during usability tests, clinical studies, and post-market surveillance.
- **Engineers and designers**—Individuals who might be asked to help perform human factors engineering work, as well as those who might participate in teams responsible for performing root cause analysis and responding to the findings by making changes to given devices. Such individuals might include mechanical, electrical, and systems engineers; project managers; software programmers; industrial designers; graphic designers; and people in many other associated professions.
- **Regulatory affairs specialists**—Individuals who manage their organizations' initiatives to comply with human factors standards that call for root cause analysis of use errors.
- **Quality assurance specialists**—Individuals who are concerned with meeting internal and externally applied quality standards for a variety of functions, including human factors engineering.

- **Risk managers and analysts**—Individuals who are responsible for their organizations' overall risk management efforts and who must incorporate root cause analysis results into their organizations' overall risk control schemes.
- **Patient safety specialists**—Individuals who seek to reduce the chance of harm to patients and the people who deliver care to them in clinical and non-clinical environments.
- **Regulators**—Individuals who (1) work for regulatory review and enforcement entities, such as the FDA, notified bodies in the European Union, and many more countries that evaluate risk mitigation efforts by manufacturers on behalf of federal entities, or (2) work for myriad organizations that advise the industry regarding regulatory strategy and responses to regulatory and legal enforcement actions (e.g., recalls, bans, consent decrees).
- **Students**—Individuals preparing to serve in the professional roles listed here.

Limitations of Our Advice

This book contains both factual information and content reflecting our professional judgment, complemented by hypothetical cases. Factual information includes definitions of the terms used to describe risk and root cause analysis, various regulatory requirements, and certain human factors engineering principles. Professional judgments include recommendations on how to approach root cause analysis, recognizing that capable professionals might take varying and equally productive approaches, and descriptions of user interface flaws that can induce use errors. Hypothetical cases of use errors and their root causes are sprinkled throughout many chapters and then concentrated in Chapter 12. Some of these cases were inspired by real cases, but we have changed the scenarios and eliminated product names to make the cases educational and to avoid targeting a particular medical device manufacturer.

This book references the most recent standards and guidance available at the time of publication. Readers should check for updates that might have bearing on how to conduct a root cause analysis to meet current standards and regulatory requirements and expectations.

To put our advice into proper context and identify other analytical options, we suggest that readers also consult other sources of guidance on root cause analysis as it is applied in the medical industry as well as in other industries (see Chapter 14 and the "Resources" section at the end of the book). Keep in mind that there is really no single way to perform root cause analysis and your needs might not be fully addressed by this book's contents.

Be aware that we have cited various root causes of the invented use errors, but that human factors engineering professionals could take issue

with our conclusions. As such, our example root causes analyses should not be viewed as the definitive root cause of use errors that you might have to analyze in the future.

Naturally, we believe that we have converged on appropriate root causes, but as we state in Chapter 2, they remain no more than educated hypotheses in most cases. This is the true nature of most root cause analyses of use errors involving medical devices. The professional judgment that is usually inherent in a root cause analysis should not be viewed as a weakness, but rather as a fundamental and necessary characteristic given that we are dealing with human behavior and not machines. The practice of medicine is similar in this regard. Accurate diagnoses usually arise from both the consideration of factual knowledge and the application of judgment.

SIDEBAR 0.1 ROOT CAUSE ANALYSIS REQUIRES JUDGMENT IN THE SAME MANNER AS MEDICAL CARE

"The medical profession is 'a vocation in which a doctor's knowledge, clinical skills, and judgment are put in the service of protecting and restoring human well-being.' A basis of this profession is *clinical judgment*. It lies at the heart of the doctor's connoisseurship, expertise and skills, being 'almost as important as the technical ability to carry out the procedure itself.' Clinical judgment is developed through practice, experience, knowledge, and continuous critical analysis. It extends

SUMMARY DISCLAIMERS

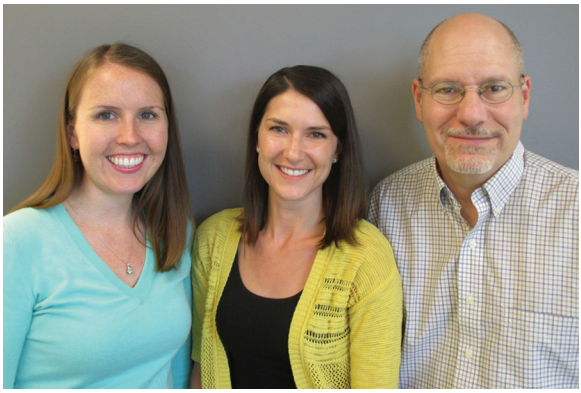
This book was prepared by the authors in their personal capacities. The opinions expressed in it are the authors' own and do not reflect the view of their employer—UL LLC.

Any similarity to actual persons, living or dead, is purely coincidental.

Hypothetical cases and medical device examples reflect a broad base of professional experience. None are attributable to a single device. Product details have been described in generic ways.

The authors are not medical specialists. They applied a reasonable standard of care to describe sample harms associated with use errors. However, this information should not be used by others as a basis for determining such harms.

Authors



Andrea Dwyer (left), Erin Davis (middle), and Michael Wiklund (right).

Michael Wiklund serves as general manager of the human factors engineering (HFE) practice at UL-Wiklund. Before joining UL, he founded and managed his own HFE consulting firm—Wiklund Research & Design—which merged with UL in 2012. He has over 30 years of experience in human factors engineering, much of which has focused on medical technology development. His work has involved working with clients to optimize their products' safety, effectiveness, usability, and appeal. He is a certified human factors professional. His other publications (serving as author and/or editor) include *Usability Testing of Medical Devices, Handbook of*

Human Factors in Medical Device Design, Designing Usability into Medical Products, Medical Device and Equipment Design, and *Usability in Practice*. He is one of the primary contributors to today's most pertinent standards and guidelines on human factors engineering of medical devices: AAMI HE75 and IEC 62366. In addition to leading UL's human factors engineering practice, he serves as professor of the practice at Tufts University, where he teaches courses on HFE.

Andrea Dwyer serves as a managing human factors specialist at UL. In this role, she leads some of UL's most challenging user research and usability testing projects. She has authored numerous usability test reports that involve root cause analysis of use errors for medical devices ranging from insulin pumps to ultrasound systems to intraocular implants. Andrea also frequently composes usability engineering (i.e., HFE) program plans, administers usability tests, and develops HFE reports on behalf of UL's HFE clients.

Andrea earned her BS in human factors from Tufts University in 2010, where she received two prizes that honor achievement and excellence in human factors studies. To complement her studies, Andrea analyzed human factors issues associated with implanted devices, telemedicine, and assistive devices for senior citizens. In addition to her work in UL's HFE practice, she is currently a part-time graduate student in engineering management at Tufts University.

Erin Davis also serves as a managing human factors specialist at UL, working alongside her co-authors. She has several years' experience conducting human factors research in the field, including usability testing. Erin earned her MS in human factors engineering from Tufts University and her BS in biomedical engineering from Marquette University. To complement her undergraduate studies, Erin served as a systems engineering and human factors co-op at Baxter Healthcare and interned at the FDA. While earning her degrees, she conducted research on utility vehicle ergonomics, memory and fatigue, and completed her master's thesis on barriers and facilitators to orthopedic surgery. At UL-Wiklund, she develops and implements human factors engineering programs and leads projects requiring expertise in user research, design, and usability testing of medical devices.

Erin's other publications include "Cusp Catastrophe Models for Cognitive Workload and Fatigue in a Verbally-Cued Pictorial Memory Task" (*Human Factors*, 2012) and "Comparative Usability Study of Novel Auto-Injector and an Intranasal System for Naloxone Delivery" (*Pain and Therapy*, 2015). Erin won the best presentation award at the Human Factors and Ergonomics Society's 2013 New England Chapter Student Conference and is serving as the New England chapter's 2015 president.

1

Introduction

We have written *Medical Device Use Error: Root Cause Analysis* as a guide for human factors specialists and other professionals who are responsible for determining the causes of mistakes that people make when interacting with medical devices. We aspired to make the book a helpful complement to many other excellent books on the topic of root cause analysis (see the "Resources" section at the end of the book). We hope this book is particularly useful to readers in the field of human factors engineering (often referred to as HFE in shorthand) who work in the medical device industry.

Technology developers have been practicing root cause analysis for over 60 years, which is about as long as human factors engineering has been a recognized discipline; the Human Factors and Ergonomics Society was founded in 1957. The technique developed at a time when designers sought to improve the reliability (i.e., reduce the failure rate) of automobiles and more complex technologies, such as rockets. Most of you have probably seen the dramatic videos of early rockets exploding on the launch pad or during liftoff, and so you can understand the importance of identifying the root causes of such failures.

The root causes of failed rocket launches over many decades have included broken bolts, electrical failures, and O-ring erosion.* By comparison, the user interface-related root causes of harm resulting from medical device use errors have included flaws such as controls placed too close together, illegible information, and inaudible alarms. These examples tell us that even seemingly small flaws can lead to catastrophe.

Indeed, there have been plenty of injurious and fatal events linked to user interface design flaws that triggered use errors. Use errors have led to death due to such consequences as electric shock, radiation, drug overdoses and underdoses, infection, exsanguination (bleeding out), blunt trauma, and hypovolemia (severe dehydration). The deaths account for a small but significant percentage (perhaps 10%)† of all fatalities in the United States per year due to medical error that total in the range of 210,000–400,000 or more according to a recent estimate.‡

Let's now go back to the topic of conducting root cause analysis for the sake of identifying user interface design flaws and protecting medical device users from harm. Root cause analysis is a form of sleuthing. A systematic approach, complemented by creative insight, it offers the best chance of identifying the cause of a problem that could lead to harm. For example, analysts discovered that O-ring erosion led to hot gases escaping from one of the *Challenger* space shuttle's solid booster rockets, which in turn led to a catastrophic explosion. Analysts working in the medical industry determined that healthcare providers were inadvertently turning off an intravenous infusion pump rather than starting an essential infusion. In principle, once you know the root cause of a problem (prospectively or retrospectively), you can take corrective action, thereby reducing or eliminating the chance of the problem occurring in the future.

Fortunately for most of us who are healthcare consumers at various times, today's human factors engineering standards and regulations call for device developers who perform validation usability tests to conduct a root cause analysis of any use errors that occur during the test. The International Electrotechnical Commission's IEC 62366-1:2015§ also suggests performing

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* Blog: Metins Media & Math. "NASA's O-Ring Problem and the *Challenger* Disaster." Available at https://metinmediamath.wordpress.com/2013/12/03/nasas-o-ring-problem-and-the-challenger-disaster/

† Peter Carstensen, who led the FDA's human factors team until his retirement in 2008, suggested that 10% of fatal medical errors occurring annually in the United States at the time were due to use error. He made this suggestion at the Human Factors and Ergonomic Society's annual meeting in September 2008.

‡ James, J. T. 2013. "A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care." *Journal of Patient Safety*, 9(3): 122–128.

§ IEC 62366-1:2015, "Medical Devices—Part 1: Application of Usability Engineering to Medical Devices."

such analyses as a principal means to reduce the risk associated with use error. A similar standard of care applies to the investigation of adverse events involving medical devices.

Accordingly, there is an imperative for medical device manufacturers to analyze the root cause of use errors effectively. These analyses may lead to one of several possible conclusions regarding a particular use error that occurred during a usability test, including the following:

- A user interface design flaw induced the use error.
- The use error was purely due to human blunder.
- The use error was triggered by a test method shortcoming (i.e., test artifact).

Bringing safe and effective medical devices to market hinges on a manufacturer's ability to recognize the true root causes of medical device use error and correct any identified user interface design flaws judged to pose an unacceptable risk. Similarly, a manufacturer's ability to bring commercially successful medical devices to market pivots on the quality of its root cause analysis, leading to insights on how to improve the device's usability, safety, and appeal.

Inadequate root cause analysis might lead to obstacles in the process of obtaining regulatory clearance for a new device, particularly if the analysis does not focus on design-related causes. Even if a device receives regulatory clearance, a faulty root cause analysis could open the opportunity for use errors to occur during actual medical care (as opposed to during usability test simulations), and possibly lead to user harm as well as significant consequences for the manufacturer.

Therefore, ensuring the safe and effective use of a medical device, as well as its commercial performance, rests in part on performing an effective root cause analysis of use errors. Most analyses will occur during product development, particularly following usability tests. But, such analyses also occur during adverse event investigation, as mentioned before. You will find that our book concentrates on the analysis that follows usability tests, but that the guidance usually applies well to adverse event postmortems.

Wrapping up this introduction, we hope this book helps you with the following:

- Taking a systematic approach to identifying the root causes of use errors.
- Understanding the regulatory imperatives to perform root cause analyses.