Russell J. Branaghan
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Emily A. Hildebrand
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Humanizing Healthcare

Human Factors for Medical Device Design

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Russell J. Branaghan
Research Collective
Tempe, AZ, USA

Joseph S. O'Brian
Research Collective
Tempe, AZ, USA

Emily A. Hildebrand
Research Collective
Tempe, AZ, USA

L. Bryant Foster
Research Collective
Tempe, AZ, USA

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Russ dedicates this book to Michael G. Egleston for his inspiration in handling challenges, great and small, medical and otherwise. I am proud to call you family!
Joe dedicates this book to his daughter, Taylor. The two most powerful words in learning are "how" and "why." Never stop wondering how the world works!

Emily dedicates this book to all the wonderful teachers and mentors she has had, especially Russ, without whom I would not be where I am today, working in the field of human factors engineering.
Bryant dedicates this book to his parents, Larry and Wendy Foster. Thank you for teaching me the value of hard work and that life is meant to be enjoyed.

Preface

Like most human factors engineers, I learned about the field completely by accident. As an undergraduate interested in neuroscience, I was pursuing majors in psychology and biology when I took a job as a research assistant in the psychobiology lab. Just prior to that, one of the professors in the department passed away, and his wife donated his entire library to our school. As the assistant, I was tasked with shelving all his books, and one book, *Human Engineering Guide to Equipment Design*, edited by Harold P. Van Cott and Robert G. Kinkade, caught my eye. As I paged through, I discovered all kinds of facts, figures, and rules about human vision, hearing, memory, attention, and decision making. These weren't just musings or guesses about how people behaved; they were real honest to goodness data compiled from hundreds of scientific studies. It then showed how to apply these scientific facts to design. It combined my interests in psychology and physiology perfectly and, more than that, proved that some lucky people actually did this for a living. I decided immediately to search for graduate programs in human factors.

Back then, there were only a few PhD programs in human factors, and they were housed in either psychology (cognitive psychology, engineering psychology, industrial psychology, experimental psychology) or industrial engineering. Interestingly, they taught largely the same courses: Research methods, statistics, sensation and perception, cognition, biomechanics, and of course, human factors, which usually combined the other topics.

All four of us have stories somewhat similar to this. We were studying something related, learned about human factors engineering (HFE) by chance, and recognized we had a real affinity for it. In recent years, device manufacturers, hospitals, and regulatory entities have recognized the perils of medical device use error and the need for human factors engineering. Because devices failed to accommodate well-known human capabilities and limitations, patients, providers, and caregivers were injured or died. This has led more people to discover the field and recognize their affinity for it, as well.

Rather than human factors engineering degrees, however, practitioners often have backgrounds in mechanical engineering, quality engineering, medicine, technical communications, industrial design, user experience design, or service design,

to name a few. As a result, many have come to us to learn about the subjects we took in graduate school. They can take courses and read books about risk analysis, formative and validation usability testing, and preparing documents for submission to regulatory industries and there are a few good edited volumes about human factors in medical device design (e.g., Privitera, 2019; Sethumadhavan & Sasangohar, 2020; Weinger, Wiklund, & Gardner-Bonneau, 2011). Also, there are good human factors texts (e.g., Lee, Wickens, Liu, & Boyle, 2017; Proctor & Van Zandt, 2018). Unfortunately, however, there were no single authored (or in our case, team authored) books that taught the fundamental human factors engineering topics, and these are important. This book is our way to share them with you. It is our hope that you will integrate the material into your own work to make the world in general, and medical devices in particular, more useful, usable, pleasant, and safe.

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There are some patients whom we cannot help: there are none whom we cannot harm.

—Lambert (1978)

Acknowledgments

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Most original images in the book were created by Natalie Sheehan. All we can say is, wow, your graphics look a lot better than ours! Stephanie McNicol also provided outstanding images and design consulting that improved the document immensely. Natalie and Stephanie represent a new kind of human factors engineer, with exceedingly strong backgrounds in experimental psychology and design.

Michael Sheehan is a medical student and photographer. Somehow, among his clinical rotations, board exams, and other medical school rigors, he conducted literature reviews, located statistics, summarized medical and popular press articles, and took photographs. He also fielded numerous phone calls to patiently explain procedures, devices, and challenges. His assistance improved the document and gave us confidence.

Then there was the editing: Several talented colleagues donated their time and talents to edit the chapters. Tonya Branaghan edited the Cognition chapter, Sarai Westbrook edited the chapters on Research Methods—Qualitative, Quantitative, and Usability Evaluation. Stephanie McNicol edited the Displays and Human-Computer Interaction chapters, and Anders Orn volunteered to edit the whole darn thing! In doing so, he provided bold advice and much needed camaraderie.

Greta Bowman was the conductor; she made sure all chapters, headings, figures, and tables were numbered correctly, organized all images and permissions to submit to the publisher, and generally kept us from dropping the ball. Tonya Branaghan kept the company running while we wrote—which is no small feat.

The content and organization of the book were sculpted by questions and discussions with Russ' students at Arizona State University and Northwestern University, as well as colleagues at several design and research companies, especially Mark Palmer at Lextant Corporation, Walter and Scot Herbst at Herbst Produkt, and Bradley Peacock at Peacock 9. Many of the ideas were refined when Russ served as

a Visiting Scientist at Mayo Clinic, working alongside Susan Hallbeck, Katie Law, Renaldo Blocker, and Bethany Lowndes.

We thank Mike McCabe and Arun Pandian from SpringerNature for their hard work and dedication. Mike was kind enough to contact us about the need for this book, and Arun guided us through the production process.

Finally, dozens of clients have enlisted our help for literally hundreds of HFE and usability projects. Each project teaches us more, challenges us more, and reminds us why we chose this as our life's work. Thank you to all of them for placing their trust in us!

Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ADA	American Disabilities Act
AE	Adverse events
AMD	Age-related macular degeneration
ANOVA	Analysis of variance
ANSI	American National Standards Institute
APA	American Psychological Association
APD	Auditory processing disorder
ATM	Automated teller machines
AU	Action units
BBFG	Bulletin board focus group
CDRH	Centers for Devices and Radiological Health
CGM	Continuous glucose monitors
CHL	Conductive hearing loss
CMC	Control movement compatibility
CPAP	Continuous positive air pressure
CRT	Cathode ray tube display
dB	Decibel
ECG	Electrocardiography
ECRI	Emergency Care Research Institute
EEG	Electroencephalography
EHR	Electronic health records
EMR	Emergency medical records
EU	European Union
FACS	Facial action coding system
FDA	Food and Drug Administration (U.S.)
FEA	Facial expression analysis
FMEA	Failure Modes and Effects Analysis
FOV	Field of view
GSR	Galvanic skin response
GUI	Graphical user interface

HAI	Healthcare-associated infections
HCD	Human-centered design
HCP	Healthcare providers
HF	Human factors
HFE	Human factors engineering
HFE/UE	Human factors and usability engineering
HTA	Hierarchical task analysis
HVAC	Heating, ventilation, and air conditioning
HZ	Hertz
ICU	Intensive care unit
IFU	Instructions for use
ILD	Interaural level difference
IRB	Institutional review boards
ITD	Interaural time difference
IVD	In vitro diagnostic medical device
JIT	Just in time
LCD	Liquid crystal display
LED	Light emitting diode
LTM	Long-term memory
LVAD	Left ventricular assist device
MAA	Minimal audible angle
MHRA	Medicines and Healthcare Products Regulatory Agency (EU)
MRI	Magnetic resonance imaging
NICU	Neonatal intensive care units
NIHL	Noise-induced hearing loss
NIOSH	National Institute for Occupational Safety and Health (U.S.)
NNR	Noise reduction rating
OR	Operating room
OTC	Over the counter
PACU	Post-anesthesia care unit
PPE	Personal protective equipment
PRP	Platelet-rich plasma
PTZ	Pan-tilt-zoom
RaS	Robotic assisted surgery
RCA	Root cause analysis
RME	Reusable medical equipment
RN	Registered nurse
ROM	Range of motion
RSI	Repetitive strain injury
SAW	Surface acoustic wave
SME	Subject matter expert
SNHL	Sensorineural hearing loss
SOP	Standard operating procedure
SPL	Sound pressure level
sRGB	Standard red green blue

SUD	Single use devices
ToT	Time on task
UE	Use-error
UI	User interface
URA	Use risk analysis
UX	User experience
WCAG	Web content accessibility guidelines
WM	Working memory
µg	Microgram
µs	Microsecond

Mnemonics

AEIOU	Activities, Environments, Interactions, Objects, and Users
BASIC	Breakdowns, Anecdotes, Scenarios, Insights, Custom Tools
FACES	Flow, Artifacts, Context, Environment, Sequence
MAUDE	Manufacturer and User Facility Device Experience
RIMS	Redundancy, Immediacy, Modality, Specificity
ROYGBIV	Red, Orange, Yellow, Green, Blue, Indigo, Violet
SOAP	Subjective, Objective, Assessment, and Plan
WEIRD	Western, Educated, and from Industrialized, Rich, and Democratic Countries

Contents

About the Authors

Russell J. Branaghan Russ is Co-founder and President of Research Collective, a Human Factors consultancy and Usability Laboratory in the Phoenix metropolitan area. He partners with medical device and pharmaceutical companies all over the world for user research, human factors analysis, usability testing, and regulatory consulting. Russ has more than 30 years of human factors experience in industry, consulting, teaching, and research. He says that industry was OK, but he likes consulting, teaching, and research a lot more. In addition to his consulting, Russ holds appointments at Arizona State University and Northwestern University and has won teaching awards at both. An avid writer, Russ has published over 100 peer-reviewed articles, book chapters, and proceedings papers. In his spare time, Russ plays guitar (poorly) and runs (slowly).

Joseph S. O'Brian Joe has been active in the world of Human Factors since 2013, contributing to the community by speaking at conferences, as well as participating on various standards and review committees. He was drawn to Human Factors through the unconventional means of learning how to fix a broken guitar as a Psychology undergraduate student. That research revealed an area of ergonomics and design that stuck with him, and instilled a passion to help make products more comfortable, easier to learn, and enjoyable to use. After completing a Master's degree in Applied Psychology at Arizona State University, Joe joined Research Collective and is currently the company's Senior Human Factors Scientist.

Emily A. Hildebrand Emily is the Director of Human Factors at Research Collective, a Human Factors consultancy and Usability Laboratory in the Phoenix metropolitan area. She leads usability, product design, and user experience-related projects for Fortune 100 and Fortune 500 clients across a variety of fields, but has over a decade of experience performing human factors (HF) studies to support the development of medical devices. In addition to consulting, she has performed research internally on medical devices and workflow processes at the VA and Mayo Clinic. She has extensive experience in product failure analysis and expert witness litigation support for medical devices. Emily has a PhD in Applied Cognitive

Science from Arizona State University and participates in the larger HF community as a member of various AAMI human factors committees, a reviewer for the HFES Healthcare Symposium, and as a speaker and attendee at HF and medical device conferences.

L. Bryant Foster Bryant is Co-founder and VP of Human Factors at Research Collective, a HF consultancy and Usability laboratory in the Phoenix metro area, where he has performed human factors and usability research for dozens of medical devices including surgical instruments, point-of-care devices, diagnostics, combination products, home-use devices, OTC products, and more. He serves as an active member of the Human Factors Engineering committee within the Association for the Advancement of Medical Instrumentation (AAMI) and also teaches a Human Factors and Design Controls course for the Regulatory Affairs Professional Society (RAPS). Bryant is also a member of the Healthcare and Product Design technical groups within the Human Factors and Ergonomics Society (HFES) and regularly speaks at both the annual HFES meeting and the HFES Healthcare Symposium. Bryant has written numerous articles about human factors, usability, and human-centered design for several publications.

Chapter 1
Introduction

1.1 Medical Error

While caring for her patient, a nurse attempted to program an infusion pump to deliver 130.1 mL/h of a particular medication. She pressed all the right keys, "1 - 3 - 0 - . - 1," but unfortunately, on this model of infusion pump, the decimal point did not work for numbers over 99.9. As a result, the pump ignored the decimal point key press and was programmed to deliver 1301 mL/h, a ten times overdose (Zhang, Patel, Johnson, & Shortliffe, 2004).

In another hospital two nurses cared for a 15-day-old baby with a congenital heart defect, breathing problems, and a rapid heart rate. The nurses gave the baby digoxin, a common drug for slowing heartbeats. Tragically, they made a mathematical mistake and administered 220 μg of digoxin rather than the intended 22 μg. The massive dose caused the baby to go into cardiac arrest, and he died a few days later (BBC, 2005).

This problem, called "death by decimal," illustrates some of the dangers of medical error in our healthcare environment. Errors in medicine are common. One recent study (Makary & Daniel, 2016) concluded that medical error kills 251,000 Americans per year, making it the third leading cause of death, behind heart disease and cancer (Fig. 1.1). According to this estimate, medical error accounts for 9.5% of all US deaths, the equivalent of two 747 jumbo jets (loaded with 364 passengers each) crashing every day, just in the United States (US). This death rate is comparable to one September 11 attack every 4 days. Even more troubling, this estimate only accounts for inpatient deaths. Many people die from errors in ambulatory settings, clinics, therapy, and home.

Medical error happens in a variety of circumstances—in hospitals, in surgery, when delivering medications, when using a medical device, and so on. Let us start by discussing medical errors in hospitals. To do that we need to understand the notion of an adverse event (AE). Adverse events (AEs), also known as harms, are injuries resulting from medical care rather than from illnesses themselves (Wachter,

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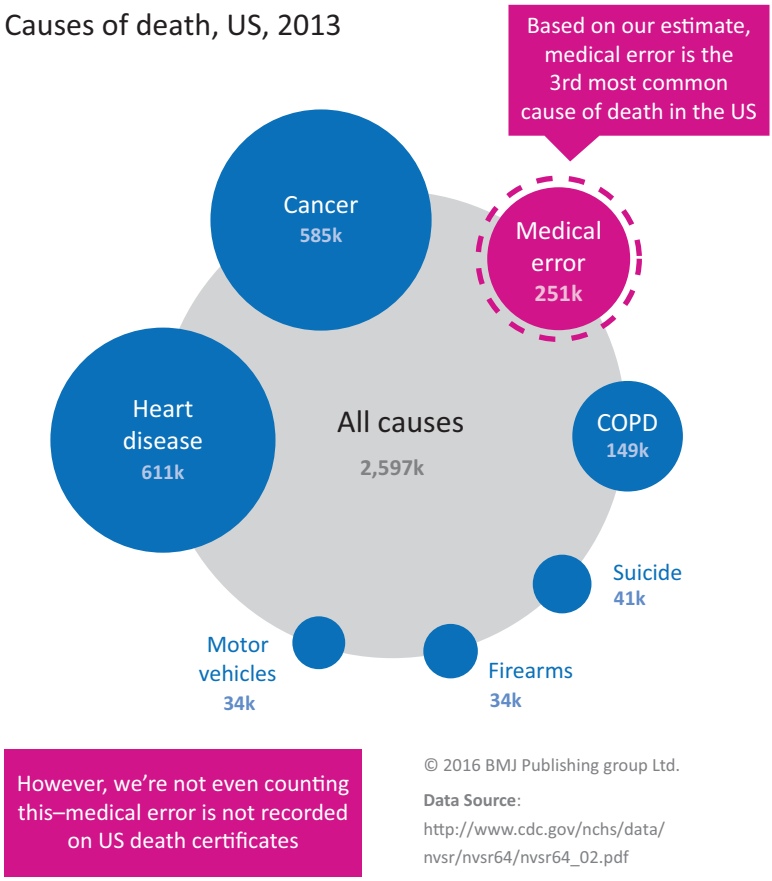

Fig. 1.1 Causes of death in the United States in 2013 (BMJ Publishing group, Ltd. is licensed under CC BY 4)

2012). Some AEs are not preventable, but those that can be prevented usually involve some type of error: either acts of omission (failing to do something) or acts of commission (doing something wrong). Approximately one-third of hospitalized patients experience some type of AE (Classen et al., 2011). While roughly two-thirds of AEs cause little-to-no harm, the remaining third unfortunately do cause harm. This is not only dangerous, but also expensive; the cost of preventable AEs is estimated to be between 17 billion and 29 billion dollars per year just in United States hospitals (Wachter, 2012). These costs are even higher when considering preventable AEs in ambulatory clinics, nursing homes, assisted living facilities, and other settings.

Problems can occur during bedside procedures as well. Several procedures related to insulin pumps, ablation systems, automated external defibrillators, duodenoscope reprocessing, and many more (FDA, 2016) have complication rates

exceeding 15%. For example, patients undergoing central venous catheter placement are at risk of arterial laceration, pneumothorax, thrombosis, and infection, each potentially deadly.

Many medical errors occur in the surgical suite. More than 20 million patients undergo surgery every year in the US. Although surgeries have become safer in recent years, many safety issues remain. For example, approximately 3% of patients who undergo operations suffer an AE and half of these are preventable (Lindenauer et al., 2007). These include anesthesia-related complications, wrong site and wrong patient surgery, medication errors, retained foreign objects, and surgical fires (Wachter, 2012). These are referred to as "never errors" because they should never happen, under any circumstances. They would be similar to a commercial jet taking off on an overseas flight without any fuel. And yet, never errors occur all the time.

One type of never error, retained objects, involves leaving surgical instruments, sponges, or other objects behind in the body after surgery. Gawande, Studdert, Orav, Brennan, and Zinner (2003) reviewed 54 patients with retained foreign bodies over 16 years, and found that about two-thirds of the items left behind were sponges or pieces of gauze used to soak up blood. The remaining one-third were surgical instruments. The rate of retained objects is about 1 in 1000, roughly equivalent to one case per year for a typical large hospital in the US (Wachter, 2012). On the other hand, this estimate is probably low because it is derived from an analysis of malpractice cases. Many, if not most, retained object errors never lead to malpractice claims, since it often takes years to discover that a surgical sponge has been left behind (Wan, Le, Riskin, & Macario, 2009). Now radio-frequency (RF) surgical sponge detection devices are used at the end of each case. The device detects RF chips placed in most sponges.

Another challenge is wrong site surgery. For example, due to diabetes and circulatory disease, a 51-year-old retired construction worker needed to have his left leg removed below the knee. Appropriately, the operating room (OR) schedule, surgical suite blackboard, and hospital computer system all indicated that the patient was to have his *left* leg amputated. Unfortunately, the patient accidentally signed a consent form to amputate his *right* leg. And, that is exactly what the surgeon did (Lieber, 2015).

One study of 1000 hand surgeons showed that 20% of them admitted to having operated on the wrong site at least once in their career. An additional 16% had prepared to operate on the wrong site but caught themselves before cutting (Meinberg & Stern, 2003). Simple solutions to this include "sign your site," in which the surgeon marks the surgical site in indelible ink (Fig. 1.2). However, even the "sign your site" strategy presented its own problems: some surgeons placed an "X" on the surgical site (as in "X marks the spot") whereas others placed an "X" on the opposite limb, meaning "Do not cut here."

Time outs as required by the joint commission have also been implemented. The time out is performed in the OR once the patient is prepped and before incision. It confirms patient identity, correct site, and correct procedure. The operating surgeon has to be present and agree to the time out.

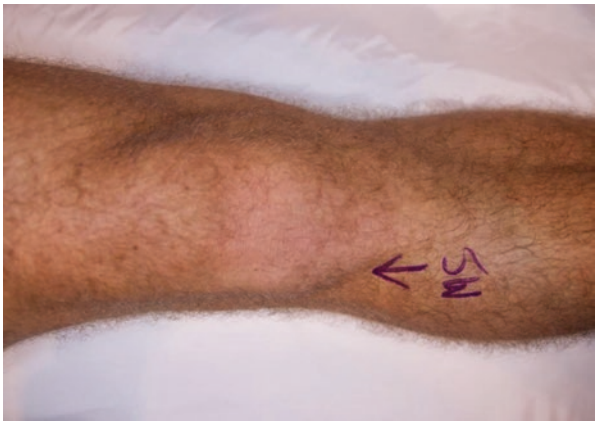

Fig. 1.2 Sign your site

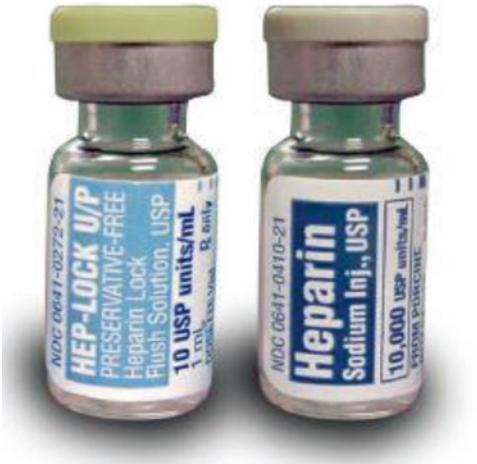

Fig. 1.3 Comparison of adult and child dosage vials of heparin (Image courtesy of ISMP www.ismp.org)

Many medical errors are more mundane than cutting off the wrong leg, but potentially more fatal, like administering the wrong dose of a common medication. Consider the following story. Dennis Quaid, the actor, and his wife Kimberly Buffington brought their newborn twins to Cedars-Sinai Hospital to be treated for staph infections. To prevent clots around intravenous catheter sites, the babies were prescribed a baby-friendly 10 unit-per-mL-dose of the anticoagulant, heparin (shown on the left in Fig. 1.3). Instead, however, they were accidentally administered the adult dosage on the bottle on the right, 10,000 units per mL. Worse, this happened twice, once at 11:30 AM and again at 5:34 PM (Ornstein, 2014). This was a 1000 times overdose of anticoagulant. The error was identified when one of the babies started oozing blood from the puncture site, and blood tests confirmed the problem. We are pleased to report that despite the potentially fatal medical error, the infants survived.

Investigating the event, Cedars-Sinai identified three issues that led to the overdoses. First, the pharmacy technician retrieved the heparin from supply without having a second technician verify the drug's concentration. Second, when delivered to a satellite pharmacy, a different technician failed to verify the concentration. Third, the nurses who administered the heparin failed to verify that it was the correct medication and dose.

When we present this case to undergraduate students, their first reaction is outrage. How could trained medical professionals be so careless? Fire the nurses immediately! Bring them up on legal charges! At the very least, students insist that the nurses and pharmacy technicians should go through training. Cedars-Sinai had a similar reaction. The employees were relieved of their duties during the investigation and "appropriate disciplinary actions were taken."

We do not agree with this reaction, however. In this case, we side with our human factors engineering (HFE) graduate students rather than the undergraduates. Because our graduate students study human performance, cognition, and design, they reach a very different conclusion. They immediately note the similar color, size, shape, font, and words on the bottles. Sure, the labels are different shades of blue, but they are clearly in the same color family, as effective brand guidelines dictate. Now imagine busy pharmacy technicians and nurses trying to care for sick babies, managing numerous medications, pieces of equipment, parents, physicians, and who knows what else. Now remember that these professionals have the same attention span, working memory, and judgment limitations as you or I. Perhaps design is part of this problem; and perhaps HFE could help.

The manufacturer reached the same conclusion as our graduate students. To reduce future errors, they changed the label on the higher concentration vials, modifying the background color, increasing font size, and adding an "alert" tear-off label.

It should be no surprise that medication errors are common, simply because there are over 10,000 prescription drugs and biologicals and 300,000 over-the-counter medications available in the United States (Aspden, 2007). An average hospitalized patient can expect one medication error per day. At least 5% of hospital patients experience some adverse drug event during their hospital stay (Wachter, 2012). And, 5–10% of the patients almost received the wrong medicine or the wrong dose, but the problem was caught in time (this is often called a "near miss").

Patients on numerous medications, as well as older patients, are most likely to be harmed because medication errors are especially common when patients are on high-risk medications, such as warfarin, insulin, or heparin. Classen, Jaser, and Budnitz (2010) found that one in seven patients receiving heparin experienced an adverse drug event. As with many errors, these are expensive. The cost of preventable medication errors in the United States hospitals is approximately 16.4 billion dollars per year (Wachter, 2012). Moreover, nearly 5% of hospital admissions can be traced to problems with medications, many of which are preventable.