



Edited by Mary Beth Privitera, M.Design, FIDSA



APPLIED HUMAN FACTORS IN MEDICAL DEVICE DESIGN



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Edited by
MARY BETH PRIVITERA



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Contributors

AAMI Human Factors Faculty Leaders:

Renée Bailey Agilis Consulting Group,
Orlando, FL, United States

Tressa J. Daniels UXD & Human Factors, BD
Medical, San Diego, CA, United States

Daryle Gardner-Bonneau Bonneau and Associ-
ates, Portage, MI, United States

Merrick Kossack Emergo by UL - Human
Factors Research & Design, Chicago, IL, United
States

Melissa R. Lemke Agilis Consulting Group,
LLC., Cave Creek, AZ, United States

Mary Beth Privitera HS Design, Gladstone, NJ,
United States

Tim Reeves Human Factors MD, LLC., Charlotte,
NC, United States

L. Bryant Foster Research Collective, Tempe,
AZ, United States

Kate Cox HS Design, Gladstone, NJ, United
States

Ian Culverhouse Rebus Medical, Bristol, United
Kingdom

Ashley French Agilis Consulting Group, LLC.,
Cave Creek, AZ, United States

Emily A. Hildebrand Research Collective,
Tempe, AZ, United States

Jessie Huisinga Agilis Consulting Group, LLC.,
Cave Creek, AZ, United States

Sophia Kalita Agilis Consulting Group, LLC.,
Cave Creek, AZ, United States

Liz Mauer Human Factors MD, LLC., Charlotte,
NC, United States

Christina Mendat Human Factors MD, LLC.,
Charlotte, NC, United States

Jeffrey Morang Sanofi, Cambridge, MA, United
States

M. Robert Garfield Abbot, St. Paul, MN, United
States

Eric Shaver Human Factors MD, LLC., Charlotte,
NC, United States

Jonathan R. Silva Washington University in St
Louis, SentiAR, Inc., St Louis, MO, United
States

Leah K. Taylor Agilis Consulting Group, LLC.,
Cave Creek, AZ, United States

Supported by:

Tor Alden HS Design, Gladstone, NJ, United
States

Jennifer N. Avari Silva Washington University
in St Louis, SentiAR, Inc., St Louis, MO, United
States

Russell J. Branaghan Arizona State University,
Mesa, AZ, United States

Deborah Billings Broky Agilis Consulting
Group, LLC., Cave Creek, AZ, United States

Author biographies

This book was supported by AAMI Faculty Members listed below.

Mary Beth Privitera, M.Design, PhD, FIDSA
Principal, HFE/Research, HS Design, Inc.
Co-Chair & Faculty, Association for the Advancement of Medical Instrumentation Human Engineering Committee
Professor, Director, Medical Device Innovation & Entrepreneurship Program
Department of Biomedical Engineering, University of Cincinnati



Dr. Mary Beth Privitera, M.Design, FIDSA, is internationally known as an expert in medical product design, specifically in the area of applied human factors. She is a principal at HS-Design, responsible for human factors and research. Additionally, she serves as faculty and co-chair of the Association for the Advancement of Medical Instrumentation's Human Engineering Committee.

Privitera also holds an appointment as Professor at the University of Cincinnati's Department of Biomedical Engineering and works collaboratively among the Colleges of Medicine, Engineering and Design. She is currently the Co-Founder and Director of the Medical Device Innovation and Entrepreneurship Program. Her previous academic appointments include industrial design and the Department of Emergency Medicine.

She has worked on devices intended for use across the practice of medicine including advanced technologies for: augmented reality for electrophysiologists, nasogastric tube placement, peripheral artery disease, intracranial aneurysm treatments, autoregulatory index monitoring for neuro ICU patients, combination drug delivery devices utilizing biometric technologies. She has observed care in nearly every area of the hospital throughout the United States and conducted studies human factors internationally. Her current research focuses on applied ergonomics, design and clinical applications involving additive manufacturing processes. She has authored several peer reviewed articles and a book titled "*Contextual Inquiry for Medical Device Design*," promoting best practices for phase zero medical device development. She has been a member of the AAMI Human Engineering Committee since 2004, an author of AAMI/ANSI HE 75 and has led the AAMI faculty team in the development of this book.

Melissa R. Lemke**Managing Director of Human Factors Engineering/Agilis Consulting Group, LLC**

Melissa R. Lemke is an industry recognized expert and thought leader in medical device and regulatory human factors engineering, and she leads the human factors consulting services of Agilis Consulting Group, LLC as the Managing Director of Human Factors Engineering. She is a biomedical engineer with formal training in human factors who understands how to design strategies and lead cross functional teams through successful human factors processes, scientific methods, and regulatory submissions. Since 2003, Melissa has managed, designed, and executed human factors analyses and user interface optimization for clients developing medical devices and combination products for a variety of intended users both inside and outside the U.S.



Throughout her career, Melissa has contributed to numerous approved pre-market and post-market human factors usability and labeling submissions involving medical products such as surgical devices, infusion pumps, endoscopes, in vitro diagnostics, reprocessing, implantable devices, mobile and web-based technologies, over the counter products, home use devices as well as a variety of drug delivery and combination products. She has designed, executed, and managed human factors evaluations with diverse intended users such as physicians, nurses, pharmacists, surgical technicians, biomedical technicians, field engineers as well as lay users, caregivers, and adolescents. Melissa has specialized training and expertise conducting studies and evaluating designs with users who have a variety of physical, sensory, and cognitive limitations.

Melissa received her Master of Science in Biomedical Engineering from Marquette University as well as specializations in rehabilitation biosystems and biomechanics during her graduate and undergraduate studies. During her thesis research, she evaluated the accessibility and usability of numerous medical products for people with disabilities and developed a mobile usability lab. She also managed and participated in various research projects as part of the Rehabilitation Engineering Research Center on Accessible Medical Instrumentation (RERC-AMI), which culminated in research findings that were leveraged in the Americans with Disabilities Act Accessibility Guidelines (ADAAG).

Melissa is an active member of the Human Factors Engineering and Home Care and EMS Environments Committees of the Association for the Advancement of Medical Instrumentation (AAMI) as well as the Human Factors and Ergonomics Society (HFES). She is a contributing author to the original HE75 (2009): *Human Factors Engineering - Design of Medical Devices*, including lead co-author of the accessibility considerations section. Most recently, she led the committee updates of the revised HE75 for the sections on Accessibility and Home Healthcare. Melissa is an AAMI University faculty member who co-teaches *Human Factors for Medical Devices* as well as *Applying Human Factors to Improve Instructional Materials as Part of the User Interface*. She has published and presented numerous works related to human factors

applied to medical device design as well as accessible design throughout her career. She began her profession in biomedical and human factors engineering after her brother sustained a spinal cord injury in 1999. Melissa remains passionate about helping clients develop and bring to market medical products that are safe, effective, and usable for people of all abilities through the application of sound human factors engineering during the design process.

Tressa Daniels

Tressa Daniels is the Associate Director of User Experience Design and Human Factors Engineering at Becton Dickinson in San Diego. Tressa has worked in the field of Human Factors Engineering for 21 years. Her expertise is in user interaction design, ethnographic research and executing human factors analyses of consumer and medical products, including infusion pumps, oral medication dispensing systems, migraine machines and DNA Sequencers. Formerly, Tressa worked at Illumina, CareFusion, HP, Intel and Xerox and was a Human Factors instructor at Woodbury University in Burbank, CA and is also a member of AAMI Faculty in Human Factors in Medical Device Design. She is a member of the Human Factors and Ergonomics Society (HFES) as well as the Association for the Advancement of Medical Instrumentation (AAMI). She serves on AAMI's Human Factors Engineering Standards Committee as well as hosts regular Webinars for AAMI. Tressa holds a Bachelors Degree in Psychology as well as a Masters in Human Factors Engineering and Applied Experimental Psychology.

**Renée Bailey****Director of Instructional Design & Creative Solutions/Agilis Consulting Group, LLC**

As Agilis' Director of Instructional Design & Creative Solutions, Renée Bailey brings more than 20 years of experience designing and developing instructional materials and strategies for medical device manufacturers, pharmaceutical, and other high-profile companies. Renée joined the Agilis Consulting Group in 2014 after 5 years of consulting in the medical device industry.

In her role as a Certified Expert Practitioner in evidence-based instructional design, Renée actively participates within a team dedicated to efficiently guiding clients while navigating the changing landscape of product regulatory pathways. Renée stays well informed of the U.S. and international regulations related to labeling and human factors to ensure instructional materials meet appropriate guidelines. She leads Agilis' instructional design team in the development of instructional materials, in collaboration with Agilis clients, to successfully meet FDA and international requirements for human factors submissions.



Renée is an expert in applying a scientific, systematic and scalable methodology based in Human Performance Technology (HPT) to produce effective instructional materials for healthcare professionals, lay user patients and caregivers, and clinical educators. Her process is focused on achieving safe and effective interactions between end-users and medical devices. Renée's instructional products include instructions for use, quick guides, training materials and programs (instructor-led, self-directed, eLearning), instructional videos, and on-device and packaging labels. Renée regularly creates and optimizes instructional materials for diagnostic kit devices, pen injectors, auto-injectors, inhalers, on-body delivery devices, life-supporting devices, reprocessing procedures for medical instruments, over-the-counter medical products, surgical devices, and robotic systems.

Prior to joining Agilis, Renée was a Performance Consultant for various Fortune 100/500 companies and a diverse list of clients which includes Medtronic, Pfizer Pharmaceuticals, Endo Pharmaceuticals, Deloitte & Touche, and Roche-Genentech. She gained vast experience and expertise leading large scale/high profile projects and project teams throughout her career. Renée strategically collaborates with global cross-functional teams and stakeholders to improve and streamline their complex, multi-level processes for producing effective user instructions across device and product platforms.

Renée is an industry thought leader and an active conference speaker on topics related to human factors engineering and regulatory requirements, evidence-based instructional labeling and training, post-market surveillance, and processes related to medical product clearance, approval and global market success. She also serves as Faculty for AAMI's human factors course, *Applying Human Factors to Improve Instructional Materials as Part of the User Interface*.

Tim Reeves, PhD CHFP
Senior Technical Director
Human Factors MD, LLC

Tim is the Senior Technical Director of Human Factors MD and founded the company in early 2001. Tim provides technical oversight to the team. He has more than 25 years of commercial experience evaluating and designing usable, effective, and safe medical devices. He is a Certified Human Factors Professional, and as a member of AAMI's Human Factors Committee, is a contributor to HE:75. He has been an invited speaker at several professional meetings, including the AAMI/FDA sponsored Human Factors and Patient Safety for Medical Devices and the first IBC's conference on Human Factors and Combination Products. Tim is the Lead Instructor and Subject Matter Expert for AAMI's popular Human Factors for Medical Device Design course. He has a PhD in cognitive psychology and human factors from the University of Toronto.



Daryle Gardner-Bonneau recently retired as the principal of Bonneau and Associates, a human factors consultancy in Portage, MI. She received the PhD in human factors from The Ohio State University (OSU) in 1983, and has earned master's degrees in psychology, industrial and systems engineering, and brass pedagogy (music), also from OSU. She is a fellow of the Human Factors and Ergonomics Society and a member of the Association for the Advancement of Medical Instrumentation (AAMI). Daryle has been involved in standards work for over 20 years. In addition to serving on AAMI's Human Factors Engineering, Alarms, and Home Care Device committees, she has served for over 10 years as the U.S. Technical Advisory Group (TAG) Chair for ISO/TC159 – Ergonomics and two of its subcommittees, and is currently the convener of ISO/TC159/SC1/WG2 on Ergonomics Process Standards. Daryle has contributed chapters to several books, and is the co-editor/co-author of *Human factors and medical device design* (2011) and *Human factors and voice interactive systems* (second edition, 2008). Her 35-year career has included academic, industry and consulting positions, and human factors research and consulting in the health care, telecommunications and aviation domains. Since retiring, she is spending increasing amounts of time on her hobbies, including Civil War history and genealogy.



Merrick Kossack has been practicing human factors engineering for over 25 years, most of that in the medical device industry. In his current role as Research Director of Human Factors Engineering (HFE) for Emergo by UL's Human Factors Research & Design (HFR&D) team (formerly UL-Wiklund), he works with medical technology developers to understand their HFE needs, develop strategies to meet those needs, and deliver the necessary HFE services. He manages the HFR&D team services in Chicago and supports the efforts in the group's other offices in Concord, MA, Utrecht, The Netherlands, Cambridge, UK, and Tokyo, Japan. His past work has involved technologies ranging from medical robotics to diagnostic and therapeutic devices to combination products.



Immediately prior to joining the Emergo by UL team, Merrick served as Principal Human Factors Engineer at Intuitive Surgical where he led the human factors engineering efforts developing the da Vinci Xi Surgical System. His responsibilities ranged from integrating human factors engineering into the organization's established design and development processes, to conducting usability studies, to providing the overall human factors strategy for each project to satisfy regulatory needs. Merrick has been a contributor to the Association for Advancement of Medical Instrumentation (AAMI) Human Factors Engineering committee responsible for work on today's relevant human factors industry standards. Merrick also taught human factors in medical device

development at the University of California-Santa Cruz and is a member of AAMI's faculty helping to teach their *Human Factors for Medical Devices* course.

Merrick received his M.S. degree in Human-Machine Systems Research from the Georgia Institute of Technology and his B.S. Degree in Industrial Engineering from the University of Illinois.

Other contributors include the following:

**Jeffrey C. Morang, MS Human Factors – Ergonomics
Usability Leader/Senior Human Factors Engineer, Sanofi
Member (2014 – 2017), Association for the Advancement of
Medical Instrumentation Human Engineering Committee**

Jeffrey Morang, MS Human Factors – Ergonomics, is a well-known human factors medical device design expert. He is currently a Usability Leader at Sanofi responsible for the application of human factors for drug-device combination products.

Jeff received his MS in Human Factors – Ergonomics from San Jose State University and has over 15 years of experience practicing human factors engineering in the industries of aviation, defense and medical device design focusing on enhancing product design as well as fulfilling regulatory requirements. Within the medical device design domain he has worked on devices for point-of-care diagnostics, intensive care units, emergency departments, surgical-assisted robotic surgery, operating theater diagnostics, drug delivery combination devices, neurological treatments, hospital sterile processing, diabetes care, and military/combat medical support. Jeff has conducted human factors research and studies across the globe and continues to promote the practice through guest lectures at local universities and international conferences and symposiums.



Ashley French Hall

Human Factors Consultant/Agilis Consulting Group, LLC

Ashley French Hall is a Biomedical Engineer and Human Factors Consultant with Agilis Consulting Group, LLC. Ashley has expertise in human factors engineering, usability testing, and optimization of user interface designs for medical devices and combination products, including experience with a wide range of devices such as surgical, diagnostic, home use, mobile, and over-the-counter devices as well as combination products such as auto-injectors, multi-use pens, syringes, inhalers, and wearable infusion devices. She also has experience designing and conducting studies with diverse end users such as lay patients and caregivers, adolescents, nurses, physicians, phlebotomists, and pharmacists. Since 2014, Ashley has led and contributed to human factors projects such as early stage heuristic analyses, formative evaluations, validation studies, post-market analyses, and post-market supplemental validation studies. She has led numerous projects through regulatory submissions that



culminated in successful human factors validation studies and FDA clearance. Ashley also is experienced with international human factors industry standards and has conducted usability testing in multiple European countries.

Leah Taylor**Human Factors Consultant/Agilis Consulting Group**

Leah Taylor is a Biomedical Engineer and Human Factors Consultant with Agilis Consulting Group, LLC. Leah works with Agilis clients to design, conduct and manage medical device and combination product human factors projects in support of global regulatory submissions. She graduated from the University of Iowa with a M.S. in Biomedical Engineering. Her graduate studies included assessment of performance in the operating room and collaboration with cross-functional teams of surgeons, medical residents, nurses and different types of medical technicians. Her previous work at the Mayo Clinic conducting research funded by the Department of Defense to assist in rehabilitation of wounded warriors.

**Deborah Billings Broky, PhD****Senior Human Factors Consultant/Agilis Consulting Group, LLC**

Dr. Deborah Billings Broky is a Senior Human Factors Consultant with Agilis Consulting Group, LLC, where she is responsible for managing, planning, executing, moderating and reporting human factors testing with the goal to evaluate and validate medical devices and products in alignment with U.S. and international regulatory guidance and standards. Since 2014, Billings Broky has worked with Agilis to design and implement human factors methodologies during all phases of product development, recommend data-driven design modifications to optimize user interface designs, and support clients with successful U.S. and international human factors regulatory submissions including client support during regulatory meetings and reviews with FDA.

**Sophia V. Kalita****Human Factors Consultant/Agilis Consulting Group, LLC**

Sophia V. Kalita is a Biomedical Engineer and Human Factors Consultant with Agilis Consulting Group, LLC. Sophia is experienced in applying human factors principles to the design, evaluation and validation of medical devices and products. Prior to joining Agilis Consulting Group, Sophia worked for a global medical device manufacturer as an R&D engineer where her focus was product design and manufacturing improvement. She advanced to project management where she led cross-functional teams to design and develop valuable medical devices. During this time, Sophia's accomplishments included managing and ensuring the success of human factors activities.



Jessie Huisinga, PhD

**Senior Human Factors Consultant/Agilis Consulting Group
Research Associate Professor/Department of Physical Therapy and Rehabilitation Science, University of Kansas Medical Center**

Dr. Jessie Huisinga is a Senior Human Factors Consultant with Agilis Consulting Group, LLC and an expert in assessing human performance with extensive experience working with individuals with neurological impairments. She has a background in Biomedical Engineering and Biomechanics, with specialized training in Neurology in order to evaluate movement patterns and task performance in persons with performance limitations. Dr. Huisinga works with Agilis clients to develop and optimize medical device and combination product user interfaces by applying various human factors methods as well as accessible design considerations. Dr. Huisinga has experience designing and conducting human factors formative and validation studies to help clients achieve successful human factors regulatory submissions and bring safe and effective medical devices and combination products to the market. She has experience assessing a diverse spectrum of home and professional use medical devices and products as well as conducting in-home and actual use usability studies.

**Christina Mendat, PhD**

**Managing Director
Human Factors MD, LLC**

Christina is a partner and Managing Director of Human Factors MD, a human factors consultancy that works exclusively on medical devices, including combination products. Christina is an expert at translating research findings such as user needs, requirements, product strengths and weaknesses into compelling design directions and solutions. She brings over a decade of experience in human factors having spent more than 5000 h in surgical suites, medical device usability studies, and outpatient facilities. She has presented papers to the Human Factors and Ergonomics Society and the American Psychology Society and has been providing multiple workshops and lectures on navigating the latest standard, HE75 and human factors integration in quality management systems. Christina has a PhD in experimental psychology and ergonomics from North Carolina State University.



Eric Shaver, PhD
Technical Director
Human Factors MD, LLC

Eric is a Technical Director with Human Factors MD. He has over two decades of human factors experience and has spent a good portion of those years on the litigation side of human factors and safety, specifically in warnings and risk communication, in addition to product development. At Human Factors MD, he contributes technically to all human factors activities throughout the product development life cycle. This includes participating in ideation sessions, understanding user needs, developing design requirements, providing input on early prototypes, developing device labeling, leading formative and validation studies, and conducting expert reviews. Prior to joining Human Factors MD, he was in charge of human factors for a medical device company in the Seattle area. Eric holds a PhD in Ergonomics Psychology from North Carolina State University.



Liz Mauer, MHCI
Technical Director
Human Factors MD, LLC

Liz has over 15 years of diverse experience in human factors research, design, and testing. She has particular expertise in planning, conducting, and analyzing findings from user research studies and translating those findings into directions for useful, usable, and desirable products. She is also experienced in applying the requirements of IEC 62366, HE75, and various FDA Guidance documents to support the development of safe and effective medical products. Liz holds a Masters Degree in Human-Computer Interaction from Carnegie Mellon University.



Dr. Ian Culverhouse

Dr. Ian Culverhouse is Co-Founder of Rebus Medical Ltd., UK and an experienced human factors consultant having worked with companies such as Roche, AstraZeneca, Smith and Nephew, Eli Lilly and Bosch Healthcare. Ian has a wealth of experience in applying HF to the design of medical devices throughout the development process, supporting manufacturers maximize their return on integrating HF into their business. In relation to Contextual Inquiry, Ian has led multiple global CI studies, including in-home and clinical environments in the UK, Germany and across the USA. Ian's PhD investigated the application of early stage interactive prototyping techniques. Today he advocates the philosophy of inclusion of early stage user testing to maximize the opportunity for learning and influencing design decisions.



M. Robert Garfield
Senior Human Factors Engineer
Abbott, St. Paul, Minnesota, USA

M. Robert “Bobby” Garfield is an experienced human factors engineer and industrial designer who has spent his career working for industry leading med-tech manufacturers and consulting agencies. Garfield is adept in the application of human factors in medical product design and has worked on programs ranging from handheld autoinjectors to next-generation robotic surgery systems. He is an alumnus of the University of Cincinnati (MDes, BSID) and Fitchburg State University (MBA).



Kate Cox
Senior Human Factors Engineer
HS Design

Kate is a Senior Human Factors Engineer and has been with HSD since September 2012. During this time, she has quickly become a key player of the design research and Human Factors team, specializing in applying human factors to the design and development of innovative medical devices for start-up and Fortune 500 companies. She is experienced in all aspects of the product development process, beginning with initial contextual inquiry research to defining requirements, analyzing risk, conducting usability testing, and developing HFE reports. She has worked on numerous devices over the years, from operating room equipment and tools, to consumer medical products, and laboratory devices. Kate has also been an integral member of the QMS team, working to further lock down quality controls within HSD to comply with ISO 13485. Kate has a Bachelor's and Master's Degree in Biomedical Engineering from Stevens Institute of Technology.



Tor Alden, IDSA, MS
Principal
HS Design, Inc.

As Principal of HSD, Tor Alden, MS, IDSA, brings his 25-year experience in user centric design, user research, strategic thinking and innovative product development to all HSD programs. His passionate collaboration to solve complex problems with innovative medical and digital health companies has led to over 45 patents and multiple design awards.

Tor is an avid speaker and writer consistently contributing to the technology, education, and design industries. Actively involved in patient safety, Tor serves on the AAMI Human Factors committee providing human factors use and usability



guidance. Alden has also served on multiple advisory boards, and has held both Chapter and Medical section chairs for IDSA including serving as an IDSA International Design Excellence Awards 2018/2019 juror. HS Design is an ISO 13484 certified product development firm specializing in medical, life science, pharmaceutical and consumer healthcare markets. The firm's 40-year expertise in product design centers on solving complex usability and system problems for medical devices, high-technology products, and new ventures. HSD's expertise includes user research, user interface design, industrial design, human factors, mechanical, electrical and software engineering leading to full prototypes of complex systems through pilot launch.

Jennifer Silva, M.D.

Jennifer Silva is Director of Pediatric Electrophysiology and Associate Professor of Pediatrics at Washington University School of Medicine/St. Louis Children's Hospital, and serves as the Faculty Fellow in Entrepreneurship for Washington University SOM. She serves on committees within the Heart Rhythm Society (Chair, Women in Electrophysiology; Member, Communications Committee) and Pediatric and Congenital Electrophysiology Society, and serves on the NIH-SBIR study section for Cardiovascular Innovation. The scope of her research has been on developing and identifying clinical applications of new and emerging technologies within cardiac electrophysiology.



Jonathan R. Silva, PhD FAHA
Associate Professor of Biomedical Engineering
Washington University in St. Louis

Russell J. Branaghan, PhD.

Russell J. Branaghan is Associate Professor of Human Systems Engineering in the Ira A. Fulton Schools of Engineering at Arizona State University. There, he is co-founder and Co-chair of the Master of Science in User Experience program and Director of the User Experience Laboratory (XLab). He teaches courses in Human Factors, Human-Computer Interaction, Healthcare Human Factors, Research Methods, Statistics, and Memory & Cognition. Russ also serves as President of Research Collective, a human factors and user experience laboratory and consulting group in Tempe, Arizona.



Emily A. Hildebrand, PhD

Emily is a cognitive scientist specializing in human factors, with 10 + years of healthcare-specific experience. She leads usability, product design, and user-experience-related projects for Fortune 100 and Fortune 500 clients across a variety of fields. She also has extensive experience in product failure analysis and expert witness litigation support for medical devices. She has performed research on medical device usability, reusable medical device reprocessing, and workflow processes at the VA and Mayo Clinic. Her research culminated in guidance recommendations to FDA and AAMI for improving the usability of medical device interfaces. Emily contributes to field as an active member of human factors and reprocessing related committees within AAMI and as a member of the HFES Healthcare and Product Design technical groups.

**L. Bryant Foster, M.S.**

Bryant's performed human factors research for dozens of medical devices including surgical instruments, point-of-care devices, diagnostics, combination products, home-use devices, OTC products, and more. He's an active member of the Human Factors Engineering committee within the Association for the Advancement of Medical Instrumentation (AAMI); teaches a Human Factors and Design Controls course for the Regulatory Affairs Professional Society (RAPS); and is as an active member in the Human Factors and Ergonomics Society (HFES) including the Healthcare and Product Design technical group, and he presents at the Annual Meetings and Healthcare Symposiums. Bryant's written articles about human factors, usability, and human-centered design for several periodicals.

**Paula Labat-Rochecouste**

Director of Human Factors and User Research
Human Center Ltd. UK



Foreword by Hanniebey D.N. Wiyor

What do we know about human interaction with medical devices? Given what we know, how then should we design device interfaces, clinical tasks and procedures so that medical device use can result in desirable clinical outcomes without causing harm to the patient? Wouldn't it be appropriate to minimize use-related hazards and risks? After all, we will be a patient someday.

Ensuring patient safety by minimizing potential use-related risk requires the application of human factors principles. A poorly designed user interface, one that lacks considerations of usability, increases the risk to patients. As medical devices become more diverse and complex, and are used with increased frequency in potentially multiple environments by users with variable skill and training levels, the importance of safe use is of interest to all involved: patients, caregivers, providers, hospitals/pharmacies, manufacturers, as well as regulatory agencies.

The above is quite possible if human factors engineering processes are incorporated

into device development. Human factors/usability engineering focuses on the interactions between people and devices: the device user interface. This includes all physical controls and display elements as well as packaging, labeling, and training. The goals of the human factors processes are to minimize use-related hazards and risk and then confirm the efforts were successful, ultimately demonstrating users can use the device safely and effectively.

This book, authored under the leadership of AAMI Human Engineering Faculty and Committee members, describes human factors processes with the intent to improve patient safety and support device users through "Applied Human Factors in Medical Device Design."

Hanniebey D. Wiyor, Ph.D.

LT U.S. Public Health Service

Regulatory Officer, Human factors Engineer

U.S. Food & Drug Administration

Foreword by Molly Follette Story

As technology advances, modern medical devices can perform increasingly amazing tasks; but those devices require varying amounts and types of interaction with human beings, whose basic capabilities have not changed.

Medical device developers are responsible for ensuring that the intended users of a device can use the device well because *it does not matter how innovative, safe, effective, reliable and affordable the medical device is unless its users are able to use the device successfully for its intended purpose.*

Human factors engineering (known in many parts of the world as usability engineering) is the science of studying and optimizing the relationship between the built environment and human beings, who tend to be error-prone. We cannot change very much about humans, but we can support development of medical devices that are error-resistant, and that humans can use well to diagnose diseases, treat

medical conditions, and achieve and maintain good health.

This book was developed to support AAMI's human factors educational courses, which is going on its 11th year and has been well attended throughout its history. The book covers the breadth of the topic and digs more deeply into some specific areas; it also describes and provides insights into key relevant current US and international standards and guidance.

It is my hope that this book will help its readers understand how to practice good human factors/usability engineering for medical devices, and that future medical devices will be much better than they are today: safer, more effective, more useable, preferable, and even emotionally gratifying.

Molly Follette Story, Ph.D.

Co-chair, AAMI Human Factors Engineering Committee, Cambridge, MA, United States

PART III

Human factors in design

Applied human factors in design

Mary Beth Privitera^a, M. Robert Garfield^b,
Daryle Gardner-Bonneau^c

^aHS Design, Gladstone, NJ, United States; ^bAbbot, St. Paul, MN, United States; ^cBonneau and Associates, Portage, MI, United States

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Do it by Design! Applied human factors is about designing systems that are resilient to the unanticipated event.

1. Introduction

Designing products for “everyone” is problematic as one person’s experience will always be different than another’s. This includes the fact that there is rarely a consensus of opinion and certainly a high degree of variability person to person. Each individual has a unique set of needs, perception and experience. In essence, environmental and human variability are perpetual. This reality must be considered when designing medical devices.

The role of the human factors engineers is to assist the design team to produce designs that better meet the capabilities, limitations, and needs of the user. In regards to capabilities, this means that the device fits the user’s mental and physical constraints. That there is limitations in place which prevent injury; and that individual needs are considered to improve usability and efficiency based on context.

Human factors experts gather information regarding human characteristics and interactions with the work environment in order to design systems resilient to use error (Russ et al., 2013). The standard ANSI/AAMI HE75 (AAMI, 2009), is the most comprehensive resource in regards to human factors design guidance. This chapter provides examples of utilizing this guidance as well as providing further clarity of specific design processes for medical device design. For the purposes of design, key sections of ANSI/AAMI HE75 include:

- Human Skills and Abilities
- Anthropometry and Biomechanics
- Alarm Design
- Controls
- Visual Displays

- Software User Interfaces
- Medical Hand Tool and Instrument Design

This list is not exhaustive however represents the minimum references a design team should consider in their process. Other Sections such as Combination Products, Workstations and Packaging Design are examples of specific topics that are further detailed in the guidance however are not included in this chapter discussion.

This chapter discusses the importance of considering human factors in the product design for both the physical product embodiment as well as any controlling user interface or complimentary computer applications. This includes sections on how to know your users, know the use environment, specific elements of human factors in design including affordances, touch points, color, materials, and finishes with a case example. It also includes a section of software design or user experience design with detailed descriptions on design intent, constraints, graphic design including aspects of detection and discrimination. It concludes with the design of alarms with highlights from recent changes in the standards as a result of advanced research into the perception of alarms.

2. Understand your users

Applied human factors in design results in total solution for the user. It addresses human factors holistically including the physical interactions as well as the mental workload (perception and cognition) required. In order to do this an understanding of basic human skills and abilities, anthropometry and biomechanics, accessibility considerations as well as cross-cultural/cross-national design considerations must be explored in the context of the proposed medical device use ([AAMI, 2009](#)).

This includes exploring the “fit” of the device. Fit as defined by the overall shape and appearance of the device relative to the location of physical interaction. For example, the fit of a hand tool is the relationship of the tool itself to hand size and finger reach. Ultimately, fit is determined by the following:

- Anthropometry: determining the physical fit with the user/appropriate sizing
- Biomechanics: physical limitations for movement and control at a given joint which are required in order to use the device. It can be further broken down into:
 - Reach: access of a control
 - Operation: use of a control
 - Injury: reduction of pinch points, consideration toward repetitive use injury
 - Safety: inadvertent control activation

It also requires an understanding of the user’s workload, stress, education and training. Specifically, the user’s capacity for cognition and perception including:

- How our senses take in and process stimuli
- Working short term and long-term memory: tasks that are built upon tacit knowledge and those which are newly experienced

Understanding the user, (capabilities, limitations, anthropometry, biomechanics, etc) and the context of use (working and social environment) cohesively impact safe and effective device use.

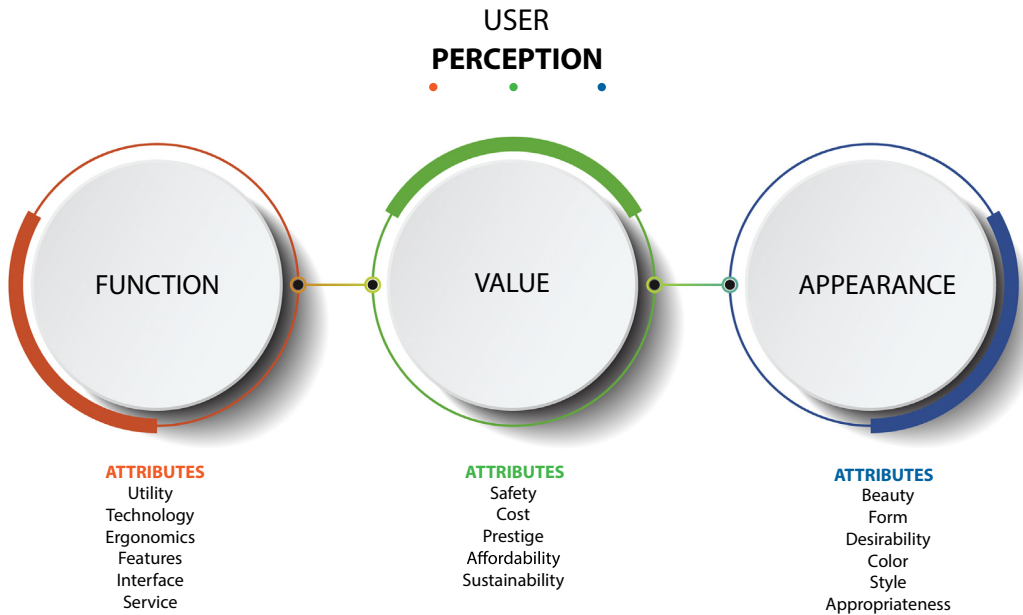


FIG. 7.1 The relationship of function and appearance to user value (Privitera & Johnson, 2009).

Ultimately, the user judges' value and decides to select a device. This judgment is based on their perceived value as a result of function and appearance. Each of these are interconnected (Fig. 7.1) and related to one another. With enhanced aesthetic order, which is appropriate for the user, it will inherently incorporate human factors thus the usability will improve. Ultimately user perceived value will increase.

2.1 Using anthropometry and biomechanics to determine fit

Anthropometry refers to the measurements and physical attributes of the human body. Biomechanics refer to the structure and function of mechanical aspects of living organisms, most importantly for device design, it often refers to joint biomechanics. Each of these dimensions are important and directly influence design requirements as they determine how the device will "fit" the user. In other words, anthropometry equates static dimension and biomechanics equate dynamic dimensions. For example:

- Anthropometry = Static (structural) measurements are based on individual parts of the body in fixed positions (e.g., seated eye height or hand breath).
- Biomechanics = Dynamic (functional) measurements relate to the body in motion (e.g., arm reach envelope or angular hand movement).

Static anthropometric measurements can determine appropriate product size and shape details. Whereas biomechanics measurements can be used to determine the human limits for strength, endurance, speed, and accuracy.

2.1.1 Understanding percentiles

Anthropometric and biomechanics data is often presented in percentiles. Common examples include 5th, 50th, and 95th percentiles. Percentiles correspond with the frequency of measurements within the distribution of the data. For example:

- The 5th percentile is a value associated with the location within the data where 5% of data is below that value.
- The 50th percentile is the middle value where 50% of the data is less than and 50% of the data is greater than that value.
- The 95th percentile is the value where 5% of the data has is a larger value.

It is a common misconception that designing to accommodate a 5th percentile female and 95th percentile male will naturally lead to a good design. The trouble is there is no such thing as a complete 5th percentile female or a 95th percentile male in every aspect. The challenge is that each measurement is an individual characteristic. Any given percentile value is specific to its measure and is only useable for comparison purposes against similar data (e.g., percentile data can be used to compare hand strength data from one age group to another).

2.1.2 Deriving device form from anthropometry

Anthropometric data drives specific design requirements that ultimately determine the product form such as overall handle length or height of a workstation.

There are several steps for selecting the appropriate anthropometric data to use when designing:

1. Determine the intended user group(s).

It is important to define who the intended users are. Every user group has unique characteristics. Factors including nationality, age, and gender impact anthropometric data.

2. Identify the relevant dimensions (body attributes).

While this may be readily identified by one main dimension, often there are several dimensions that are important for a device design. In this case, a list of functional dimensions should be generated with prioritization and focus on the elements that are most influential to device performance.

3. Define the target percentile/size range.

An ideal design would accommodate everyone. Unfortunately, this is often not practical or possible. While there may be some anthropometric characteristics with narrow dimensional ranges, which can be entirely accommodated, many measurements include a wide range of data. There are a few paths to choose from that may help in selecting a target value. These include:

- Design using the average.

Using 50th percentile data is an approach that provides “average” inputs for a design. Although this path may not produce a good solution for any given individual user, average data can be acceptable depending on the situation.

- Design using ‘edge’ cases.

Selecting dimensions from either or both ends of the spectrum (e.g., 5th and 95th percentile) can be successful. This path can help accommodate the largest and/or smallest users for critical limiting dimensions. This path involves defining requirements that balances maximum and minimum limiting factors. For example, if a hand tool’s grip span accommodates the smallest users and is acceptable to largest users, the overall design may be very inclusive.

When multiple connected dimensions are required, a different approach is necessary. As it is the case that when multiple variables interact, stacking errors occur since there is no “average”, 5th percentile, 50th, or 95th percentile person. Therefore, it is not possible to select multiple variables and maintain inclusiveness. The use of two 5th to 95th percentile ranges results in a range that is far less than 90% inclusive. For example, a group of individuals that fall between the 5th and 95th percentile for stature and weight includes only 82% of the targeted population (Robinette, 2012). Solving for multi-dimensional non-interactive size/shape characteristics can be achieved by expanding the range for each measure (e.g., to the 1st to 99th range) (Robinette, 2012). If multiple dimensions interact other tactics are necessary including: 3D-CAD anthropometrics models, testing with live human subjects, and calculation of multi-variable sample boundary conditions (Robinette, 2012).

4. Consider constraints.

Anthropometric data can provide a robust framework to define requirements however there are limits to blindly using the data one-to-one. Common constraints include:

- Population changes.

The dimensions of the general population are ever changing; improving living conditions have resulted in a population that is taller and larger today than previous generations (Eveleth, 2001). Anthropometric percentiles within older textbooks and references may not reflect the exact measurements of the current population.

- Sample size limitations.

Available reference data may be based on limited sample sizes or narrow subpopulations and may not be generalizable. For example, a study on the strength and size of military age males and females conducted by the U.S. Army does not represent the broader population.

- Environmental factors.

It may be necessary to adjust anthropometric data to more accurately represent the intended user in their use environment. Adjustments for gloves, clothing or other personal protective equipment (PPE) are not included in the data. Anthropometric measurements are typically taken against bare or minimally covered skin. It is important to adjust the data to accommodate environment specific factors that were not included when the measurements were taken.

- Linear measurements versus 3D solutions.

Most anthropometric data is provided as 2D values. There are limitations to directly using this data to construct 3D designs. Designers may need to adapt 2D measurements to better

represent users in 3D space. 3D-CAD anthropometric models assist with complex design problems where there are multiple size constraints and multiple body attributes to accommodate (e.g., automotive interior design). Software programs such as JACK ([Siemens Inc., 2011](#)) and RAMIS ([Intrinsys Ltd., 2018](#)) can be used to evaluate designs using interactive anthropometric models. These ergonomic CAD software programs are widely used in automotive, industrial, and defense applications and are helpful for complex workstation design ([Blanchonette & Defence Science and Technology Organisation, 2010](#)).

- The necessary data is unavailable.

Texts such as the Human Factors and Ergonomics Design Handbook ([Tillman, Tillman, Rose, & Woodson, 2016](#)) or HE75 ([AAMI, 2009](#)) provide common anthropometric measurements. If these or other resources do not provide the required data, it is possible to fixture a measurement tool in order to collect data. Tools such as dynamometers, force gages, or load cells to capture novel measurements. Using statistics, a correlation can sometimes be found between custom measurements and one or more standards measurements. This mathematical relationship enables project teams to predict a range of capabilities based on published databases of the standard measurements, instead of having to conduct a larger study for the custom measurements.

5. Test prototypes with users.

In all cases, anthropometric driven requirements should be confirmed via prototype evaluations with representative users. These studies ensure anthropometric design requirements fit the intended user.

Additional information on human abilities, anthropometry, and biomechanics can be found in ANSI/AAMI HE75 Basic Human Skills and Abilities and Anthropometry and Biomechanics.

2.2 Use related injury prevention

Injury prevention is for both the user and the patient. In some instances, the patient is the user, as devices can be used on oneself. The design of the device should prevent user injury from repetitive motion, vibration or from forcing users to exert themselves beyond their capabilities.

2.2.1 Nature of injuries

The nature of injuries includes acute trauma, which can be traced to a single incident or sudden trauma (broken bones, strained ligaments, etc.) or cumulative trauma disorders (CTD). CTD develop over time as a result of “microtraumas” to the soft tissues of the body e.g. repetitive motion injuries. The following CTD risk factors are known to increase the likeliness of developing chronic injuries of the upper extremities: extreme postures, forceful exertions repetitive motion, contact stresses, low temperature, and vibration exposure Putz-Anderson (1988).

2.2.2 Using physiological measures to determine injury potential

By using physiologic measures such as goniometers (joint angles), electromyography (EMG), pressure mapping or heart rate when assessing a potential design, injuries may be avoided.

For extreme postures, using a goniometer to record joint measurements can demonstrate postures which are out of range and could be injurious. This is best done if assessing repeatable task.

To measure how hard muscles are working, use EMG testing. EMG is a technique for evaluating and recording electrical activity produced by the muscles. The stronger the contraction, the more neurons firing the results are traces increase in amplitude with more activity.

To measure pressure distribution of tool-hand interaction, pressure sensors can be added to the users' hand then measured as an objective determinant of stress.

This can be an indicator of stress which is unavoidable. For example, if heart rate is used to measure stress during a complex life or death surgical case, it would be appropriate to have sharp increases at times. This information would have to be coupled with perceived stress in order to be maximally useful.

3. Know the use environment

Device designers must know how a device will be used, what it must accomplish and all aspects of the use environment in order to ensure the design is safe and effective. Inherently, device designs are context dependent; it may not be appropriate for all applications or locations.

This requires exploration of the use environment in order to determine those constraints that the device design must accommodate such as ancillary equipment in the workspace, work height and orientation, lighting, noise, temperature, temperature as well as possible distractions. Each of these contribute to context specific design requirements, e.g. the design must provide thermal protection at all use interaction points due to extreme temperatures.

Specific environmental considerations include:

- Use work space

Devices are used in a variety of work spaces (e.g., hospitals, homes, and mobile scenarios) and may also be deployed in multiple environments. Each unique use scenario must be analyzed for unique characteristics. Multiple use environments may have conflicting factors which need to be balanced during development.

- Use workspace height and orientation

The height, orientation, and location of a device within its environment directly influences how it is used. For example, in laparoscopy users may have severe shoulder abduction-elbow flexion as a result of pistol grip designs, as a result of user position relative to the surgical table height and while this is not necessarily problematic, it will cause the users discomfort and reduced capabilities in forces required to activate controls. Device use is also influenced by other objects in the environment in regards to storage and access.

- Lighting

Lighting includes ambient illumination as well as direct sources of light. Dark or low light environments require special accommodations such as backlit screens and glowing touchpoints for easy identification and improved readability. Devices which reside within environments with extreme lighting often require display monitors that reduce/control for

glare to ensure sufficient labeling contrast. Solutions for lighting are task and risk specific in the overall device design.

- Auditory noise

Ambient noise impacts all audible signals a device may present. Additionally, alarm conditions can induce alarm fatigue and cause users to ignore or overlook important warnings. Devices that provide excessive auditory feedback are a distraction which can overpower vital information and/or hinder peer communication. The level of noise in the intended use environment must be considered when developing auditory features.

- Temperature and humidity

Temperature and humidity directly affect device and user performance. They also impact the clothing worn by users e.g. they may require protective clothing.

- Distractions

Distractions come from multiple sources and take various forms. Users may be distracted by ambient noise, background music, peer communication, multi-tasking requirements, fatigue, and stress.

To better understand the use environment in order to determine specific design requirements, contextual inquiry (Chapter 5) should be utilized as part of a robust human factors strategy.

For more information environmental considerations, see ANSI/AAMI HE75 Environmental, Organizational, and Structural Issues. Additional information on environment-specific design constraints can be found in ANSI/AAMI HE75 Design of Transportable Medical Devices and Devices Used in Non-Clinical Environments by Laypersons.

4. Device design

Physical products come in all shapes and sizes with varying degrees of complexity (Fig. 7.2). They range from simple tools (e.g., scalpels) and handheld devices (e.g., blood pressure monitors) to large workstations (e.g., CT scanners). The design process for developing these physical products is consistent: user research, requirements generation, design exploration, prototype, and test. This iterative process elicits feedback on ease of use and requirements fulfillment.

Design teams must solve for multiple human factors constraints to be successful. This section provides a brief overview of a human factors influences that when taken into consideration during development drive good physical product design. These range from universal factors such as the environment and workflow to hardware specific details such as color, materials, and finish.

4.1 Affordances and design cues

Users construct mental models of how the world around them functions. This extends to the operation of the products they interact with in their day-to-day lives. Common behaviors and design conventions associated with one product are often assumed to extend to another.



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FIG. 7.2 Varieties of medical devices from hand held devices, software, to large lab equipment and workstations. *Image provided by HS Design.*

To assist users' understanding of proper device function, a physical product's form should embody how it is used. This is accomplished through affordances and design cues.

Affordances are design features that assist users in understanding how a device works; they can be real attributes or perceived properties of proper use (Norman, 1990). In physical product design, multiple elements of a design assist in communicating proper use. These cues are embodied by a product's visual form and the feedback provided to users.

Conscious and subconscious hints can be provided through simple design elements or expressed through the broader product embodiment. A product's surfaces (edges, ridges, styling lines) and textures (e.g., bumps for grip or ridges for friction) can imply directionality and movement. Labeling and visual indicators (e.g., arrows) also provide modest but powerful assistance. Likewise, handle location and form communicate use related information. For example, the provision of a power versus precision grip handle can imply the appropriate level of force to apply during use.

Affordances and design cues can also be utilized to prevent inadvertent action and error. Forced constraints and poka-yoke features help users avoid mistakes. In this regard, keying mechanisms stop misconnections from being made and steer users away from incorrect locations or orientations. Surface features can also be used to reduce error (e.g., physically recessed power buttons prevent inadvertent actuation).

Designers should provide cues for proper use as part of a physical product's exterior form and user interface. These cues should build upon common design conventions and/or communicate any variability from the norm. Additional information regarding common conventions, mental models, affordances, and design cues can be found throughout ANSI/AAMI HE75 including General Principals.

4.2 Aesthetic beauty as it relates to usability

Both aesthetics and affordances are considered to be measures of product success as designers use these two ostensibly distinct theoretical elements in order to provide effective ways of interaction (Xenakis & Arnellos, 2013). In combination, these enhance a user's ability to detect action possibilities (affordances) that allow the user to form an opinion of aesthetics. The aesthetic experience can be viewed as a complex cognitive phenomenon that constitutes several processes that emerge through interaction (Xenakis & Arnellos, 2013).

There is a stereotype that "beautiful is good and good is useable," while beauty is accessible immediately through visual presentation, usability reveals itself only through interaction (Marc Hassenzahl & Andrew Monk, 2010). There is a correlation of beauty and usability that implies devices are either both beautiful and useable or ugly and unusable (Marc Hassenzahl & Andrew Monk, 2010). Visual aesthetics do affect perceived usability, satisfaction and pleasure (Moshagen & Thielsch, 2010).

The formal parameters of aesthetic objects include simplicity and diversity, color and craftsmanship (Moshagen & Thielsch, 2010). Each of these parameters carry a unique meaning which are:

4.2.1 Simplicity

Simplicity reflects the aspects that facilitate perception and the cognitive processing of layout. This includes clarity, orderliness, homogeneity, grouping and balance (Moshagen & Thielsch, 2010).

4.2.2 Diversity

Diversity is the visual richness, dynamic nature, variety, creativity, and novelty of a design (Moshagen & Thielsch, 2010).

4.2.3 Colorfulness

This includes the number of colors and their composition.

4.2.4 Craftsmanship

Craftsmanship refers to the construction of the design itself. It can be characterized by skillful and coherent integration of all design dimensions (Moshagen & Thielsch, 2010).

The initial reaction a user has to a device is the functional role of aesthetically-oriented emotional values to detect interactive opportunities or threats (Xenakis & Arnellos, 2013). The second is to signal other functions which control our decisions and behavior regulation processes. This emerges in relation to success or failure in reaching a potential goal. Interaction aesthetics aid the user to construct meanings that make clearer the way (action) to goal achievement (Xenakis & Arnellos, 2013). It is the role of the designers to enhance devices with characteristics which embody simplicity, diversity, appropriate colorfulness with skillful craftsmanship. This ultimately leads to perceived value (see Chapter 1 Section 3 Why might we want to do more).

4.3 Use interaction touch points and control selection

User interaction touchpoints (e.g., handles) and controls physically connect the user to the product. They are the primary areas of interaction and can be defined as:

- Controls are input mechanisms that allow users to change the state of a product or feature. They take a variety of forms including thumb wheels, toggle switches, triggers, slide controls, pushbuttons, and rotary knobs. Alternatively, they may be interactive screen button representations or icons with which the user can control the device.
- Touchpoints describe areas of targeted user interaction and points of contact with a product. They are the locations of physical interaction such as door latches, input controls, and handles.

4.3.1 Use interaction touch points

As described earlier, the use of affordances or cues can assist in the user interface design. For example, in Fig. 7.3 the overall shape of the device impacts how the device is held and is explored (Figs. 7.5, 7.7, and 7.8).

While this illustrates a handheld device, use touchpoints refer to any area that the user is expected to interact with and can include areas such as handles for pushing or carrying, push buttons, control levers, etc.

The shape, color and texture provide the affordance/cue to the user in device design. Designers should factor the obviousness of use interaction areas when developing the overall device architecture and detail design of the outer housing (physical design) or screen display (software design).



FIG. 7.3 Form sketches exploring use interaction touch points (how it feels in the user's hand). Image provided by HS Design.

4.3.2 Control selection

The selection of controls begins with mapping the functions that require controlling with how they should be managed. This includes the control type (e.g., button vs. switch) as well as control function (e.g., multi-state, dual-state, and continuous controls). Selection of control type and function is typically dependent on access requirements, frequency of use, as well as determining if control function is continuous or discrete in activation.

Recommendations and available options for control size, shape, positioning, travel distance, labeling, activation force, and feedback vary by control type and application. Each attribute should be tailored to a device's intended user, task, and environment of use. The design of physical controls should match common interaction paradigms, user preferences, and users' mental models of devices/control functions.

4.3.3 Layout

The position of controls and touchpoints on workstations, devices, and handheld tools can be determined based on their importance, type, or sequence of use. Control layout should consider risk and potential use errors such as inadvertent activation.

Each control type and functional option has different geometry and can be organized based upon access, use, and visibility. These attributes are driven based on the perception, cognition, and physical abilities of users. Anthropometric and biomechanics data is a primary

driver for control placement and layout. It is particularly important for layout and placement of controls on handheld tools.

There are nuances for the implementation of controls on fixed input panels for devices and workstations versus handheld tools and instruments. For application specific information on touchpoints, controls, and layout see ANSI/AAMI HE75:

- Controls
- Medical Hand Tool and Instrument Design

4.4 Color, materials, and finish

The selection of color, materials and finish during the design process goes beyond brand guidelines and user preference. These visual and tactile design characteristics influence product perception, safety, and ease of use.

4.4.1 Color

Color is an influential attribute for function and aesthetics in a product's design. Color coding can be used to distinguish different elements from one another or associate discrete functions. Color plays a powerful role as a signifier for prioritization and order of operations. It is also influential as a mechanism to highlight safety critical elements, providing warnings for areas of risk. Additionally, it can serve as a status indicator, distinguishing between functional states (e.g., traffic lights).

The specific meanings derived from colors are influenced by psychological and cultural norms. U.S. specific color codes and conventions for medical applications are not applicable in all countries. Designers need to ensure the selected color conventions match the product's target market.

Color selection is influenced by human limitations. Color blindness affects 8% of men and 2% of women in the general population (AAMI, 2009). Designers should choose colors (including attention to tone, tint, shade, and hue) with these limitations in mind. Common forms of color blindness include protanopia (red blindness), deuteranopia (green blindness), protanomaly (reduced sensitivity to red light), and deuteranomaly (reduced sensitivity to green light) (AAMI, 2009).

Common conventions and multiple standards influence proper color selection. For example, IEC 60601-1-8 provides input on the use of color for the prioritization of alarm conditions: red reflects high priority alarms whereas yellow should be used for medium priority conditions (IEC, 2006). Additional influences can be drawn from guidance provided by HE75 (AAMI, 2009), the American National Standard for Safety Colors ANSI/NEMA Z535.1-2017 (NEMA, 2017) and the Occupational Safety and Health Administration (OSHA). These sources provide detailed descriptions for colors, their meanings, and their application. Designers should use these references and check for updates regularly.

Additional information on human vision and use of color for product development can be found throughout ANSI/AAMI HE75 including:

- Basic Human Skills and Abilities
- Cross-Cultural/Cross-National Design
- Software-User Interfaces

4.4.2 Materials

Material selection directly influences product appearance and functionality. Aspects including weight, appearance and tactile feel are influenced by material selection. In addition to manufacturing constraints, functional and economic considerations, the selection process must consider the tangible and intangible influences materiality plays on usability. There are several human factors attributes to consider as part of the material selection process, these include:

- Temperature

Materials can transfer temperature which may result in the material of handles can transfer the temperature from the internal mechanisms or the use environment to the users' hands. For example, the use of metal handles within a cold environment may negatively impact user comfort.

- Energy isolation

Materials can provide energy (e.g., electrical, or magnetic) insulation and isolation. These functional properties can help reduce the risk of injury to the user.

- Vibration

Materials can reduce the impact of vibration on the user by dampening its effect.

- Cleaning and sterilization

Some materials can more difficult to clean or during sterilization the material properties may change. Careful assessment of cleaning and sterilization needs must be considered. This process may be expedited by selecting materials with imbedded antibacterial properties or those materials with proven performance.

- Friction

Moving parts or connector interfaces are always subject to friction. Reducing friction can help lower activation forces and reduce injury risk.

- Weight and center of gravity

A product's weight and center of gravity is directly impacted by the materials used in manufacturing. By balancing the design for the use context and application, usability will be improved. This avoid situations like tipping in moving large equipment or awkward movements in hand tools.

- Visual and functional properties

Material selection affects the color and feature options available as part of an overall design. For example, plastic and glass provide options for transparent components which can improve visibility of internal mechanisms or provide the ability to check fluid levels. The material selection process should ensure that intended visual and functional properties of a given design are achievable.

4.4.3 Finish

Material finish includes the visual appearance, tactile feel and surface treatment of the exterior of a product. These attributes can be selected independently from the underlying material. Various manufacturing processes can be used to achieve desired finishes including in-mold texturing and two-shot over molding, as well as secondary processes including milling, sandblasting, and paint.

Final surface selection should be resistant to damage and wear, textured to improved grip, and suitable for easy cleaning (e.g., limit crevasses). Surface texture can also be used as a signifier for touchpoints or other areas of interest.

Additional application specific information on materials and finish can be found within ANSI/AAMI HE75 including:

- Connectors and Connections
- Medical Hand Tool and Instrument Design
- Workstations

4.5 Case study: applied ergonomics for hand tool design

Ergonomic hand tools link the user, the device, and the use environment ([Aptel and Claudon, 2002](#)). To meet this goal, designers must control multiple characteristics to transform user needs and design inputs into finished concepts ([Garfield, 2015](#)). A parallel inside-out (internal mechanism) and outside-in (external housing) development approach is beneficial. Using this approach, engineers lead internal mechanism design while human factors and industrial design experts develop exterior handle concepts (areas of hand and tool interaction). These multidisciplinary collaborations balance relevant technical constraints along with users' capabilities.

For the purpose of brevity, this case will only describe the activities of the human factors and industrial design team in their concept development. This includes four main activities: (1) handle shape selection; (2) control selection and placement, (3) handle and controls size definition, and (4) form language and surface refinement.

4.5.1 Step 1: handle shape selection

The initial step is selection of the handle shape (type), angle of use, and grip position.

The position of the hand tool relative to the user's body and the work area directly influences the recommended handle shape ([Quick et al., 2003](#), [Ulin, Ways, Armstrong, & Snook, 1990](#), [Ulin et al., 1993](#)). Based on information found in ANSI/AAMI HE 75:

- Power-grip pistol handle allows users to exert a high degree of force while maintaining a neutral hand position (e.g., linear laparoscopic staplers);
- Precision-grip inline handle provides users a direct axial connection to the tool's end effector.
- Inline hands are beneficial for steering and rotating devices within a fixed lumen (e.g., cardiac catheters).

In this case, an inline handle shape was selected based upon contextual information regarding user position relative to the target. Specifically, the hand tool is used in a minimally invasive procedure with a small thoracotomy approach (small incision between the ribs).

Note: both human factors references and information regarding the user and use environment were used to select device shape.

4.5.2 Step 2: control selection and placement

Controls connect the user to the device's intended function. It is important to consider multiple aspects when determining control type and placement including the underlying mechanism, similar hand tools, anthropometric constraints and the user's mental model of device function (Garfield, 2015). There are multiple control types and hybrid options to choose from (e.g., triggers, switches, rotary, slide, and push button controls) and each has unique attributes tailored to specific applications. Further compounding the control selection and placement process are devices with multiple controls. Multi-control layouts need to take into consideration factors such as task frequency, workflow, and elevated use-safety constraints (e.g., inadvertent cross-control activation).

Exploration of control selection and placement via a control's possibility matrix (Fig. 7.1) assists in answering the underlying questions of what controls to select and where to place them on the handle. A possibility matrix uses symbols (color dots) to represent a control type and a potential location providing a visualization of potential control layouts. The matrix starts with multiple outlines of the predetermined handle shape; and colored dots or other signifiers are placed to symbolize various control options. Using a possibility matrix as a discussion guide with engineering teams can expedite the design process and tradeoff discussion to best meet functional and usability requirements.

The human factors related to individual control type and constraints can be found in ANSI/AAMI HE 75 and provide the backbone of a possibility matrix. This information includes the maximum/minimum force capabilities and will be required by the technical team.

Note: Using published HF data regarding controls, different device configurations can be quickly generated that include the technical requirements. This enables robust conversation regarding tradeoff decisions required to maximize functionality and optimize usability.

4.5.3 Step 3: handle and control size

The process to determine size (e.g., cross-sectional size, control spacing, handle length, form elements) balances factors including anthropometric guidelines, the internal mechanism and feedback from users. It is important to assess basic environmental inputs (e.g., gloved hands) and critical hand dimensions (e.g., finger loop size minimums, grip span limits, and hand breadth) to ensure the design is appropriate for intended users. User testing with prototype models further assists with detail design process (Fig. 7.2).

Note: both published literature and user testing can assist in further form refinement to assess "fit."

4.5.4 Step 4: form language and surface refinement

3D Surface refinement builds on the previous steps of the process and involves determining cross-sectional shape, form language, surfaces textures, and materials (Fig. 7.3). These attributes communicate critical interface elements to the user. They directly influence hand placement, touchpoint identification, and grip friction. Adding guards, removing sharp edges/creases, and eliminating pinch points are also important to increase safety of the final design. The visible features of the handle are not the only aspects of design refinement.

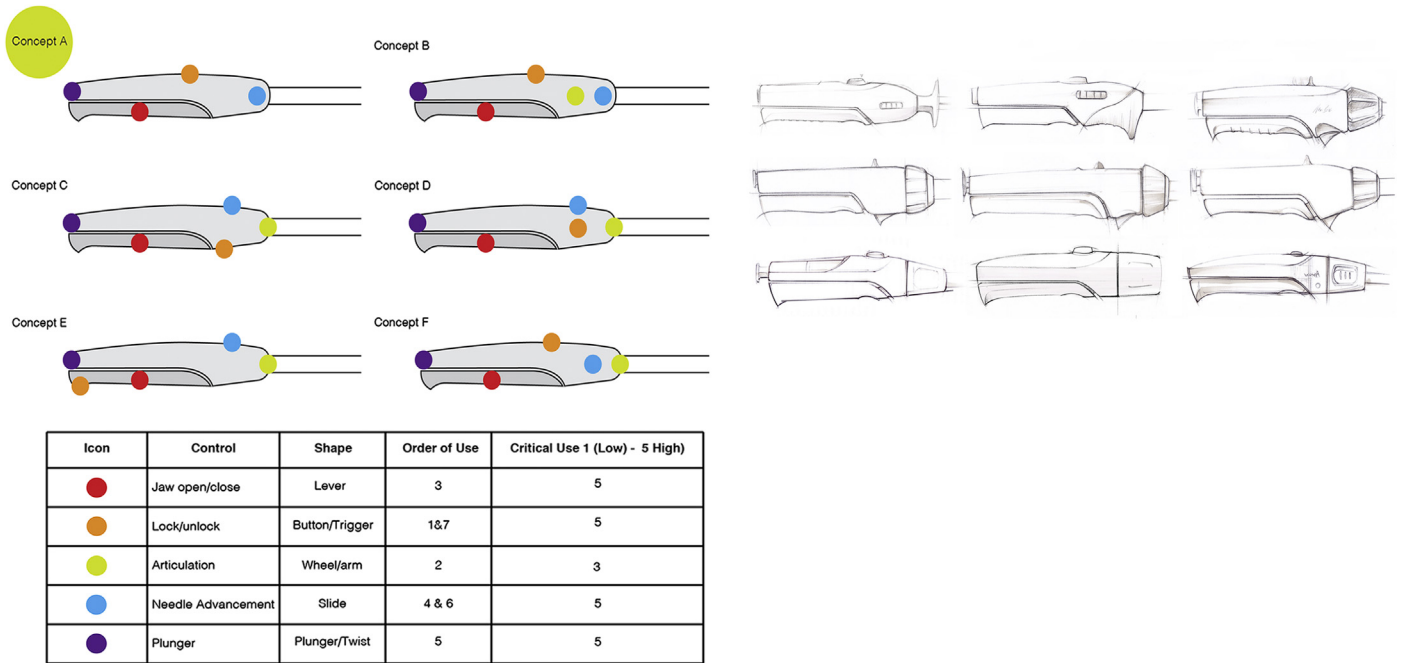


FIG. 7.4 Controls possibility matrix for an inline handle (Left) and corresponding hand sketches (Right) by Kevin Zylka.

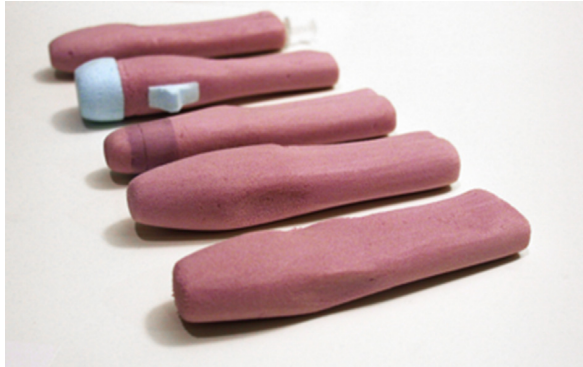


FIG. 7.5 Form handle prototypes by Kevin Zylka.

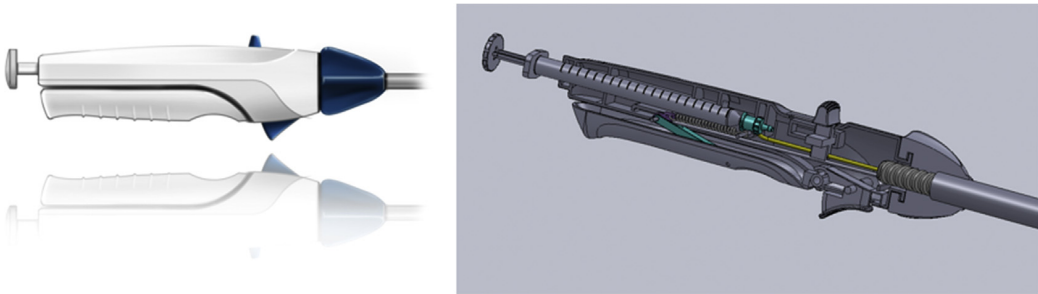


FIG. 7.6 Sketch Rendering of final visual direction (Left) and final mechanical design (Right) by Kevin Zylka.

Control activation forces and feedback, as well as weight, center of gravity, and tether location impact ease of use and use safety.

As with all product development, hand tool design is an iterative process. Models of increasing fidelity facilitate evaluation and refinement. The process involves a give and take between engineering and industrial design where the benefits of textbook solutions are weighed against technical constraints. Successful designs find an equilibrium that thoughtfully navigates these tradeoffs.

Note: form refinements prevent pinch point injuries, provide cues for the gripping surface and the use of color and shape indicate controls.

For detailed information on ergonomic hand tool design refer to ANSI/AAMI HE75 Section 22 Medical Hand Tool and Instrument Design.

5. Software design: user experience (UX) design

The design of software either embedded within a physical product design or as a standalone product, has the same design process: requirement elicitation, system specifications, design, implementation to functional prototypes, unit and system testing, release, and maintenance.

The biggest difference between software design and hardware design are that updates and substantive modifications of software become readily available. This section describes considerations for improved design by incorporating key human factors principles at the onset of design and throughout the development process.

5.1 User experience design

User experience design is the art and science required to integrate all the elements that comprise an interactive system. This includes the programming, interaction design (means of input), interface design (interactive graphics), information design (relationship and user comprehension), motion, sound, graphic design, and written language. These elements combined comprise an interactive system as a user does not naturally distinguish individual elements of the system. Table 7.1 below provides an example of individual elements with further definition.

TABLE 7.1 User experience elements.

Element	Definition
Programming	Code for data input, processing, and retrieval
Interaction Design	Workflow, system flow/behavior and human comprehensibility provided by the user interface
Interface Design	Graphic information design utilized to indicate data control or manipulation
Information Design	Text style, graphics, aesthetic order (composition & hierarchy) for information structure, meaning, relationship and user comprehension
Motion	Animation, motion, changes, time, or rhythmic movements of elements
Sound	Audible signal, music, voice used to enhance experience as feedback or input
Graphic Design	Shapes, symbols, lines, color, texture, dimension, composition, and all elements of the visual screen representations
Language	Users natural language e.g., English, Spanish, Japanese, etc.

5.2 Describing the design intent and constraints

In virtually every software design, the design intent is to be clear and concise to maximize usability and ease of use. By stating the design intent in general with increasing detail, better decisions can be made regarding the overall design aesthetic to optimize clarity and visibility of the information presented. A design intent statement will include specific details regarding the user and any training requirements. Below is an example design intent statement:

The ACME 2000 Graphic User Interface is designed to be clear and concise, maximizing usability and ease of use principles from published guidelines. The interface utilizes flat visuals, bright colors, and high contrast to optimize clarity and visibility of the screen. Users are expected to undergo training or in-service on the entire device prior to using.

There are several common design constraints that impact UI/UX, these include:

- Display

The physical screen size and the active area of display. The screen bezel often limits how closely a user can touch to the edges of a screen.

- Screen resolution

The resolution limits how smoothly curves can be rendered for a given size and must be considered when designing the screen visual elements.

- Viewing distance of the user

The viewing distance impacts the visibility of elements and can vary within various use cases e.g., a nurse may input control parameters on a screen while viewing from 20 inches from the screen, however this information is referenced by a physician standing 9 feet from the screen. There are often competing constraints regarding viewing distance.

- Input methods and response

Input methods are increasing in variety and should be carefully assessed regarding the use context. Input methods can be in the form of a: keyboard, mouse, touchscreen (see box), scan, pen/stylus, hardware button, or numerical keypad, etc. Entering specific details may be accomplished utilizing functions such as: scroll-select, virtual thumbwheels, gestural typing or constrained data entry using traditional input means. With innovative technologies available input methods expand to include voice, gaze, and gaze-dwell (see Chapter 21).

Touchscreens: resistive or capacitive?

A resistive touchscreen is made of two thin layers separated by a thin gap. These are not the only layers in the resistive touchscreen however they are the focus for simplicity of discussion. When these two layers of coating touch each other, a voltage is passed which is in turn processed as a touch in that location. A stylus or other instruments can cause a “touch” to occur. Resistive screens are readily cleanable, typically cheaper, and less sensitive to touch. These screens also tend to be less durable, have lower resolution and if not properly designed can register “false touches” as they are not as accurate as capacitive.

A capacitive touchscreen makes use of the electrical properties of the human body.

A capacitive screen is usually made of one insulating layer, such as glass which is coated by a transparent conductive material on the inside. Since the human body is conductive, the capacitive screen can use this conductivity as input. When a touch is completed there is a change in the screen’s electrical field. Other devices can be used to input on this screen however they must be conductive. These screens are relatively expensive however are accurate, cleanable and have higher resolution. For medical applications, these can be slightly more difficult with gloves and can be sensitive to touch if the user hovers over the screen. As a result, usability testing early with contextual elements is recommended.

5.3 Communicating interactive conceptual design

Table 7.2 below communicates all the necessary details regarding the “general settings” screen design for a novel software system. The description includes the purpose of the screen and the functionality intended to be delivered by the software. The screen design and navigation is communicated as is a reference to developed visual guidelines for asset management. The term asset refers to each visual element within the user interface. There is opportunity to describe dynamic behaviors of elements and specific conditions that the operating system must accommodate. This type of communication can assure human factors principles are applied to the user interface and provide a traceable document for design modifications.

5.4 Graphic design: detection and discrimination

The visual channel has more bandwidth than touch, hearing, smell, or taste.

It is the strongest signal and reaches the brain first then dominates attention using contrast as the biggest determinant of signal strength. Visual elements such as borders, edges, color, and size create powerful contrasts. While visual elements may be clear in contrast, users in general are bad at conceptualizing differences and comparing things from memory. Rather, users will need to discriminate what is in front of them rather than rely on recall. This means that in user interface design, the overall composition of individual elements and navigation pattern will determine system usability. The sections below describe composition and comprehension in more detail.

5.4.1 Composition: grouping and organization – how does the mind group signals at a pre-attentive level?

The brain finds patterns to reduce its workload, even if there was not supposed to be a pattern there. Cognitive science describes a step between seeing something and making sense of something called “pre-attentive sensing.” The brain tries to make things easier for the attentive mind by grouping. Signals that share similar qualities are grouped together and sent along as a single chunk. In visual design, this includes:

- Proximity
- Alignment
- Symmetry
- Similarity in size, color, or shape

This leads into Gestalt principle wherein the sum is greater than the individual elements. In this case if someone squints until this text is unreadable, they will see pre-attentive groups and read words as shapes rather than putting individual letters together for words. When designing a user interface, it is reasonable to assume that when grouping elements and objects together:

- White space is least intrusive
- Common background color is next
- Use borders/frames as a last resort

TABLE 7.2 Design communication table highlighting interactivity.

General settings design details	
Purpose	The overall purpose of the settings menu is to provide the user with a way to navigate the various settings. The purpose of the general settings screen is to provide the user with an opportunity to modify the current date and time, and to adjust the brightness and volume of the device.
Description	The user must press the settings button on the home screen to enter the settings menu. The user must also be able to navigate back to the home screen directly from the Settings Menu. The date, presented in two formats, can be adjusted via a numerical keypad initiated by selecting the text fields. The format is specified via a radio button. Formats provided are DD-MM-YYYY and MM-DD-YYYY. The time is presented in a 12-h format by default, and is also adjusted via a numerical keypad initiated by selecting the text fields. The user can choose to use 24-h time format by selecting the checkbox. The device should default to the current date of system set-up. The time zone is selected from a drop down menu. By using the (–) and (+) buttons, the user can adjust volume. The (+) buttons increase volume. The (–) button decreases volume. There are 10 settings for both brightness and volume. Selecting “Save” will save all changes and selecting “Reset to Default” will return all settings on menu to system default.
Screen Design	
Visual Guidelines	Refer to Appendix A for styling and visual guidelines.
Dynamic Behaviors	Date and Time: Text fields initiate a keypad for manual entry. Brightness and Audio Volume: Button “pressed” state change appears upon selection. As each setting level is reached, the black boxes will fill with light gray to communicate the current level. User must receive a visual and single-tone audible alert indicating the change in audio volume. See “XXXXX-YYYYYY& Visual Guidelines.pdf” for specific asset descriptions.
Conditions	The last saved entry will appear in the button until the entry is either reset or changed.

Used with permission from HS Design.

5.4.2 Comprehension: meaning and working memory- can users find meaning at a cognitive level?

Working memory has a limited capacity, limited duration is highly volatile and is affected by motivation. ANSI/AAMI HE75, describes three kinds of memory-sensory, long term memory and working memory (short term).

Working memory acts as a scratch pad where information is processed. It is where the thinking happens. Working memory gets information, either by sensing it from the outside world or by retrieving it from long term memory and then processes it. There are three important descriptors for working memory: it has limited duration, limited capacity and is highly volatile.

Research has demonstrated that the magic number of objects working memory can hold is 7 ± 2 (although this number is smaller if the objects are more complicated) and another study suggests working memory is limited to 4–7 chunks of information. Further that the capacity of working memory gets smaller with old age, learning disabilities, anxiety, or exhaustion.

Working memory has limited duration in that it only holds information for 20–30 s. The mind can keep it in working memory longer with effort such as repeating the information over and over. Which indicates that it is highly volatile; working memory can evolve or be corrupted as it sits there for its 30 s life. Alternatively, it may disappear entirely e.g. asked to remember something and then there is a sudden distraction of significance it will be gone forever.

Research also indicates that working memory is increased by motivation and decreased by anxiety. Reward, gratification, pleasure, and efficiency motivate users. They can extend their biological and cognitive abilities to reach complete use when they are motivated. Anxiety in small doses can also help us stay focused and fully engaged but too much anxiety overwhelms working memory. If designing something that deals with a sensitive topic, then users may have higher levels of anxiety resulting in use errors or inefficiencies which are unanticipated.

In designing a UI, considerations for a heavy cognitive load must be considered. For example, when the tasks require more cognitive processing/thinking than a person can give, there will be mistakes and abandonment of the software. Asking people to perform fine discrimination tasks between similar sounds/colors/shapes draws on working memory, which as described above is limited. This means that it is even possible for a person to detect two signals however fail to discriminate between them as different, like a nurse who is busy and confuses 2 similar sounding medications.

People are engineered to only give enough to get by. They are good at efficiency, including auto responses and unitizing. They sample bits and pieces; yet they do not devote their full attention to everything. People are also foragers. Information theory says that they will seek, gather, and consume the flux of information in an environment to understand and complete a task if the proper motivation is present.

5.5 Learning and long-term memory - can users retain and recall knowledge at a metacognitive level?

People expect new systems to mirror the ones they already know but can learn new ones with greater ease with help from cognitive scaffolding.

While working memory is limited, long term memory can hold an enormous amount of information for a lifetime. People arrange knowledge into semantic networks also known as schemas. When a schema stores information about systems, they are known as mental models. These mental models help people anticipate events, reason, and underlie the explanation. When a person interacts with a system for which they have no categorization, they ‘thrash about’ randomly. While the medical device loves new technology and innovation, their users love familiarity. When designing an interface, intuitiveness is accomplished by mapping what people already know (even if technology is groundbreaking) and examining the intended shifts the new technology will require.

The building of mental models and long-term memory retention is accomplished through the following exercises:

- Rehearsal-rote memorization where the muscle memory “wears a groove” into the mind
- Elaboration-where users build on understanding with a self-generated information
- Duration-longer time spent learning helps it stick; for example, 10 half day sessions are better than 5 full day sessions.
- Distribution of presentation-users need time to absorb, assimilate and accommodate information.

Learning new processes and methods can be aided by cognitive scaffolding where helpful guides are set up at the beginning and serve as a framework then reduced until the learning is complete. If the use environment is constantly changing or there is a long gap in time between uses, the cognitive scaffolding may require it to be permanently included. For example, software that is not readily used in day to day tasks however is critical to accomplish a complex surgical intervention may have an embedded user manual or training session to refresh a user on the workflow.

Legacy users have ingrained user behavior that makes innovation on workflow a challenge. Habits and known workflows can lead to negative transfer. Negative transfer from a diabetes user (extreme comfort with needles and self-injection) when using other forms of self-administered drug delivery – they may be careless, ignore the IFU, act out their routine even if it runs counter to the simple directions of the alternative product. Legacy users can give a design team the hardest constraint as new users may not have any preconceived notions of the system and be readily able to pick it up and use it. Legacy users may have habits and ingrained behaviors that need to be taken into consideration.

Developing a wireframe for navigation design of software

Ultimately, the user’s workflow serves as a guide for the system architecture as well as the user interface design. Developing a workflow is closely related to a Task Analysis (see Chapter 6) however it includes the response anticipated by the system, decisions, and actions that the user must

complete to complete the task and is typically represented in a block diagram with reference to software specifications and supporting documentation for additional details. Fig. 7.7 below provides an example wireframe for a single task. It does not include the Perception-Cognition-Action

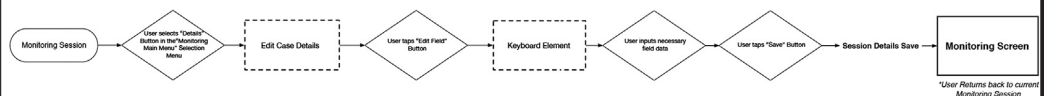


FIG. 7.7 Example wireframe based on a single task.

model of a task analysis, rather, it describes use case scenarios within the system constraints.

The process of developing a wireframe includes determining a high-level use navigation and interaction then visualizing it using block diagram format. A representative key is below in Fig. 7.8.

designers and the human factors team. In the process of developing software, a team may elect to initially configure the visual user interface design then workout the wireframe. For the purposes of conducting preliminary usability analysis on conceptual software user interfaces, both the wireframe workflows and initial screen designs can be

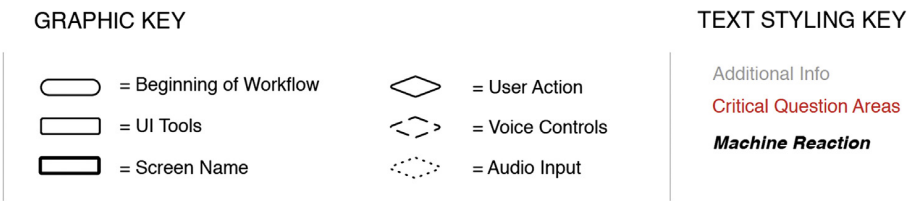


FIG. 7.8 Graphic and text styling key for block diagram generation.

A complex software will have multiple wireframes each following a task and may have embedded relationships within the navigation which must be clearly communicated to both the software engineers, product

evaluated by users and documented as an early formative study. This testing is highly effective for assessing the overall layout of information and graphic element priority.

6. Alarms (Daryle Gardner-Bonneau)

The design of effective medical device alarms and alarm systems poses many challenges. There are several reasons why medical device alarms are so problematic in practice. First, alarms and alarms systems are typically designed in isolation for a single piece of equipment, with little or no regard of the fact that, in practice, there may be many pieces of equipment in a health care environment, each with its own alarm system. There are, practically speaking, very few, if any, systems that can integrate the alarm conditions and alarm signals from multiple pieces of equipment operating simultaneously. Thus, an intensive care unit in a hospital is often filled with alarm signals coming from many pieces of equipment, attached to several or more patients. As a consequence, health care personnel can be overwhelmed by the sheer number of alarms, and alarm fatigue is a serious problem that must be dealt with very far downstream from the actual design process of any given piece of equipment.

Further, up until recently, medical device auditory alarm signals consisted of patterns of, essentially, pure tone “beeps” that were very abstract, having no inherent meaning. They were, therefore, difficult to learn. Further, these sorts of alarms were also difficult to localize

in space (e.g., which patient's heart monitor is alarming in the intensive care unit), and they were subject to masking effects. (Masking can occur when two auditory alarms occur simultaneously, and one cancels out or "masks" the other, perceptually.) Two simultaneous alarms can also combine, perceptually, in such a way that the ear "hears" an unidentifiable third signal that is actually a combination of the two that were presented. Up until, perhaps, 20 years ago, the reason for having such poorly designed alarm signals was technological; i.e., due to bandwidth issues, "beeps" were all the typical computer could produce. However, now that just about any sound can be digitized, we are no longer limited to designing with "beeps" (and have not been for some time), but the medical device industry has been slow to catch up to the fact that we can now use *meaningful* sounds that allow listeners not only to perceive that an alarm has occurred, but to identify what kind of an alarm it is.

The problem of too many alarms and alarm fatigue, described in the first paragraph, is a human factors problem, but not one that can be solved by device designers until such time, if ever, that it is possible to develop integrated alarm systems that are "smart" enough to pre-process sensed alarm conditions from multiple sources, in order to know what alarms, need to be presented to health care personnel. At present, human factors specialists can only work on solving the alarm fatigue problem through means other than device design, per se.

Improving alarm signals, on the other hand, is something that device designers and human factors specialists with a strong background in auditory pattern perception can do *today*. Luckily, a significant amount of work has already been done, during the revision of ISO 60601-1-8 – *Medical electrical equipment – Part 1–8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*, to aid human factors engineers in designing and implementing better alarm signals.

The earlier version of this standard did include a set of "melodic" alarms in an annex, which were thought to be easier to identify than the set of "beep" alarms signals defined in the main body of the standard. These "melodic" alarms provided an option for developers who wanted to use them rather than the set specified in the main body of the standard. However, these "melodic alarms" were never validated, and those who tried to use them found them to be difficult to identify and confusable. The "melodic" alarms in that standard were, to some degree, based on melodic patterns that people with a music background or an "ear" for music might find easy to identify; however, for those with no such background, the sounds were difficult to identify, and still too abstract.

Judy Edworthy, whose work on auditory perception and alarm systems, specifically, is quite well-known, see [Edworthy \(2017\)](#), with support from the AAMI Foundation, was tasked with developing and validating a set of meaningful alarm sounds to replace the "melodic" alarms in the annex of the standard. Dr. Edworthy has conducted a number of studies over the past several years that tested this new set of alarm sounds, not only against the set in the annex of the standard, but against other sound sets, which varied in the extent to which the sounds were abstract or concrete. She also conducted studies with regarding to masking and sound localization of the set of new alarm sounds ([Edworthy et al., 2017a,b](#)).

The results of her studies showed that the alarm sounds that appear in the revised version of the standard were much better identified than any of the other alarm sound sets tested, including the one from the older version of the standard. The new alarm signal set employs

auditory icons that sound like what they represent. For example, a “heartbeat” sound is used for a cardiovascular system alarm; the sound of pills in a pill bottle being shaken is used for a medication alarm. There are 14 auditory icons in all, representing low and high priority alarms for cardiovascular, perfusion, ventilation, oxygenation, temperature/energy delivery, drug or fluid delivery/administration, and equipment or supply failure. In addition, the alarm icons are preceded by an “auditory pointer” sound that serves solely to alert the user that an alarm is about to be presented. Because the auditory icons are meaningful, they are easy to identify. In addition, because they are complex sounds, acoustically, they are more easily localizable and less subject to masking effects. Finally, care was taken to ensure that the acoustic characteristics of the icons used differ enough so that one icon in the set is not confused with another.

The revised version of ISO 60601-1-8, in addition to providing this new set of validated alarm signals in a normative annex, has an additional annex which lays out a process for validating alarm signals, based on what Judy and her colleagues did in their validation studies with users. This annex should encourage human factors specialists to conduct work to improve upon the set of auditory icons in the standard, and to develop auditory icons for other auditory alarm conditions, as occasions arise. People are very good at identifying meaningful sounds in their environment, so the possibilities are almost limitless for the creative designer.

Although improving the alarm signals themselves won’t solve all of the human factors challenges related to medical device alarms, they are likely reduce some of the alarm-related chaos that currently exists in hospital intensive care units and other places where multiple devices are used simultaneously for one or more patients. The healthcare provider will be able to identify much more easily than in the past what the nature of the alarm is, as well as the patient associated with the equipment from which the alarm is originating. The fact that the sounds are so highly associated with their meaning lowers the cognitive and memory burden on users. Even a lay person with no knowledge of the equipment could probably guess correctly what many of these alarm signals signify.

6.1 Designing auditory alarms

Öscan et al. (2018) recommend an audible alarm design process that is much more collaborative than what has been used in the past. It is one in which manufacturers, regulators, academic specialists, and users (clinicians, family members, and patients) are all involved with much more attention is paid to the broader context in which alarms will be used.

The auditory icons specified in the annex of the revised ISO 60601-1-8 may need to be modified, or new icons created, for several reasons. It may be that a particular use environment makes an icon less detectable than it typically would be (e.g., if there is an especially noisy environment, or there is other medical equipment running noisily that interferes with detection of the auditory icon). It is also possible that manufacturers will want to create more specific auditory icons, within the seven categories specified in the standard (e.g., a specific cardiovascular alarm), or may wish to create additional categories of alarms for which auditory icons will be developed.

There are particular criteria for the design of auditory alarm signals, generally, that should be considered during the design and validation process for auditory icons:

1. An auditory icon must be detectable in the environment for which its use is intended.
2. The association between the auditory icon and the alarm condition it represents should be as meaningful as possible, and easily learned by the intended user.
3. The design of the icons should consider the other auditory icons in use for the device to ensure that any new icons are not confused with existing ones by users (i.e., the icons should be as discriminable as possible by the users).
4. The auditory icon should be easily localizable in 3-dimensional space.
5. Designers need to ensure that no masking effects are occurring which would interfere with recognition of the auditory icon when it occurs simultaneously with another auditory icon or another auditory signal of a different type.
6. Auditory icons should not be displeasing or obnoxious to anyone in the environment (patients, health care providers, family members, staff) where the auditory icons will be used.

In addition to providing information about validating auditory icons, an annex in the revised ISO 60601-1-8 provides some information about the methodology that can be used during the earlier developmental stages for new icons. The standard recommends, for example, obtaining input from users about potential sounds that might be used to represent the alarm condition for which an auditory icon is being designed.

Similarly, if one or more new categories of alarm conditions are to be defined, it is recommended to use a card-sorting task with potential users in order to determine the categories to which users “naturally” assign particular alarm conditions. This will assist the designer in determining whether new categories are actually needed, and how those categories should be defined. Designers should not assume that categories that seem “natural” to them will be “natural” to the actual users. The revised standard also supplies specific details with respect to conducting the card-sort task.

Finally, it must be noted that auditory perception and auditory pattern perception are not, typically, strong suits for most human factors professionals, who tend to focus more on visual or physical user interface design. Aspects of design such as sound localization and masking effects can be very complex, technically; in addition, sound detection, recognition, and discrimination changes with age and various health conditions, and the designer needs to be aware of these effects, particularly when designing auditory icons for a broad audience of users (e.g., in the case of home care devices). Thus, it is highly recommended that if you are going to design new auditory signals for medical device alarms that you have an auditory perception/auditory pattern perception specialist on your design team so as to avoid mis-steps in the process.

7. Summary

As previously stated, medical device safety should be inherent by design as the initial risk control priority (ISO/IEC, 2007). A user will interact with devices with dynamic presuppositions of interaction from the initial experience to the detection of affordances ultimately leading to actions (Xenakis & Arnellos, 2013) that assist a user in reaching their goal.

A successful medical device design considers the users capabilities, uses human factors standards (to determine fit) and processes (to understand the context). This chapter communicates the importance of integrating human factors standards and the principals of design in order to optimize usability.

Design is the most effective means at improving safety, efficacy and usability.

8. Further reading

- ANSI/AAMI HE 75
- “Design of Everyday Things” by Donald Norman
- ISO 9241-210 Human centered design for interactive systems (2010)
- Healthcare Information and Management Systems Society (HIMSS), Selecting an EHR for Your Practice: Evaluating Usability (2010)
- ISO 60601-1-8 Medical Electrical Equipment
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Combination devices

Jeffrey Morang^a, Mary Beth Privitera^b

^aSanofi, Cambridge, MA, United States; ^bHS Design, Gladstone, NJ, United States

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Everything should be made as simple as possible, but not simpler. Albert Einstein.

1. Introduction

Combination devices are unique as they are used as “diagnostic or therapeutic products that combine drugs, devices, and/or biological products.” (FDA, 2018). Continual technological advancements in drug and biologic research and development coupled with those in engineering and manufacturing of drugs, biologics and devices have resulted in an increasing use of combination devices in nearly every environment. The FDA acknowledges that they expect “to receive large numbers of combination products for review as technological advances continue” (FDA, 2018). Furthermore, the European Medicines Agency (EMA) is currently working on creating guidelines on the assessment of device components in combination devices under the Medical Devices Regulation (MDR) (Haigney, 2018).

According to the National Institute of Biomedical Imaging and Bioengineering (NIBIB), a drug delivery system is defined as a system of engineered technologies for the targeted delivery and/or controlled release of a therapeutic agent (National Institute of Health, 2019). Historically, clinicians have directed their interventions to areas of the body that are at risk or affected by disease and dependent upon the medication, the way it is delivered, how our bodies respond and the side effects that sometimes occur (National Institute of Health, 2019). This includes designing drug delivery systems for both local (directly on area affected) and systemic (affecting the whole body) in order to decrease side effects. The routes of delivery vary and may include swallowing, inhalation, absorption through the skin, or by intravenous injection (National Institute of Health, 2019).

A few examples of drug delivery systems include hand-held injection devices, pulmonary inhalers, nasal sprays, infusion systems, ambulatory syringe pumps. As listed, these examples of delivery devices represent broad categories of delivery systems without regard to the limitations associated the drug agent being delivered, the patient, the disease state and/or comorbidities. Each of these must be carefully considered when applying human factors to the design of drug delivery systems.

Increasingly, patients are more responsible for their own healthcare and as a result of their medical condition may be enduring reduced cognitive abilities, memory and physical limitations. As such, this chapter discusses the evolution of healthcare, the uniqueness of combination devices, approaches to design, and the special considerations required when designing drug delivery systems. It is not intended to be exhaustive in regards to all types of combination products; rather it is focused on drug-delivery systems for use in the home or in care situations.

2. Health care (R)evolution

It is a fact that drug-device combination products play a vital role in the diagnosis and treatment of a wide range of disorders, including chronic diseases such as heart disease, cancer, respiratory diseases as well as diabetes (Masterson, 2018). They originate in a variety of industries including the pharmaceutical, biopharmaceutical, biotechnology and medical device sectors and draw on different conventions (Masterson, 2018). Manufacturers in this

arena often face complex regulatory processes and all require the application of human factors processes.

Landers et al. (2016) describe the fact that America is experiencing a dramatic shift in demographics, and in 2019, people older than 65 years will outnumber those younger than five. As people age and live longer, increasing numbers of them will live with multiple chronic conditions (e.g., diabetes or dementia) and functional impairments (e.g., difficulty with the basics of life like mobility and managing one's household). One of the greatest health care challenges facing developed countries is ensuring that older citizens with serious chronic illness and other maladies of aging can remain as independent as possible. Our success with this challenge will help ensure that citizens age with dignity in a manner that meets their expectations, preferences and care needs. In turn, this also impacts the financial health of federal and state governments. Meeting this challenge will require envisioning the potential value of home-based health care, creating a pathway for home-based care to maximize its potential, and integrating it fully into health care systems globally.

Home healthcare has become an area of increasing focus for the pharmaceutical industry with anticipated growth in the United States of approximately 2–5% until 2022 is forecasted (IQVIA, 2018). This statistic includes the rapid growth of self-injection devices/systems which offer convenience by allowing patients to administer physician-prescribed medications in their preferred setting. Self-injection devices also continue to grow in outpatient care with the introduction of new injectable therapies for the treatment of chronic diseases, autoimmune disorders, infertility and many other diseases affecting large populations.

This longer life expectancy coupled with growth in home healthcare e.g., self-administration requires a comprehensive approach to the application of human factors. A thorough understanding of the potential users' behaviors, motivations and needs and for those with chronic conditions, the best designed delivery systems will meet the needs not only when first diagnosed but also in long-term care options. Further research into the environment of use wherein designers and engineers have the ability to observe users in the midst of daily distractions, caring for aging parents while interacting with children, pets, noise, temperature and lighting conditions to create patient and user centered designs are as much needed as required.

3. Designing useable combination products

For drug delivery systems in particular, the overarching design goal is to support users through the entire dosing process in a patient centric approach. This requires the design of clear alarms and alerts regardless of use environment; the need to connect patient use adherence (or lack thereof) with providers or provide instructional information for proper device use through designs that encourage use rather than deter as well as the use of mobile applications.

As mentioned in Chapter 7, understanding your users, knowing the use environment are key elements to successful device design in general but what happens when the conditions of device use change over time i.e., move from hospital administration to home administration. The section below builds on the foundation of Chapter 7 in order to support the design of drug delivery systems.

Described below are key elements and theories in support of AAMI HE 75 Combination Product Section. This section of HE 75 is a new addition and should be read in its entirety prior to undertaking the design of a combination product.

3.1 Support the user throughout dosing: patient centricity

At the center of every medical device design is a person, an end user. For most devices and systems the primary end user may be a health care professional. The uniqueness of a combination device is that the primary end user is commonly the patient. This simple fact means that designing with, or for, the patient as the central focus is paramount. Humans are individually unique, coming in all shapes and sizes with capabilities and limitations that are as exclusive as our personalities. This can be in stark contrast to the motivations and goals of device design teams who, likely, and usually, have the task of designing a one-size-fits-all solution. In such situations, taking the time to research, understand and define the end users possess much value; increasing knowledge and understanding reduces design risks that cause use errors (i.e., mistakes and difficulties related to use) decrease the time and costs of unnecessary design iterations (Stegemann et al., 2016).

Research has demonstrated that when it comes to drug delivery devices, the majority of patients are aware of options and willing to pay for advanced technology and user-friendly features. A well-designed drug-delivery device can impact three of the five dimensions that affect medication adherence as described by the World Health Organization. These include therapy-related factors, healthcare team factors, as well as patient-related factors. Simply put, designing a simple and easy to use device can increase the patient's confidence in their ability to follow the treatment regimen. This is accomplished by ensuring that the device requirements are appropriately designed and the targeted support material compensates for the capacity, or lack thereof, of the healthcare system and within the constraints of the patient's abilities. Of equal importance is about the desire a person has to follow the treatment regimen. When combination device designs are excessively complicated, require additional steps to complete a task (dose preparation, dose administration) and/or perceived as unnecessarily complicated then users will be less likely to want, or actually use the device to adhere with their treatment regimen. Furthermore, the anxieties or frustrations of the user will decrease the pain threshold thereby compounding and worsening an already anticipated unpleasant experience. Adherence of the treatment regimen increases when users' experience is clear and pleasant.

Drugs are only effective if delivered as prescribed, in an accurate and consistent manner and a challenge for the design of drug delivery systems includes ensuring that the patient has received the correct dose of medication (McConnell & Ulrich, 2017). This is especially true during a medical emergency and can be difficult if the emergency happens when in a community with no assistance from healthcare professionals is available (Edwards, Edwards, Simons, & North, 2014). This requires that devices themselves provide clear indications of dose delivery and completion in order to ensure proper dosage is achieved and for some types of devices, this is readily available such as the case with syringes.

In other delivery systems, the steps to properly deliver a dose or the dosing status may be unclear and can lead to use errors. The most common example of this is the stopping of a nebulizer treatment too early or pulling an autoinjector away from the injection site

prior to dose completion. In these examples, the user was not supported during the dose administration phase of the device use.

There are three phases to the use of combination devices:

1. Preparing the device for use
2. Dose administration
3. Disposing of device (potentially disassemble), cleaning and storage

The best way to support users is to provide “directed use” which incorporates design principles wherein the device itself indicates to users the proper operation (McConnell & Ulrich, 2017). The more users can rely on the device itself, the more likely dosing adherence is achieved (McConnell & Ulrich, 2017). For example, this can be achieved in design by incorporating a digital display, voice commands and/or clear device labeling, etc.

The absence of a “directed use” device requires a reliance on the users’ mental model (see Chapter 7 Section 4.5 for more information on mental models). As Sir Francis Bacon said, “The human mind when it has once adopted an opinion draws all things else to support and agree with it.” This translates directly to the development and importance of mental models. Mental models are basically the byproduct of learned reality based on individual perception and understanding. Simply, practice makes permanent. Ironically this reality can be invented, distorted and occasionally unstable. However, the purpose, and occasionally the benefit, of mental models are their ability to reduce cognitive load to free up those resources so they are available for use on other activities considered to be a higher priority; e.g., looking for and paying attention to the feedback given by the device for the status of dose delivery. They are pragmatic solutions to the complexity of life. In other words, using mental models has proven much benefit for accomplishing tasks as much as it has contributed to survival throughout human history.

Therefore, it should not come as a surprise that mental models are as much great allies as enemies to the practice and application of Human Factors. Researching and understanding existing mental models of the intended end users is extremely beneficial in understanding design improvement opportunities as well as potential use-related hazards to avoid. For example, it could be very valuable to know that the majority of the intended end users currently use devices that require them to push a button after they have inserted a needle into their body. That type of mental model could be leveraged in a new design or it could be disruptive because the new design requires un-learning and re-learning. Again, practice makes permanent and the new design is up against what has become permanent due to routine practice and use.

Training can be a valuable method in aiding with mitigating use errors and dose regimen delinquency by constructing, or reconstructing, a mental model through un-learning and relearning. It is important to note that often training might be considered by some device professionals to be the best, most successful option to mitigate use errors and increase adherence. However it is problematic and less effective than design aspects that support “directed use” because of its reliance on a person’s perceptual, cognitive and memorization, both muscular and implicit, capabilities. Reliance on training to mitigate or prevent mistakes and difficulties should be a lower priority. This applies as much to a reliance on instructions as it does a demonstrative explanation from a person’s doctor; the former is dependent upon an explicit willingness to open and read instructions whereas both are dependent upon cognition and comprehension translated into proper action.

Researching and understanding mental models help chart a design strategy that incorporates avoiding the use-related obstacles and pitfalls during the definition and design project phases before usability evaluations are conducted or the design is complete or “frozen.”

3.1.1 The power of predicate devices: known use-related problems

There is a lot of value in knowing and understanding known use-related problems in order to identify what mistakes to avoid. Understanding the products or devices a drug-delivery device may replace or compete with is both best practice and recommended per [FDA \(2016\)](#) Human Factors Guidance (see Chapter 14 for more information).

Patients and caregivers will expect or, as previously stated in the previous section, apply their mental model, correctly or incorrectly, to similar/like devices to function in like ways i.e., the buttons, alarms, interfaces require the same interactions or steps of use. In considering this in the design, mismatches and confusion between the user expectations and the actual product function can be avoided. This starts with a search on common use-related errors associated with existing devices ([Edwards et al., 2014](#)). For example, search attributes in currently marketed drug-delivery systems may include inadequate product differentiation, unexpected device operation, complex device operation, and unclear messaging ([Edwards et al., 2014](#)).

To provide further clarity, this can include the following details.

Inadequate product differentiation, such as:

- Within a product line or similar products
- Between active product and demonstration/trainer product

Unusual or unexpected device operation, such as:

- Injuries due to users incorrectly holding the device

Confusing or complex device control activation, such as:

- Poor labeling
- Too many buttons
- Too much force to activate or manipulate controls

Electronic display illegible, such as:

- Lack of visual contrast
- Incorrect font size e.g., too small for sight impaired
- Confusion regarding the use of decimals related to dose

Outcomes related to “lost dose hazards” wherein patients do not receive the full dose due to unintentional use errors such as prematurely drawing the device away as in the case of autoinjectors.

In gathering this information, previous use errors can be analyzed in regards to root cause and used to inform the design of a new drug-delivery device for the optimization of design elements toward increased usability. It is best to conduct a root cause investigations by acquiring a device identified to have use-related hazards/use errors and performing the use tasks so that a more comprehensive understanding can be gained.

3.1.2 Considering dose features and feedback modalities

Dose windows may have different purposes depending on the type of product (see AAMI HE 75 Combination Products Section). For example, a dose window can indicate how many doses remain, confirm that a dose was given or allow flexibility in dosing by communicating a selected value as in a dial pen injector. However, a dose window may not be the best modality to support the user for using the device. For example, using a dose window to indicate that a dose has been delivered for only delivering into a leg when sitting may not best support the user to see the dose window and confirm the dose has been delivered. The chosen modality must be patient centric and based on the researched and defined capabilities and limitations of the users as well as the nature of the task(s).

The design of a combination product should provide feedback e.g., visual, tactile or audible cues that serve to reinforce and supplement instructions for use. In short, the use of the device should be obvious as a result of design. This includes:

- the shape indicates areas of use interaction e.g., form indents on gripping surface;
- visual (labeling) indicators being easy to see (based on the task) and remaining present until the task is completed or provide just in time information in the case of “remaining doses”
- audible indicators (clicks, tones, recorded tones) are incorporated appropriately to the context of use e.g., button to receive voice prompts on instructions or clicks/beeps upon dose completion
- tactile indicators that a device is assembled correctly or incorrectly

When designing feedback cues, careful attention to the use environment is required in order to ensure appropriateness e.g., if the device is intended to be used in a loud environment, the use of vibration plus a visual signal would be a better mode of feedback than an audible click. Fig. 8.1 below illustrates a digital interface intended to be used by patients who suffer



FIG. 8.1 Digital display of user interface utilizing backlit transparent housing in order to dim brightness accommodating a specific disease state in which light sensitivity is increased in patient user. Photo courtesy of HS Design.

light sensitivity yet may be using the device in a dimly lit room. To accommodate these needs, it was concluded in usability testing, a backlit display with large dosing information was more acceptable to users than the use of a touch screen. It is best to use multiple, redundant cues to be sure that the feedback is perceived; e.g., visual and audible or audible, tactile and visual. Lastly, it is important to match the cue with the actual event as well as how that event is interpreted by the user. For example, an audible click that indicates the beginning of an injection followed by a second audible click that indicates the event is *almost* complete will likely confuse users resulting in use errors.

3.1.3 Please, don't make me think

Cognitive tasks such as estimating time, wherein users estimate the time that has lapsed during a potentially discomfoting experience, should be avoided as counting seconds will vary from one individual to another. In these instances, the device should provide the necessary feedback i.e., count on behalf of the user for the most effective approach.

Tasks that require a burden on memory, both working and long-term, should also be avoided. Where possible avoid relying on the user's memory to track uses, instead it is better to support this task by providing a means to help the user; e.g., automate this task, upload this information automatically and provide a clear and easy method for access. This includes the avoidance of any user performing calculations.

3.1.4 Demonstration devices

In order to support the user it may be helpful or necessary to create a device replica for demonstration purposes and/or to allow end users an opportunity to practice using the device. Demonstration devices need to look and perform in a near identical manner to the actual device containing the drug product performs, but without hazards; e.g., an injection needle. This is particularly important for devices that are to be used infrequently such as in emergency situations or when the drug product requires infrequent dosing.

When including a demonstration device it is important to include these additional considerations:

- Define the intent for the demonstration device, i.e., is it for practice purposes or will it be used for training (see [Section 6.2](#) for additional information);
- Identify what users will receive the devices (i.e., health care providers or patients) and how will access be granted; i.e., do they need to be ordered separately, are they delivered by a salesperson, etc.;
- Clearly indicate the difference between an actual device and a demonstration device (see [Section 4.2.1](#)).

3.2 Know the environment: considering the pharmacy, the home, storage, the cat and the TV

An environment is the sum total of all surroundings of the user, including natural forces, other living things (pets), and dwelling conditions such as ancillary objects (furniture, nick-nacks and general clutter), lighting conditions and ambient noise (television, phone, people talking, other product alarms/noise). Use environments ([Fig. 8.2](#)) will have diverse

characteristics that may impact the use of a combination device and the device might be used in more than one location including both indoor and outdoor use. This may require that the manufacturer design for all potential environments or place clear and obvious on-product warnings for special hazardous conditions that may result or that are critical to safe and effective use; e.g., overheating when placed in direct sunlight.



FIG. 8.2 Diabetic patient at home prepped with insulin pen for obvious reasons.

Additionally, manufacturers must evaluate whether the environment will potentially impact the physical, perceptual or cognitive abilities of the user when a device is in use as the majority of environments are not as seen in television advertisements. For some drug-delivery devices the environment of use, as well as the user, may change throughout the use scenario (Fig. 8.3). For example, a PICC line will be placed in the hospital then accessed for extended periods of time in the home or as another example, a surgeon may place a pain pump for the care giver to administer when upon release from hospitalization would be intended for the patient to use. In this example the location of device use originated in the operating room (physician is user), transferred to a hospital room (nurse is user) and finally to the patient's home (patient is the user).

Additionally, adherence to the treatment regimen may dictate the use environment and require the user to use the device in uncommon, off-nominal environments; e.g., an airplane bathroom or a manufacturing floor. For these situations it is important to work with the teammates focused on chemistry, manufacturing and control (CMC) to ensure that the device use interface, including the storage box and instructional materials, support the user using the device in any anticipated environment.

See Chapter 5 for more information on research methodology in the environment (context) of use and the user.

3.2.1 Design clear alarms and alerts

Clear indications of device readiness and when the device needs attention are fundamental alerts in the design of drug delivery devices. For the home, in general, alerts such as “the dose is complete” and “refill or preparation” are always required. See Chapter 7, Alarms sections



FIG. 8.3 Patient prepped with PICC line for home use while in hospital. In this image current drug delivery is managed by an infusion pump.

for more discussion on the design of alarms in general. Best practices for drug delivery devices include:

- Use alerts for urgent information only. Users will ignore alerts that come too frequently or include non-critical information
- Use multi-sensory alerts where possible (see AAMI HE 75 Alarms section)
- Use simple visual and/or auditory cues for alerts. Where possible, use universally accepted icons as recognized by the intended user group.

By providing a clear feedback of what is happening now (i.e., the state of the device/system), what needs to happen next, when the action needs to happen or how long the user has to complete the action and when the action is completed, the usability of drug delivery devices are improved.

Incorporating good Human Factors practices and techniques to design will reduce the amount of use errors committed by end users, but not completely prevent them. On the other hand, devices and systems do fail. When failures or use errors occur then users need to be supported in their efforts to troubleshoot and correct the problem. Therefore, when specifying feedback mode(s) it is important to design them to provide information that includes:

- What happened; e.g., what is the problem experienced by the device/system
- Why it happened
- How can the problem be corrected by the user; e.g., explain what steps need to be completed to fix the problem

Finally, when supporting the user with indications keep in mind that it is unhelpful to users when:

- Technical terms, e.g., “Syntax error 606”, or acronyms, e.g., “the C-DMA is overloaded”, are used, unless the acronym is a part of the users’ common vocabulary, e.g., SCUBA;
- The indication tells the user to refer to the instructions or operator’s manual for the error state definition
- Information for how to fix the problem is long and requires many steps because humans can only hold a limited amount of information in short-term/working memory
- The indication occludes or blocks access to a part of the user interface needing access to fix the problem; this frequently occurs with indications in software platforms

3.3 Design of connected devices: those that incorporate software and smartphone applications

The most critical aspect combination devices that are connected to a software application or system is the need to ensure that the system is safe, effective and serves its intended purpose (to deliver a drug) despite any challenges in software functionality (see AAMI HE 75 Combination Products Section). When combination products include software, the relationship between the drug delivery device and the software application or system should be assessed and optimized. In some instances, such as a smart wearable, the software is integral to the device whereas others, it may be an optional add-on e.g., an electronic dose tracking mobile application.

See Chapter 7, Section 4 for more information regarding the design of software and connected devices.

3.4 Design of packaging, labels and on-device labeling

Packaging is considered part of the user interface and is integral in facilitating safe and effective use of a combination product. When designing the package, considerations for whether to include opening/use instructions, device storage pre- and post-use, durability as well as any informational leaflets. Equally important are how the labels and labeling support the intended end user(s) and use environment(s).

The development of labels and labeling is product specific and the risk for errors will differ as a result. There is no “one size fits all” for labeling, in fact it may be vital for someone to clearly and easily see the difference between labels and labeling (see [Section 4.2](#)). Labels should be designed to be distinctive enough from other likely drug products which might be administered at the same time. In some instances, the use of a transparent label may be most appropriate to enable visual inspection of the device and/or the drug. Careful attention should be placed to assure the durability of the label is appropriate for the use context, user(s) and use environment and that there is no “look alike” label that can lead to medication errors.

Typography (i.e., font type, size and appearance) and legibility (i.e., readability) are important considerations as they determine how likely and how well the user will see and be able to read the information. For example, 10-point font is adequate both typographically and legibly for the general population; however a larger 12–14 point font better supports people

who are older. Sans serif font types are commonly harder to read compared to Serif and Times Roman fonts ([FDA, 2011](#)). On-device labeling refers to the printed text or graphic labels which are directly applied on a drug container and/or device component as part of a combination product. This might include the following types of information:

- identifying information (drug product's name),
- drug strength/dose concentration,
- lot number,
- expiration date,
- warnings or precautions.

For labeling, in general, the devil is in the details. Considering more complex systems wherein there are components which are single use and some that are reusable, these elements should be clearly identifiable by the user and often labeling is used to accomplish this. Additionally, abbreviations and acronyms should not be used because they are easily misinterpreted. As is the case for trailing zeros and/or leading zeros which often go unseen by users. In cases where it is unavoidable to use decimals, include specific knowledge comprehension tasks pointing to numerical values in formative usability assessments.

Other labeling considerations include drug product strength and concentration, expiration dating, and storage requirements. Each of these elements is important to consider throughout the use scenario from product selection, use, disposal and/or storage. This information should be delivered in an obvious (to the user) location and at the exact moment of need.

4. Risk-based design approach

Frequently, conflict among design elements arises, and decisions must be made regarding the overall risk benefit impact a particular design element may bring. This approach to the combination device design can be extremely valuable in the conceptual or design phase of a new product.

Listed below are common attributes that may be unique to a combination product and may require additional testing feedback (see Chapter 16 for full human factors testing of combination devices).

Common design features that relate to use related risk can include:

- Removing from packaging or outer case
- Knowing how a device is to be removed from its outer case
- Meaning of icons (see [Isherwood, Mcdougall, & Curry, 2007](#))
- Timing of voice or display prompts
- Control activation
- Specific instructions on an IFU/comprehension of illustrations and written captions
- Feedback on dosing status

In a study by [Oray et al. \(2017\)](#), patients together with healthcare professionals selected a device [concept] that best suited their personal needs, taking various factors such as control activation [manual or automatic] into consideration ([Oray et al., 2017](#)). In this study, it was described that an initial prototype was designed to inform the design through a risk and preferential human factors evaluation.

When developing combination products it is important for the Human Factors practitioner to form and maintain a tight partnership with whoever is responsible for risk management activities. This is helpful as proper use of the device is also commonly linked to the risks and efficacy of the drug being administered and to success of the treatment regimen. Having a tight partnership with risk management will also facilitate better cohesion between the risk and human factors documentation thereby making it easier to build a more comprehensive story of the human factors activities as related to the use-related risks. As such it also allows the Human Factors practitioner to demonstrate what improvements have been made to the user interface design to mitigate or prevent use errors and facilitate the path that ends with the completion of the Human Factors Validation Study and final report culminating the Human Factors activities.

5. Developing use requirements: the evolution of user needs

Designing for patient centrality ensures the product design is the right size and comfortable for the user with appropriate functionality to support use-related tasks. Design engineers need to consider how users need to and will interact with the product in addition to unintentional misuse. This is particularly important when establishing User Needs for combination devices due to the breadth of users. Furthermore, User Needs are best created in a manner in which they can be validated in the Human Factors Validation Study. It is recommended to omit statements containing use error mitigations, design specifications or qualitative information into a User Need. When any of those are included it will likely become difficult to properly validate the user interface.

To illustrate this point, assume a needle-based self-injection device user interface is being designed to be used by rheumatoid arthritis patients; a User Need may state:

The user shall be able to manually control needle insertion and retraction by a single user interface.

Note that the User Need example does not include addition use error mitigation, design attribute or qualitative statements like:

- ... *without making safety critical errors.*
- ... *shall be able to manually control with ease ...*
- ... *and retraction by a cylindrical user interface 4 cm in diameter.*

It is best to include these additional statements in other, more specific documents related to design requirements and risk definitions. This allows design teams the flexibility needed to create and define the design requirements for the user interface.

For more details regarding the creation of User Needs and design input requirements consult the following publications:

- ANSI/AAMI HE75:2009/(R)2013 Human factors engineering – Design of medical devices
- AAMI TIR59: 2017 Integrating human factors into design controls
- Chapter 3: Strategy and Planning
- Chapter 5: Contextual Inquiry

5.1 Considerations for requirements

Anthropometrics, human performance and biomechanics, i.e., range of motion and strength, data for human beings of all ages and sizes are vital for defining device design requirements. Anthropometric data sets can vary significantly between user populations. Such data are particularly important and valuable when defining the requirements of combination device for people with a specific, unique disease state, chronic conditions, functional limitations and/or comorbidities. For combination devices, the importance of understanding and applying anthropometric, human performance and biomechanical data to design requirements translates to patient adherence to a given dose regimen; if the device is too large or small then the patient may not be able to complete the task(s) required to administer the drug. For example, a device intended to deliver a drug dose via the nasal passage by using a transfer of pressure generated by the user's own exhalation requires an understanding and application of nostril sizes as well as the distance from the nasal septum to the mouth.

Just like anthropometrics, human performance and biomechanics, the perceptual and cognitive capabilities and limitations of users will vary significantly between users within the intended user population as well as between groups within the intended user population. The reasons for these variations range from education and health literacy to the effects of a given medical condition and/or the combination of medical conditions including the side-effects of other medication regimens.

General design requirements for drug delivery device will likely include, but not limited to, the following considerations:

- The importance of anthropometrics and biomechanics
 - For combination devices, the importance of anthropometrics translates to patient adherence; if the device is too large or small then the patient may not be able to complete the task(s) required to administer the drug
 - Existing anthropometry and biomechanical data may be based on a healthy population and may not provide the correct measure of the user population and may require extrapolation and interpretation; e.g., obese or elderly data may not be readily available.
 - Considering biomechanics and the context of the use situation may require interpretation of existing data i.e., data readily available may not appropriately account for the dynamics of actual use.
- Design the device to be similar or familiar in appearance or function or alternatively, purposefully develop a design that is obviously dissimilar to indicate the device should be used in a new manner ([McConnell & Ulrich, 2017](#))
- Support all phases of dosing (in general)
 - For example, provide a checklist or on-screen instructions for connected devices or devices with a digital user interface.
 - Provide different levels of information available for each step in order to provide shortcuts for advanced users.
 - Provide a visual indicator when dosing progress is not obvious
 - This may include status indicators visible from across the room (for hospital or care environments)
 - For example, provide a countdown (or timer) of drug administration remaining

- Provide a clear indication of “dose complete”
- Support all phases of dosing for patient centricity
 - Indicate to the patient what state the device is in (ready to use, dose delivery, dose complete)
 - Provide direction on the next steps e.g., if using a mobile application the screen might read “ready” to indicate the device is adequately prepared to deliver a dose.
 - Use of lights and sounds in blinking patterns should use simple colors and a few audible combinations to indicate the dosing state. Care should be taken to avoid overly complex blinking patterns (see Chapter 7, Section 5 on the design of Alarms).
- Support unit dose packing- Your package may be the device.
 - Prevent accidental exposure, e.g., child-proof bottles that prevent ingestion by children.

5.2 Differentiation

For some users and use environments, it is likely that multiple combination products may be used and/or stored by a single household and that certain disease states may increase the likelihood a patient is prescribed multiple medications. The box containing the device(s) is considered to be a part of the user interface, just like the device itself, therefore it is important that developers of combination products consider what the clinical outcome would be if two products were confused. If the risk for an error exists, appropriate differentiation strategies aimed at minimizing risks of administering the wrong drug should be created. This includes considering:

- Packaging differentiation; including, if used, color and graphical elements
- Physical differentiation; including the device and/or the device box
- Label differentiation; also including, if used, graphical elements

Ideally, these may need to be combined in order for effective product differentiation.

In addition to the intended end users, commonly there are multiple development project/program stakeholders from different disciplines that are impacted by a chosen commercial differentiation scheme. Each of these stakeholders will have different goals and responsibilities that will drive different perspectives that should be considered. For example, the marketing stakeholder will likely have an interest in maintaining the brand identity whereas the one responsible for regulatory matters will have more interest in ensuring mandatory information is included.

When creating a differentiation scheme it is best to identify all of the stakeholders that will be impacted and include them at the beginning and throughout the differentiation scheme development. This will ensure all stakeholder needs are included early, reduce design iteration cycles and reduce the risks of missing the inclusion of important details that may otherwise not be included.

Again, the box containing the device(s) is considered to be a part of the user interface and should be evaluated in formative usability evaluations to assess how well it supports end users in determining the difference versus competitive products and, if needed, products

within a product portfolio and/or dose concentrations. Finally, the commercial differentiation scheme must be included in the final HF Validation Study.

5.2.1 Differentiation of demonstration or training devices

When developing a demonstration or training device is important for users to clearly see and identify the difference between an actual device and a demonstration or training device. This is particularly critical if the device and drug content is intended to be used for emergency medical treatments, e.g., the delivery of epinephrine. If a demonstration/training device is created then it too should be included when developing a differentiation scheme. The risks associated with the importance of a user choosing the correct device, actual versus demonstration, may determine it is best to conduct formative usability evaluations with realistic use scenarios to ensure the demonstration/training device can be clearly seen and identified. As such, it may also be determined to include the demonstration/training device in the Human Factors Validation Study.

6. Design of instructions for use

IFUs that use illustrations and graphics rather than text to convey information may make user guides more accessible (Hettinger et al., 2014). This includes the following details:

1. Clarity of explanation
 - The task can easily be completed without errors (task scenarios)
 - The text could be understood by a user with limited reading ability
2. Continuity and consistency of instructions
 - Task step were logically ordered (task scenarios)
 - Terminology was consistently used throughout the manual
3. Visual recognition
 - The illustrations accurately represented the task (task scenarios)
 - The manual provided illustrations when they were needed
4. Aesthetic and minimalist design
 - Font size and appearance is readable and large enough for the average user

Fig. 8.4 below detail an example of instructions for use of a drug delivery syringe system. It includes details such as all components of the Sypfyny®: the barrel, plunger, dosing clip and multiparticulate drug. The steps of use are broken into sections. In this example, text supports illustrations and arrows direct the user to key actions. Use tips are also provided under areas where use challenges were identified through formative usability testing.

The layout of instructions for use will vary for combination drugs and could include: a fold out card to be included in the packaging, a booklet and/or printed use details on the outer packaging. Selecting a layout for use instructions requires a clear understanding of the user, use context as well as the drug and related pharmacokinetics. All instructions, regardless of layout, should be included as early as possible in usability tests.

See Chapter 9 for more information.

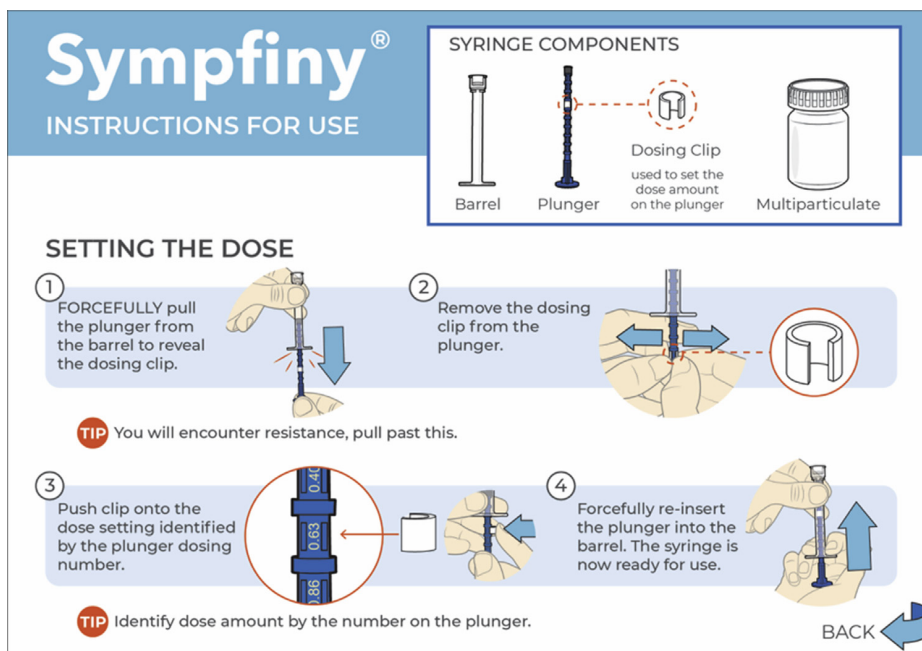


FIG. 8.4 Example of use instructions incorporating illustrations, clear steps of use supported with key text. Image courtesy of HS Design.

7. Special considerations for human factors testing of combination products

7.1 Pre-clinical versus clinical studies

A pre-clinical study is strongly recommended before any clinical trials are started with humans. The goal of a pre-clinical study for drug development is to identify the adequacy and ability of the device user interface to support safe and correct use. For a combination product, this includes the identification of potential use errors through human factors methodologies, including formative studies.

As it is common for drug delivery devices to have very large populations of users and may require several design iterations and many formative evaluations. Table 8.1 below provides an example of a formative usability testing plan for a device intended for general population use. A total of 12 formative studies are described including the features tested and purpose of the study. In this table, an iterative design approach is undertaken moving from low fidelity concept storyboards to fully functional designs. The purpose of the study is described in order to provide examples that a series of formative studies might be the best approach for assessing the usability of the user interface, use case scenarios as well as independent features or design attribute.

TABLE 8.1 Example table of formative testing (12 in total) the features tested and study purpose.

	Study	Features tested	Purpose
Formative (exploratory) Testing I	1	All design features (physical)- using storyboards, foam models	Explore potential design, determine design direction
	2	Simulated injections, IFU, dose-dispensing, buttons, GUI	Explore details in user interface with more fidelity
	3	Simulated injection directed by GUI with IFU and training	Define needs of the GUI, IFU and training throughout dosing process
	4	Simulated injection, dose cartridge exchange	Assessing details concerning device longevity
Formative (fully-functional prototypes) Testing II	5	Options in injection means, interactive GUI, warning messages	Increasing fidelity in design, identify use errors, knowledge comprehension of warnings
	6	Simulated injections, dosage regimens, USB port use	Identify use errors regarding dosage regimens and data communication means
	7	Simulated injections in use case scenario, charger, injection tracking	Identify use errors in charging the design and tracking
	8	GUI alarms, GUI regimen and injection tracking, use case simulated injections	Identify use errors and/or points of confusion regarding alarms, dosing and tracking
	9	Injection tracking and physician communications	Identify use errors related with injection tracking and communications
	10	Simulated injection, packaging, dosing regimen, IFU	Assessing usability on near final design
	11	Set-up instructions, storage case, on-box use instructions	Assessing effectiveness of set-up instructions and usability of storage case
	12	Entire use scenario	Assuring preparation for HFE validation study

Whereas a formative evaluation has the ability to be somewhat fluid in study moderation, a clinical study follows a specific plan and includes strict adherence to the methodology described in the study protocol. Equal to a clinical study protocol adherence is the human factors validation study. See Chapter 15, Section 1.1 on combining a Human Factors Validation Study with a clinical study for more information on the similarities/dissimilarities.

7.2 Do not rely on training

As described in ISO 14971, design is the most effective means of reducing risk. For the design of combination products, this translates to the importance of good design without

reliance on training as the largest risk mitigation as the manufacturer would be required to demonstrate assurances that training would be carried out in an effective manner upon regulatory agency review. When training is required it is considered part of the user interface and it would be anticipated that a manufacturer would have appropriate administrative control as well as provide evidence that the training is an effective risk mitigation.

On the contrary, if providing training, it is expected to occur and occur consistently. In designing a training program it is important to consider the following:

- What will the training encompass?
- How will the manufacturer ensure that every user receives the training?
- Who will be responsible for conducting the training?
- How will the training be performed e.g., in person, video, online?
- How will consistency in the training be ensured?
- How often will training occur?
- What training materials will be provided?

The training decay time in human factors studies must be appropriate and reflect [clinical] reality. That means a manufacturer will encounter users who will be distracted in training or simply are un-interested. Additionally, for combination products, it is best practice to include an arm of a human factors validation study wherein no training is provided prior to device use. The aim of this practice is to assess the effectiveness of information materials aimed at supported safe device use.

As a result, the design of the user interface should not rely on training.

See Chapter 15, Section 4.3 for more information regarding training and Chapter 16, Section 1.4 for further information.

7.3 Literacy versus health literacy

Literacy is defined, most simply, as the ability to read and write. Yet, it also includes the ability to use language, numbers, images, computers and other basic means to understand, communicate, gain useful knowledge, solve mathematical problems within a specific culture. A person's ability to identify, understand interpret, create communicate and compute using written materials in varying contexts, is fundamental in all medical device design. However, literacy in general is not the same as health literacy.

According to the US Department of Health and Human Services (DHHS), Office of Disease Prevention and Health Promotion, health literacy is the degree to individuals have the capacity to obtain, process and understand basic health information and services in order to make appropriate health decisions (DHHS, 2018). The impact of health literacy is a person's ability to navigate the healthcare system, share personal health information, engage in self-care and/or chronic disease management as well as comprehend mathematical concepts (probability and risk). Low health literacy has been linked to poor health outcomes such as higher rates of hospitalization and less frequent use of preventative services (DHHS, 2018).

Improving the usability of health information in consideration of health literacy, especially in the design of user interface in combination products is especially important and can be achieved by:

1. Ask “is the information appropriate for the user?” E.g. in the product labeling, IFU or digital support material, do the materials reflect the age, social/cultural diversity, language and literacy skills of the intended users?
2. Assess the users’ understanding before, during and after the introduction of information when asking knowledge comprehension tasks.
3. Ask “is the information easy to use?” E.g. by design, are the number of messages limited, does the material use plain language and focus on action?

In the design of support materials, instructions should be supplemented with visuals in order to make written communications look easy to read. Additionally, use of headings or bullets to break up the text with plenty of white space around the margins. For more information of IFU design, See Chapter 9.

8. Summary

This chapter discusses designing useable combination products. Patient centricity is the overall theme wherein the user is supported throughout all phases of dosing with detailed consideration toward the context of use. This approach emphasizes that the users of a combination product may have unique sets of capabilities and limitations which must be considered when designing a combination device. Factors such as the environment of use, the delivery of instructional materials, demonstration/training devices and device differentiation and labeling become of primary importance when considering a risk-based design approach. Finally, as the delivery of healthcare continues to evolve at a rapid pace, so does the development of drug delivery systems. Applying human factors to the design of combination products is not only a regulating agency requirement; it is also a humanitarian need.

9. Further reading

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- ANSI/AAMI HE75:2009/(R)2013 Human factors engineering – Design of medical devices
- AAMI TIR59: 2017 Integrating human factors into design controls

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Applying design principles to instructional materials

Renée Bailey

Agilis Consulting Group, Orlando, FL, United States

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When all else fails, read the instructions. Agnes Allen

1. Introduction

Given growing regulatory emphasis on instructional materials (i.e., labeling and training) for users of medical and drug delivery devices, it is crucial for companies and professionals in the industry to have a practical and systematic approach to designing and evaluating instructional materials. Instructional materials are part of the user interface as referenced in key industry standards such as [IEC 62366 \(2015\)](#) and FDA guidance ([CDER 2016](#); [CDRH 2016](#)). Instructional materials should be evaluated as part of the human factors strategy to show the materials promote safe, effective and accurate performance when used by the end user. Within the context of human factors, many teams and professionals can face challenges with how to effectively design and evaluate these materials and subsequently optimize them based on study data.

This chapter provides a practical guide to applying design principles during initial development of the instructional materials, or when identifying root causes and recommended improvements based on human factors study data.

Author's note: Performance based instructional design is a scientific field in and of itself and top professionals in this field have years of training and experience translating desired performance of tasks into relevant and effective instructional materials for end users. It is impractical to communicate the full science of this field in this chapter. Thus, this chapter focuses on fundamental instructional design principles and practical application of instructional design within the context of human factors for medical devices or drug delivery products. Ultimately it is beneficial and recommended to work with a trained and experienced instructional designer when developing instructional materials for medical and drug delivery devices.

2. What are instructional materials?

Instructional materials help support safe and effective use of a device, and they include materials such as:

- Instructions for Use (IFU), Quick Reference Guides (QRGs), printed or electronic manuals,
- On-board or electronic performance support systems (EPSS) or graphical user-interfaces (GUI) which provide on-screen navigation and task related instructions,
- Instructor-led or self-directed training and eLearning, and
- Device and package labels which provide instructions, warnings, cautions or contraindications.

For the purposes of this chapter, the focus is specifically on materials that are part of the user interface and are intended to support safe and effective use of the device. Marketing and promotional information, communications, and other supplemental information and materials are not considered instructional materials or part of the user interface, so they

are not part of the scope of this chapter. However, it is always a good idea to assess the effectiveness of other materials (or any materials that are intended to guide or influence user performance).

3. Integrate instructional design with the human factors process

The process of designing and optimizing instructional materials integrates with the human factors process. Even though instructions and training use a different method of design compared to the device, instructional materials should be tested and optimized along with the rest of the device interface. Instructional designers use the same inputs as human factors (user profiles, use environment profiles, use cases, and task use-error analysis) when designing and developing instructional materials. And similar to the way engineering design or industrial design principles are applied to optimize the device-user interface, instructional design principles should be applied to optimize the instructional materials.

Integrating instructional design with the human factors process is as important as applying instructional design principles correctly. An integrated process allows you to efficiently design, develop and optimize instructions through formative human factors testing. This process helps avoid problems with the instructional materials emerging during validation studies when it is too late to iterate the instructional materials while still meeting submission deadlines.

A poorly integrated process can lead to countless formative studies, mandates to incorporate regulator feedback into instructional materials, or even repeating validation or summative studies due to data showing the instructional materials are not optimized. An ineffective process for developing instructional materials leads to significant added costs, timeline delays and delays with regulatory submissions and product launches.

Fig. 9.1 provides an example of an effective framework to integrate development of instructional materials into the human factors process. The final instructional interface can vary based on the nuances of different users, use environments, device complexity and associated use-related risks for any given device or system. However, by following the process outlined in this chapter, you will determine the instructional components and design needed for the final instructional interface of a given device or product.

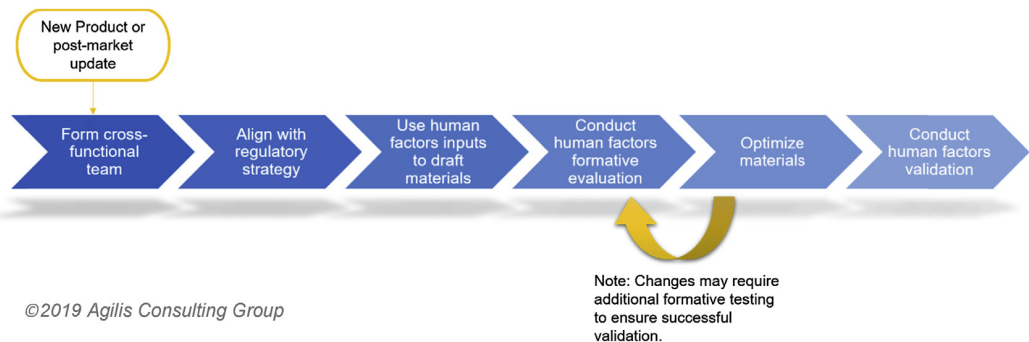


FIG. 9.1 Process for integrating instructional design with human factors.

4. Include instructional designers in the cross functional team

A stakeholder responsible for the design and development of instructional materials should be included early and throughout discussions about a new device or post-market update to a device. For a new product, the timing to involve instructional designers is recommended to be as early as the concept and feasibility stages when prototypes are being tested with representative users.

Cross functional teams for new products can include stakeholders from several different functional areas. Ensuring the instructional designer is included on the cross functional team early is important so they understand:

- The regulatory strategy which helps identify the requirements for the instructional materials. For example, there may be specific guidance or regulations that dictate content or placement of information in the instructional materials.
- Product design and how the device is intended to work such as features, controls, device feedback, etc. Understanding the product design helps the instructional designer draft instructional materials that communicate user-device interactions accurately.
- Risks associated with device use according to the development of the risk assessment. Instructional designers are alerted to the risks to be mitigated by the instructional materials, which helps to ensure this information is prioritized into the design of the materials.
- Human factors approach and upcoming human factors evaluations. When early formative studies are conducted with prototypes and representative users, the instructional designer can produce early drafts of instructions to include in formative testing. Early formatives allow evaluation and optimization of the instructional materials in parallel with optimization of the device design.

For post-market updates, include the instructional designer early so they understand the reasons for the updates, how the instructional materials could be impacted or how the materials need to be updated. Cross functional discussions provide the instructional designer with information they need to make decisions and updates that support the post-market update while also adhering to sound instructional design principles.

5. Align instructional design with the regulatory strategy

Instructional designers need to be aware of certain regulatory information early in the process. Changes to the regulatory strategy over the course of product development could impact the human factors strategy, risk assessment and subsequently the design of the instructional materials. The classification of a device, device type and the regulatory pathway for submission can link to specific regulatory requirements for labeling, which often means design requirements for the instructional materials.

For example, FDA has specific guidance documents for infusion pumps ([CDRH 2014](#)) and reprocessing ([CDRH/CBER, 2015](#)) with sections outlining guidelines and expectations of

labeling (i.e., instructional materials). The guidelines provide expectations for different types of users (healthcare professionals and lay users) and use environments as well as human factors validation testing of the instructions. Other international standards that may be applicable are also referenced, such as [IEC 60601-1-2 \(2015\)](#) regarding electromagnetic compatibility.

The instructional designer needs to be in alignment with regulatory expectations for the specific device, class, device type and submission or post-market update strategy. By including the instructional designer early in discussions about the regulatory strategy, any additional expectations outlined by regulators can be included in the instructional design process. Additionally, if decisions are made that alter the original regulatory strategy, the instructional designer is involved and can assess any impacts to the instructional materials.

6. Design the instructional materials

Instructional designers are ready to start drafting instructional materials when they understand the regulatory guidelines and expectations that apply and have at least a working prototype of the device. As mentioned in the earlier framework ([Fig. 9.1](#)), the instructional materials are designed with instructional design principles, just as the device is designed with engineering design and industrial design principles.

This section describes how instructional materials are developed using human factors inputs and instructional design principles.

6.1 Gather industry references

Many industry resources provide guidance on developing instructional materials with regulatory submissions and usefulness for the end users in their use environments in mind. Anyone responsible for the design of instructional materials should keep abreast of various references including, but not limited to the following:

- [ANSI/AAMI HE75 \(2009\)](#) – Human factors engineering – Design of medical devices
- [AAMI TIR49: 2013](#) Design of training and instructional materials for medical devices used in non-clinical environments (that also includes information useful for devices used in clinical environments)
- US FDA CDRH, Guidance on Medical Device Patient Labeling, published on April 19, 2001
- US FDA CDER, Guidance on Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors, draft guidance published in April 2013
- ANSI Z535.6-2011, Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials
- [ANSI/AAMI HA60601-11:2015](#), Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance
- US FDA CDRH/CBER, Design Considerations for Devices Intended for Home Use, published November 24, 2014

6.2 Gather human factors inputs

Instructional designers use fundamental human factors inputs to make decisions about the design of the instructional materials. For example:

- **User and use environment profiles** are used to make decisions about media, writing style, formatting of instructional content, physical layout of printed materials, design of on-board instructions, etc.
- **Use cases or scenarios of use** are used to determine appropriate sequencing and scope of the instructional material for each user group and may help define distinct sections of complex sets of instructional materials.
- **Task analysis** (including PCA and risk assessment information) is used to identify skills/knowledge needed; identify tasks that are large (many steps) or complex; make decisions about media to be used; determine if training is necessary; identify details that help draft instructional content.

To understand why human factors inputs are important to instructional design, consider the following examples:

Scenario 1 – A multi-dose pen injector is used by nurses and patients to deliver the medicine. While the information both nurses and lay user patients need is the same, the nurses and lay user patients have different user characteristics. Different instructions for both user groups may be necessary. Or one set of instructions could be developed for the lay user patient assuming the nurse could follow the same set of instructions.

Scenario 2 – An implanted device includes multiple components that are used by different healthcare professionals in different hospital settings. The implant procedure involves a surgical team, post-operative care involves a critical care nurse, and a nurse educator is responsible for training the patient before the patient is discharged from the hospital. Considerations must be made to determine what is appropriate instructional material for each type of user and how those materials should be sequenced and written to support safe and effective device use.

Note: Additional information can be referenced in [AAMI TIR49 \(2013\)](#) Section 7.2.1.1.

6.3 Determine the instructional components needed

Using the human factors inputs of user profiles, use environment profiles, use cases, and task use-error analysis, the instructional designer can make preliminary decisions about the instructional components needed to support safe and effective device use.

Most devices require printed material such as instructions for use (IFU) or a user manual. This type of material is developed using the task use-error analysis as a basis to ensure each use case is covered, the instructions are written accurately based on task definitions, and risks to be mitigated in the instructional materials are addressed in the materials. But, how should decisions be made to include other types of instructional components?

Using the user profile and the task analysis, instructional designers consider some of the following elements:

- Whether use cases or tasks are completed frequently or infrequently
- Tasks which are large (with many steps) or require multiple decisions
- Tasks that are complex for the representative end user

Using this information, the instructional designer can then make preliminary decisions about the types of instructional components that may be necessary to support safe and effective device use. Some examples are provided below.

Scenario 1 – An autoinjector for a common therapy which has only one use case and a short series of steps may only require an IFU to provide users instructions.

Scenario 2 – An *in vitro* diagnostic home use kit has multiple use cases and steps for preparing to use, collecting the sample, interpreting results, labeling the samples and shipping for further analysis at a laboratory. In this case, a larger set of instructions may be needed, but training may not be feasible given it is a home use product. If human factors testing reveals users require further assistance to effectively use the kit, the instructional designer may consider developing a short video as supplemental information to the printed instructions.

Scenario 3 – A complex surgical system with many use cases and tasks, multiple user groups with different roles and responsibilities, and a high-risk profile will likely need well designed user manuals for different user groups performing tasks in different use environments. In addition, due to the complexity or criticality of performing certain tasks, a training program may also be considered. The training program may contain additional components such as eLearning, video, classroom training with hands-on practice, and post-training support or refresher training for infrequently performed tasks. Quick reference materials may also be needed to guide users with infrequent critical tasks such as emergency procedures.

Note: Additional examples and information can be found in AAMI HE75.

Keep in mind that determining which instructional components are needed is a preliminary decision that may need to be adjusted throughout the device and instructional design process. As instructional materials are included in human factors testing (and the user interface of the product may also be iterated based on formative testing), the preliminary instructional strategy may need to change. It is important to evaluate the planned instructional interface based on human factors study results throughout human factors testing and update the strategy as needed. Some examples of changing strategies are provided below.

Scenario 1 – An inhalation product has only one use case and a simple set of steps. The preliminary decision is made to only include an IFU with the product. However, after several human factors studies and revisions of the IFU, representative participants still struggle with the specific inhalation technique required to ensure the full dose of medicine is inhaled. In this case, development of additional instructional components such as a demo device and training may be considered as parts of the instructional interface since users are unable to interpret and correctly complete a critical task from the printed material alone. In this case, the strategy could be revised to include additional instructional components.

Scenario 2 – An on-body infuser has multiple use cases and critical tasks, although none of the tasks are very long or complex. It is initially thought that the end users may require training in addition to a user manual to safely and effectively use the device. However, after conducting human factors studies where participants only used the user manual, user performance showed the device could be used safely and effectively without training. In this case, the strategy could be revised to omit the instructional component of training.

Just as the device design and human factors strategy is revisited based on results of human factors formative evaluations, the instructional design strategy may also need to be revisited and adjusted.

6.4 Design and develop instructional materials, starting with human factors inputs to draft the primary source materials

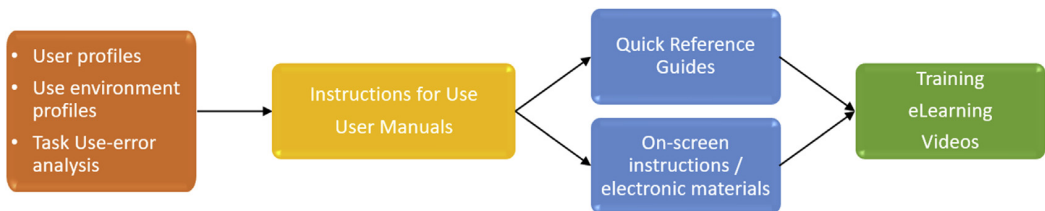
During the instructional design process, certain materials are better to start with as they can feed into other components identified as part of the instructional interface. Early materials to draft include instructions for use, user manuals or other comprehensive materials that instruct the user through each use case and task. These materials can then be leveraged and drive what is included in other instructional components such as quick reference materials, videos, eLearning and training. Fig. 9.2 shows an example sequence of development for different types of instructional materials.

Materials such as the instructions for use or user manual are often the *primary source materials* that contain the full information for device use. From there, additional materials or components may be developed based on that same content. The key is to be consistent with information across the full instructional interface to avoid user confusion or use errors. Information in the primary materials should match other components such as quick reference materials or videos. Best practice is to work on materials in a sequential order, as shown in Fig. 9.2, to avoid multiple revisions on different components, or worse, having different information in different components of the instructional interface that leads to user confusion, use errors or difficulties.

Instructional designers should start designing and developing the instructional materials with the human factors task use-error analysis. The benefits of using the task use-error analysis, especially if it includes PCA analysis, include the following:

- Provides the use cases, tasks, steps and sub-steps that are needed to organize instructions effectively (assuming the use cases and tasks are defined from a **user** perspective and not a device perspective).
- Provides the criticality (based on the risk assessment) associated with each task which helps identify areas of focus in the instructions.
- Provides critical knowledge tasks the user must be able to see and understand in order to avoid or mitigate certain risks associated with using the device or product.

An important requirement of the task analysis is that it should include all the user tasks, otherwise your instructional materials risk missing those as well as critical knowledge that should be included in your human factors testing. A common shortcoming of the task analysis is that only device tasks are included, but other supplemental tasks that users must



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FIG. 9.2 Example sequence of instructional materials development.

complete to use the device correctly are excluded. Some examples are steps to prepare a device for use the first time, gathering supplies in preparation of device use, how to clean a device, how to transport the device, etc.

6.4.1 Start with low fidelity drafts

Instructional materials design and development is a process that can and should start early in product development and human factors testing. Evaluation of low-fidelity drafts of instructions and preliminary ideas for illustrations is beneficial and can easily be incorporated into early human factors studies. Starting early is incredibly important for effectively and efficiently iterating instructional components while building human factors data that support the design of the instructional interface.

Starting with low-fidelity drafts is efficient and cost effective because it allows the instructional designer to work in a format of instructions that is easily manipulated and revised. Using word processing software, such as Microsoft Word or Google Docs, can be very efficient for early iterations. Alternatively, iterating initial drafts of instructional materials that are in a commercial format is possible, however, this approach can be very time consuming and expensive. This can unnecessarily drain resources and increase your timeline to iterate the materials.

6.4.2 Identify sections and content required

The use cases and task use-error analysis developed by human factors can be used to help identify logical sections and sequences of instructional materials content. Consider information that may be required for end users including the following from AAMI HE75:

- Indications/Intended Use
- Device description including illustrations and identification of device parts
- Additional supplies needed to use the device
- Support information including any customer service or support phone numbers or patient hotline
- Safety information including warnings, cautions, contraindications
- Instructions for using the device which can often be divided into sections using the use cases for the device

Also consider if there are regulatory requirements for sections and sequencing such as those outlined in the FDA guidance document (2001), Guidance on Medical Device Patient Labeling.

Note: Additional information can be referenced in [AAMI TIR49 \(2013\)](#) – Sections 7.2.1.2 and 7.2.1.3 as well as in AAMI HE75.

6.4.3 Write effective instructions

The writing style and language used to develop effective instructions involves considering the users, use environments, and specific writing techniques. Consider the following types of users in their representative environments:

- Healthcare professional in a busy hospital environment with many distractions
- Lay user patient undergoing chemotherapy using a device in their home healthcare environment

In both cases, certain writing styles work best to communicate instructions users can quickly, easily, and accurately understand and follow.

Note: Methods for writing effective instructions are outlined in AAMI HE75 and [AAMI TIR49 \(2013\)](#) Section 7.2.1.5.

While AAMI HE75 provides more details than provided here, the most important aspects of writing effective instructions are considered to be:

- Write simple, task-oriented sentences with one action per step while avoiding prose and multi-sentence “steps”
- Use sequential lists to indicate a sequence of steps users need to complete
- Place warnings and cautions with the relevant step
- Use wording that has clear meaning and is not left open to interpretation

These writing techniques help avoid common issues found in human factors evaluations of instructional materials. The following are examples of some common issues and root causes seen in evaluations of instructional materials that are related to writing style.

Example 1 – Users do not know what words or symbols mean.

Words and symbols can be difficult for users to understand, because they often leave room for interpretation and do not provide specific or meaningful information to the user. Including wording that is more meaningful to the end users and is specific (this could be based on the PCA analysis) can clearly communicate the performance expected.

List of words and phrases users commonly misinterpret or do not understand:

- Utilize
- Initialize
- Frequently
- Large bubble
- A few times
- Modify
- < (less than symbol) or > (greater than symbol)

Example 2 – Users do not complete all steps or skip some steps.

When looking specifically at the instructional design and why users did not complete steps, there can be multiple reasons including ([AAMI, 2017](#)):

- The step as written takes too long (more than 20 seconds to complete).
- The step contains more than one step or action and the additional steps or actions were not seen or read.
- Writing style is prose rather than direct, active voice leading the user to ignore or skim blocks of dense text, and miss important details.
- It is unclear when a user should perform or stop performing an action or step and the user was not alerted to the cues by the instructions.
- Instructions are written in paragraph format or in a bulleted list rather than a sequential list of distinct, single actions which leads users to skim information rather than follow as instructions.

- Steps are out of sequence in the instructions.
- Additional or important information is located in another section or on a prior/next page which the user does not see.

When users miss completing a step, proper writing techniques can be followed to alleviate most issues. Evaluating the materials again in a human factors study will provide data on whether the issue has been mitigated with the update to the instructions.

6.4.4 Create effective illustrations and graphical elements

Drafting instructions and drafting appropriate visuals or illustrations that support the instructions is done together. As the instructional designer writes the instructions, they should also consider, “How can the instructions visually show the desired performance?” Illustrations are best used to support instructional content and tell users (AAMI, 2017):

- When to do something
- How to do something correctly
- What an outcome looks like

Illustrations also include elements of the task use-error analysis, especially if PCA analysis is included. What the user is seeing, feeling, or hearing helps inform the content and design of the illustrations.

A good way to start when developing early drafts of instructions is to take photographs. Photographs are easy and cheap to take and iterate if a concept does not work with end users. Photographs can also be turned into illustrations by a graphic designer. A graphic designer can help determine a specific styling, perspective and coloring that works best with the end users. Styling can range from very simple line drawings in black and white, to full photo-realism that shows much more realistic detail.

Although photographs can be useful during early development of instructions, illustrations are typically more effective than photographs for end users. Illustrations allow you to control how much detail is visually presented to the end user. Certain device, product or environmental aspects can be emphasized or de-emphasized in illustrations, and background clutter or distraction that is often present and difficult to control in photographs can be eliminated in illustrations.

There are also times when photographs may be more effective for end users than illustrations. An example in which photographs might be beneficial is when medical procedures are involved. Surgeons and surgical teams may find it more useful or informative to see photographs of an actual procedure using a device, rather than an illustration where the necessary realism is lost or difficult to replicate. In this situation, using photographs might be a better option than illustrations.

Note: Additional information can be referenced in the AAMI HE75 section on Instructional Materials.

6.4.4.1 Elements that improve the usefulness of illustrations

Just having an image or illustration is not always enough to influence safe and effective user performance. For example, it may be unclear just from the illustration exactly what the

user should do or exactly how to hold or manipulate the device. A variety of additions can be applied to illustrations to improve user interpretation of the illustration and subsequent safe and effective use of the device. Some examples of these additional elements are:

- **Captions or callout text** – provide text directly next to the image or with a line pointing directly at an aspect of the illustration. The text can help clarify things like “hold here” or “grasp firmly.”
- **Placement and size relative to the text** – if all the illustrations are going to be very small, users may not be able to identify aspects of performance or the device. Try to make illustrations large enough that important details are not lost.
- **Angle and perspective** – use an angle and perspective (self-perspective or observer-perspective) that is easy to visualize, and users can quickly determine the performance depicted.
- **Hands or no-hands** – often hands and placement of fingers can influence users to perform a step exactly as depicted. There may be times when hands would obscure important elements of the device interaction or may cause user confusion. Testing illustrations with and without hands may be done during formative evaluations to see if there is any difference in user performance.
- **Cropping and enlarging areas of focus** – start with a larger illustration with all details or context of the step being performed. If a specific aspect is difficult to see or focus on, crop the illustration down and enlarge the specific area to focus on the details as needed.
- **Directional arrows** – use thick or block style directional arrows so that users can clearly determine the motion or direction required. Very thin or light-weight lines are ineffective when the illustration size is reduced for final commercial formatting.

Table 9.1 provides a list of common issues regarding illustrations that can cause confusion or use errors with participants in studies and how to correct them.

6.4.5 Add organizational and navigational elements

Many components of instructional materials stand alone and must provide certain structural and navigational cues to the user. This is true for various types of media including print, electronic, on-device screens, web-based, etc. Users rarely read all printed instructional materials from beginning to end like a book, which makes it imperative to incorporate well-designed and well-placed organizational and navigational elements to ensure the overall effectiveness of the materials. If users cannot find the information, there is little chance they will read it and follow it, which could expose them (or patients) to risk of harm.

6.4.5.1 Use headings, table of contents, index, and cues for page turning (as necessary) in printed booklets

For printed materials that will be in a booklet format, it is key to include meaningful headings, a table of contents, and for larger manuals, an index. Users may use these elements in various ways, but often the user looks for key words in headings, the table of contents and index to locate specific information. If the headings are not written in a meaningful way containing key words that resonate with the end users, this may cause users to not find information or to not use the instructional material at all.

TABLE 9.1 Common issues with illustrations and how to fix them.

Issue with illustration	How to fix the issue
User is confused about multiple actions included in the illustration	Include one action per illustration and match the illustration placement with the step text
User cannot visualize the intended performance from a technical or engineering style illustration	Use a styling method such as simple line drawings or photo-realism illustrations avoiding dark backgrounds and ensuring very clear contrast of lines against the background
User is confused because colors in the illustration do not match what the user sees on the device	Use shapes or graphical treatments to call attention to device parts and keep device parts colored accurately in the illustration
User cannot follow hand or finger placement in the illustration	Ensure the best hand or finger placement for performing the task is included in the illustration
User did not notice the color graphic highlighting certain aspects of the illustration	Use color carefully and avoid using so much color it reduces its affect to call attention to important information or aspects of performance
Illustrations are too small and detailed for users to interpret	Crop or enlarge the most important portion of the illustration to add visual clarity
User did not see the illustration until after performing the step	Align illustrations with the respective text and make placement consistent, allowing users to see the illustration first and read text if and when needed
User could not tell what illustration was conveying, illustration was confusing	Consider alternative perspectives to clarify the illustration. Perspective may be from user point of view or observer point of view.

Note: Some high-risk devices or systems can generate long lists of warnings and cautions that must be placed into the instructional materials. It is difficult for users to find relevant warnings and cautions in such long lists. To alleviate this issue, consider grouping warnings or cautions by specific topic areas. Use meaningful headings for each topic area and separate the long list into smaller lists under each heading. Additional information can also be located in the [AAMI HE75 \(2009\)](#) section on Instructional Materials.

Another consideration for printed materials is page turning. In booklets, if information is continued on the next page, an indication should be included to alert the user to turn the page for more instructions or information. If the end of a page or section gives an instruction for what the user should do next (e.g., repeat steps, go to another task, immediately perform step on the next page), the instruction needs to include what should be done and where to reference additional instructions. Often, page turns that are not identified can lead to users missing important information or instructions by not turning the page.

6.4.5.2 Use clear identifiers, graphical treatments, and cues for page turns for large format printed sheets

When printed materials are large-format sheets (e.g., newspaper style), a different approach is required. First, the outside of the final folded sheet should be clearly

identified as instructions. There can be multiple pieces of printed information that accompany a device and the instructions should be clearly identified to the user. Graphical treatments to help the user unfold the sheet completely may be needed. Folds can cover important information and navigational cues can help users unfold the sheet and see all the information provided. If the sheet is two-sided, a graphical element can be helpful to encourage users to turn the sheet over to find information on the other side. Large format sheets also require meaningful headings to group information and separate informational sections from instructions.

6.4.5.3 Consistently organize electronic materials

Electronic materials should be organized in a similar manner to the primary source materials (e.g., instructions for use, user manuals). However, the navigation should match the standard navigation already established for the electronic delivery method. For example:

- Instructions that are presented on a web page should use standard conventions for navigating a web browser.
- On-board instructions embedded in a device should provide very clear navigation to move back and forth between screens and may leverage other standard navigation conventions.
- eLearning should provide standard navigation conventions appropriate for the user. Some lay users may have never used eLearning interfaces, so the process of navigating should be clear and may need to mirror other, familiar navigation conventions.

6.4.6 Apply formatting to instructional materials

Different instructional components will have different formatting according to the media selected for delivery to the end users. For example:

- Printed instructional materials may have a variety of layouts applied from booklets, to folded leaflets to single page quick start guides or cards, etc.
- Electronic materials may be delivered in an electronic document or may be formatted for delivery over standard web browsers.
- eLearning is typically drafted using storyboards that are easily updated and manipulated. The storyboard defines all the images, graphical elements, text, navigation, etc. planned for each screen included in the eLearning. The storyboard is then used to create the electronic design.
- Classroom training materials may consist of a presentation with printed materials for the trainer and the training participant.

While minimal formatting may be applied during early formative evaluations, once you approach late stage formative testing, a formatting design close to the commercial or clinical study design should be tested. Often final formatting design and branding can influence user performance and will need to be optimized with the other aspects of the instructional interface.

Instructional materials made available in different media for the commercial or clinical study device should generally follow the acceptable guidelines for that specific media type. The [AAMI HE75 \(2009\)](#) section on Instructional Materials comprehensively describes several

important formatting considerations for instructional materials design. The list below discusses some formatting issues that are common in human factors testing of instructional materials:

- Text formatting that makes instructional material difficult for users to read
 - Size of the text is too small (smaller than 10 pt. font size)
 - All UPPERCASE words or phrases are used throughout the text
 - **Too much bolding reducing the effect of emphasizing certain words**
 - Bolding the wrong words
 - Light, thin or compressed fonts that have poor contrast
 - White or light text on dark backgrounds which are difficult to read
- Contrast of both illustrations and text makes it difficult for users to visualize the content
 - Dark backgrounds used behind illustrations or text
 - Illustration line weights do not offer enough contrast
- Use of too much color makes it difficult for users to focus on important information or details
 - Too much color is used to emphasize information along with color illustrations, branding and graphical design elements
- Flow of information makes it difficult to easily read or navigate to different sections of instructional materials
 - Users cannot easily navigate the material or navigate to the wrong information at the wrong time
 - Users tend to have a more difficult time reading down a column and moving over to the next column and reading down again. A more natural reading pattern is across rows of information rather than down columns then across the page.
- Position of illustrations and accompanying text is not consistently aligned making it difficult for users to follow text and illustrations in the correct sequence
 - Illustrations are placed after steps or in areas where they fit on the page instead of before steps

Note: Additional information can be referenced in [AAMI TIR49 \(2013\)](#) Section 7.2.1.6.

6.4.6.1 Additional formatting and layout considerations for printed materials

In most instances, it is best to have nearly final content and illustrations before placing printed material into a commercial or clinical study layout. This is due to the time and effort associated with iterating in a final layout design. It is often impractical for some organizations to continuously edit within the final layout and instead, a low-fidelity version is best to use until the content of the instructional materials has been optimized for end users.

Once you have a draft of text and illustrations that work well for end users, it is time to apply the commercial or clinical study design (i.e., layout and formatting) to the materials. Many factors influence the final design of the materials. Along with the full scope of the content to be included, the instructional designer also needs to know:

- **Footprint of the instructional materials.** Materials provided within the packaging of a device or product will need to fit inside the packaging dimensions (length, width and depth). If the design is a booklet, the booklet size and thickness will be limited to the packaging design and dimensions. If the design is a large-format sheet or leaflet, the final folded size of the instructional material must fit into the packaging.

- **Color vs. black and white.** Printing in color generally costs more, and there may be constraints on how much the production of instructional materials can cost. The instructional designer will need to evaluate the costs of printing early and whether color is an option or if black and white should be considered as a less expensive alternative.
- **Considerations for separate materials.** Some materials may be provided separately for a large, complex system and thought should be given to where the material will be stored and if it will also be made available electronically and displayed on a monitor or mobile device.

Some large systems with numerous use cases and many tasks may have instructions placed in a content management system. Templates and layouts may be prescribed for large booklets that are produced from content management systems. In this case, the formatting of the final product may be dictated by the templates available in the content management system. However, testing these instructional materials in their final format is still important to ensure the layout does not create difficulties or use errors.

Other cross-functional stakeholders should provide input for the printed materials including packaging and distribution as well as manufacturing. This is to ensure the automated production and packing of the instructional materials is considered before the layout design is finalized. The following may be concerns of the additional stakeholders and should be considered for the design of the printed layout:

- Limitations on sheet size and printing capabilities for large-format sheet sizes
- Limitations on color
- Automated machine folding of leaflets
- Automated picking and packing of the instructional materials on the manufacturing line

It is recommended to get input from any additional stakeholders as early as possible to agree on a format that will work for end users and can be accommodated for commercial production. These stakeholders should receive early drafts of the commercial materials to run production tests and alert the instructional designer of any modifications required.

6.4.7 Develop additional instructional materials or components

As discussed and illustrated in [Section 6.4](#) of this chapter, it is recommended to develop some instructional materials or components *after* primary source materials are developed (e.g., instructions for use, user manuals). Development of the following types of materials is usually best after the content for the primary source material is finalized.

- Quick reference materials
- On-screen or on-board instructions (EPSS)
- Training videos
- Training and eLearning

Developing materials in this recommended sequential order increases consistency and accuracy of all materials. Additionally, it reduces duplication of effort to make updates across materials, which happens often during early development and iterative human factors testing.

6.4.7.1 Create effective quick reference materials

The most common issue seen in human factors testing with quick reference materials is use errors or difficulties caused by missing information. Quick reference materials can be designed to avoid this issue by.

- Including all steps and safety information for the task(s) covered
- Directing users when to reference the full instructions and where in the instructions to go
- Making it obvious that the quick reference materials only include a subset of the full instructions
- Only using quick reference materials when required:
 - In general, a preliminary assessment of the task analysis and the frequency of task completion by users will help inform the need for quick reference materials. Through the course of human factors testing, users may also express ideas about tasks for which quick reference materials would be beneficial.
 - For example, an auto-injector with one use case and a small number of steps should not require a quick reference guide. Producing a quick reference guide for marketing purposes to show the auto-injector can be used in “two simple steps” (e.g., load dose and inject) is inaccurate from a user performance perspective and an incorrect application of the quick reference guide when users should see and understand all the information related to safe and effective use of the auto-injector.
 - In another example, an implanted device that has different components used in the operating room (OR), the intensive care unit (ICU) and at home with the patient could require quick reference materials. If tasks in the ICU are completed infrequently with a separate component of the system, adding quick reference materials to instruct nurses to perform specific tasks could be required. The materials could be laminated and attached to the equipment for easy reference with explicit mention of the full user manual if additional information is needed.

Often, quick reference materials leave out steps, warnings and cautions, or information designed to mitigate use errors. Without complete information, users may not perform critical steps, may not use the device correctly and may make mistakes that could have been avoided with additional information. The design principles in this chapter all apply to quick reference material, and the quick reference material should be consistent and complete compared to the primary source materials (i.e., instructions for use, user manual).

Note: Additional information can be referenced in [AAMI TIR49 \(2013\)](#) Section 7.2.2 and the [AAMI HE75 \(2009\)](#) section on Instructional Materials.

6.4.7.2 Create effective on-screen or on-board instructions (EPSS or GUI)

The on-board instructions embedded on a device display may start with storyboards developed from preliminary drafts of use cases and related tasks and steps. It is recommended the storyboarding and development of these instructions leverage the primary source instructions to ensure accuracy and completeness.

Instructional design principles can also serve as useful tools during the development of the storyboards, including how instructions, decisions, prompts, messages and warnings are presented to users in the software or graphical user-interface (GUI). Instructional designers

should be part of the cross-functional design team during software development, ensuring any instructional elements of the software are optimized and promote accurate understanding of information and performance by end users.

Note: Additional information can be referenced in [AAMI TIR49 \(2013\)](#) Section 7.3 and the AAMI HE75 section on Instructional Materials.

6.4.7.3 Create effective training videos

Developers of training videos frequently experience similar issues to quick reference materials where the training video becomes ineffective and problematic because it does not contain enough detail for users to completely understand how to use the device correctly.

There are many ways to integrate video with electronic materials posted on a website or within training programs. Videos that thoroughly depict device use could be quite long (approximately 20 min or more), even for a device with a single scenario of use. In such cases, it should be examined how to divide a long video into smaller segments that users can access and view as needed, much like sections of instructions for use or user manuals. For best results in user performance, training videos should have content that is consistent with the primary source materials (i.e., instructions for use, user manual).

Note: Additional information can be referenced in the AAMI HE75 section on Instructional Materials.

6.4.7.4 Create effective training and eLearning

Development of training is another separate process within instructional design that requires special expertise to ensure training will be an effective risk mitigation as part of the user interface. It is highly recommended to work with experienced instructional designers who use a performance-based methodology to create a training program, especially for high-risk or complex devices or systems.

While preliminary training decisions are made and investigated early in the human factors program, definitive training decisions are made later in the process and according to a systematic, structured approach. Well-designed training programs are built from the task analysis and primary source instructions. Using these inputs, the instructional designer identifies the skills and knowledge users need to safely and effectively use the device, and designs training interactions to build the required user skills and knowledge. [AAMI TIR49 \(2013\)](#) provides explicit detail about the systematic process used to design and develop training, and this process is also referenced in AAMI HE75.

eLearning is also part of the systematic, structured training design approach outlined in [AAMI TIR49 \(2013\)](#) Section 5.2. eLearning may be identified as a method of training delivery during the design stages of the training program. Once the different components of the training program have been outlined, those areas to be covered in eLearning go through a storyboard process. The storyboarding process should leverage the primary instructional materials (i.e., instructions for use, user manual) but will also outline formatting, page navigation, links to additional resources and documents, planned learning interactions, graphics, illustrations, video, etc. that make up the entire eLearning portion of the training program. These elements combined are designed to ensure end users build requisite skills and knowledge as part of the eLearning component.

[Table 9.2](#) lists issues commonly seen related to training programs and how to avoid these common mistakes.

TABLE 9.2 Common issues with training and how to avoid them.

Issue with training	How to fix the issue
Not including instructional materials available to the user (e.g., instructions for use, quick reference guides) in the training and hands-on demonstrations with the device	Most training does not include time to train users for long-term retention and recall of knowledge or skills. Best practice is to teach users how to use the materials available in the entire instructional interface to support performing tasks. This leads to users being much more likely to use the available instructional materials when they need these supports, and ultimately, they are much more likely to use the device safely and effectively.
Not considering the baseline skills and knowledge the user has before completing the training (or differences in baseline skills and knowledge for experienced versus naïve users)	Training should provide specific delivery methods to the trainer which accommodate different levels of user experience with the device. For example, tailor training content for experienced users to understand what is new or different about the device being trained as well as practice with the device that focuses on those differences until the user can safely and effectively use the device. On the other hand, inexperienced users should be offered enough training and practice to ensure that they achieve a high-level of self-efficacy in performing tasks with the device using the provided instructional materials.
Not allowing users enough practice to become proficient at using the device	Users need practice to develop skills. The training should accommodate different types of users and allow them to practice using a device as many times as needed to gain proficiency at device tasks. Refresher training may be needed to assess and ensure infrequent and important tasks (e.g., emergency procedures) are practiced often enough to increase retention and recall of the task performance when users need to perform these tasks in an actual use environment.
Not assessing skills at the conclusion of training to ensure user proficiency meeting the prescribed criteria for safe and effective performance	User performance of tasks generally needs to meet certain standards of safety and effectiveness, which relate back to the task analysis. Final assessments of certain use cases or training segments should be included in training to assess the user's abilities to perform tasks safely and effectively with the requisite skills and knowledge. If users cannot perform the tasks correctly, feedback and additional practice should be provided until the assessment demonstrates the user can safely and effectively perform the task.

7. Conduct formative evaluations of instructional materials

Building in the testing of instructional materials into early human factors studies helps optimize the user interface based on user performance and feedback. The goal of testing instructional materials is to optimize until:

- Instructions for use, user manuals or quick reference materials stand alone and support safe and effective device use when used
 - After training, the user can perform tasks safely and effectively
- This section covers strategies for optimizing instructional materials through formative evaluations.

Note: Additional information can be referenced in the AAMI HE75 section on formative and summative testing as well as Chapters 10, 11 and 15.

7.1 Include instructional materials in early formative evaluations

Incorporating draft instructional materials, even low-fidelity versions, early in product development and testing is key to optimizing the materials as part of the user interface. Testing instructional materials during early formative work identifies any improvements from the user perspective such as wording or terminology that is confusing or easily misunderstood, text that is interpreted in different ways by different users, and illustration updates that would better support user performance.

There may be specific parts of the instructions that need to be isolated and tested to mitigate a use error or difficulty, such as a specific step of instructions or a particular sequence of illustrations. In this case, you may only need to test that portion of the instructions to focus on exactly what needs to be iterated or changed.

Formative evaluations can be a tool to alleviate extensive internal reviews of instructional materials. Often internal reviewers within a cross-functional team are not representative end users of the instructional materials or device. Therefore, these internal reviews may offer input that contradicts sound instructional design and may not ultimately be what representative end users need. If the cross-functional team discusses the instructional materials at length and cannot agree on certain aspects of the design, a few strategies can help:

- Ask participants to use up to 2-3 different design alternatives of the instructional materials in a formative evaluation. In this case, it is important to consider the appropriate participant sample size to allow each sub-group of users to use a different “primary version” of the materials so the sub-groups can be compared. Then the cross-functional team can make informed, meaningful and data-driven decisions based on user performance with the design alternatives.
- Have 2-3 alternate designs for a particular step or illustration that is expected to be problematic ready to present to participants in the formative evaluation. Get agreement from the cross-functional team on the primary design to be tested during the study session, and present one design to all participants. Then gather subjective feedback from participants at the end of the scenario or study session comparing the alternates to the primary design they used. This approach will help determine if participants think a design alternative would help them better understand the intended information.

7.2 Optimize instructional materials based on human factors data

Once human factors data are collected from a formative evaluation, it is important for the instructional designer to apply the instructional design principles in AAMI HE75, [AAMI TIR49 \(2013\)](#), and this chapter to identify potential changes. Often feedback is provided by study participants to change the materials in specific ways, but the changes proposed by participants may or may not be effective. Worst case scenario is that the changes may induce new or unanticipated use errors or difficulties that were not seen in previous testing. Therefore, it is imperative to conduct effective follow-up interviews with participants and good root-cause analysis to help the instructional designer make informed decisions.

Example: optimizing in early formatives

Instructions were designed for an infusion system used by healthcare professionals and lay user patients. The instructional materials were tested throughout the human factors program as part of multiple formative evaluations.

During the formative testing, the instructional materials were optimized as follows:

- Illustrations were revised to clarify performance by including one step per illustration.
- Steps were formatted as sequential lists rather than large blocks of text.
- Color was changed to provide better contrast between steps and safety information and illustrations.
- Sections were reorganized to flow better from the user perspective and the sequence in which users would perform tasks.

As a result of the formative testing and attempting to resolve early use errors and difficulties with the lay user task, the decision was made to improve the device design. The instructional materials were updated to reflect the new device design.

Due to including instructional materials in formative testing early, device design and instructional design was optimized in parallel with positive results.

7.3 Optimize after late-stage formative evaluations

Once early formative evaluations have been conducted and instructional materials have been iterated and optimized, changes in later stage formative evaluations should be implemented with extreme caution. The instructional designer and cross-functional team should carefully consider the impact of late stage changes and only make those changes directly resulting from study data. Changes that are unrelated to study data could cause use errors and difficulties not observed previously, which will cause more iterations to become necessary. The scenarios listed below highlight how making non-data driven changes after late-stage testing can be detrimental to the overall project timeline and budget.

Scenario 1 – The graphic design team was not involved in discussions of study data or changes to be made. A request was made for the graphic designers to change the line weight of a specific line in one illustration to make the device part clearer to end users. When the materials were tested again, there were new use errors attributed to the illustrations and negative subjective feedback from study participants about the illustrations. Upon further review of the instructional materials, the graphic artist had updated all the illustrations with the new line weight making them very difficult for users to understand.

Scenario 2 – Throughout early formative testing, no use errors were seen for a specific step. In late-stage formative testing, a new use error was observed performing the step and user comments suggested that an element of the illustration did not stand out and contributed to the use error. When the earlier instructional materials were compared to the newer version, it was determined that the background color had been changed causing the element to no longer stand out. The background color change was not based on a need identified by the prior formative work.

Example: optimizing in late-stage formatives

Instructions were designed for a combination product to be used by lay user patients who have disease and age-related limitations. The predominant limitations affecting the use of the instructions were decreased vision, limited manual dexterity, lack of stamina and some possible loss of cognition.

The instructional materials were printed as large-format (e.g., newspaper style) instructions that were tested in two formative evaluations. Through the formative evaluations, the instructions were optimized with the following revisions:

- Improved illustration styling to add contrast and detail missing from original illustrations.
- Illustrations were added to more steps to make the steps of use clearer.
- Format of the printed layout was updated to make sections of the large-format sheet clearer.
- Navigational aids were added to columns on the sheet to ensure users

were able to follow instructions to the next column.

- Safety information was included to avoid use errors that would lead to a missed dose or underdose.

One task in the instructions caused multiple use errors in each formative evaluation. The design included a graphical table with images and text. The design was iterated, and several alternatives were tested over the course of the formative evaluations.

Regardless of the iterations and optimization, the instructions could not be modified further to increase the correct completion of the critical task. The cause of the incorrect performance could not be corrected by the instructions, instead the device interface needed to be updated. Due to the characteristics of the end users, the instructional materials could not overcome the device design to promote correct performance of the task.

Example: optimizing in late-stage formatives

Instructions were designed for an *in vitro* diagnostic kit to be used by lay user patients in their homes. The instructional interface included a user manual, a label sheet to identify the samples, and shipping instructions to send the samples to the laboratory.

The instructions were tested through a series of formative evaluations and optimized after each formative evaluation based on the study data. Revisions to the materials included:

- Improved illustration styling – removing dark background and using high-contrast illustrations for an older age demographic

- Included one action per illustration and one illustration per step to make the process clear for low literacy users.
- Added sequential lists for steps instead of large blocks of text.
- Revised intended use, how the kit works and other informational content to simplify prose style writing and increase comprehension for low literate users.
- Updated the sequence of sections to match regulatory requirements and to provide important information before the instructions for use.

One critical task had use errors and difficulties in each formative evaluation. The illustrations had to support user performance more than the text due to the low literate user group. Several alternate illustrations were tested until the use errors and difficulties were reduced significantly.

In the validation study, user performance was not perfect, however, the residual risk assessment showed the iteration of the instructional materials and determined no further optimization could be made to the instructional materials.

7.4 Optimize after validation

Just as optimizing materials in late-stage formative testing should be done judiciously, the same is true after validation testing. Changes made post-validation could lead to a supplemental validation study if the change(s) could introduce new risks or could have an impact on user performance. The impact a change could have on user performance can be difficult to predict, therefore supplemental testing may be required to gather data proving the effectiveness of the changes (especially since the final user interface is required during validation testing).

There may be times when a specific portion of the instructional materials has been especially problematic during human factors testing. The instructional content may have been iterated, multiple versions tested, and still in the validation study there are observed use errors and difficulties. In this case, consider the residual risk and the human factors data related to the instructional interface that were gathered throughout the overall human factors process. The residual risk analysis and human factors data specific to the instructional materials may show improvements in task performance, even though use errors and difficulties were not fully eliminated in the final design. If the instructional materials have been optimized as much as possible, consider building residual risk rationale using human factors data related to the instructional materials.

8. Summary

Instructional design is a structured, systematic process of designing and developing the instructional interface. Correct application of instructional design principles influences user behavior and promotes safe and effective use of medical devices and drug delivery products. There are many resources available to the person or team responsible for developing the instructional interface. These resources guide the application of instructional design principles for the best possible design of instructional and training materials.

To create the safest and most effective instructional interface, the instructional design process is integrated with the human factors process. Instructional materials are part of the user interface and should be designed and tested early in the overall design process, along with the device, as part of human factors studies. Based on the human factors testing data,

the instructional interface can be optimized in a similar manner as the device-user interface. Iterative design and testing of instructional materials yields the best instructional interfaces that will support end users while also building the evidence needed for regulatory submissions to demonstrate the labeling and training foster safe and effective device use.

9. Further reading

- [ANSI/AAMI HE75](#) Human factors engineering – Design of medical devices
- [AAMI TIR49: 2013](#) Design of training and instructional materials for medical devices used in non-clinical environments
- US FDA, Guidance on medical device patient labeling. April 19, 2001
- US FDA CDER, Guidance on Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors
- ANSI Z535.6-2011, Product safety information in product manuals, instructions, and other collateral materials
- [ANSI/AAMI HA60601-11:2015](#), Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance
- US FDA CDRH, Design Considerations for Devices Intended for Home Use, Guidance for Industry and Food and Drug Administration Staff
- AAMI Workshop entitled Applying Human Factors to Improve Instructional Materials as Part of the User Interface

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- ANSI/AAMI HA60601-11.* (2015). *Medical electrical equipment – part 1-11: general requirements for basic safety and essential performance.*
- ANSI/AAMI/IEC 62366-1.* (2015). *Medical devices – part 1: application of usability engineering to medical devices.*
- FDA guidance entitled, applying human factors and usability engineering to medical devices that was published by CDRH,* FDA on February 3, 2016. (2016).
- FDA guidance entitled, Human factors studies and related clinical study considerations in combination product design and development that was published by CDER, FDA on February 2016.* (2016).
- FDA guidance entitled, infusion pumps total product life cycle guidance for industry and FDA Staff, that was published by CDRH, FDA on December 2, 2014.* (2014).
- FDA guidance entitled, reprocessing medical devices in health care settings: validation methods and labeling, that was published by CDRH/CBER, FDA on March 15, 2015.* (2015).

P A R T I V

Formative design evaluation & reporting

Heuristic analysis, cognitive walkthroughs & expert reviews

Mary Beth Privitera

HS Design, Gladstone, NJ, United States

OUTLINE

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Design isn't finished until someone is using it. Brenda Laurel

1. Introduction

Heuristic Analysis, Cognitive Walkthroughs and Expert Reviews are all types of usability inspection methods using analytical techniques that do not require users per se. They can generate results in a fraction of the time and costs as empirical techniques. This chapter defines heuristic evaluations and cognitive walkthroughs, describes their differences and communicates the processes of each technique for the purposes of medical device design. Each of these techniques are considered cost-effective, flexible techniques aimed at improving

the usability of a system. These methods are valuable for the determination of usability issues and are complementary to formal usability testing with users. They are often performed by experts in usability/human factors and result in: a list of usability issues and strengths, a severity or priority ranking, and recommendations for design improvement. They can and should be used throughout the design process, often with multiple iterations as the design of the user interface increases in fidelity.

2. Background

Heuristic evaluation was originally proposed by Neilson and Molich in 1990 as a means of identifying usability issues found in software. The intent of this evaluation method was to evaluate a user interface by simply looking at the interface and passing judgment according to own's own opinion, in essence an expert review. Wharton, Rieman, Lewis, and Polson (1994) proposed the cognitive walkthrough method in the book "Usability Inspection Methods" as another tool to uncover problematic issues in user interface design. While these methods focus specifically on user interface design, they are also applicable to the physical design of a product, which allows them to provide an analysis of the entire user interface, both digital and physical.

For medical device design, the FDA specifically encourages the use of heuristic and expert analyses to identify use-related hazards and hazardous situations. The methods are clearly described within their guidance in Sections 6.3.2 and 6.3.3 (FDA, 2016) as an effort to identify problems and make recommendations for improving the usability of a device (FDA, 2016). Following this recommendation, each method is described in detail below.

3. Heuristic analysis

Heuristic evaluation focuses on improving effectiveness and efficiency with respect to user testing (Hvannberg, Law, & Lárusdóttir, 2007). A heuristic evaluation is a human factors method intended to uncover areas of improvement that improve usability. It is an evaluation of the use interaction at all touchpoints, such as input forces, fit and biomechanics. It can be used throughout the design process to identify optimum ergonomic product architecture, assess use risk and review overall usability. Conducting a heuristic evaluation involves having a small set of evaluators examine the user interface against recognized usability principles (the heuristics) (Nielsen, 1995; Nielsen & Molich, 1990).

Nielsen (1994) provides 10 usability heuristics which have been validated and built upon. They are:

1. Visibility of the system status: Always keep users informed about what is going on through appropriate feedback in a reasonable amount of time.
2. Match between system and real world: The system should speak the user's language with words, phrases and concepts familiar to the user rather than system-oriented terms.
3. User control and freedom: Users often choose functions by mistake and will need a clearly marked route to correct the issue.

4. Consistency and standards: The design should follow conventions found that comply with the appropriate standards. A standard ensures that users understand the individual interface elements in a design.
5. Error prevention: Careful design prevents a problem occurring in the first place. It is accomplished by eliminating error-prone conditions or checking for them and presents users with a confirmation option before they commit to taking an action.
6. Recognition rather than recall: Minimize the user's memory load by making objects, actions and options visible.
7. Flexibility and efficiency of use: This is the ability for a user to tailor frequent actions.
8. Aesthetic and minimalist design: Extra information competes with relevant units of information and diminishes their relative visibility.
9. Help users recognize, diagnose and recover from errors: Good error messages are polite, precise and constructive. They explicitly state something has gone wrong in language readable by users and constructively suggest a solution.
10. Help and documentation: Provide help and documentation that is easily searched, focused on the user's task and which lists steps that assist in carrying out the task.

Since it would be difficult for one person to identify all the usability problems in an interface, an evaluative team approach is warranted. This will yield overlapping results and highlight key opportunities for improved usability as each reviewer analyzes the interface independently and then compares the results. The process consists of identification of problem areas and then providing an assignment of severity. The suggested severity rankings include the following (Chen & MacRedie, 2005; Kushniruk, Monkman, Tuden, Bellwood, & Borycki, 2015; Nielsen, 1994):

- 0 = not a problem
- 1 = cosmetic problem; fix if possible
- 2 = minor; fix the problem; however, low priority
- 3 = major; important to fix
- 4 = catastrophe; important to fix before release

In order to complete a heuristic evaluation of software, the following steps should be completed:

1. Determine the number of evaluators with recommendations by Nielsen of between 3 and 5 (Nielsen, 1995).
2. Define heuristics and determine approach; e.g., domain specific, use of sub-heuristics.
3. Conduct evaluation.
4. Develop recommendations and document in a report.

Table 10.1 below provides a template for completing a heuristic evaluation using Nielsen's methodology:

Using Nielsen's work as a backbone, Zhang (2003) expanded the list of heuristics in order to modify the traditional heuristic evaluation method and make it applicable to medical devices as well as to evaluate patient safety. As a result, the list of heuristics expanded from 10 to 14; all of these were validated (Zhang, Johnson, Patel, Paige, & Kubose, 2003). A list of these heuristics and description is below (Table 10.2):

TABLE 10.1 Heuristic evaluations using Nielson’s methodology.

Heuristic	Evaluation
1. Visibility of system status	Rating- brief description & justification
2. Match between system & real world	Rating- brief description & justification
3. User control & freedom	Rating- brief description & justification
4. Consistency & standards	Rating- brief description & justification
5. Error prevention	Rating- brief description & justification
6. Recognition rather than recall	Rating- brief description & justification
7. Flexibility & efficiency of use	Rating- brief description & justification
8. Aesthetic & minimalist design	Rating- brief description & justification
9. Help users recognize, diagnose & recover from error	Rating- brief description & justification
10. Help & documentation	Rating- brief description & justification

TABLE 10.2 Zhang’s 14 heuristics for usability evaluation of medical devices (Zhang et al., 2003, pp. 25–26).

Heuristic	Definition	Examples
1. Consistency	Users should not have to wonder whether different words, situations or actions mean the same thing. Standards and conventions in product design should be followed.	a. Sequences of actions (skill acquisition). b. Color (categorization). c. Layout and position (spatial consistency). d. Font, capitalization (levels of organization). e. Terminology (delete (del) and language (words, phrases)). f. Standards (e.g., blue underlined text for unvisited hyperlinks).
2. Visibility	Users should be informed about what is going on with the system through appropriate feedback and display of information.	a. What is the current state of the system? b. What can be done at the current state? c. Where can users go? d. What change is made after an action?
3. Match	The image of the system perceived by users should match the model the users have about the system.	a. User model matches system image. b. Actions provided by the system should match actions performed by users. c. Objects on the system should match objects of the task.
4. Minimalist	Any extraneous information is a distraction and a slow-down.	a. Less is more. b. Simple is not equivalent to abstract and general. c. Simple is efficient. d. Progressive levels of detail.

TABLE 10.2 Zhang's 14 heuristics for usability evaluation of medical devices (Zhang et al., 2003, pp. 25–26).—cont'd

Heuristic	Definition	Examples
5. Memory	Users should not be required to memorize a lot of information to carry out tasks. Memory load reduces users' capacity to carry out the main tasks.	a. Recognition versus recall (e.g., menu vs. commands). b. Externalize information through visualization. c. Perceptual procedures. d. Hierarchical structure. e. Default values. f. Concrete examples (DD/MM/YY, e.g., 10/20/99). g. Generic rules and actions (e.g., drag objects).
6. Feedback	Users should be given prompt and informative feedback about their actions.	a. Information that can be directly perceived, interpreted and evaluated. b. Levels of feedback (novice and expert). c. Concrete and specific, not abstract and general. d. Response time. • 0.1 s for instantaneously reacting; • 1.0 s for uninterrupted flow of thought; • 10 s for the limit of attention.
7. Flexibility & efficiency	Users always learn, and users are always different. Give users the flexibility of creating customization and shortcuts to accelerate their performance.	a. Shortcuts for experienced users. b. Shortcuts or macros for frequently used operations. c. Skill acquisition through chunking. d. Examples: • Abbreviations, function keys, hot keys, command keys, macros, aliases, templates, type-ahead, bookmarks, hot links, history, default values, etc.
8. Good error messages	The messages should be informative enough such that users can understand the nature of errors, learn from errors and recover from errors.	a. Phrased in clear language, avoid obscure codes. Example of obscure code: "system crashed, error code 147." b. Precise, not vague or general. Example of general comment: "Cannot open document." c. Constructive. d. Polite. Examples of impolite message: "illegal user action," "job aborted," "system was crashed," "fatal error," etc.
9. Prevent errors	It is always better to design interfaces that prevent errors from happening in the first place.	a. Interfaces that make errors impossible. b. Avoid modes (e.g., vi, text wrap) or use informative feedback, e.g., different sounds. c. Execution error versus evaluation error. d. Various types of slips and mistakes.
10. Clear closure	Every task has a beginning and an end. Users should be clearly notified about the completion of a task.	a. Clear beginning, middle and end. b. Complete 7-stages of actions. c. Clear feedback to indicate goals are achieved and current stacks of goals can be released. Examples of good closures include many dialogues.
11. Undo: Reversible Actions	Users should be allowed to recover from errors. Reversible actions also encourage exploratory learning.	a. At different levels: a single action, a subtask or a complete task. b. Multiple steps. c. Encourage exploratory learning. d. Prevent serious errors.

(Continued)

TABLE 10.2 Zhang’s 14 heuristics for usability evaluation of medical devices (Zhang et al., 2003, pp. 25–26).—cont’d

Heuristic	Definition	Examples
12. Use users’ language	The language should always be presented in a form understandable by the intended users.	a. Use standard meanings of words. b. Specialized language for specialized groups. c. User-defined aliases. d. Users’ perspective. Example: “we have bought four tickets for you” (bad) versus “you bought four tickets” (good).
13. Users in control	Do not give users that impression that they are controlled by the systems.	a. Users are initiators of actors, not responders to actions. b. Avoid surprising actions, unexpected outcomes, tedious sequences of actions, etc.
14. Help and documentation	Always provide help when needed.	a. Context-sensitive help. b. Four types of help. • task-oriented; • alphabetically ordered; • semantically organized; • search c. Help is embedded in contents.

In some instances, the development of sub-heuristics has been effective in providing further clarity for the purpose of analysis (Chen & MacRedie, 2005; González, Masip, Granollers, & Oliva, 2009; Hermawati & Lawson, 2016). This points to the fact that in practice, the heuristics, as described may not include all the features of a design that impact usability. Nielson’s heuristics are intended to be generally applicable to a wide variety of software interfaces and not intended to be comprehensive to an entire user interface nor a domain-specific set of heuristics. Kölling & McKay (2016) hypothesize that a smaller, more concise, more orthogonal (or independent) set of heuristics is easier to use than a larger one and furthers criteria for individual heuristics as:

- Being able to uniquely identify a set of actual known issues in existing systems from the target domain;
- Sufficiently orthogonal to the remaining set to avoid ambiguity in classification of identified faults.

In order to accomplish this, the entire set of heuristics was small enough to manage and supported the identification of major known problem areas of the target domain. This approach was also completed by Chen and MacRedie (2005) in order to prescribe a step-by-step or pragmatic approach for usability inspections. For facilitation, a detailed, structured checklist was developed to maximize the number of usability problems which could be identified. A comprehensive review of 70 studies related to usability for specific domains conducted by Hermawati and Lawson (2016) discusses a deficiency in validation efforts following the heuristic proposition; however, results were inconclusive due to a lack of

validation quality and clarity on how to assess the effectiveness for specific domains. For future heuristic analyses in which the heuristic is domain specific, Hermawati et al. recommend:

- Robust and rigorous validation and adoption of standard measures as indicators of heuristics' effectiveness.
- Building on heuristics that already exist in a domain.
- Better definition of what constitutes expertise with respect to usability and specific domain.

In summary, a heuristic evaluation is a type of usability evaluation against a set of known usability principles. The ones presented above have been validated through research. While it is possible to develop new heuristics or sub-heuristics, care should be taken in order to validate the measure of the heuristic itself.

4. Cognitive walkthrough

A cognitive walkthrough is an evaluative method for the design of a user interface with attention to whether or not a novice user can easily carry out tasks within a given system ("[Cognitive walkthrough | Usability.gov](#)," 2018; Jones, 2018). It is a method in which people work through representative tasks and ask questions about the task as they go. It focuses on the tasks, the interface and the learnability. A cognitive walkthrough begins with task identification and then a performance assessment of the device's usability. It is a proven method of attaining early feedback on whether a design solution is easy for infrequent users to learn and why/why not. It is most helpful with prototypes or mock-ups before a system is implemented, when there is no access to real users. It is not intended to be a substitute for a user evaluation.

The goal of the assessment is to predict whether the user will try and achieve the correct outcome. This question examines the inherent design assumptions about the user's level of experience or knowledge. It can predict when a user's expectations of an action do not align with the actual action taken because they are using other reference points and becoming confused (e.g., a blinking light used to communicate "system charging" in one instance and in another area communicating "system working")

The process of conducting a cognitive walk-through consists of the following steps:

1. Identify specific traits or persona for infrequent users of a design solution.
2. Develop a set of tasks emphasizing the experience of a new user.
3. Designate a team member to play the role of this user having the previously determined trait(s).
4. Ask the "user" (team member playing the role) to accomplish their goal using a printed or interactive design. Ask them to verbalize what they would attempt, or do next, as they proceed.
5. If the "user" becomes lost, the evaluation team should not lead the user through the task. Instead, they should ask questions in order to gain an understanding of intent and causality.
6. Assess the "user's" ability to easily and/or quickly move through the task, paying specific attention to expected outcomes.

7. Analyze the walkthrough results, highlighting challenging areas and identifying what areas of the design require improvement.

For each action accomplished by the user, the evaluator must ask two fundamental questions, according to [Spencer \(2000\)](#), these are:

- 1. Will the user know what to do at this step?
- 2. If the users do the right thing, will they know that they did the right thing and that they are making progress toward their goal?

Other common questions asked during a cognitive walk-through include ([Blackmon, Polson, Kitajima, & Lewis, 2002](#)):

- Will the user try to achieve the right outcome?

Hidden or obscure controls are problematic for users. Often users can be overwhelmed with the number of options available, which can result in confusion. By reducing options, controls and/or tasks become easier to accomplish.

- Will the user notice that the correct action is available to them?

Requiring complex actions to be undertaken will be problematic for novice users. Intuitive selections are those that do not “make the user think” about what needs to be done in order to execute a task.

- Will the user associate the correct action with the expected outcome?

Feedback to the user that an action has been correctly completed or that an action is necessary demonstrates a functioning system.

- If the user performs correctly, will he/she see progress toward the intended outcome?

If feedback is missing, badly worded, easy-to-miss or ambiguous, it may result in user frustration or use error.

[Table 10.3](#) provides a template for performing a cognitive walk-through, which enables a usability evaluation for each task.

As a result of the task orientation of cognitive walk-throughs, this method is commonly used in order to complete a full Task Analysis (see Chapter 6).

TABLE 10.3 Cognitive walk-through template.

Analysis questions	Task 1	Task 2	Task 3	Task 4
1. Will the user try to achieve the right outcome?	Y/N – why?	Y/N – why?	Y/N – why?	Y/N – why?
2. Will the user notice that the correct action is available to them?	Y/N – why?	Y/N – why?	Y/N – why?	Y/N – why?
3. Will the user associate the correct action with the expected outcome?	Y/N – why?	Y/N – why?	Y/N – why?	Y/N – why?
4. If the user performs the task correctly, will he/she see progress toward the intended outcome?	Y/N – why?	Y/N – why?	Y/N – why?	Y/N – why?

5. Expert reviews

Expert reviews are a process in which a usability interface expert inspects a system in order to identify possible issues within the user interface. The difference between heuristic evaluations and expert reviews is often blurry within organizations; however, more generally, an expert review expands on heuristic evaluations by assessing the design against known heuristics, principles of usability according to cognitive psychology and/or human-computer interaction, the reviewer's expertise and past experience in the field. An expert review may also be a review conducted by a representative user, often internal to the organization, however may not be a human factors expert.

The results of the review are typically presented in a written form and contain detailed information with recommendations. These can serve as justification for design changes throughout the design process. As such the reviewer should have deep knowledge of usability best practices and a large amount of past experience, but not have been involved in creating the design to be reviewed in order to prevent bias.

The process of conducting an expert review consists of the following steps:

1. Determine the areas of product design to be analyzed.
2. Review existing research, literature, device use.
3. Identify all touchpoints.
4. Identify user workflow.
5. Analyze UI for adherence to user disciplinary tenets.
6. Analyze UI for adherence to published ergonomic standards e.g., ANSI/AAMI HE 75.
7. Analyze entire UI for use error risk
8. Determine strategies for improved UI/usability.
9. Determine design improvements for UI/usability.
10. Generate report.

5.1 Syringe example

Below is an example of an expert review of a conceptual design with the goal being to optimize the physical interaction of the device. The example presented is a combination product which mixes two medications prior to delivery. In this example, the areas of the physical interface are explored (Fig. 10.1) and the design is compared with ANSI/AAMI HE 75 standards (Figs. 10.2 and 10.3).

In Fig. 10.1, the device interaction within the hand is fully explored and illustrated. Usability weaknesses are called out in an issue list.

Fig. 10.2 highlights applicable gripping considerations as described in ANSI/AAMI HE 75. It also provides a recommendation for design improvement.

Fig. 10.3 describes usability considerations in order to provide the user adequate feedback that an intended goal has been accomplished as described in ANSI/AAMI HE 75.

By providing a review of all use interactions in the context of usability standards, the product design can be improved in subsequent iterations.

CONCEPT Syringe

Fit and Gripping Surfaces

ISSUES:

1. No indication to Pull Tip: on/of may be confusing
2. No gripping surface to enable Pulling Tip
3. No clear indication how to hold product overall
 - **View 3** enables considerable force; users will likely dispense more than requirement and may empty syringe
4. Index-middle finger interaction can be problematic depending on grip style
 - **View 4** fingers at maximum spread provides users less control
 - **View 5** has the best fit between index-middle fingers with minimal spread between them
5. Dispensing is completed with a continuous flow; users will rely on visual feedback only during dispensing



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FIG. 10.1 Expert review of syringe.

HUMAN FACTORS

General Considerations Dispenser

GRIP:

- Overall Grip Considerations include size, diameter and shape. *Reference 16.2.4 and 16.2.4.2 in HE 75*

See guidelines:

- **16.19** Tool size accommodates differences in handedness, strength and work capacity
- **16.21** Grip diameter enables fingers to wrap 270 degrees around the gripping surface
- **16.39** For fine manipulation tasks, handle diameter should be between 0.5 and 1.6 cm
- **16.44** Pommels or flanges should be used to prevent the hand from slipping.
- **16.45** A cylindrical handle should be used for fine manipulation that requires gripping by fingertips
- **16.62** Minimize weight to decrease tremor

Recommendation: Where possible use cylindrical shape (.5-1.6cm diam.), flanges for grip cues/slipping and encourage fingertip grip



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FIG. 10.2 Recommendations for specific design pulled from ANSI/AAMI HE 75.

HUMAN FACTORS

General Considerations for Dispenser

FEEDBACK:

- When using a hand tool, users should receive tactile, visual and/or auditory feedback regarding the status of the tool and the task. *Reference 16.2.7.5 in HE 75*
See guidelines:
 - **16.134** Provide tactile feedback
 - **16.136** Keep handle clear of markings where they can be obscured by the user's hand
 - **16.139** Discrete control positions should be indicated by tactile and auditory feedback.
- Feedback should be provided to user that a motion has been accepted by the device. *Reference 7.1.2.2 in HE 75*
See guidelines:
 - **7.10** Immediate feedback
 - **7.11** Clear feedback
 - **7.12** Redundant feedback is advantageous (multi-modal concurrent feedback will make it more likely users will be able to use a control accurately and reliably).
 - **7.14** Auditory feedback is most effective in environments with low ambient noise levels
 - **7.15** Confirmation of critical actions



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FIG. 10.3 Specific feedback recommendations from ANSI/AAMI HE 75.

6. Comparability of these methods

Heuristic analysis, cognitive walk-throughs and expert reviews are similar in that they are flexible, inexpensive approaches to identify usability issues. They rely on an individual evaluation completed by usability experts, most often done as part of an analytical team and completed at any time in the device development process. In research conducted by [Kushniruk et al. \(2015\)](#), both heuristic analysis and cognitive walk-throughs were combined with the intent to leverage the strengths of both techniques. The commonalities between these inspection methods includes: having multiple expert reviewers yields the best results; the ability to uncover many usability problems; conducting the test in-house without users but following a Users' point of view; and the ability to be more thorough than User Testing as there are typically no constraints of the number of tasks evaluated therefore the reviewers are able to seek all the nooks and crannies of a user interface.

According to a study by [Khajouei, Esfahani, and Jahani \(2017\)](#), heuristic analysis and cognitive walk-throughs do not differ significantly in regards to the number of usability issues identified; however, differences were described regarding the severity and coverage of some usability attributes.

In summary, heuristic analysis is intended to broadly reveal usability issues; cognitive walk-throughs have the same intent; however, are aligned with the specific tasks involved throughout use. Expert reviews can be a combination of both (heuristic analysis and cognitive walkthroughs) and compare specific usability aspects or tasks to known industry standards (e.g., an expert review may include comparison of the force required to manipulate a control against known ergonomic standards).

Each method is appropriate for medical device design and may be most powerful as a combined approach with the intent to provide identification of usability issues on the user interface. Once an issue is detected, it is most helpful to use published standards such as ANSI/AAMI HE 75 or like standards to provide justification for design improvements.

7. Assessing risk and identifying design opportunities using heuristic evaluation, cognitive walk-throughs or expert reviews

Risk assessment can and likely should happen throughout the design process because using Heuristic Analysis, Cognitive Walk-throughs or Expert Reviews as a backbone to identify usability issues can assist in defining risks found in particular tasks or situations that are the result of product design or workflow. These risks can then be further mitigated by developing comprehensive design opportunities. [Fig. 10.4](#) below highlights a detailed analysis using visual language to describe a step with sub-steps within a workflow based on previous user research (contextual inquiry) and a proposed design. Each step is described and visualized.

From this figure, the potential risk areas can be identified and risk mitigations proposed alongside defined opportunities for improved design. In completing this type of analysis, the resulting product design can have improved usability.

8. Assessing competitive ergonomics

Using an OTC device as an example, the photos below ([Figs. 10.5 and 10.6](#)) illustrates evaluation techniques needed to determine competitiveness and relative usability between two devices with the same intended functionality or clinical utility. For this example, 2 TENS unit/pain-relieving muscle stimulating devices (FDA approved) were purchased and analyzed for usability. This was completed solely to provide a brief example for the purposes of this book and is not intended to provide recommendations for a next-generation device.

According to the FDA, a user interface includes all points of interaction between the product and user(s), including elements such as displays, controls, packaging, product labels and instructions for use, etc. The user interface descriptions always include graphical representations of the UI, descriptions of the UI, device labeling and an overview of operational sequence of device and expected user interactions with the UI. As such, the entire use experience was considered for this evaluation.

Using the validated usability scale 0 (no problems)—4 (Catastrophic problems), each system was evaluated and compared ([Table 10.4](#)).

From this evaluation, the Healthmate Forever[®] scored higher in overall usability, whereas the Mini Massager proved problematic for user control, consistency and standards and error prevention, as well as flexibility and efficiency. If the intent were to provide recommendations for improved design, this evaluation would be used to prompt further analysis into the root cause of the usability issue(s) and then suggest improvements.

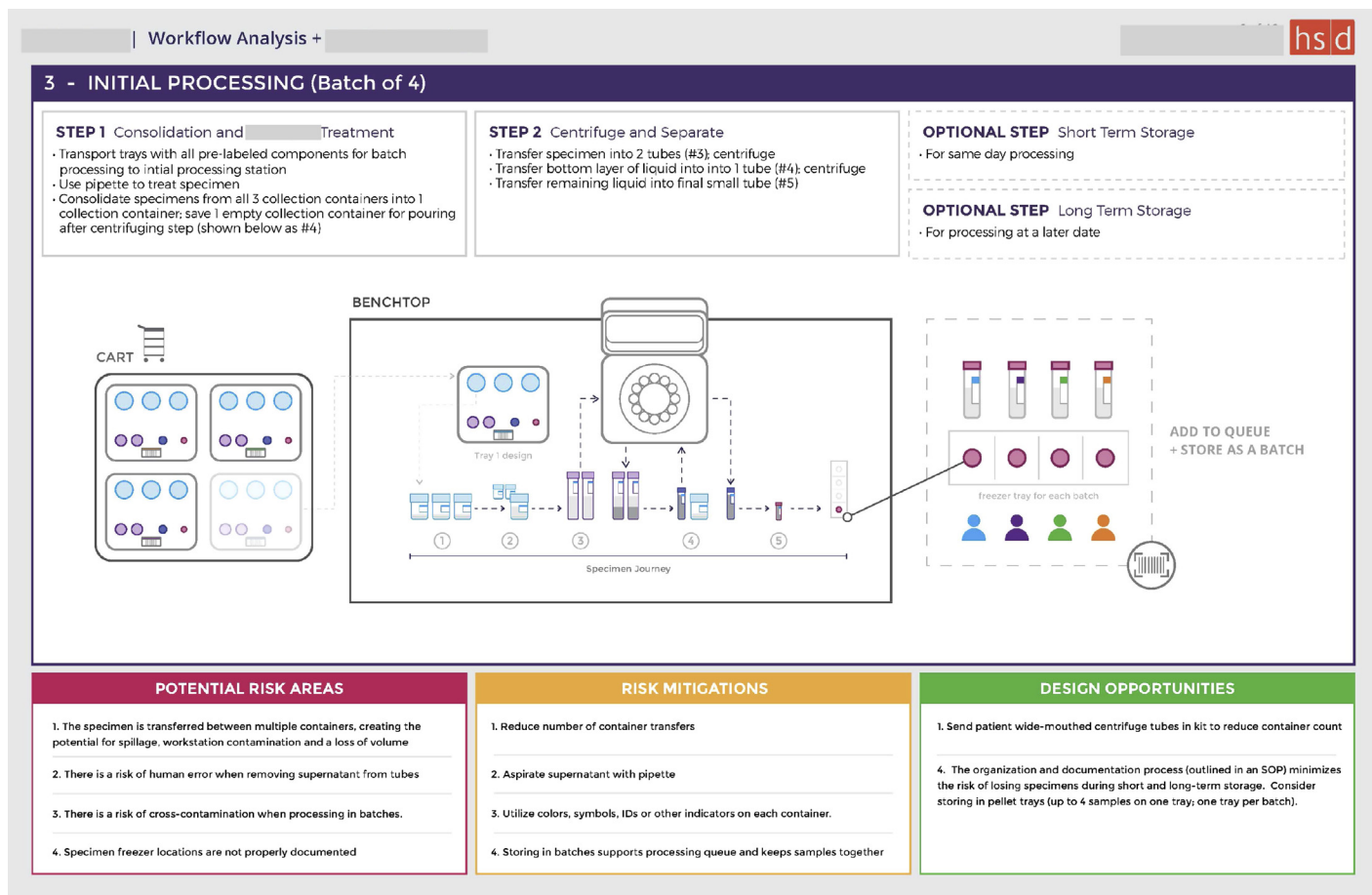


FIG. 10.4 Workflow analysis of lab equipment with potential risk areas, risk mitigations and design opportunities identified.



FIG. 10.5 Device 1: Healthmate forever (R) pain relief TENS & powered muscle stimulant.



FIG. 10.6 Device 2: Mini massager tens unit by Cartiya.

IV. Formative design evaluation & reporting

TABLE 10.4 Usability comparison of devices using Heuristic review.

Heuristic	Healthmate forever [®]	Mini massager by Cartiya
Visibility of system status	1- Status is clearly displayed on the interface. Both electrodes do the same task	3- it displays both modes and allows for variability between the electrodes; however, discrimination is difficult
Match between system & real world	1- Easily understood icons	1- Easily understood icons
User control & freedom	2- Changing modes is difficult	3- Changing modes is difficult
Consistency & standards	0- Uses common icons	2- Uses some common icons
Error prevention	0- easily change modes	2- knowing which electrode is controlled by A or B is a challenge
Recognition rather than recall	0	2- When you change modes, need to remember to change intensity
Flexibility & efficiency of use	0	3- Double modes is confusing
Aesthetic & minimalist design	1- the pictures are small in the IFU and on screen	3- Too busy
Help users recognize, diagnose & recover from error	2- Modes on screen do not have clear delineation	3- Challenges between which electrode is being controlled by UI
Help & documentation	4- Too small yet simply written	2- Nice guide for electrode placement per ailment

9. Summary

Heuristic Analysis, Cognitive Walk-throughs and Expert Reviews are common practice in medical device design and are widely used when there have not been any previous human factors work. When properly documented, they are methods which can be utilized as a Formative Usability Study, as the intent of each method described in this chapter is to identify usability issues and improve the product design.

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Simulated use formatives

Deborah Billings Broky^a, Tressa J. Daniels^b,
Melissa R. Lemke^a

^aAgilis Consulting Group, LLC., Cave Creek, AZ, United States; ^bUXD & Human Factors, BD Medical, San Diego, CA, United States

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1. Introduction

Human factors testing for medical devices has one overarching goal: To optimize user interface design and demonstrate to the regulatory agency that the device is safe, effective and usable by end-users as a requirement prior to market release. Formative evaluation

studies feature usability testing with simulations using prototypes in order to explore overall usability objectives (AAMI, 2009). These evaluations are intended to identify user interface design strengths, weaknesses and unanticipated use errors (IEC, 2015). Simulated use evaluations (“formatives”) conducted prior to final validation testing add great value to a human factors submission. They enhance the final validation report by providing details regarding the incorporation of human factors throughout device development in order to optimize the user interface. Further, formatives help sponsors better define the uses and use environments in terms of user interface and users. Ultimately, formatives inform the use-related risk analysis for the device. Results from formatives can also be used to identify critical tasks, to update task categorizations and risk analyses based on newly uncovered or unanticipated risks, and to provide meaningful justification for including or excluding certain design elements evaluated in the final validation. Formative data can be quite valuable within a submission as regulating agencies may ask sponsors to provide formative evaluation data that helped sponsors determine the designation of tasks or interface design requirements.

It is a fact that a medical device design can have some use-related risks yet achieve regulatory clearance. Granted, in these cases, the design development history presents compelling evidence that the sponsor has considered end users in the design process and shown the use-related safety and effectiveness of the design has been optimized such that no further design mitigations would reduce or eliminate the residual risk. Simulated use formatives play a major role in assuring the usability of a device and ultimately preparing a device for human factors validation testing. For example, well-documented formative findings could potentially:

- Confirm that design elements of the user interface (including implemented risk mitigations) prevent use errors from occurring;
- Demonstrate that labeling materials promote safe and effective use of the device;
- Establish that user training provided and managed by the sponsor as part of the user interface (UI) is an effective mitigation; and/or
- Show that the validation methodology is unbiased and appropriate, use scenarios are realistic and that the correct data can be collected (i.e., conduct a formative using validation methodology to provide pilot study data).

According to ANSI/AAMI HE75 (2009), formatives provide a means to:

- Identify and prioritize tasks according to potential harm as derived from the inherent analytical techniques;
- Guide the development of use scenarios;
- Identify unanticipated use errors;
- Identify critical tasks early in the design process;
- Guide the modification of device user interface elements; and
- Clarify the dynamics of user-device interaction within the use scenarios.

While some sponsors only see additional costs to formatives as burdens with the potential to extend project timelines and require development schedules, the benefits of implementing these formatives prior to validation testing often outweigh the costs. Performing formatives early in the design cycle can identify design issues early in device development when design changes are much easier and less costly to implement rather than at the end of the

development cycle. When formatives are conducted, sponsors are much more likely to optimize user interface design (including Instructions for Use, IFU) and have a successful validation without any last-minute surprises. It’s recommended to not rush to human factors validation testing without considering how formative evaluations may benefit your design and submission.

2. What are formative evaluations?

Existing standards and guidance documents define “formative evaluations” similarly (see [Table 11.1](#)). They offer a way to identify usability problems with device design during the development cycle. Formatives do not have strict assessment criteria or endpoints like validation studies or clinical testing; rather, well-planned formatives can provide a variety of data about the design of your device user interface in order to inform design changes and optimize device design. Formatives allow sponsors to base design decisions or changes on concrete user performance data and subjective feedback instead of making decisions based on user preference or arbitrary modifications that the regulatory agency may not trust as valid.

A formative evaluation may be conducted in many ways, including: heuristic analysis, cognitive walkthroughs, expert review (see Chapter 10) or by using a **simulated use study methodology**. This chapter focuses on simulated use methodology and provides detailed explanations.

TABLE 11.1 Definitions.

Guidance	Definition of “formative evaluation”
FDA CDRH (2016)	<i>“Process of assessing, at one or more stages during the device development process, a user interface or user interactions with the user interface to identify the interface’s strengths and weaknesses and to identify potential use errors that would or could result in harm to the patient or user.”</i>
HE75	<i>Referred to as “formative usability testing” and “quick and dirty” preliminary testing. “Usability testing that is performed early with simulations and the earliest working prototypes and that explores whether usability objectives are attainable, but without strict acceptance criteria.”</i>
IEC62366 Part 1	<i>“User interface evaluation conducted with the intent to explore user interface design, strengths, weaknesses and unanticipated use errors.”</i>

3. Conducting simulated use studies for formative evaluations

A simulated use study involves testing with representative users completing realistic tasks with a device user interface in a simulated and/or representative use environment. Objective (i.e., performance) and subjective (i.e., information from the user’s point of view) data are obtained, analyzed and then used to inform design decisions. Simulated use studies should be considered because they can **minimize risk** of a device performing poorly going into a human factors validation test.

Simulated use studies do not have to be time-consuming and costly. There are ways to streamline the approaches to maximize the benefit of the data collected while minimizing the burden to both timeline and budget. These are discussed in further detail below.

As mentioned previously, a simulated use study is one of several options for a formative evaluation. While it is best practice to conduct a simulated use study as a formative evaluation, it is not required per se in the standards and guidance. However, a simulated use study is required for all human factors validation studies (see Chapter 15) with strict adherence to methodology proposed in IEC 62366 and FDA Human Factors Guidance. Although a simulated use formative and a validation study both use a simulated use framework, there are major differences between a formative and validation study that should be considered during planning stages, as described in [Table 11.2](#).

TABLE 11.2 Simulated use studies: different considerations for formatives versus validation studies.

Simulated use study considerations	Formative evaluation	Human factors validation study
Methodology	Range of “rapid insight usability testing” to a more formalized methodology can be effective. The study protocol can change/be updated as necessary relative to progress in the device development process.	Formalized methodology that aligns with agency (FDA) guidance is required. Strict adherence to study protocol is expected.
When to test	As early or late in a device life cycle as needed to answer specific questions about the user interface design.	After device user interface (e.g., device design, labeling, packaging, training, etc.) has been finalized.
Test frequency	As many times as necessary to optimize a device user interface, which includes device, labeling, packaging and any other materials that the user will interact with.	Typically, one time to demonstrate that the device user interface is safe and effective; additional times if further device modifications are needed to address residual risk or user interface updates are being implemented.
Test materials	With early prototypes, later device designs or the final device design (low or high fidelity), with the option to test alternative designs.	With final design.
User-device interactions to test	Small or large set of specific tasks, incomplete workflow (e.g., only test tasks associated with cleaning the device) or all tasks involved in use scenarios (complete workflow).	All tasks involved in use scenarios (complete workflow).
Outcomes	Decide what modifications to make to the user interface based on performance data and design recommendations.	Decide if residual risk is acceptable so that the device is safe and effective, and if the device user interface has been optimized as much as practicable.
Data analysis	Quantitative data can include time on tasks, success rates and other data tied to successful completion of tasks.	Quantitative data include success rate and data tied to successful task completion (e.g., timing a participant to ensure that he holds an injection for the required 10 s).
	Qualitative data can include comments and feedback from participants, which can be elicited throughout the session and at the time a use error or difficulty is observed, if desired.	Qualitative data can include comments and feedback from participants during the debriefing interview.
	Root cause analysis identifies causes for use errors and difficulties and can lead to recommendations for design modifications.	Root cause analysis identifies causes for use errors and difficulties and can lead to recommendations for design modifications.

3.1 Simulated use study purpose

Simulated use studies focus on safe and effective user-device interactions rather than user preference data. As such, they utilize representative users, use environments and use scenarios with the intention that users interact with the device in manners similar to real-life or representative use/s. A simulated use approach for formatives can incorporate a wide range of objectives throughout the development process. These are described in [Table 11.3](#).

3.2 Formative study timing

Simulated use formatives can be appropriate during early stage device development or during later stage development; the benefits are ultimately dependent on the formative objective(s). [Wiklund, Kendler, and Strohlic \(2016\)](#) describes impacts to device development, estimated timelines for formative evaluations and information about decisions that could increase or decrease monetary costs for conducting formatives. [Table 11.4](#) below provides a summary of the costs and benefits of conducting formatives at different times during the development process.

In summary, simulated use studies that are conducted early in the device development cycle can benefit a sponsor by allowing product optimization based on user performance data. However, if a sponsor only conducts a simulated use study towards the end of the device development cycle (or chooses not to conduct a simulated use study at all prior to validation), the sponsor could likely observe unanticipated use errors and use-related problems during the human factors validation testing that may require re-design of the UI, supplemental validation testing of the modified UI, or repeated validation testing altogether. Conducting a simulated use study with an early concept or prototype can expose potential use-related problems that present significant risk of harm to users. Catching these use-related problems early in the design process allows the sponsor an opportunity to revise the design to mitigate risk and provides a strong foundation for use-focused risk management.

4. Planning a simulated use study

When designing a simulated use formative, there are five study components to be considered. These include the following:

1. **Task selection:** What tasks should be included?
2. **Testing methods:** Which methods will be most effective in capturing the data required in order to inform design? What are the specific strategies that support the formative study objectives? What types of test environment and materials should be used?
3. **Participants:** What are the inclusion criteria (e.g., adults 18 years and older) and the exclusion criteria (e.g., must not have participated in any other studies for Device X) for participants? How many participants should be included? And why?
4. **Data collection and analysis:** What data should be collected, and how will they be analyzed?
5. **Writing the report and implementing design modifications:** How formal or informal will the report be? What should be included, at a bare minimum? What recommendations will be included that will enhance device usability? How will implemented recommendations be documented and tracked through the development process?

TABLE 11.3 Objectives of simulated use formatives.

Objective/focus of formative	When should it occur?	Description	Example
1. Inform device design and help assess new design iterations	Any time design is iterated or a safety related design decision is being made (pre- or post-market)	Inform device design throughout the device life-cycle (early to late), or in post-market evaluations. Evaluate risk mitigations and modifications to device design that were implemented.	[Device X] injector was iterated to include audible feedback when injection is complete. Formative evaluation can determine if this mitigation is effective in preventing users from prematurely removing the injector before administering a full dose.
2. Test specific or hypothesized use-related problems	Early in the design process is better	Focus on potential problems associated with certain aspects of the user-device interaction versus the entire process(es). Identify potential use-related risks or further explore risks identified in other analyses.	Pen injectors have known issues with users not holding the device long enough for a complete injection. Formative evaluation can determine if this is also an issue with [Device X] injector.
3. Verify assumptions early in the design process	Early in the design process is better	Verify or iterate assumptions of users, environments, tasks, simulated use scenarios and potential use errors, as well as help identify critical tasks.	[Device X] is a diabetes therapy, and the designers assumed users would understand terminology like units of insulin, volume, needle gauge, etc. A formative can either verify these assumptions or debunk them to help with the design of effective packaging, labeling and training.
4. Determine effectiveness of labeling and/or training	Earlier in the design process is better to test initial version of labeling and training. After labeling/training have been finalized, can be used to ensure these UI elements are optimized and effective prior to the validation study.	IFU focused formative: Show that participants can safely and effectively use the device when the IFU is explicitly used. Training formative: Show that representative training is effective. Determine representative learning decay and when no training may be appropriate, even if training is guaranteed (e.g., an infrequently used emergency device).	Users are directed to use [Device X] labeling to complete simulated use scenarios to determine if labeling is an effective mitigation to prevent use errors from occurring. This is a clean, unbiased way to evaluate labeling.
5. Evaluate validation study methodology (Pilot Study)	Late, once validation methodology is determined and user interface is near final.	Conduct pilot testing designed to “practice” study methodology and ensure Moderator guide, use scenarios and knowledge task questions are clearly communicated and generate necessary data. Helps to determine readiness to proceed to the validation study in order to avoid costly situation where a validation turns into a formative.	A formative can determine if simulated use scenarios for [Device X] are appropriate, and if representative users understand Moderator instructions (in order to avoid introducing any potential study artifacts into a validation).

TABLE 11.4 Timing of simulated use formatives in the development process.

Timing	Benefits	Costs
Early in design life cycle (i.e., conducted with low fidelity prototypes)	1. Mitigate risk early in design before changes become more costly. 2. Identify use-related risk and unanticipated use errors. 3. Address small problems before they become bigger. 4. Reduce probability of use-related problems post market. 5. Provide evidence that UI design decisions (e.g., symbols, text, images or colors in an IFU) were based on user performance data. This allows a sponsor to justify design decisions to the agency. 6. May reduce overall device timeline to market because it can identify design problems early and reduce the amount of re-work that is needed late in the development process.	1. May increase project timeline up front, but allows for planning and more assurance going into the validation. 2. Requires project budget in the near-term, depending on the fidelity/complexity of the formative methodology.
Late in the design life cycle	1. Will identify most use-related problems that could lead to an unsuccessful validation. 2. IFU testing may provide support for risk mitigation. 3. Pilot study can identify any issues with validation methodology a priori so that they can be fixed.	1. Conducted with near-finalized device; device design that cannot be easily changed. Manufacturing lines may need to be changed based on late stage user interface changes. 2. Can slightly increase a project timeline. 3. Can increase project budget.
No simulated use formative evaluations planned	1. Initially, very expeditious project timeline. 2. No extra resources need to be allocated.	1. Potential for surprises in the validation (e.g., unanticipated problems) and questions from the agency. 2. Risk mitigations may be expensive and time-consuming to address.

Each of these components are described in additional detail below. While this list is not exhaustive, it represents high-level questions that should always be considered when planning a simulated use formative evaluation.

4.1 Participant task selection

Participant task selection refers to the task that a user will be asked to complete during a simulated use study. Often times, the question of “Do I need to test everything?” comes up. The simple answer is no. The first inclination in the design process may be to test everything because perfecting the design is the ultimate goal. However, it is important to remember that having users perform all tasks in one simulated use study can take a great deal of time and may result in fatigue and even frustration. In order to get the most out of allocated budget, consider prioritizing task selection criteria on the following:

- a. User tasks that are relevant to safety or could potentially lead to harm;

- b. User tasks that may be unusually complex and/or could require the user to look for help (e.g., in an IFU or from a nearby colleague);
- c. User tasks that may occur rarely or infrequently but are critical to safe use (e.g., critical alarms);
- d. User tasks that are relevant to the ease of use, appeal or competitiveness of the device; and
- e. Areas of the user interface that the designer wants specific feedback on.

Focusing task selection on the items above likely will fill the time available for a testing session. If the tasks selected increase the session time to an unreasonable length, consider testing portions of a workflow rather than an entire workflow from start to finish. This allows the opportunity to gather feedback concerning the highest priority portion of the workflow while keeping the session length reasonable. For example, in a task such as changing user settings on a programmable infusion pump: if it is known that a user has no issues locating and accessing user settings, then try skipping over that and going to the next setting screen or menu where the user can interact with the specific setting which is unknown and warrants evaluation.

Note that if the purpose of the simulated use formative is to test a validation methodology (pilot study), it should include all tasks that are to be included in the human factors validation testing protocol. This will better predict overall readiness to proceed to the validation study.

If time permits, it is generally best practice to collect data on all tasks regardless of task categorization (whether they are critical or non-critical) as formatives can often lead to updates in assumptions or re-categorization of tasks. It is easy to dismiss data that is determined to be meaningless if a task is deemed unimportant or non-critical, but it is challenging or, in cases without video recording, impossible to go back and collect some types of data. This is especially true for participant interview data, which can help identify root causes of observed use errors or difficulties.

4.2 Development of simulated use testing methods

Creating the formative testing protocol and Moderator guide enable the Moderator to collect the right data at the right time. When followed, this assures thoroughness, repeatability and comprehensiveness. Examples and discussion are presented below.

4.2.1 Protocol development

Developing, documenting and approving a testing protocol prior to the formative evaluation are important tasks. These steps formalize the testing so that it can be replicated, if required. The testing protocol can then be referenced in the sponsor's Design History File (DHF), which in turn provides traceability and evidence of human factors work throughout the design life cycle. While a formative evaluation does not require an extremely detailed and formalized protocol like a validation test; the formative protocol should still be well-developed and documented. If using a "rapid insight usability" formative approach, the need for traceability and documentation remains to ensure that results can be reported in the Human Factors Engineering/Usability Engineering (HFE/UE) or validation study report (and included in the regulatory submission).

4.2.1.1 Contents of a protocol

The following elements should be included in designing a formative research protocol:

Research question(s) and objectives

- Clearly articulate the research question/s so that data collection is aimed to provide evidence. This forms the framework for the study. For example, a formative study may include the following question: Which packaging design is easiest to open, allows users to quickly find the instructions and is most intuitive for guiding users to safely store the device components?
- Identify all specific objectives for the study to ensure that data collection meets the goals. The objectives may change during a formative evaluation, especially if new issues are identified during testing. If objectives change, document those changes carefully. An example of a study objective is: Determine if representative users can understand and follow the device IFU without causing errors or failures that could result in harm to users or patients. This example is focused on the IFU and should specifically target collecting participant performance data associated with IFU usage along with comprehension tasks.

Identify participants, test materials, test environment and training

- Document the number and type of participants, along with any specific inclusion and exclusion requirements plus justification for decisions. For example: 5–8 injection experienced and 5–8 injection naïve participants for an autoinjector formative.
- Estimate session length, keeping in mind the potential of fatigue by participants or test personnel. It is best to maintain test duration between 1 and 2 hours, although duration is always dependent on the activities completed as well as the additional time for interview questions. For example, a 1.5 hour study session may include the following activities: study introduction (10 min), completion of 3 use scenarios (45 min), completion of 8 knowledge task questions (15 min) and Moderator interview questions/probing to collect participant subjective data (20 min).
- Outline key characteristics of the actual use environment and how to simulate important characteristics within the environment. In a simulated use study, there is the opportunity to test “worst case” conditions such as low lighting, high noise, wet gloves, etc. This is important as any of these environmental conditions could impact safe and effective use of the device. A technician who reprocesses medical instruments and surgical equipment in a sterile processing department is expected to wear personal protective equipment (PPE) when performing reprocessing activities. Therefore, a simulated use environment should include access to PPE to reflect conditions under which users complete reprocessing activities in the actual use environment (e.g., wearing wet gloves, full body fluid resistant gown, face mask or goggles, etc.). Wearing PPE may impact how well users can see and manipulate the instruments during reprocessing, so it is very important to account for this equipment in the simulated use environment so that results from the study can be generalized to the actual use environment.

- Identify any training that the participants will receive as part of the study, including any training materials and periods of training decay between training and testing. This may involve a statement about how the training provided in the simulated use formative corresponds to real-world training for participants. For example, if cardiologists are your intended users and all cardiologists receive a sponsor-led 2-hour in-service training before using the device independently, consider including this in-service training as part of the formative evaluation. Because a cardiologist could potentially receive in-service training and then use the device in their clinic on the same day, it may be appropriate to include a minimal training decay period between the in-service training and the testing. An alternative approach is to conduct the simulated use study without training to demonstrate that intended users are capable of using the device with no training, which perhaps might be a worst-case scenario in real life.
- Develop a study documentation plan that includes the versions of the UI being evaluated (e.g., IFU version, software version). Sometimes a high-level fidelity UI is used, and other times low fidelity prototypes are used. There is no hard and fast rule for the level of fidelity needed, however it should be sufficient in fidelity to enable the user to interact with the device in a representative way without introducing study artifacts which may impact user performance either positively or negatively. Using low fidelity prototypes has the advantage of counteracting participant bias and proclivity to only respond with positive feedback. Low fidelity suggests to the participant that the design is incomplete and negative participant subjective feedback about the UI is acceptable, whereas higher fidelity often gives the perception of a polished and complete device. For some lay users, the more refined the prototype, the more likely it is for participants to accept the design as complete without providing critical comments. [Table 11.5](#) below provides examples of the different levels of prototype fidelity that could be used in a formative evaluation, including paper prototypes, grayscale wireframes and interactive workflows.

Identify tasks to be tested and determine how to collect the data

- Determine which tasks should be included in the formative and clearly indicate means of data collection. As previously mentioned, not all tasks associated with a device use have to be evaluated in a simulated use formative. For example, if no packaging is available at the time of testing, the formative evaluation tasks may exclude tasks associated with the packaging. If a new risk mitigation has been implemented, focus might be solely on tasks that involve that mitigation.
- Identify the best structure regarding the use scenario/s to incorporate tasks as well as how this may impact your data collection and analysis. This includes considering factors such as task sequencing, timing and repetition (e.g., opportunity for learning effects in actual use). For example, a formative could include repeated use scenarios for a pen device that is used to administer medication once or twice daily. This methodology may show any learning effects that a user may experience, given that the pen is intended to be used on a frequent basis.

TABLE 11.5 Examples of prototype fidelity for formative evaluations.

Examples of acceptable prototype fidelity for formative evaluations	Illustration of prototype	Best uses
Low fidelity prototypes: Low cost materials are used to mock up a user interface. For example, paper sketches drawn by hand to represent a digital display. Other materials such as cardboard, foamcore or clay can be used to generate user interface prototypes.	 Fig. 11.1 Simulated use study with foamcore prototype and paper user interface; <i>image provided by HS Design.</i>	A paper prototype of a software UI or a low fidelity prototype of hardware is best used to determine user needs.
	 Fig. 11.2 Foam models; <i>photo courtesy of HS Design.</i>	
Static grayscale wireframe and 3D models: Upgraded version of the paper prototype in digital form. Human factors engineers often display these in PowerPoint and in some cases print them just as you would a paper prototype. For hardware, 3D printed models can be used to generate prototypes of user interfaces such as hand tools.	 Fig. 11.3 High fidelity 3D <i>printed</i> prototypes; <i>photo courtesy of HS Design.</i>	Greyscale wireframes are used to evaluate the workflow without visual clutter of a full interface. 3D printed models are more time and cost effective to develop when a design is still being iterated. The 3D model can be weighted to test the ergonomics, and levers and knobs can be interactive as well.

(Continued)

TABLE 11.5 Examples of prototype fidelity for formative evaluations.—cont'd

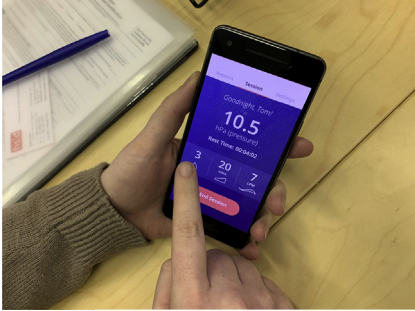
Examples of acceptable prototype fidelity for formative evaluations	Illustration of prototype	Best uses
Interactive workflows or interactive prototypes: Much more representative of what the final device might look like. Often color is applied, buttons are clickable, fields are editable, parts are movable, and the interaction provides a realistic experience of device use to the user. High fidelity hardware prototypes may be the initial appearance models of your device, meaning that the prototype looks like and feels like the final product and can even have functioning moving hardware components as needed for testing purposes.		Higher fidelity and interactive prototypes provide the optimum usability evaluation.
		

Fig. 11.4 Interactive software prototype;
photo courtesy of HS Design.

Fig. 11.5 Virtual reality prototype using
Hololens to provide scale; *photo courtesy of
HS Design.*

- Operationalize data collection. For example, what is the most appropriate way to assess whether a user has administered a complete dose of therapy? Timing may be appropriate if time is tied to a complete dose (e.g., 5 s to inject a dose from an autoinjector after dose initiation), or perhaps identifying if any medication is observed when a user removes an autoinjector from simulated skin (e.g., wet injection). A combination may be more appropriate in some cases, but it is important to identify how to collect data a priori so that data are collected in an unbiased way.
- Determine how observational (objective) and subjective data will be collected for each task, and outline specific strategies for doing so. Qualitative feedback (i.e., subjective feedback from participants) is promoted by FDA and is important to document (FDA, 2016). Participants oftentimes share thoughts in the form of subjective data that cannot be observed. Ensure that the study methodology outlines how both objective and subjective data will be documented and analyzed for each task. Subjective data are especially important for root cause analysis, and FDA encourages the inclusion of verbatim participant quotations in analyses and reports. This may include video recording from multiple perspectives in order to adequately observe device use and enable a review of comments provided throughout the simulated use formative study for root cause analysis. Alternative to video recording may be simply audio recordings or diligent notetakers.

4.2.1.2 Formality of study protocol

A simulated use formative protocol can be less detailed than a validation study protocol; however, there are advantages to providing sufficient details. Consider following FDA Human Factors Guidance (FDA, 2016: Appendix A) that outlines different sections of a HFE/UE report as the framework for formative testing protocols. While this may seem to require “extra” work, in the long run, it helps ensure that human factors documentation for the device is consistently formatted, traceable and presented in a way that can easily be integrated into the HFE/UE report, including details that agency reviewers are familiar with.

An adequate protocol ensures consistent methodologies are applied across participants, which ultimately enhances conclusions as a result of evidential data. It will also allow easier comparisons of methods and performance outcomes across formative evaluations and the validation study should it become necessary to show how human factors data informed design decisions (i.e., design traceability). For example, observing performance improvement in a validation study because a design mitigation was implemented as a result of a formative evaluation further indicates the mitigation was effective. Details such as number and type of participants, scenario scripts and order of tasks evaluated provide the documentation trail that will allow you to make important comparisons, including within the final HFE/UE report.

Detailed documentation can also help provide rationale for including or excluding user groups and/or certain tasks, as well as provide an argument for the inclusion of design elements to improve performance when otherwise you may receive questions or push back from regulating agencies.

Using formatives as evidence of good design requires good documentation

A sponsor with a combination device anticipated FDA concerns about using a stop sign symbol in the device IFU that could potentially lead to patient confusion. The sponsor conducted a formative evaluation focused on user understanding of the stop sign within the context of operational use of the device. One of the study objectives was to determine: Did representative users correctly interpret the “Stop Sign” symbol in the IFU? Using a non-biased approach, findings showed that users overall recognized the symbol in the way it was intended to be interpreted; i.e., users

knew to stop and make sure they followed the action outlined in the IFU text where the stop sign symbol appeared.

The sponsor was able to provide FDA with evidence to argue that the inclusion of the stop sign symbol in the IFU helped mitigate risk to the users (patients) by reiterating the importance of stopping at a critical point in the device use process. **The response was accepted by FDA, which highlights the importance of documenting design changes and study findings, even in formatives.**

4.2.2 Development of Moderator and Notetaker Guide

The Moderator and Notetaker Guide is one of the more important pieces needed to run a consistent, replicable formative evaluation. It ensures that the Moderator and Notetaker (if available) can collect all necessary data in a systematic and similar way for all participants. Although a Moderator-Notetaker team is ideal for collecting simulated use data, a Notetaker may not always be available for a formative evaluation. A detailed and efficient guide is especially important when only one person will be moderating as well as collecting data.

A Moderator and Notetaker Guide can be in electronic format or paper-based, depending on the needs of the Moderator and the Notetaker (if available). Paper-based may be more appropriate if the formative requires a lot of movement around the testing environment, but will then require data entry to compile and analyze all data electronically. An electronic format is more appropriate when all user-device interactions occur in one place (e.g., at a table). This type of guide functions as a more efficient data entry tool and allows the Moderator (and Notetaker) to enter data directly into the form for data analysis following the completion of the formative. See [Table 11.6](#) for an example of a Moderator and Notetaker Guide.

The Moderator and Notetaker Guide should include at a minimum:

- Moderator script to ensure consistency in instructions across participants;
- All tasks outlined, with success criteria and scoring method to record observation data; and
- Space to document Moderator (and Notetaker) observation notes, subjective comments from participants during the tasks and probing/interview data on difficulties and use errors.

TABLE 11.6 Example of a Moderator and Notetaker Guide for a combination device.

WF-1: Program a syringe infusion pump

Our first software task will start with a syringe infusion for Midazolam as listed on the order card I have handed you. Let's imagine you have already manually primed the syringe for 0.5 mL, please show how you would turn on the pump and program the infusion for your patient in the NICU.

Steps	Scoring	Notes
1. Press power button	C CI NC X	
2. Patient Setup	C CI NC X	
3. Press 'Current Patient'	C CI NC X	
4. Select 'Neonatal Care' for Care Type	C CI NC X	
5. Place badge near badge scan icon to unlock	C CI NC X	
6. Syringe Programming	C CI NC X	
7. Enter dosage	C CI NC X	
8. Press Start	C CI NC X	

Would you describe that task as easy or difficult? Can you tell me about that?

FOLLOW-UP QUESTIONS

1. What does the term "Patient Setup" mean to you?
2. When do you think that you would use this "Patient Setup" function?
3. What do you think about the location of the "care area" options?
4. What do you think about the name of the button as "Current Patient"?
5. [If don't like name ask] What would you name the button instead?
6. Did you have any difficulty on this task? [If so] Can you tell me about that?

C, completed successfully; CI, completed with issues; NC, did not complete; X, not assessed.

4.2.3 Strategies for conducting simulated use studies

Many different strategies can be employed to conduct simulated use studies, but the decision should be made based on the objectives of your formative. [Table 11.7](#) describes 9 strategies that can be used to support your study objectives.

4.3 Participants

Identifying the right type and number of participants for your simulated use formative is important because it impacts the usefulness and application of the data. A total of 5–8 participants per distinct user group is generally recommended in literature. According to [Faulkner \(2003\)](#), a sample of 5 users can detect a minimum of 55% and an average of 86% of problems with a user interface. [ANSI/AAMI HE75 \(2009\)](#) provides further rationale for a sample size of 5–8 per user group based on the law of diminishing returns. That is after 5 participants, subsequent participants will be less likely to identify any new UI issues, and any gains in new meaningful information will be limited.

TABLE 11.7 Specific strategies for simulated use formatives.

Strategy	Description	When to use
1. Rapid insight usability test	Early, quick formative usability test conducted using prototypes or partial designs to test certain aspects of the UI. Formatives can be short in duration with around 5 participants, and participants do not necessarily need to be representative users (although they should not be people on the design team or perhaps even within the sponsoring company in general).	Used to quickly evaluate certain design elements early in the design process and to evaluate low-hanging fruit (e.g., Do IFU graphics depict what is needed, do the images work with the text provided so that they are easily interpreted, is any new terminology being included?). For example, this strategy can be used to evaluate new device terminology and whether lay users (and perhaps users with low literacy, depending on intended users) are able to understand certain terminology specific to your device. Words that product development teams view as simple or that have inherent meaning can be quite confusing for lay users.
2. Partial task evaluation	Explores only part of the operational context of use for a device instead of all user-device interaction tasks. This can minimize study duration and focus on the data that are truly important to ongoing design efforts.	Can be used when problems have been identified (or hypothesized) with only certain aspects of the UI. For example, if the device developers of an infusion pump suspect that the software menu options for delivering a bolus may be confusing to users, a part-task evaluation can focus only on the tasks relating to programming a bolus. Can also be used when only certain parts of the UI are ready to be evaluated. For example, if not all software development has been completed.
3. Rapid iterative testing and evaluation (RITE)/prototyping	RITE methodology takes advantage of sponsor capabilities to make changes to the UI “on the fly” (during or immediately following test sessions) in order to test and iterate potential design mitigations for observed problems that occur in the same study. In other words, if participants are observed to have problems, data analysis and root cause are discussed and design changes may be made in between participants or before the end of the session. Then, these new changes are presented to the participant in the session and/or tested with subsequent participants in the same study.	Used when sponsors want to evaluate design changes (usually labeling changes) on the fly to mitigate problems observed in the study. Labeling revisions are often the focus for this strategy, as design can be changed relatively easily. Labeling changes can be low fidelity (e.g., pasting different image over the existing image in the IFU) or high fidelity (e.g., creating a completely new IFU), depending on resources and time.
4. Comparison of alternatives	Presents the participants with two or more alternative UI designs (often labeling designs) and asks the participant to compare the alternatives and provide subjective feedback. This usually occurs after the participant has completed use scenarios with one of the alternatives. This is not the same as preference testing and should be based on objective performance data to support the subjective user feedback.	Used when a sponsor wants to evaluate several design alternatives, which may include different images, layouts, etc. This strategy will help to determine if one concept/design is better than another from the user performance perspective. During early formatives, a sponsor may choose to evaluate a competitor’s device as an alternative to identify best features of the existing device (see AAMI HE75 for additional information).

TABLE 11.7 Specific strategies for simulated use formatives.—cont’d

Strategy	Description	When to use
5. Eliciting subjective feedback	Different strategies to elicit subjective feedback can be used but should be outlined in your testing protocol. Talk aloud methods are when Moderators ask participants to verbally talk through the use scenario and tasks they are performing to better understand the cognitive processes used to interact with the UI. However, talk aloud methods are not generally representative of actual use and may be awkward for participants. Moderator probing to elicit feedback “along the way” can generate valuable feedback if participants do not independently talk aloud. Uninterrupted task performance is when the Moderator does not intervene as participants complete a task, which gives more realistic data on user-device interactions. In this method, probing usually occurs after the use scenario has been completed.	Method for eliciting subjective feedback should be based on the objectives of your formative. For example: • Use talk aloud methods when conducting exploratory evaluations, typically early in the design process. • Use probing “along the way” to elicit feedback when observations are noted to help better understand participant thoughts and actions. • Use uninterrupted task performance as you near validation testing and want a more accurate gauge of user performance.
6. Explicit direction to use IFU versus representative use	Moderator either <i>explicitly</i> directs the participant to use the labeling or presents the labeling but does not instruct the participant to use the labeling, which is representative use because a Moderator would not be directing users in the actual use environment.	Method for directing participants to use the IFU should be based on the objectives of your formative. For example: • Direct users to use the IFU when you want to evaluate the effectiveness of the labeling. • Allow users to choose to use the labeling (or not) if you are conducting a pilot test prior to a validation or want to observe representative use where users are not instructed to use any labeling in actual use environments. Some researchers may choose to test the device first without specific instruction to use the IFU, followed by asking the participant to repeat the use scenario(s) while using the IFU. This has the potential to bias participant interaction with the IFU, and may also be inconvenient due to time constraints. A cleaner method would be to conduct a separate, performance-based IFU formative evaluation to demonstrate labeling effectiveness.
7. Introduce problems/device error state or alarms	Introduces problems, alarms or error states on the device user interface to observe how participants respond. For example, can users perceive, interpret and successfully act on (resolve) an alarm without causing harm? Use scenarios should be developed to expose participants to device states (i.e., problems and alerts) that could be otherwise difficult to observe in a simulated study with normal use conditions.	Use when testing critical alarms or alerts that are critical to the safe and effective operation of your device. Note that alarms and alerts that occur infrequently and may not occur during regular use but that are critical to device safety are important to FDA. For example, a critical low battery indicator for an assistive cardiac care device may occur fairly frequently, and an imminent shutdown warning may occur rarely. However, correct responses to both of these alarms are critical to delivering life-saving care and should both be evaluated as part of the UI.

(Continued)

TABLE 11.7 Specific strategies for simulated use formatives.—cont’d

Strategy	Description	When to use
8. Testing both labeling and device	Test performance without Moderator intervention or direction to use the IFU, then ask participants to use labeling for second time through use scenario. When not directed to use the IFU, many participants choose not to use any labeling. This strategy allows sponsors to evaluate the IFU after collecting representative performance data. This approach can bias how participants interact with the device because they have already used it once—the Moderator may not get a clear picture of the effectiveness of labeling, so this is not always an appropriate method.	Can be used when the sponsor wants to test representative use of the device UI (i.e., uninterrupted task performance, not directing the user to use the IFU) but also wants to evaluate the effectiveness of the IFU in the same study. An alternate may be to ask participants to use labeling first if the objective of the formative is to evaluate the labeling.
9. Evaluating different aspects of training	Includes representative training for participants in the formative evaluation using appropriate training materials, training criteria and adequate training/learning decay.	If the sponsor will be providing and managing user training as part of the UI, you can evaluate your training program through a formative evaluation to show effectiveness of training as a risk mitigation. Alternately, sometimes a sponsor will opt to include training and no training arms of the study to demonstrate that training helps mitigate additional risk, but that users are still able to safely and effectively use the device even if training is not provided (as a worst-case scenario).

Participants who are representative intended users should be recruited for simulated use formatives, as the overarching purpose is to observe representative users interact with the device in a simulated and representative use environment. However, using a broader and less specific participant population may be appropriate during early formatives when “rapid insight” testing, or when recruitment of specific participants who are representative of intended users, may be more difficult or time-consuming (e.g., patients who are diagnosed with a rare medical condition). Regardless, care should be taken not to include stakeholders as participants in simulated formatives (e.g., designers, R&D employees, project managers, regulatory, etc.) or to generalize findings to representative users that may not be applicable.

Consider also recruiting user populations with certain characteristics and limitations that could impact device use and may be associated with higher risk for use-related problems (e.g., elderly patients, colorblind, left-handed, patients with comorbidities, etc.). This allows designers to catch any potentially problematic design elements for these users before final design decisions are made.

4.4 Collecting & analyzing data

Formative data collection focuses on both objective (quantitative) performance and subjective (qualitative) feedback. During sessions, a Moderator will take notes in the Moderator and

Notetaker Guide of their observations of potential issues participants have while interacting with a user interface, while a Notetaker (if available) can assist the Moderator by recording all observations of issues as well as successes. The Notetaker will also record subjective feedback provided by participants during the more conceptual discussion sections of the study and will have the opportunity to inform the Moderator of any missed use events that can be subsequently investigated.

There is value in collecting both quantitative (objective) and qualitative (subjective) data for formatives. One builds on the other and can give a bigger picture of the possible issues associated with a device. For example, a participant may tell the Moderator that they really like a specific workflow (qualitative data), yet the Moderator may observe that the participant does not use the device feature correctly during performance of that workflow (quantitative data). The Moderator could then redirect the participant back to that feature and probe for more information on the user's ideas, opinions and beliefs of how it works. Often times the Moderator can show the participant how to use the feature correctly and gain additional insights.

Objective data or quantitative data usually come in two forms: (1) time on task and (2) success rates and error rates. Time on task should be included in testing when there are tasks that have time components associated with successful completion (e.g., injection hold time) as well as tasks that would require quick response times in an emergency situation (e.g., response time for an alarm). It is also helpful to include time on task measurements with the device and with the competitor's device. For simulated use studies, time on task can also be informative for non-emergency tasks to help make the device design more efficient (e.g., time spent navigating a menu structure for a programmable infusion pump). Success rates and error rates on the other hand should always be measured. Recording observed errors helps focus the designers on areas of the user interface that need improvement and offer the opportunity to probe the participant on what would have helped them complete the task without difficulty.

Subjective data or qualitative data can be gathered in two ways: (1) collecting and following up on participant feedback and (2) probing on observed body language that conveys confusion or frustration. Typically, qualitative data include user comments about the device made while participants are interacting with the device or afterward as the Moderator probes on observed issues as well as potential unobserved issues. However, body language or other non-verbal signs should not be ignored. Moderators often observe "confused looks" which should prompt Moderators to ask what the participant is thinking. Other non-verbal cues include folding arms, long sighs and long pauses between actions. All of these cues can mean that there is a struggle with the design of your device that should be explored within the context of the session.

Data collection should be recorded if possible using video cameras placed around the room to capture interaction between participant and device as well as any comments regarding use experience with the device. The research team may also take still photos during the sessions. However, keep in mind that all participants must give consent to be recorded in any manner, which is typically outlined in the informed consent document that all participants must sign before participating in the study. Audio and video capture enables the Moderator to review performance and subjective data if necessary after the formative has been completed. Video data also can provide evidence of study observations for regulatory reviewers and/or members of the design team who may want additional context about use problems, if requested. The data collection and coding for a formative usability test is usually designed to identify potential issues and understand the root causes of those potential issues.

Observed design issues should be captured and documented for further investigation of the root causes.

Interviewing, which probes into root causes, establishes participant awareness of potential issues. Thus, they can explain their expectations of what causes may have contributed to the error occurring and provide opinions on what they would do in real life upon encountering the issue. If the research team observes issues during the formative, it is helpful to compare the subjective feedback from participants against the task analysis and PCA analysis (see Chapter 6) to help determine root causes of issues.

Tips for moderating simulated use formatives

- Take your time; give the participant time to think. Silence is not bad.
- Do not phrase questions that sound accusatory and make the participant feel that it is their fault for use errors (e.g., Ask “How did you know to do that?” instead of “Why did you do that?”).
- Do not ask leading questions (e.g., “When you did x, y, and z, did you use the IFU to help you correct your mistake?”).
- Address the participant as the expert in the room so they feel empowered to share their thoughts and opinions.
- If the participant appears to be getting upset or frustrated, remind the participant that you value their opinion about the device, they are not alone in experiencing difficulty and this type of experience is exactly why the sponsor is bringing in users to improve the device.
- If participant is unaware that an issue occurred, an alternative to explicitly pointing out the issue (and potentially upsetting the participant) may be to request the participant talk through certain steps first. In many cases, the participant self-identifies the issue when using this approach.
- Body language speaks volumes! Be aware of what you are communicating to the participant. For example, use friendly and non-threatening body language (e.g., do not lean back and cross your arms when talking with participants). [Fig. 11.6](#) depicts active listening.
 - Sit or stand comfortably.
 - Make eye contact.
 - Acknowledge the user.
 - Show understanding.
 - Listen actively.



FIG. 11.6 Interviewer who is actively listening to participant. Photo provided by HS Design.

The Moderators and Notetakers can use the following coding examples to categorize their task observations in real-time during study sessions so that data are organized appropriately:

- **Completed (C):** Successful completion of a task without any observed or reported use errors or close calls.
- **Completed with Issues (CI)**
 - **Close Call:** Completion of a task with an observed or reported use error that participant self-corrects or where a participant almost experiences a use error but recovers and completes the task without a use error before causing harm.
 - **Difficulty:** The task was completed by the user, but difficulties were observed or expressed in the process. The user was able to complete the task. Difficulties might be revealed by multiple attempts to perform the task, anecdotal comments about the task's difficulty, or taking longer than expected to perform a task.
- **Did Not Complete (NC):** A task that was not completed, completed incorrectly or required assistance from the Moderator.
- **Not Assessed (X):** A task that was not assessed due to insufficient time in the study or a prerequisite task not being completed. Tasks that are not assessed should be documented in the report but removed from the data set for that particular task when calculating success rates and error rates for each task. For example, if 1 of 8 participants did not have time to complete the final knowledge task question, the performance data tables in the report should indicate that 7 of 8 participants responded to the question. The success rate should then be calculated out of 7 participants instead of 8.
- **Other observations to document:**
 - **Use Error:** User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user, (2) was not caused solely by device failure and (3) did or could result in harm.
 - **UI Elements that Support Participant Performance:** The task was completed by the user with assistance from IFU, online help, quick reference guide, user documentation and/or simulated supervisor or helpline. When the user chooses to use an additional UI element like the ones described above to assist in task completion, the Moderator should document what part of the UI the user is using, how they are using it and whether the user was able to successfully complete the task with the support of the additional UI element. These data should be reported in conjunction with the scoring of "Completion" and "Completion with Issues," depending on the observed performance outcome.
 - **Study Artifact:** Performance that was caused by an aspect of the study environment or study materials, rather than the participant actions or decisions. Artifacts will be removed from the data set (i.e., reduced N for that specific task) when calculating success rates for each task. Examples of study artifacts include: technical issues with the device (e.g., an implantable pump programmer encounters a bug, and menu selection does not display properly), use scenario instructions are not clinically

relevant for the participants (e.g., a doctor states that she would never do tasks a, b, and c because her nurse routinely performs those tasks for the doctor), participant misunderstanding of Moderator instructions (e.g., the participant misunderstands a knowledge task question), and aspects of the use scenarios that may be perceived as artificial tasks from the participant's perspective (e.g., differentiation between similar devices).

Once the study is complete, data analysis begins. Results are compiled into a summary report that includes participant demographic information, as well as the empirical and subjective findings for each task. The specific use issues that occurred for each task are identified, along with the root cause of each issue. Additionally, the major themes of subjective feedback provided by participants regarding each task are identified.

4.5 Documenting the report & recommendations

As noted previously, documentation provides evidence of applied HF throughout the device development and includes all formative studies. The simulated use formative report should note exactly what was done (or reference the testing protocol), what data were collected and analyzed, what the findings were, and what specific mitigations were recommended or implemented as a result. It should link specific design recommendations to data (objective and subjective). For example: A user is supposed to enter 2 into a keypad, but incorrectly enters 23 and comments that the spacing between the keys is too narrow. A recommended design change linked to this task may be to increase the key size and spacing on the keypad, and literature can be referenced to identify key size measurements and layout recommendations that may be appropriate for the user population (see HE75 for specific guidelines on control spacing). If a design modification is warranted based on performance data, propose detailed solutions as appropriate. Document any UI iterations based on study results in the report for later reference, including as the HFE/UE report is drafted and the preliminary analyses are summarized. It is also helpful to describe the user characteristics and demographics data for formative participants, along with detailed root cause analysis (Chapter 13) for all difficulties and use errors.

The bottom line is that while the formative report does not need to be a formalized document, **best practices suggest that a strong report should document everything to provide transparency for the regulatory reviewer as well as a documentation trail for the design team who may need to look back across the history of the design iterations.**

5. Developing recommendations for improved design

Performance data from formatives often lead to recommendations for design modifications that are hypothesized to improve participant performance and reduce or eliminate risk. A residual risk analysis can be completed at the end of a later stage formative evaluation and should assist the sponsor in determining which, if any, modifications should be made to the device UI.

Considerations for design modifications

1. Based on residual risk, should design modifications be implemented?

Determine if one or more device design mitigations are necessary to reduce or eliminate residual risk. In other words, did the sponsor conduct a residual risk analysis on formative findings and determine that the device has not been optimized? Is there a way to further reduce the risk associated with using the device? When residual risk is found to be unacceptable, mitigations should be implemented and validated (even if that means a delay in production or device approval). Risk management options include the following, which are ordered for preference and effectiveness according to [ANSI/AAMI/ISO 14971](#): (1) modify design of device itself; (2) incorporate specific safety measures in the device itself; and (3) include or modify labeling and/or training.

2. Is there traceability? Are design modifications traced to findings from formative evaluations? It is good practice to link design changes with data that suggest the modification is necessary and to avoid arbitrary changes that are not linked to user performance data.

3. Are you prepared for a successful validation study? Have the modifications been tested to verify that the risks were successfully mitigated and new risk was not introduced? Some sponsors choose to test modifications prior to a HF validation study, which minimizes the risk of an unsuccessful validation. Other sponsors choose to proceed straight to the validation study in hopes that the modifications will be shown to be successful in the validation study.

6. Summary

Conducting simulated use formatives is good human factors practice and should be an important consideration during device development. With a relatively small sample size and a wide variety of methods and testing strategies, formatives can inform the design process and help to reduce the overall amount of risk to end users and patients. These evaluations are useful tools for sponsors throughout the development process, and early formatives are highly recommended. Careful documentation of formative evaluations, design features directly linked to performance data and critical task categorization rooted in preliminary analyses findings can help lead to a HF validation study in which the use related safety and effectiveness of your device is successfully optimized and validated as required by FDA. The included references at the end of this chapter provide further information about simulated use formatives.

Acknowledgments

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APPLIED HUMAN FACTORS IN MEDICAL DEVICE DESIGN

Applied Human Factors in Medical Device Design describes the contents of a human factors toolbox with in depth descriptions of both empirical and analytical methodology. The book aims to improve the ability of designers and developers to incorporate human factors principles regarding usability throughout the design development process. It begins with a justification of the importance of incorporating human factors, including a listing of all human factors standards (ANSI/AAMI HE 75, etc.) and agency guidance (FDA, MRHA). It then goes on to explain each method and describes, in detail, why each method is important, the potential impact, when it is ideal to use or not use, and challenges that may occur. Also discussed are the challenges wherein barriers, such as communication breakdowns between users and design teams hindered integrating human factors in medical device design.

Applied Human Factors in Medical Device Design is an excellent reference for Medical device industry professionals in human factors, design, engineering, marketing, quality and regulatory.

Key Features

- Focuses on meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union.
- Explains technology development and the application of human factors throughout the development process in consideration of the healthcare environment.
- Covers IEC, FDA and MHRA regulations.
- Case examples included with each method.

Dr. Mary Beth Privitera, M.Design, FIDSA, is internationally known as an expert in medical product design, specifically in the area of applied human factors. She is a principal at HS- Design, responsible for human factors and research. Additionally, she serves as faculty and co-chair of the Association for the Advancement of Medical Instrumentation's Human Engineering Committee.

Dr. Privitera also holds an appointment as Associate Professor at the University of Cincinnati's Department of Biomedical Engineering and works collaboratively among the Colleges of Medicine, Engineering and Design. She is currently the Co-Founder and Director of the Medical Device Innovation and Entrepreneurship Program. Her previous academic appointments include industrial design and several years in the Department of Emergency Medicine.

She has worked on devices which are intended for use in: orthopedic surgery, trauma, neuro-critical care, drug delivery devices, anesthesia, diabetic care, endovascular neurosurgery, cardiology, general surgery, vascular surgery, wound healing, temperature management and central access devices. She has conducted human factors studies globally and has been an invited lecturer throughout the United States, Cambridge University and Loughborough University in UK. Her current research focuses on applied ergonomics, design research and clinical applications for additive manufacturing processes. She has authored several peer reviewed articles and a book titled "Contextual Inquiry for Medical Device Design," promoting best practices for phase zero medical device development.



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