JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 14, No. 1, January 2018 "Happy Trials to You"

Integrating Human Factors/Usability Engineering and Usability Testing into Medical Device Total Product Life Cycle

By Kathi Durdon

> In 1999, Building a Safer Health System estimated that 44,000 to 98,000 deaths per year were attributed to preventable medical errors. This number was actually low due to underreporting and has since been revised upwards. If we can be responsible and effective in building HFE/UE into our design controls process following quality systems, we can prevent serious incidents and promote quality-driven, user-enhanced product and service design.[1]

TPLC

The total product life cycle (TPLC) of a medical device starts with the concept and continues through the device's "end of life," when the device is no longer in use. Data acquisition throughout TPLC is important because it can:

- Determine whether the user interface is intuitive.
- Identify functions that might cause confusion or frustration.
- Determine whether training documentation leads to correct use.
- Determine whether design changes work as intended.
- Identify and report adverse device effects.
- Determine root causes for any problems.
- Identify improvements for future product versions.

Human Factors Engineering/Usability Engineering (HFE/UE)

HFE/UE promotes the design and manufacture of safe and effective medical devices. To incorporate HFE/UE into a quality system, you must observe, understand and apply product design requirements that facilitate human interaction with technology in varied environments.

According to the FDA, medical device HFE/UE incorporates three major components of the device-user system:[2]

- **Device Users.** Device users include "any and all humans that might handle, operate or interact with the medical device,"[3] including assemblers, clinicians, trainers, family members, caregivers and patients.
- **Device Use Environment.** Medical devices must meet safety and performance requirements in a variety of environments. For instance, an automated external defibrillator (AED) intended for public use must be operated quickly with no prior training. An EKG device might need to travel with a seriously ill patient in an ambulance over rough roads and then transmit its data confidentially over WiFi in a hospital emergency room.
- **Device User Interface.** The device user interface consists of those parts of the device that users see, hear and touch.[4] Therefore, the product development team must consider ambient noise, screen and font size, color, alarms and other factors that affect use.

Usability Testing

The scientific evidence collected during usability testing supports labeling and regulatory submissions, and might be important to hospitals and other customers.

The FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices," discusses usability testing for the following purposes:

- Identify anticipated use-related hazards and initially unanticipated use-related hazards and determine how hazardous use situations occur.
- Develop and apply measures to eliminate or reduce use-related hazards that could result in harm to the patient or the user.
- Demonstrate whether the final device user interface design supports safe and effective use by conducting human factors validation testing.

Because it is very difficult to anticipate all the potential issues that might arise when a device is put in the hands of actual users, usability testing is usually iterative.

Scientific Evidence

The federal regulations that govern usability testing are the same as for any other testing of an investigational product involving human subjects, regardless of whether the subjects are patients, clinicians or assemblers. Examples of the FDA regulations that govern the development of medical devices include:

> **Determination of safety and effectiveness (21 CFR 860.7(e)(1)).** There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.
>
> **Investigational Device Exemptions Scope (21 CFR 812.1).** The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standard, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose.
>
> **IRB review of research (21 CFR 56.109(e)).** An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity.
>
> **Informed consent of human subjects (21 CFR 50.20).** No investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

It is also important to be aware of country-specific approval requirements dependent upon where you plan to sell your medical device/service. For instance, the European Union (EU) requires that, after May 26, 2020, medical device manufacturers must conform to Regulation (EU) 2017/745 and all harmonized standards, including ISO 14971 "Application of Risk Management to Medical Devices." This regulation requires reducing risk to a residual amount and then providing evidence of validation of these risk reduction methods, including usability testing. (See Shortt N, "Regulation (EU) 2017/745, what does it mean for usability testing?" July 5, 2017, Medical Device Usability).[5]

HFE/UE Integration into the Design Control Process

Integrating usability testing into the design control process includes the Design & Development Planning stage, the Design Inputs stage, the Design Outputs stage, and throughout Task and Risk Analysis. (Manufacturers may have differing integration process and naming conventions.)

The Association for the Advancement of Medical Instrumentation (AAMI) Human Factors Committee developed an Activities and Deliverables Map (Appendix 1) as part of the new Technical Information Report 59 (TIR59), "Integrating Human Factors into Design Controls." Appendix 1 presents a staged approach to the HFE/UE integration process from the initial Pre-Design Control stage through Market Release. In the initial stage, you gather information for a new product, such as reviewing a closely comparable (predicate) product that is already on the market. In this stage, you create a preliminary Risk Analysis. As you move into the next stages (Design & Development Planning, Design Inputs and Design Outputs), most often referred to as "Design Controls," you conduct iterative usability testing to refine the user interface requirements. Eventually, you conduct Design Validation to substantiate the risk mitigations and other design improvements that you iteratively developed, as described in the product's Risk Analysis.

Per FDA guidance:[6]

- For both establishing the design input for the user interface and carrying out design verification, manufacturers should conduct human factors activities throughout the design program.
- Design validation should be used to demonstrate that the potential for use error that can lead to patient injury has been minimized. The regulation requires testing the device under actual or simulated use conditions, and requirements do not end when a product is launched.

And as shown in Appendix 1, after the product goes to market, you collect post-market surveillance data to continue to provide inputs to the product's Risk Analysis, which can inform the Design Control process for future improvements to that product.

The FDA Quality System Regulation (21 CFR 820) advises manufacturers to document HFE/UE integration. Therefore, integrating HFE/UE into your Risk Assessment, Design Inputs, Design Outputs, and Good Clinical Practice SOPs and related work instructions is advisable. For instance, you can incorporate the following statements into your SOPs:

Risk Assessment SOP

- This SOP is in compliance with the ISO 14971 ISO standard for the application of risk management to medical devices to identify hazards; estimate and evaluate associated risks through use, assembly and operation of the device; to control risks and monitor effectiveness of controls.
- This SOP is applicable to all stages of the life-cycle of the medical device.

Design Output SOP

- Total finished design output consists of the device, its packaging, labeling and device master record.
- Results of a design effort is reported and reviewed during a product team review meeting at each design stage and at the end of the total design effort.

Good Clinical Practice SOP

- Where human subjects are involved in research, the Clinical Affairs team is involved early in project planning.
- The following GCP SOPs are applicable to HFE/UE process: Determining the Classification of a Medical Device, Protocol Design and Content, Informed

Consent, IRB Submission, Administration of Clinical Investigations, Records and Reports.

Integration of HFE/UE into Design Controls promotes intuitive products that are easy to assemble, easy to work with for the clinician, easy to assess by hospital purchasing organizations, and safe and effective for the patient, surgeon and operator.

"Successful development of safe and usable medical devices and systems requires the application of HFE principles and processes throughout the product design cycle. Doing so can help reduce use error, enhance patient and user safety, improve product usability and efficiency, and enhance user satisfaction."[6]

References

1. "To Err is Human: Building a Safer Health System, Institute of Medicine, Shaping the Future for Health"
2. FDA, Human Factors Considerations
3. IEC 62366-1:2015 "Medical devices – Application of usability engineering to medical devices,"
4. FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices
5. http://medical-device-usability.com/blog/regulation-eu-2017745-of-the-european-parliament-and-of-the-council-what-does-it-mean-for-usability-testing
6. FDA Guidance: Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation

Additional Reading

"To Err is Human: Building a Safer Health System." Institute of Medicine, Committee on Quality of Health Care in America; 2000 Apr 15.

"Crossing the Quality Chasm: A New Health System for the 21st Century." Institute of Medicine, Committee on Quality of Health Care in America; 2001 Aug 19.

Flack M, Reed T, Crowley J, et al. "Identifying, Understanding, and Communicating Medical Device Use Errors: Observations from an FDA Pilot Program." In: Henriksen K, Battles JB, Marks ES, et al., editors. "Advances in Patient Safety: From Research to Implementation (Volume 3: Implementation Issues)." Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb. Available from: https://www.ncbi.nlm.nih.gov/books/NBK20540/

Strochlic A, Wiklund M. "Medical Device Use Error: Focus on the Severity of Harm." MedTech Intelligence; 2016 Nov 10.

Wiklund M, Dwyer A, Davis E. "Medical Device Use Error: Root Cause Analysis." AHRQ PSN

Comstock J. "Nurses say lack of medical device connective interoperability creates medical errors." MobiHealthNews; 2015 Mar 12.

Additional Resources

Standards

ISO 14971: Medical devices – application of risk management to medical devices

IEC 62304: Medical device software – software life cycle processes

ANSI/AAMI HE 75: Human factors engineering – design of medical devices

IEC 60601-1-6: Medical electrical equipment – general requirements for Safety

IEC 62366-1: Medical devices: application of usability engineering to medical devices

ISO 14155: Clinical investigation of medical devices

FDA

CDRH Learn. https://www.fda.gov/Training/CDRHLearn/default.htm

FDA Inspection Guide: Design Controls.
https://www.fda.gov/iceci/inspections/inspectionguides/ucm170251.htm

FDA Inspection Guide: Quality Systems.
http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm

FDA Guidance: Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development.
https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm484345.pdf

FDA: Guidance for Content of Premarket Submissions for Software Contained in Medical Devices
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089593.pdf

FDA: Make Sure the Medical Device You Choose is Designed for You
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/HumanFactors/ucm128206.pdf

FDA Modernization Act of 1997, FDAMA

Human Factors at CDRH – Office of Device Evaluation.
http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/ucm124822.htm

FDA Human Factors Considerations.
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/ucm124829.htm

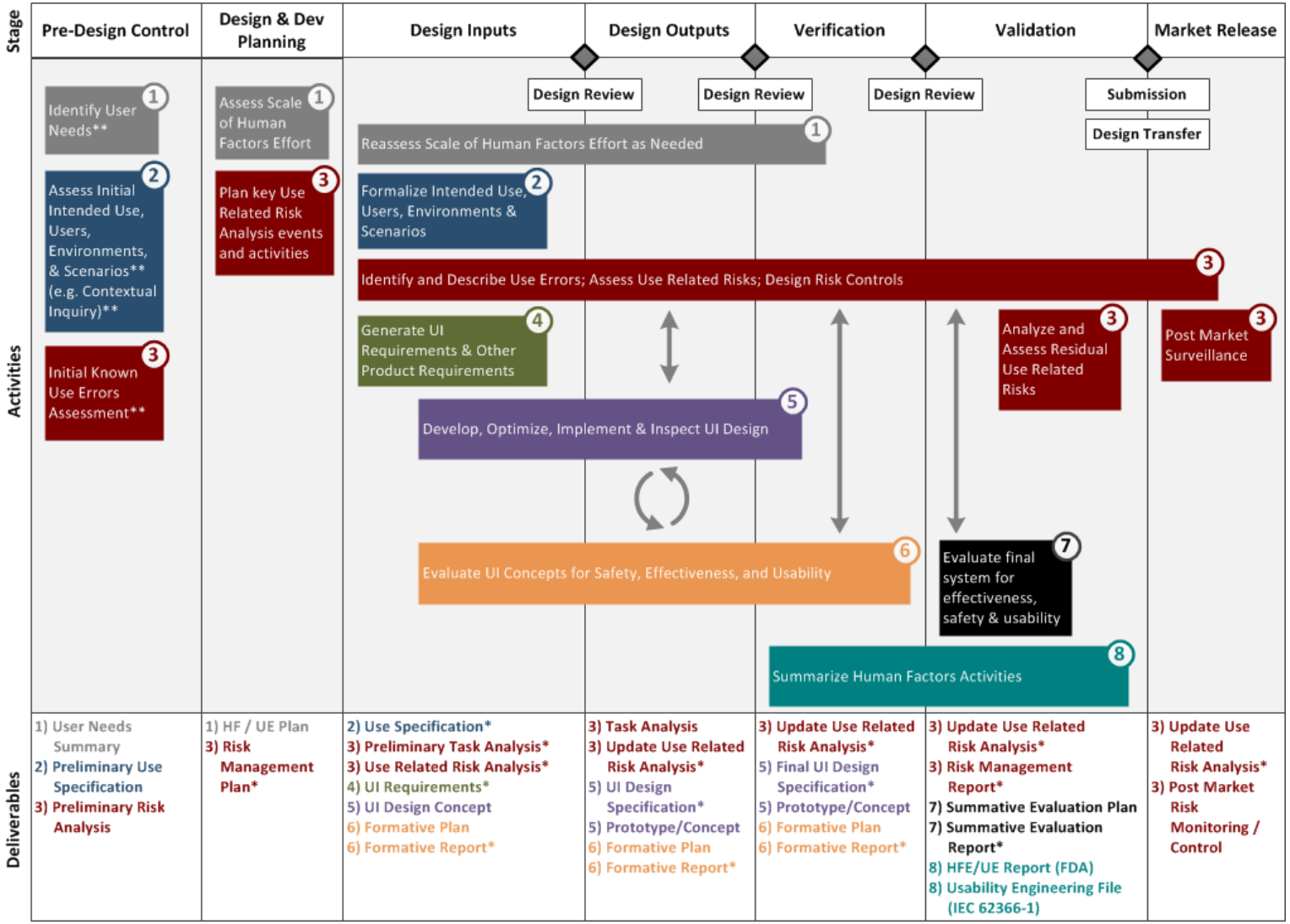
FDA Human Factors and Medical Devices.
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/default.htm

Author

Kathi Durdon, MA, CCRP, is Director of Operations at the CNY Biotech Accelerator. Contact her at durdonk@upstate.edu.

Appendix 1. Design Controls and HFE/UE Activity Mapping

Used with permission. AAMI TIR59:2017 Integrating human factors into design controls



* Items go into the Usability Engineering File per IEC 62366-1 ** These activities are an input to the Design Control process