Transforming Device Development Through Human Factors Engineering

Rigorous human factors testing and iterative product design are critical in the development of medication infusion devices, particularly with the current emphasis on preventing medication errors in the hospital setting. Safety features that are intuitive and easy-to-use can effectively help reduce errors such as underdosing, overdosing, and administering the wrong medication. This article examines how a medical device manufacturer developed a next-generation medication infusion device with superior human factors design by involving users and stakeholders in multiple phases of product development.

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Hospira developed Symbiq in collaboration with clinicians to create an intelligent infusion pump that is simple, intuitive, and easy to use.

Medication errors impact 1.5 million people in the United States per year, according to a 2006 report from the Institute of Medicine of the National Academies (IOM).1 A study published by the *Journal of the American Medical Association* shows that most potential adverse drug events occur at the drug ordering stage and 54% involve administering incorrect intravenous (I.V.) medications.2

The goal of today's infusion device developers is to make smart, ergonomic medical devices that reduce the potential for medication errors and empower clinicians to provide better patient care. The advent of enhanced safety software has the potential to drastically reduce infusion pump programming mistakes. Examples of preventable errors include misplaced decimal points, underdosing, and overdosing. Human factors "misses" also exist such as awkwardly placed buttons, difficult-to-read screens, confusing "screenflow," and ineffective alarms. These issues can make safety solutions cumbersome in a fast-paced, chaotic hospital setting.

In today's high-paced medical environment, it is critical to use human factors engineering to evaluate each new product iteration by extensively testing them with end-users. Incorporating human factors into the design process ultimately makes programming infusion pumps easier for clinicians and safer for patients.

A poorly designed device or hard-to-use software can result in nurses routinely bypassing high-tech safety software on infusion devices when administering I.V. medications. Safety software was designed to add a layer of protection for clinicians, not impede their efforts.

The user interface, which enables clinicians to program the infusion pump, has been the subject of negative commentary for the past 20 years. A few years ago, the IOM challenged medical device manufacturers to more fully utilize a user-centered—or human factors—design in their device development.

As a device developer that has been providing hospital products for over 70 years, Hospira's procedures require human factors testing be performed throughout the development process—from working with end users early on to conducting formal usability studies at the company's Solutions Center—a clinical suite at the infusion device manufacturing plant where customers can view and test products. This commitment ensures that product designs align with best practices, industry benchmarking, and customer needs, and is an integral success factor for the company.

Hospira has been invested in and committed to human factors testing for decades. Symbiq, a next generation infusion pump, represents a quantum leap in ease-of-use and improved patient safety. The pump's user-centered design makes it easier to set up, transport, manage, monitor, and program. This state-of-the-art infusion pump was the first pump designed where nurses can't opt out of using the safety software that is built into the pump and makes the use of advanced safety technology automatic. Symbiq was also tested under rigorous conditions to make sure it could be utilized in various hospital settings.

Before the first design drawings were even prepared, the team was in the field interviewing nurses, anesthesiologists, physicians, hospital administrators, nurse and pharmacy managers, and biomedical engineers. The team members listened carefully to the interviewees' perceptions of existing infusion devices and what they thought was needed to make the ideal infusion pump. Interviews were conducted in the midst of various clinical settings so that the concerns could be observed firsthand. Detailed observations were made with an eye toward understanding user workflow issues. The input was used in the conceptual development phase.

Early in the design process, flow diagrams were created for every potential task performed on the infusion pump. As part of the use-error risk activities, tasks likely to lead to potential medical errors were discovered. These tasks were prioritized first for further scrutiny during the design process. The design team then established performance measures of success for each task (e.g., "90% of experienced nurses will be able to insert a medication cassette the first time with

minimal training”). Finally, clinically experienced nurses were brought in to do hands-on device testing and what worked well for them and what was problematic was carefully noted.

Hospira tested several key user interface features while developing the Symbiq. As a result of clinician feedback, the company redesigned and repeated testing on several features. The development of the following features was among many that involved usability evaluations:

Based on feedback from human factors testing, the design team made a key decision to select a large, 8.4 inch color LCD touch screen display for the pump control. The screen is considerably larger than any other pump on the market and it gave nurses a feeling of access and ease of usability they’d not experienced before. In fact, it provided an at-a-glance view of medication status from up to 12 feet away, under normal circumstances.

Nurses also felt that the rolling screen choices on the first mock-up of the pump were cumbersome, so the screen was revised to mimic the familiarity of an ATM machine with larger fonts and color prompts. The more intuitive LCD display featured a simple layout and touch-activated buttons to help minimize programming errors.

After additional testing, the nurses explained that the screen change was a good enhancement. Using it was intuitive, and they could set and verify dosages quickly and accurately. They even stated that programming the pump felt natural and automatic.

Nurses and other clinicians also flagged the need for more effective alarms, both visual and auditory, to alert them to fault conditions such as entering the wrong medication dosage. Emergency rooms, labor and delivery units, and many other hospital treatment areas are noisy and full of other equipment with competing alarms. To be effective, the team knew that the new pump’s alarm needed to stand out.

To solve this problem, the recommendations of a recently approved international standard for medical device auditory alarms (IEC 60601-1-8:2003) were adopted. Unique melody patterns were used for infusion pumps in order to distinguish them from other devices, such as ventilators and vital signs monitors. The new auditory and visual alarms were installed, and again, nurses were brought in to test them rigorously in clinical conditions. Hospira decided upon the final calibrations for the product based on the nurses’ preferences on a range of efficacy factors.

Advanced features were also incorporated, including the capability for intermittent, delayed start, and multi-step infusions. The interchannel sequencing feature enables channels to be run in any order—a big plus for nurses changing out medications rapidly for critical patients.

The best human factors design evolves as its users evolve. More importantly, device designers must consider all potential users. People and devices can and must work

together to enhance the care-giving experience. This includes involving the design engineers in the human factors activities so they observe users interacting with the device first hand. Hospira's approach to rigorous human factors testing defines a commitment to improving clinician workflow and reducing errors that can serve as an industry example.

Conclusion

In 2006, Hospira was honored with the User-Centered Product Design Award from the Human Factors and Ergonomics Society. This award recognized the many user-defined requirements Hospira incorporated into the Symbiq design. Additionally, the award further illustrates the exceptional value human factors engineering can have during the product design process.

In medical equipment design, the incorporation of human factors principals can help prevent medical errors or even death. In chaotic hospital settings, counter-intuitive devices can be dangerous. It is only through careful listening, extensive testing in usage environments, and maintaining an open mind to user input that device designers succeed in helping to prevent human error rather than compounding it.

References

1 IOM. Preventing Medication Errors. (pre-publication copy) Washington, DC: National Academy Press. 2007.

2 Bates DW, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA*. 2001; 285: 2114-2120.

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