Journal of Diabetes Science and Technology
Volume 6, Issue 2, March 2012

SYMPOSIUM

Introduction to Human Factors

Eric Bergman, Ph.D.

Abstract

This paper provides an introduction to "human factors engineering," an applied science that seeks to optimize usability and safety of systems. Human factors engineering pursues this goal by aligning system design with the perceptual, cognitive, and physical capabilities of users. Human factors issues loom large in the diabetes management domain because patients *and* health care professionals interact with a complex variety of systems, including medical device hardware and software, which are themselves embedded within larger systems of institutions, people, and processes. Usability considerations must be addressed in these systems and devices to ensure safe and effective diabetes management.

J Diabetes Sci Technol 2012;6(2):229-230

Several articles in this issue focus on human factors in diabetes management. While some readers may be familiar with "human factors," the term may be unfamiliar to others. I would like to briefly introduce the field of human factors and its growing importance, in general, to medical device development and, in particular, to diabetes management.

In everyday language, technologies are described as "user friendly" or "intuitive" and, unfortunately, too often as *not* being so. We are all familiar with the frustrations of trying to use technologies that do not match our expectations or confuse us. Health care professionals encounter patients who struggle to understand not simply how to manage their diabetes, but also how to use diabetes management technologies—from technologies as potentially complex as an insulin pump to those as (superficially) simple as a blood glucose meter.

Challenges in use and usability have human factors issues at their core. There are many definitions of human factors—the Human Factors and Ergonomics Society website lists over 20.[1] What all definitions have in common is that human factors focuses on interactions between people and systems (especially, but not exclusively, technology). Sometimes called "usability engineering," human factors in the medical device domain draws from research in perceptual and cognitive psychology and allied fields (e.g., biomechanics) to apply our understanding of human capabilities, expectations, tendencies, and limitations in order to design systems that better meet user needs—to enhance performance and reduce the likelihood of use error.

The Food and Drug Administration (FDA) has noted that, for some medical products, use errors may pose a greater risk to user and/or patient safety than functional failures.

Author Affiliation: LifeScan Inc., Milpitas, California

Abbreviations: (FDA) Food and Drug Administration

Keywords: blood glucose meters, design, diabetes, Food and Drug Administration, insulin pumps, human factors, usability

Corresponding Author: Eric Bergman, Ph.D., LifeScan Inc., 1000 Gibraltar Dr., Milpitas, CA 95035; email address *ebergma1@its.jnj.com*

Notice that the term of art is *use* error, not *user* error. In cases where product usability impacts use, we assume that resulting errors are in some measure a consequence of product design. A "user error" ascribes a problem to the user, but a "use error" simply describes what happened.

Human factors is especially relevant to diabetes, where patients have a greater role in self-management and decision-making than in almost any other medical condition. In the case of devices for patients with diabetes, the user and the patient are typically one and the same. Patients perform *in vitro* testing, interpret test results, and determine dosage of a powerful hormone. If, based on inadequate understanding of the interactions in this system, the patient makes an inappropriate decision or, in some cases, fails to act, the consequences can be significant.

During product design, human factors engineers seek to mitigate risk of use error through multiple means. Human factors domain knowledge enables them to recommend software and hardware design approaches likely to reduce the probability of use error and to evaluate designs for potential pitfalls with respect to use error. In addition, analytical techniques enable human factors engineers to identify tasks and interactions that are likely to challenge users and thus potentially pose a risk.

Perhaps the most powerful tool in human factors engineering is the usability study (sometimes called a "usability test"). In these studies, users are typically asked to perform tasks while interacting with a system in simulated use. Studies are video recorded for analysis of patient behavior. In the realm of diabetes, simulated-use testing could mean having patients use a blood glucose meter to determine a dose of insulin while testing with control solution in place of blood and providing verbal report of desired insulin dose in place of dose administration.

In usability studies, scenarios that would be impossible or unethical to evaluate in actual clinical use can be explored to understand potential for use error. For example, one can ask a pump patient using a bolus calculator to assume that, 1 hour ago, they ate a meal with a given number of carbohydrates but had forgotten to take a mealtime bolus. After providing a (simulated) current blood glucose reading, the patient is asked to calculate a bolus. Now we can explore the question of whether the patient understands that their current blood glucose reading reflects the carbohydrates from that meal or if they "double count" carbohydrates and administer both a meal bolus and a correction bolus. If we identify such challenges in use, then we have the opportunity to design the system to mitigate against them.

While human factors engineering in the medical device domain is necessarily concerned with patient and user safety, it also plays a critical role in driving improvements to overall usability and user experience independent of safety. Medical device companies have an emerging awareness that, just as with an interactive consumer product such as the Apple iPhone, device ease of use and resulting efficiency and satisfaction can significantly impact the success of such devices. In the realm of diabetes management, patients do not want to use meters, pumps, and management software that are difficult to learn and use. The potential benefits for health care providers, with respect to reducing requirements to train and support patients, seem clear.

In June 2011, the FDA released a draft guidance document[2] that outlines the FDA's expectations regarding human factors activities and documentation for medical device manufacturers (see Wilcox and Drucker[3] in this issue). By applying human factors engineering early in product design, it is possible to mitigate the impact of use error by "designing it out." This involves identifying user needs and requirements, understanding user capabilities and constraints, evaluating prototypes, and providing continuous input to the design. In this way, human factors engineering contributes to the increasing usability and safety of medical devices, in general, and of products for people with diabetes, in particular.

References:

1. Human Factors and Ergonomics Society. Definitions of human factors and ergonomics. http://www.hfes.org/Web/EducationalResources/HFEdefinitionsmain.html.
2. Food and Drug Administration. Draft guidance for industry and Food and Drug Administration staff - applying human factors and usability engineering to optimize medical device design. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm.
3. Wilcox, Drucker. Implications of the new FDA draft guidance on human factors engineering for diabetes device manufacturers. J Diabetes Sci Technol. 2012;6(2):231–5.