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Medical Evolution

FATHER OF ID ■ SMART TO WISE ■ NEW DIRECTIVES


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THE BENEFITS OF APPLYING HUMAN FACTORS ENGINEERING

Is the awakening over? Has the medical industry finally come to embrace the benefits of human factors engineering, arguably decades after the aviation, military and consumer product industries did so? Let's give the medical industry the benefit of the doubt and say *yes*.

Although for many years now industrial designers have been included in the product development team for medical devices, as recently as the early 2000s only a small proportion of medical companies had really embraced human factors engineering. Those that had did so primarily to give them a competitive advantage in the market, as opposed to meeting safety goals, per se. Today, however, medical device manufacturers are doing a reasonable job of integrating human factors engineering into their design processes. A key motivating force has been FDA regulations calling for devices to meet users' needs, as well as a slowly increasing level of agency oversight and enforcement. Regulatory agencies and surrogates (for example, notified bodies in the European Union) in many other nations have followed suit.

However, an unintended consequence of this situation is that a large proportion of medical companies now seem to view human factors engineering primarily as a regulatory imperative tightly linked to risk management rather than to product development. They perform human factors engineering with the goal of controlling risk so that they have a safer device and can obtain regulatory clearance to put it on the market. This means that regulatory affairs and quality management, rather than product development professionals, often control the plans and budgets for human factors engineering, resulting in a disruption of what we take to be the natural state of affairs: the integration of human factors engineering with industrial design. Oddly, there appears to be little discussion about how human factors engineers can work with industrial designers to improve a device's usability and competitiveness in the market, as well as to meet safety and regulatory goals.

We propose that medical device manufacturers should now consider a return (or, we could call it a progressive step) toward a middle ground where human factors engineering in conjunction with industrial design is applied to address both regulatory and commercial imperatives. This is likely to be the place where companies can make strides toward increased user satisfaction and profit while maintaining protection against what can feel like a disaster: a regulator rejecting their product.

The readers of INNOVATION are likely to be well informed about what constitutes good human factors engineering. If not, tutorial resources include the FDA's own Human Factors Guidance to medical device manufacturers, standards published by the Association for the Advancement of Medical Instrumentation and the International Electrotechnical Commission (IEC), and multiple textbooks on the subject. So this article dispenses with further tutorial content except to summarize that good human factors engineering involves three imperatives: learning about users; establishing proper user-interface requirements and applying human factors engineering design principles to produce good user interfaces; and conducting iterative studies of users interacting with preliminary, refined and final designs to confirm their safety, effectiveness and usability. Oh, and may we add

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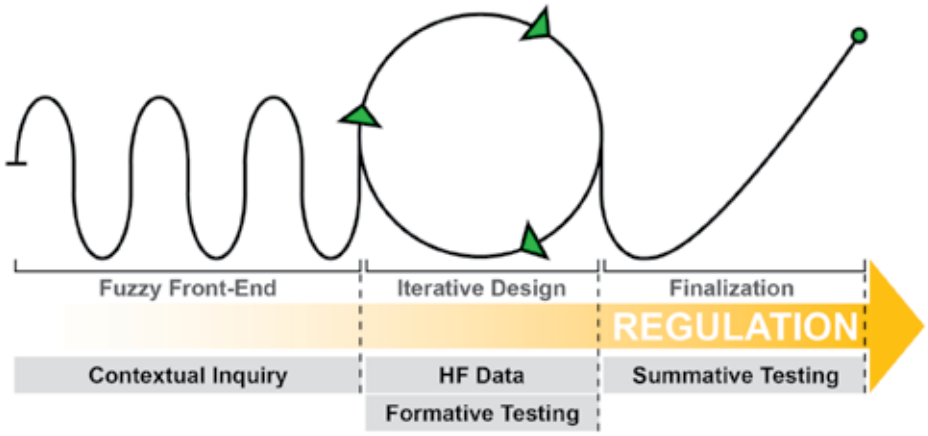


a fourth: confirming that users can interact with a device in a satisfying manner.

The fourth objective is the key to moving back toward a middle ground where commercial imperatives receive their due. Accordingly, the balance of this article discusses how manufacturers can fine-tune their human factors engineering processes so that they are not just about fulfilling the requirements of FDA's guidance, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 2011*, or IEC's broadly-applied human factors engineering standard ISO/IEC 62366:2007, *Medical Devices – Application of Usability Engineering to Medical Devices*.

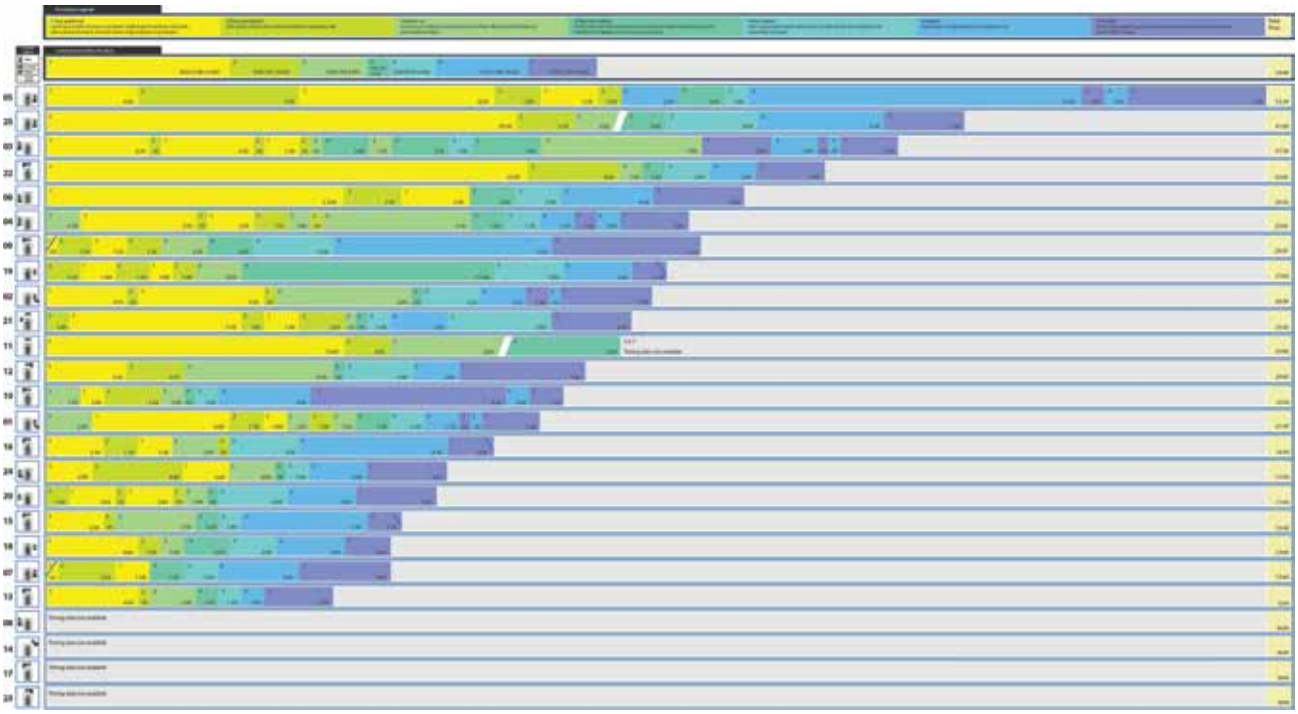
In our view, achieving design excellence for a medical device's user interface requires gathering accurate information about users and how they might ideally interact with the given device. It also requires bringing users and evolving design solutions together on a sufficiently frequent basis to keep a device's design moving in the right direction. Thus, for the remainder of this article we will discuss a couple of our pet topics—ethnographic research and usability testing—providing an update on how these well-established techniques are still having an impact on design. Companies that master these techniques and engage competent designers are sure to produce medical devices that rise above others, delivering on the promise of safety, effectiveness, usability and user satisfaction.

Ethnographic Research

The figure above provides a fairly abstract summary of where ethnographic research and usability testing (as well as the application of technical human factors information) fit into medical product development. We take the term *contextual inquiry* to be equivalent to ethnographic research and have used the former in the figure because it is what tends to be used in the relevant standards and guidelines. The point of the figure is that the regulatory imperatives increase as the product development process advances toward completion. Moving from left to right, ethnographic research is not required, strictly speaking, but is encouraged by both the IEC standard 62366:2007 and by the FDA Guidance mentioned previously. Also, iterative formative testing is not strictly required. However, speaking from experience, a Design History File (documentation required by the FDA) that does not show evidence of formative testing raises a red flag among regulators. It suggests that the manufacturer has not applied human factors engineering in an appropriately comprehensive manner. Summative testing, on the other hand, is a hard requirement.

The Role of Human Factors in Medical Device Development

One consequence of placing disproportionate emphasis on the regulatory aspects of human factors engineering is a concomitant reduction of resources applied to ethnographic research in favor of more resources applied, particularly, to summative testing. We think this is a mistake. The purpose of ethnographic research (and its methodological cousins) is to create a foundation of information about the real world of product use. Without this foundation, the design team is at risk of doing a brilliant job of solving the wrong problems because of misconceptions regarding what ethnographic



Information graphic applied to the use of a surgical kit

research is designed to illuminate: who the users are, what the environment of use is and what procedures a given device will be subjected to. In fact, this plays out later, vis-à-vis regulation, because the summative testing that is ultimately done will have to be defended to the notified bodies, including the FDA, as realistic—realistic in the choice of participants, realistic in the use environments that are simulated and realistic in the tasks that participants are given to perform. Without direct evidence of what goes on in the real world, it can be difficult to defend these choices.

Another, sometimes overlooked, role of ethnographic research is to establish accord among the design team. Without a body of valid evidence to refer to, the team is vulnerable to the expert who has veto power over its ideas by virtue of the expert being the only one with knowledge of actual use. The team is also vulnerable to the gridlock that can result from staying in the realm of opinion rather than the realm of evidence. **Without solid evidence about users, use environments and actual procedures to drive design decisions, the design process can be slowed by endless debates resulting from the fact that everyone, inevitably, has an opinion.** Thus, good evidence can speed product development by providing a way out of this opinion-based gridlock.

We do not have space here to go into great detail regarding the conduct of ethnographic research, but let us provide some advice regarding what we have found useful in the context of medical device development:

- Document the research using high-resolution multichannel video. The complexity typically associated with the use of medical devices and the need to capture the

details puts a particular premium on high-quality video. On the one hand, close-ups of clinical details are often important; on the other hand, it is usually necessary to understand what each member of a multiperson team is doing. It follows that the video system must be able to accurately capture fine details as well as multiple actors—the case for both high-resolution and multiple cameras.

- Analyze the video to achieve rigor for the research. The results of ethnographic research are typically reported in an anecdotal fashion. This approach may not be adequate for the life-and-death nature of medical device development. Video analysis can yield quantitative data crucial for a full understanding of the key issues, for example detailed timing of key events and frequency counts of errors or problems. Such data do not replace the user-centered insights that are the hallmark of ethnographic research, but can serve as an important supplement to them.

- Use information graphics to report the research. Given the complexity of the phenomena captured, graphic approaches to summarizing the information can be necessary to make that information accessible. Creating tools for visualizing information is another role that the designer can play in medical device development.

  The image on the left provides an example. Each row represents an actual use of a multipart surgical kit, with each item of the kit represented by a different color and the transition through the rainbow from yellow to purple (summarized at the top) representing "correct" use. Time is represented on the horizontal axis. Thus, at a glance, one can see that there is a good deal of variation in the timing of kit use and that there are several departures from the expected procedure—items of the kit are used in a variety or orders.

- Use videoconferencing for home-healthcare projects. For example, for chronic diseases such as diabetes or renal failure (of increasing importance for medical device developers), it is not necessarily efficient to spend all day at a patient's home waiting for the periodic events of interest to occur. Setting up videoconferencing for indirect observation can, thus, be a reasonable compromise between relying solely on interviews and direct observation.

In sum, ethnographic research is important for medical device development, and it requires tools and methods that may not typically be used for such research outside of the medical area.

Usability Testing

Is there anything new to be said about usability testing that is not covered—and then covered again and again—by the literature? We believe so. It is about conducting usability tests in a manner that covers the regulatory bases without forsaking product commercialization benefits, maintaining them as a tool for the design team, not just the regulatory professionals.

We advise medical device manufacturers to design their formative usability tests—those conducted while a device is in the flexible development stage—to generate the maximum amount of insight possible about the user experience. We recommend strongly against making such tests just about safety issues and the basic ability of users to complete tasks.

We offer the above advice because a safe and effective device might still be rejected by the market. After all, plenty of safe and effective devices are selling poorly; they would not be on the market if regulators had not deemed them so. They are probably selling poorly for many reasons (such as high price, poor service, missing features), but a crucial one might be poor usability compared to competitive offerings. Noting that usability is a high priority for medical device users, devices with poor usability certainly can languish.

A properly designed formative usability test may be a company's salvation. Here is a checklist to be sure that a formative test serves the multiple goals it can and should serve:

- Focus on frequent and critical user interactions with the device. Call upon users to perform tasks that will have a disproportionately large influence on their ability to use the device for its intended purpose, certainly in a safe and effective manner, but also with satisfaction. It

A scene from a test conducted in UL,-Wiklund's medical usability test lab.

is OK to ask users to perform tasks that are not safety-related. You are testing for your own company's sake, not just to satisfy the regulators.

- Call upon test participants to state what they like most and least about the device and ask for detailed suggestions on how to improve the device. This is not biasing the test participant, and it fits right in with the goal of identifying opportunities for product improvement while there is still time. Remember that formative usability testing is not nearly as constrained as summative usability testing, which manufacturers perform to validate a design and support a regulatory submission.

- Go so far as to ask participants to compare the tested device to their vision of the ideal device, which might be quite similar or different from that presented. Also step back and ask them to compare the device to its contemporaries already on the market. You might learn that your device represents a great leap forward in usability, or that it is not much of a step forward and needs work.

- Consider conducting larger than usual formative usability tests if the user population is particularly heterogeneous such that you expect a wide range of user characteristics and manners of device use. Conventional wisdom and common practice suggests that eight to 12 test participants might be sufficient to gain deep insight into a device's interactive performance. But a larger test might be the solution to gaining more nuanced and beneficial insights into how to optimize the device's user interface. And, in what might seem antithetical to common practice, the greatest benefit from usability testing might occur at an earlier stage of design, when things can be changed for a reasonable cost. Alternatively, think about conducting many—perhaps a half dozen or more—small formative usability tests en route to the best possible user interface design and resulting user experience.

To be sure, we are not advocating a departure from using formative usability tests to achieve safe and effective design solutions, which is the most important among human factors engineering imperatives. However, there is every reason to derive broader benefit by also focusing on non-safety-related design matters.

A Fuller Vision

Our main point is that if you must do a rigorous job of human factors engineering to satisfy safety and regulatory requirements anyway, why not also apply human factors engineering in a manner that will lead to products that people love? We fear that the last few years have led to the partial or full displacement of human factors engineering from product development in favor of regulatory affairs and quality control. We certainly do not object to the new focus on medical device risk. But let's get back to applying human factors engineering to enhance the user experience as well as make medical devices safer. This will afford greater opportunity for industrial designers and human factors engineers to work collaboratively to create great products that deliver great user experiences. ■