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SYMPOSIUM

# Implications of the New Food and Drug Administration Draft Guidance on Human Factors Engineering for Diabetes Device Manufacturers

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## Abstract

This article discusses the implications of the new Food and Drug Administration's draft guidance on human factors and usability engineering for the development of diabetes-related devices. Important considerations include the challenge of identifying users, when the user population is so dramatically broad, and the challenge of identifying use environments when the same can be said for use environments. Another important consideration is that diabetes-related devices, unlike many other medical devices, are used constantly as part of the user's lifestyle—adding complexity to the focus on human factors and ease of use emphasized by the draft guidance.

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## Introduction

The Food and Drug Administration (FDA) recently released draft guidance for applying human factors engineering and usability engineering (HFE/UE) to medical device design.[1] When finalized, it will supersede its 11-year-old predecessor, *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (2000)*. However, even before finalization, it serves as a good indication of the FDA's current thinking.

By creating the new guidance document, the FDA has indicated its commitment to including HFE/UE as a required component of device development. Among other things, this draft guidance[1] reflects FDA's ongoing commitment to ensuring that HFE/UE work is done in a manner that is systematic and documented. The notion conveyed by the draft guidance is that HFE/UE should be as integral to the device development process as any other design issue that designers and engineers struggle with.

The draft guidance[1] describes a best-practices methodology (really best-practices *methodologies*). An important point about this methodology is that it (and that described in other FDA-recognized standards, such as ANSI/AAMI/IEC 62366:2007, *Medical Devices—Application of Usability Engineering to Medical Devices*) should be followed from the beginning. Trying to retrofit a device development

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**Abbreviations:** (FDA) Food and Drug Administration, (HFE/UE) human factors engineering and usability engineering

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program with a sound HFE/UE methodology after the fact is awkward, difficult, and likely to require costly and time-consuming changes. On the other hand, if a manufacturer can show that proper processes have been followed from the beginning, we predict that the FDA (as well as Notified Bodies, such as TÜV SÜD for the European market) is less likely to call the results of those processes into question.

The draft guidance[1] lays out a vision of what is expected, vis-a-vis HFE/UE, for any device developer who intends to seek FDA approval. After some introductory sections, in which the Draft Guidance clearly states that the focus is upon *safety*, it lays out a process for minimizing use error and the associated risk to patients and others, as is summarized in **Figure 1**. As the figure shows, the idea is to begin by using various analytical methods to understand users and use environments, then to design the user interface of a device in a cyclical fashion, using risk analysis and formative evaluation (which, in turn, is informed by risk analysis) to identify use-related hazards and applying risk mitigation strategies, as needed, until the hazards have been eliminated to the extent that it is feasible to do so.

Thus, sections 5–11 of the draft guidance[1] contain the following information:

1. Section 5 describes the analysis of users, use environments, and user interfaces, which analyzes the logically necessary precursors to address the safety of a to-be-developed device.

2. Section 6 then describes a number of different analytical methods that might be used for "understanding use-related hazards"—methods, such as interviews and "task analysis," that are typically applied relatively early in the device design process.

3. Section 7 goes on to describe formative evaluations, i.e., empirical user testing of prototypes and simulations that are performed to identify and address problems as part of the design process.

4. Section 8 covers "mitigation and control of hazards."

5. Section 9 briefly describes design verification, the process of confirming that the requirements are met.

6. Section 10 covers "validation testing." This is the final "summative testing" that is required to demonstrate that the final design is adequately safe and free of use error.

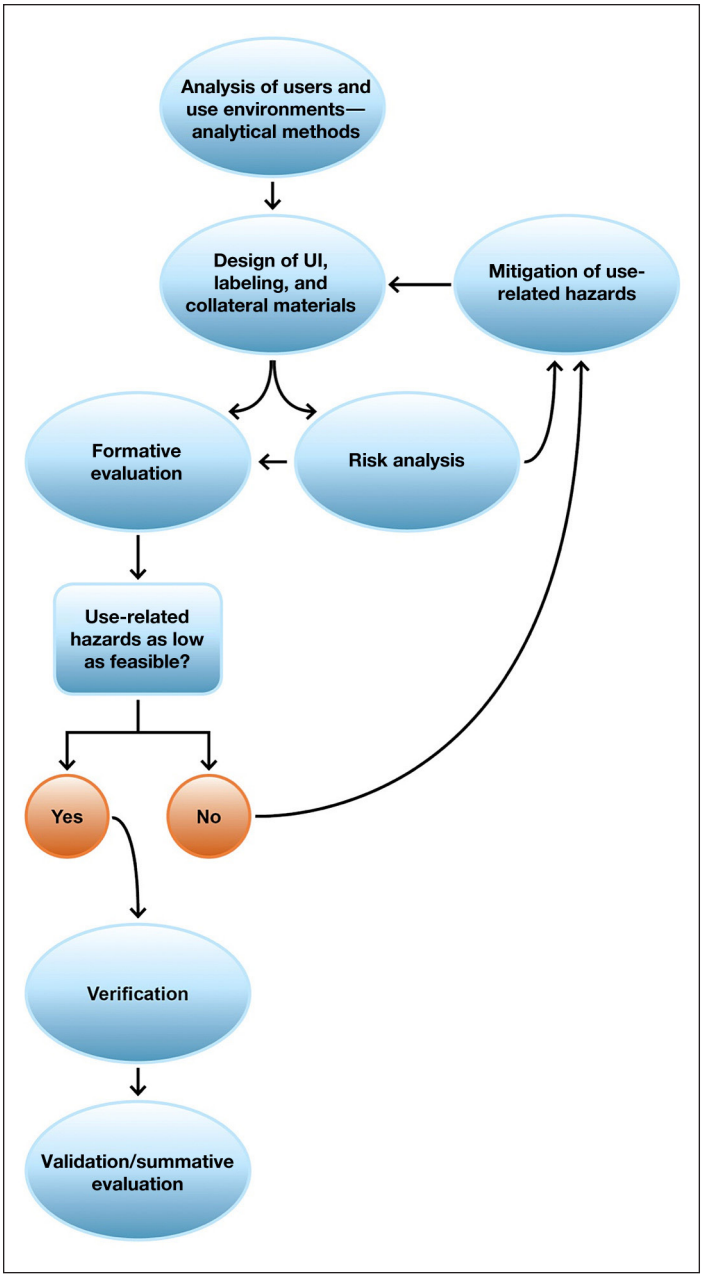


**Figure 1.** Overview of the process described in the new FDA Draft Guidance.[1]

7. Section 11 provides guidance for documenting the process.

Then, after a brief concluding section, the draft guidance[1] provides three useful appendices—a detailed outline for creating a "HFE/UE Report," some guidance for choosing sample sizes for studies, and references.

What follows is a summary of some key issues related to this draft guidance that, we believe, are particularly relevant for those who develop diabetes-related devices.

We have not attempted to provide an exhaustive discussion of this draft guidance, since the document speaks for itself, but highlight a few key points.

## Users

The consideration of device users is central to the draft guidance.[1] As it points out

> Individuals in the intended user populations should be able to use medical devices safely and effectively and without unintentionally making errors that could compromise positive outcomes…. The ability of a user to operate a medical device depends on his or her personal characteristics (Section 5.1).[1]

It goes on to list 14 different types of characteristics, from "physical size, strength, and stamina" to "willingness and motivation to use a new device." Also, it specifically mentions diabetes:

> For example, people with diabetes often have some degree of retinopathy…which causes impaired eyesight" (Section 5.1).[1]

From these considerations follows a requirement:

> You should evaluate and understand essential characteristics of all intended user groups and describe them for the purpose of HFE/UE evaluation and design activities (Section 5.1).[1]

In the case of, say, a surgical instrument, "all intended user groups" may be relatively easy to define. And, of course, there are some diabetes-related devices that are akin to surgical instruments in that they are used (we hope) exclusively by medical professionals. However, because many diabetes-related devices are used by the patients themselves, HFE/UE practices have to consider an extremely wide range of user types. Diabetes is a microcosm of the world, affecting all ages, races, educational backgrounds, and cultures. And, by its very nature, many of those with diabetes have various disabilities, from visual deficits to difficulties with dexterity.

On the other hand, those involved in device development most likely are living in one of the large developed countries, well educated, and relatively free of disabilities. A general principle of HFE/UE is that, everything else being equal, it is more difficult to do HFE/UE to the extent that the users of a device will be different in culture, experience, and/or physical and cognitive abilities from those who develop the device. Thus, the wide variety of target populations to be considered can make it challenging to identify the sort of use errors to be expected—a particular focus of FDA. Even the most careful analytical methods (e.g., failure modes and effects analysis or the various forms of task analysis) may not be adequate to predict what will actually unfold in practice.

As one simple example, the typical engineer or industrial designer is highly familiar and comfortable with menu-based systems. However, menu-based systems may be quite foreign to an elderly meter user in a developing country. Such a user may have no natural intuitive understanding of basic user interface metaphors, such as arrows, or conventions like scrolling text, which include offscreen elements, or hierarchically organized menus. Labeling is not an adequate mitigation strategy when users cannot read a written language or, because of their retinopathy, cannot adequately see the text in the first place.

In sum, the requirement in the draft guidance to "evaluate and understand essential characteristics of all intended user groups" can be particularly challenging for diabetes-related devices. It follows that many of the specific methods listed in the draft guidance for understanding users are particularly important and need to be applied creatively.[1] For example

1. Contextual inquiry (Section 6.2.1)[1]

   > The Draft Guidance describes contextual inquiry as a method of assessing user–device interactions in their naturally occurring contexts. The method generally involves a researcher observing and interviewing users while they use a device as they normally would.

   For a diabetes-related device, it is logically necessary to conduct contextual enquiry with the range of users that reflects the expected population of actual device users—i.e., observing a range of "real worlds" and (as discussed later), a range of use environments.

2. Interviews and focus groups (Section 6.2.2)[1]

   As with contextual enquiry, working on a diabetes-related device logically expands the range of people to be included in methods such as interviews.

3. Expert methods

> The other specific methods listed in the draft guidance—*function and task analysis* (Section 6.2.3), *heuristic analysis* (Section 6.2.4), and *expert review* (Section 6.2.5)—require one or more members of the device development team to predict the errors made by users, as discussed earlier, a challenging requirement when users vary widely and are not particularly similar to those doing the predicting.[1]

The implication of the aforementioned challenge is that for most diabetes-related devices, the burden of addressing users may be particularly high. It is especially important to study users directly and to include a range of user types in these studies to reflect the range of to-be-expected users.

## Use Environments

Another central focus of the draft guidance is on the *environments* in which devices are used, as the following passages indicate:

> To understand use-related hazards, it is necessary to have an accurate understanding of how a device will be used (Section 3).[1]

> The environments in which medical devices are used may present a range of complexities…. Non-clinical environments can present additional challenges (Section 5.2).[1]

The document goes on to mention nine examples of challenging environments, from "Carpeting or stairs [that] make it hard to move medical devices around the space" to "Electromagnetic interference from other equipment…"[1]

As with the consideration of device users, the challenge for diabetes-related devices regarding environments of use is that those environments can vary through a wide range, including the absence of climate control or electricity (which characterizes the majority of households worldwide), extreme temperatures, rain, dust and dirt, bright sun, noise, etc.

It follows that a representative range of environments should be studied in order to have an accurate understanding of how a device will be used. An advantage of contextual enquiry, discussed earlier, is that, unlike interviews and focus groups, it allows for the study of the environment of use as well as the study of users. However, if a product is to be used worldwide, this suggests that contextual enquiry should also be conducted worldwide, a potentially daunting burden, although, of course, FDA's purview only includes the United States.

## Conclusions

The wide range of users and use environments to be expected for diabetes-related devices makes the application of the new FDA HFE/UE draft guidance particularly challenging. In practice, the burden it puts on device developers to address expected users and use environments means that a wide range of users and use environments should, logically, be included in the mandated research—in initial research such as contextual enquiry and in user verification and validation testing of prototypes and/or the final device (described in draft guidance sections 9 and 10[1]). The range of users and use environments tends to make it less possible to rely exclusively on purely analytic methods that depend upon the judgment of experts in place of direct study of device users.

In the case of diabetes-related products, staying in the climate-controlled lab may not be adequate.

On the other hand, it typically makes sense to address the user characteristics that we know are associated with diabetes, for example, by incorporating:

1. Large, clear, and easy-to-read displays with a minimum of ambiguity.
2. Well-separated buttons.
3. Multisensory feedback (e.g., tactile, as well as visual and auditory).
4. Simplicity of operation, especially for commonly used or critical functions.
5. Unobtrusive appearance.

Finally, let us not forget that diabetes-related devices are used constantly as part of a daily lifestyle, which has both benefits and drawbacks, as summarized in **Table 1**.

These factors can add another complicated dimension to the HFE/UE process when developing a diabetes-related device.

**Table 1.**
**Summary of the Advantages and Disadvantages of Using a Device Constantly**

| Advantages | Disadvantages |
|---|---|
| Common tasks are highly practiced. | Infrequent messages or mistakes can be easy to overlook, because patients might see what they expect to see. |
| Use becomes an integral part of life, with patients forming a close relationship with their devices. | Minor user interface rough spots can become a major annoyance when multiplied by hundreds or thousands of repetitions. |
| Tasks are well learned, to the point of becoming unconscious. | Patients may be overconfident and skip steps when possible, or circumvent safety features. |
| Tasks become part of the user's routine, which can help minimize environmental variability for some. | Use in an unfamiliar environment may be very difficult if they are unaccustomed to it. |

**Acknowledgements:**

We acknowledge the faculty of the AAMI Human Factors Course for providing an earlier version of **Figure 1**. However, we have made minor alterations in the logic provided in their original version, so that they should not be held responsible for any conceptual errors that might be in **Figure 1**.

**Disclosures:**

Design Science is a consultancy that focuses on the usability of medical devices, including diabetes-related devices.

**References:**

1. 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; 2011.