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Context

Computerized Systems used in Healthcare have an impact on safety of public health, in fact on "Life" itself. Computerized Systems include information systems and/or devices. Such systems should recognize when things are not going well or malfunctioning. To do so, they should be diligently designed by humans in the systems development phase, and pragmatically used by users in the systems use phase. There is at least one major benefit in having humans intimately involved with computerized systems in this context: Humans often notice little things that may or may not mean anything. This term paper research will identify the ergonomic interventions in the design and use of Computerized Drug Dosing Systems with focus on "Humans as Assets". Computerized dosing system is more appropriately a decision support system for the clinical investigators in the research clinic of the pharmaceutical firm. Such systems have potential to drive reminders, provide alerts for prescribing interactions or test results, interpret complex investigations (interface with instruments to produce medical reports), aid diagnosis, and calculate drug doses. The user of the system in this context is the physician (with the end impact on the patient). So much depends on the physician/nurse (and the human factors) in using the system to treat the patient and make clinical decisions. In fact, in Phase I clinical trials the physicians deal with healthy volunteers. Developers/ Designers/Validation analysts work very closely with the users in the development, release and use of such systems. Such systems have so much potential in improving the quality of primary healthcare. *Computerized System*, in this context, means software/user interface and device.

The Problem

Hazards arise in the use of computerized system due to the inherent risk of medical treatment, from system failures (or malfunctions), and from system use. Hazards resulting from such a system impact patients, family members, and professional clinical investigators. This paper addresses hazards resulting from interactions between users and computerized systems. It does not focus on hazards inherent to medical treatment or caused by system failure. An Institute of Medicine report released in November 1999 estimates that as many as 98,000 people die in any given year from medical errors that occur in hospitals, which is more than the number who die from motor vehicle accidents, breast cancer, or AIDS. Though many of these errors are not related directly to the use of computerized systems, some are, and the importance of incorporating HFE principles into system design to reduce system related medical errors is critical. Use-related hazards occur for one or more of the following reasons:

- Systems are used in ways that were not anticipated,
- Systems are used in ways that were anticipated, but inadequately controlled for,
- System use requires physical, or cognitive abilities that exceed those of the user,
- System use is inconsistent with user's expectations or intuition about system operation,
- The use environment (see Figure 1) effects system operation and this effect is not understood by the user.

Possible Solution Approach – Humans as Assets

Safe, effective, or unsafe, ineffective use of computerized system is determined by the following major components of the system: (1) Use Environments, (2) User Characteristics, and (3) System User Interface Characteristics. This interaction and its possible results is depicted Figure 1.

1. System Use Environments

Use environments for systems can vary widely and can have major impacts on system use and use-related hazards. The amount of thinking and concentration a person exerts while using a system is called *mental workload*. The mental workload imposed on users by the environment in which they use systems can exceed their abilities to use systems properly. For instance, in a research clinic, there could be too many alarms on different systems for a physician/nurse to be able to identify the source of any single alarm. Mental workload is often used synonymously with mental "stress". There can be a physical component to workload associated with system use (*physical workload*) that also adds to the stress experienced by the user. Under high stress levels, the user is distracted and will have less time to make decisions, consider system outputs, follow complex operating logic, or physically manipulate system/device controls. Systems that can be used safely under conditions of low stress (i.e., low workload) could be difficult or dangerous to use under conditions of high stress.

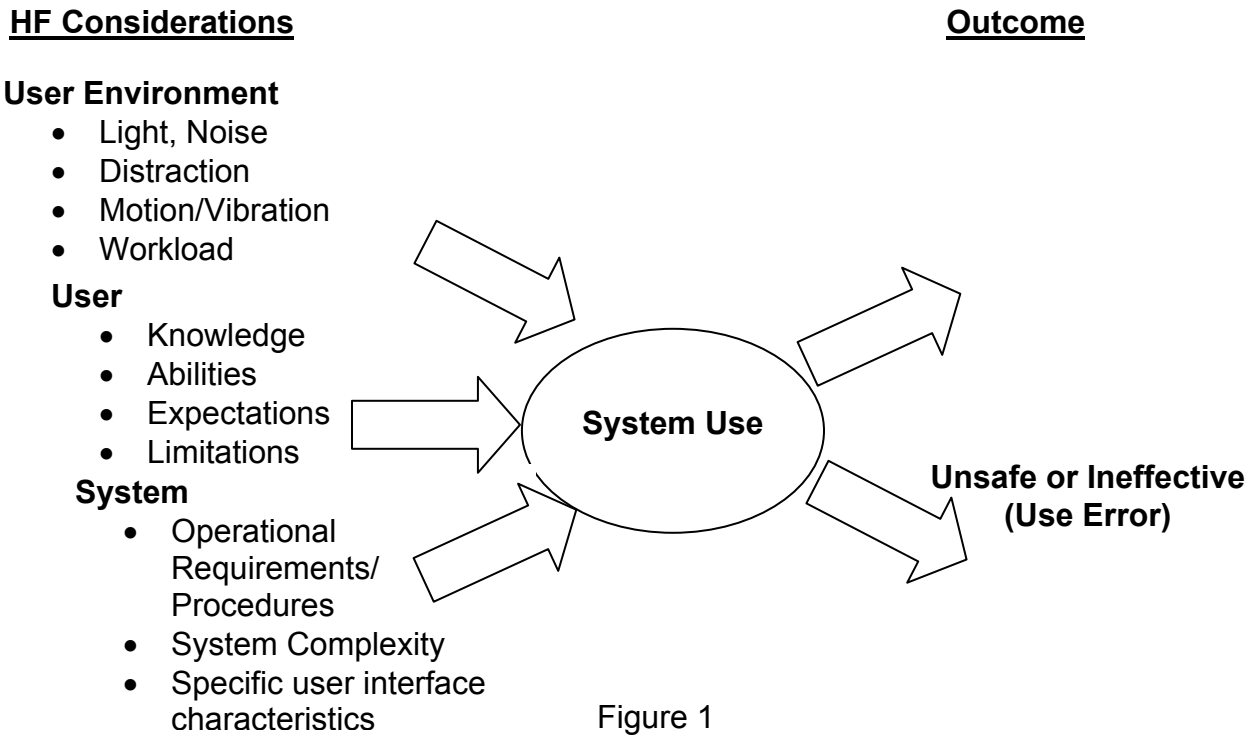

Figure 1

Use environments can also limit the effectiveness of visual and auditory displays (lighted indicators, auditory alarms and other signals) if they are not designed appropriately. If the users cannot understand critically important information, errors are

likely. For system used in noisy environments, the user might not be able to notice alarms if they are not sufficiently loud or distinctive. When multiple alarms occur for different systems or on the same system, the user could fail to notice them or to make important distinctions among them. Similarly, motion and vibration can affect the degree to which people are able to perform fine physical manipulations such as typing on the keyboard portion of a system. Motion and vibration can also affect the ability of users to read displayed information.

Important considerations for displays (including visual alarm indicators) and system/ device labeling include ambient light levels, viewing angles, and the presence of other systems/devices in the use environment. If the system will be used in low light conditions, display scales or system/device status indicators might not be clear to the user. Some scales will be read inaccurately when viewed from an angle due to parallax or because part of the display is blocked. Other display information can be lost under brightly lit conditions due to insufficient contrast. When certain types of equipment are used in close proximity with other systems/devices, it could be difficult for users to associate visual displays and auditory signals with the corresponding equipment. With too much distraction, important information could be missed.

2. System/Device Users

A system that is easy for one person to use safely and effectively might present problems for another person. Similarly, a system that is easy for a certain group of users to use safely and effectively could be difficult for another group. Users need systems that they can use safely and effectively. To assure that these needs are met, it is necessary to understand abilities and limitations of the intended users. It is convenient to refer to the group of users who use a given system as its *user population.* It is then helpful to describe the user population with respect to the abilities and limitations of its members. For any system/device, the abilities and limitations of the user population might be relatively uniform. On the other hand, the user population might contain sub-components that have significantly different abilities. Examples are young and old users, or remote clinical research administrators and professional clinical investigators (physician/nurse). Fatigue, stress, medication, or other temporary mental or physical conditions can temporarily affect ability levels of system users.

Important characteristics of user populations include:

- General health and mental state (stressed, relaxed, rested, tired, affected by medication or disease) when using the system,
- Physical size and strength,
- Sensory capabilities (vision, hearing, touch),
- Coordination (manual dexterity),
- Cognitive ability and memory,
- Knowledge about system/device operation and the associated medical condition,
- Previous experience with systems/devices (particularly similar devices or user interfaces),
- Expectations about how a system/device will operate,
- Motivation, and ability to adapt to adverse circumstances.

For example, older users might have difficulty remembering specific sequences for operation, using their hands to do tasks that require fine manipulation, or sensing system outputs such as auditory alarm sounds or information displayed visually. Highly trained and motivated users (i.e., developers, sales personnel, participants in previous use-studies, expert users) are often much more capable of operating complex systems than typical users. They are also likely to adapt better to unexpected or variable circumstances. *Motivated and adaptable users are more likely to take actions to compensate for problems with the design of a system.* But, if the same system is placed in the hands of more typical users, unexpected use scenarios possibly resulting in hazards could occur. With proper application of HFE, the design of a system can often be made to compensate for limitations in user ability. For example, diabetics often suffer from some degree of retinopathy (degenerative disease of the retina) resulting in impaired eyesight. These users have difficulty reading the results of blood glucose test kits when the meter displays are very small. Blood glucose meters with small displays were not a good design for this user population. After this problem was understood, subsequent models with larger displays mitigated this hazard. User experience and expectations are important considerations. Users will expect systems and system components to operate in ways that are consistent with their experience with other similar systems or system interface components. For example, users are likely to expect that the flow rate of a given dose (such as a gas or liquid flow) will increase by turning a control knob counter-clockwise. Hazards result when an electronically driven system/device control operates in the opposite direction.

3. System/Device User Interfaces

HFE considerations relate directly to the system *user interface* and responses of the system to user actions. A well-designed user interface will facilitate correct actions and will prevent or discourage actions that could result in hazards. The user interface includes all components of a system with which users interact while using it, preparing it for use (e.g., calibration, module set-up, unpacking), or performing maintenance (e.g., repairing, cleaning). It includes hardware features that control system operation such as switches, buttons, and knobs and system features that provide information to the user such as indicator lights, displays, auditory, and visual alarms. The user interface also includes the logic that directs how the system responds to user actions including how, when, and in what form information (feedback) is provided to the user. An important aspect of the user interface is the extent to which the logic of information display and control actions is consistent with users' abilities, expectations, and likely behaviors. Increasingly, user interfaces for new medical devices are computer-based. In these cases, interface characteristics include: the manner in which data is organized and presented, control and monitoring screens, screen components, prompts, navigation logic, alerting mechanisms, data entry requirements, help functions, keyboards, mouses, and pointers. The size and configuration of the device are important parts of the user interface, particularly for hand-held devices. Device labeling, packaging, training materials, operating instructions, and other reference materials are also considered part of the user interface. An important concept pertaining to user interface use-safety is *error tolerance*. Error tolerance is the quality of a user interface that prevents or mitigates dangerous or disastrous consequences when an error occurs.

Humans make errors. Some kinds of error can be anticipated and are essentially unavoidable – such as inadvertently pressing an adjacent key on a keypad, or bumping the keypad inadvertently while doing other tasks. The application of HFE approaches to system design will increase the likelihood that the design is tolerant of errors that are likely to be made by users. The logic of system/device operation can also determine its degree of error tolerance. For example, some systems/devices include “interlocks,” or mechanisms that prevent a critical process from being initiated without users verifying their intent to initiate it or necessitating extra control steps to be performed before proceeding. In other cases, system/devices can be designed to do tasks that users do not do well, such as timing certain steps in remote-testing procedures, remembering set-up parameters, or test dates, or performing calculations. For complex procedures, systems/devices can prompt users to perform the appropriate action at critical points in the procedure.

Conclusion

After use-related hazards are understood, the hazards are mitigated or controlled by modifying the system/device user interface (e.g., control or display characteristics, logic of operation, labeling) or the abilities of users to use the system/device (e.g., training, limiting use to qualified users). The field of human factors provides a variety of useful approaches to help identify, understand, and address use-related problems. The goal is to minimize use-related hazards, assure that intended users are able to use medical systems/devices safely and effectively throughout the product life cycle.

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