UPCARE: AN ANALYSIS, DESCRIPTION, AND EDUCATIONAL TOOL FOR MEDICAL DEVICE USE PROBLEMS

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Abstract: The "UPCARE" model was developed as a tool to help reporters or investigators describe and analyze medical device use problems. It is also intended to serve as a structured repository for additional information on use problems. The content and structure was developed from discussions with nurses (various specialty areas), and biomedical engineers, and was further supported by analyses of known use problems with medical and non-medical devices. Key descriptors from these interviews were incorporated into the model if they provided useful and accurate information while still being applicable to more than a single device or device type.

1. INTRODUCTION

Medical device "use problems" occur within the interaction process between human users and medical devices. They result in many adverse patient outcomes annually. For instance, the Center for Devices and Radiological Health (CDRH), receives approximately 100,000 Medical Device Reports (MDR) in a given year, about one third of which mention "error" on the part of the device users. The nature of these "errors" is not often described well, making it difficult to understand how these things happen, and what should be done to reduce the risk associated with them.

This lack of clarity for investigating and reporting use problems is not confined to submissions to Government reporting systems. Almost one half of medical device recalls by manufacturers involve "design" issues, yet manufacturers often have difficulty understanding customer complaints for devices that are returned as defective – especially when the latter are tested and found to operate within specifications. The reason for the device's return then remains a mystery and, although use-related issues are often suspected, these are not usually investigated. Similarly, hospital biomedical engineering departments often receive devices from point-of-care personnel described as "broken" but, when tested, no problem is found. Unless they have been involved in a serious event, these devices are returned to the floor.

Technological advances have greatly diminished the risks of medical device mechanical and electronic failures, while providing new levels of patient care and treatment. Users of devices have noted that the risk of bad outcomes resulting from the *use* of devices is increasing in proportion to, and in some cases is greater than, the risk of bad outcomes associated with device failure. Since the phenomenon is not well understood, and therefore not well described, the true prevalence of medical device use problems and associated harm and can only be estimated.

Best practice would dictate that comprehensive studies of user-device interactions be undertaken using human factors methods, and that these studies would include a broad "systems" approach (Woods & Cook, 1999). Such studies have allowed progress toward understanding certain problems with device types such as anesthesiology equipment (Gaba, 1987), but good understanding and effective response to use problems with medical devices, especially smaller, less elaborate devices, remains a largely unmet challenge for the medical community. Moreover, the larger systems analyses are often not practical given time and other constraints in the healthcare setting. There are several other important obstacles in this area, not the least of which is the inherent difficulty in understanding and describing device use problems. This is due to the complex dynamics involved and the often subjective and frustrating issues of human ability and behavior, which must be considered.

2. UPCARE MODEL DEVELOPMENT AND THEORETICAL CONTEXT

This research involved discussions with medical device users on device use problems and post hoc analyses of the information obtained. Most of the users interviewed were nurses. We included a variety of nursing specialty areas: emergency room, critical care, long-term care, traveling, and visiting. Additionally, we met with groups of biomedical and clinical engineers, and with human factors specialists from the medical device industry. Our questions and discussion techniques were developed to elicit descriptions of use problem scenarios with those medical devices most familiar to the participants.

Our original intent was to develop a prioritized list of devices, on the topic of problems associated with use, from the perspective of actual device users. The information we collected showed insufficient agreement between groups with regard to the priority of specific devices. In retrospect, we were not surprised to discover that the user's specialty area, the devices they used, and the conditions of use all heavily influenced this variation in opinion.

Despite the lack of consensus regarding priority, we did notice *common issues* across different devices and user specialty areas. Inspection of the stories we had gathered through interviews and discussion revealed that some of these common issues lent themselves to groupings along the perceptual, cognitive, and motor components of the "Model Human Processor (MHP)," first described by Card, Moran, and Newell (1983). We decided to incorporate as much of the information on use problem scenarios into a structured adaptation of this model. This model, represented by Figure 1 below, considers the device-user interaction as a closed-loop system. We represent the continuous cycle beginning with *device operations* which produce i*nformation*, processed by the user's *perception* and *cognition* and turned into *action* through device *controls.*

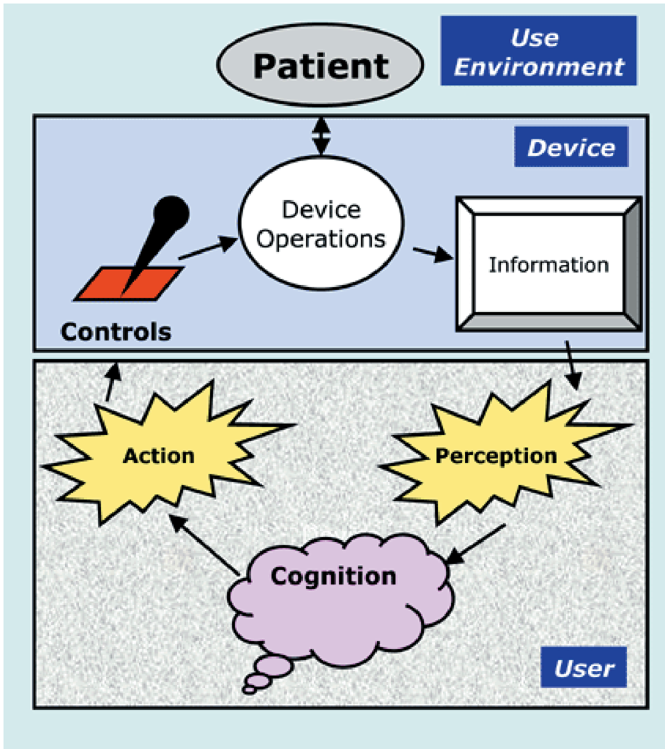

Figure 1. The Device-User Interaction Cycle

We then focused a subsequent round of discussions about device use problems with nurses on the issues concerning what users perceived (i.e., saw, heard, or felt), how users interpreted or knew what to do, and what physical actions the user took. When we structured our inquiries specifically around these categories, the participants provided more detailed, contextual information about a use problem, and were also better able to focus their recollection and analysis of the problems.

To find additional features in the information, we applied a post hoc analysis approach similar to Hooey and Foyle (2001), who identified distinct classes of pilot navigation errors through a post hoc review of performance during simulated exercises. With this general approach, we found that the three categories we were already using, (i.e., perception, cognition, behavior), associated well with many of the scenarios, and we populated the model with components and subcomponents under these domains that use generic (non-device specific) descriptions. But there were some scenarios that did not fit well; namely those that involved cases where a user's need was *unmet* by the design of the medical device.

The distinction is important, but subtle, when retroactively analyzing the users tasks. For instance, we determined that a use problem scenario would have a *perceptual component* if the user could not hear a device's alarm. If, on the other hand, the use situation warranted an alarm, but the device did not have one, we realized that we needed another domain in the model: the unmet user need. Once we made this discovery, it became clear that some scenarios presented unmet user needs, not because they *lacked* some physical design component, but because the overall design or theory of operation failed to effectively support the needs of the user.

The result of a device use problem is its central defining feature. To maintain coherence when evaluating use problems, and also allow the model to illustrate the range of impact and importance of device use problem scenarios, we included a result domain to the model. Because most recollections of scenarios by participants are associated with an adverse patient outcome, a frustrating or frightening use experience, or unexpected damage to a device, etc., we populated the result components of the model with general, but real-world examples.

As the purpose of UPCARE is to further investigations and research into use problems that arise, the final domain, "evaluation", was added to the model. For each use problem studied, we identified those human factors evaluation and research strategies that could be undertaken. We then grouped these strategies together based on the unmet user need and the perceptual, cognitive and/or behavioral components in the scenario. Many of the evaluation strategies we outlined are well-developed methodologies, such as the field observation and structured interview techniques detailed by Beyer and Holtzblatt (1998), as well as task analysis (Kirwan and Ainsworth, 1992) and usability engineering methods (Mayhew, 1999). These evaluation components – or similar human factors techniques – are intended to direct the investigator to a deeper understanding of the human perceptual, cognitive, and behavioral capabilities and limitations evidenced in the use problem, and the latter's potential risks.

After the framework of the model was developed we added some components that were not found in discussions, but from reports of medical device use problems or from the authors' experiences with non-medical device problems. For example, no participant described a problem for which an "emergency off" capability, (e.g., one that would stop the device's operation), would have helped. Since radiation oncology devices and robotic manufacturing control consoles both have "emergency off" controls, we included a subcomponent like this in the model within the *unmet user needs* domain, (see below).

3. APPLYING THE MODEL

The UPCARE model presents several potential advantages:

Better description of use problems: The difficulty of addressing a use problem described previously can be greatly reduced if the problem can be described as a scenario or "story" that conveys the central aspects of what occurred. The UPCARE model provides examples of actual problems, which might fit the problem considered, and a structure to facilitate understanding. Initial work with the model leads us to believe that a novel use problem can likely be described in additional detail with the help of the structure and current examples contained in the model.

Consistent and meaningful terminology: If more use problems could be discussed using terminology included in the model (e.g., "the user was confused by," "didn't know he had to," "couldn't see the display,") this would greatly improve the current state of device reporting and discussion.

Likely sources of problems: The model can better focus our investigations into the sources of use problems, such as whether an alarm is detectable, or whether users remember how to perform a complex or subtly challenging set-up process.

Candidate solutions: Describing the problem in greater detail – including the three central components (perception, cognition, and action) – will direct the analysis toward logical points where effective intervention is possible.

Better understanding of use problems for medical devices: Initial work and presentation of early forms of the model have indicated that the model itself is a good educational tool for understanding medical device use problems in general.

Focusing further evaluation: In essence what this model can do is move us from a poor understanding of the problem to a better understanding. Because it cannot provide a full or complete understanding of the use problem and context of use, it is not intended to suggest design changes by itself. When the information available limits the extent to which a use problem scenario can be understood and responded to, the model provides support by focusing on what subsequent evaluations would be most effective and informative. In this way, it simply facilitates our analysis and our ability to identify likely sources of problems. Any conclusions regarding the cause of use problems should be verified at least analytically (Kaye and Crowley, 2000).

A repository for new information on use problems: Given the complex nature of user-device interaction, this model is clearly not complete, but can provide a basis for an increasingly comprehensive repository of structured device use problem summary information.

3.1 Model Description

The UPCARE model takes its name from its six domain areas: 1) Unmet User Needs, 2) Perception, 3) Cognition, 4) Actions, 5) Results and 6) Evaluation. Each of these areas is broken down into components discovered in the analysis of use errors involving medical devices, or in the case of the "E" component, technique areas for further evaluation of use problems. These areas were described in the preceding section ("2. UPCARE Model Development and Theoretical Context").

3.1.1 Unmet user needs

The user needed, but didn't have:

Set-up, configuration, repair

1. Efficient, intuitive set-up and start up procedures
2. Effective cues or instruction for proper device operation
3. Instructions on how to use device under atypical conditions or for specific applications

User-device interaction

1. Indication of current setting or default mode
2. Safe default mode / fail-safe mode
3. Ability to immediately stop device action or process
4. Feedback in response to critical control actions
5. Handy quick-reference material or embedded help

6. Assistance in solving problem or troubleshooting
7. Sufficient device quality to get reasonable results in time allowed
8. Relief from need to “work around” requirements of device use

Monitor and detect normal v. abnormal state (in patient and/or device)

1. Indication of critical change in patient condition
2. Indication that device was operating properly
3. Indication of device failure or critical change in device operation
4. Indication of battery (or charge) end-of-life condition in time to respond

Understanding of device output

1. User unaware of how to correctly interpret clinical meaning of device output (e.g., diagnostic test results)

3.1.2 Perception

User couldn’t see device displays, labels, or markings

1. Blocked from view
2. Not bright enough
3. Glare on display
4. Font size too small

User couldn’t hear device alarms or audio feedback

1. Volume too low
2. Audio frequency too high or low

User couldn’t feel or interpret tactile feedback from device

3.1.3 Cognition

Information interpretation

1. Text, number, or status indication difficult to visually locate in a complex display
2. Packaging, markings, or displayed data on two or more devices or components appeared similar causing misidentification or confusion
3. Labeling on device or overall device configuration was misleading regarding identity, operation, or use
4. Input, output, level, or calibration values confusing because of unexpected or nonstandard names, abbreviations, or units
5. Navigation through menus or other interface features difficult / confusing

Feedback

1. Difficult or impossible to understand state or mode of device from inadequate, confusing or lack of feedback in response to user actions
2. Misleading feedback or cues provided by device indicated different device or clinical condition than actual

User expectations

1. Expected device operating status or mode to be different than it was
2. Expected device (or component) to operate like similar device previously used due to general appearance / name
3. Expected device-based treatment parameters (e.g., treatment, dose) to be consistent with prior experience
4. Excessive alarms, signals, or emphasis of unimportant information desensitized user to priority of critical information (“nuisance alarms”)

Knowing what to do

1. Instructions inadequate to support user while using device
2. User training inadequate
3. Device data insufficient for user to diagnose patient situation – adjust treatment, etc.
4. User does not understand device communication (e.g., error codes, status indication, etc.)
5. User was confused by required sequence of actions for device use

3.1.4 Actions

Set-up

1. Connected components incorrectly
2. Placed, inserted, or secured components incorrectly
3. Assembled components incorrectly

Input and control

1. Unintentionally activated wrong key, button, or other control (e.g., keystroke error)
2. Activated device or component at wrong time or in incorrect sequence
3. Took action to solve problem and caused a future problem (e.g., defeated alarm which allowed unsafe patient condition to go undetected)

Physical damage

1. Walked or bumped into device / component, knocked over, etc.
2. Damaged device while adjusting, moving, or transporting patient
3. Repeated use degrades device interface components (e.g., fingernails scratch surface or break keypad)

3.1.5 Results

To patient

1. Patient injured or died
2. Unnecessary clinical complication

To device user

1. Death or injury of caregiver or bystander
2. Delay in providing treatment
3. Necessity to use less-preferred treatment option
4. Frustration, anxiety for user or healthcare provider team

To device or environment

1. Device damaged or destroyed

3.1.6 Evaluation

Collect user-device interaction information

1. User interviews
2. Field observations

Analyze context of use error

1. Task walkthroughs
2. Task analysis

Test user-device interaction

1. Usability evaluation

4. MODEL POTENTIAL FOR MEDICAL DEVICE DESIGN

We have discussed the potential application of the UPCARE framework in the medical device manufacturing, end-user (both clinician and patient), and regulatory environments. It has the potential to help healthcare providers, or patient device users, discuss a recent use error experience in better detail. A short set of generic questions based on the model's existing components and subcomponents for each domain, can assist an event investigator in collecting and structuring their interview with the device user. The model also has the potential for helping device makers sort and classify customer complaints and device returns and identify problems that need further investigation.

5. CONCLUSIONS AND SUMMARY

Certain cautions are recommended for using this model. The focus is clearly upon the interaction between users and devices. Because of the material from which it was developed, it does not include the broader "systems" perspective described by Reason (1991), Woods and Cook (1999), and others. All of these perspectives are clearly important, however many professionals in government, industry, and healthcare, are faced with the requirement of responding to use problems in "real time" when changes to organizational structure, perception of safety, and other system issues, typically require coordination and long-term effort. For this reason, the broader systems studies are not always an option – or at least a timely one when these issues appear on one's desk. The intent here is not to lead users of the model to premature or biased conclusions but to get them on the path to productive responses to these very important problems. Fixing a problematic device design that has caused death or injury can, and has, prevented further deaths and injures.

As we have begun to discuss UPCARE as a work-in-progress to audiences within the CDRH and in the healthcare community, we have received feedback that indicates its usefulness in better understanding use errors with medical devices. In this way it promises a high potential for acceptance and effectiveness. However, the model is not in final form. It has yet to be evaluated with groups who may best use it such as risk managers, biomedical engineers, and human factors professionals. We intend to test its application to more report data and with new use error scenarios. Ultimately, we would like to develop UPCARE as a guide for better description of device incidents that involve "use error."

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