

# 3 ways clinical nurses can mitigate device safety hazards

When you participate in the usability process, you provide vital safety information.

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**M**edical devices undergo a lengthy process before arriving at the bedside for use in patient care. Although many factors affect device safety, a robust usability engineering process is key to success. As part of the science of human factors, usability engineering studies the interactions between people and the systems in which they function, including ease of use, the conditions under which a device is used, the tasks completed by the user and the expected outcomes of use, and device users.

Unfortunately, the perspective of the device end users is sometimes lost among the input of other stakeholders, including designers, engineers, and investors. As a nurse who provides direct patient care, your contributions are vital to the process, but you may need to take initiative to have your voice heard to ensure the devices you use enhance—not hinder—your work and promote patient safety.

You can contribute to the usability process in three areas: device development, procurement, and hazard analysis.

## 1 Device development

Your input can begin at the initiation of product development. From sim-



ply providing feedback on current practices to participating in formal usability testing, you can help shape the final device design. Your insight about current devices, workflow, and potential risks can help generate vital input that might not be discovered without you. (See *Nursing involvement in product development*.)

When products are ready for user testing, you can continue to have impact by participating in

## Nursing involvement in product development

Developed by the MedStar Health National Center for Human Factors in Health-care, this process for usability depicts typical phases of product development and how nurses can contribute at each step along the way.

### Product development phase

### Nursing activities

#### Concept development

#### Analysis and requirements

#### Design and development

Allow observations in the clinical environment. Provide feedback on currently used systems. Participate in interviews and focus groups. Discuss workflow constraints. Help generate assessment of device risk. Identify heuristic violations in new designs. Conduct iterative prototype evaluations. Participate in formative user testing.

#### Testing and evaluation

Participate in simulated use testing. Participate in final product validation. Ensure design has mitigated potential risks.

#### Post-launch monitoring

Identify potential use problems and hazards. Report usability issues to device manufacturer. Examine usability influence on adverse events.

simulated-use studies where you perform tasks that are part of your daily work.

Once a device is near market-ready, a human factors validation study is conducted to meet the expectations of the U.S. Food & Drug Administration (FDA). Validation is the final verification of new device safety, ensuring that the design has been optimized to reduce risk. By participating during this phase, you help provide assurance that devices will be operated safely after reaching the market.

## 2 Device procurement

After a device has been approved by the FDA, you can have a role in the procurement process, helping to determine which devices should be used in your healthcare environment. Procurement decisions typically rely on information from device fairs and manufacturer demonstrations. However, this information often focuses only on positive features, failing to provide insights into how a device might realistically function in practice. Ideally, nurses should test these products before a purchasing decision is made.

A recent case study of a hospital system's new infusion pump purchase illustrates the importance of nursing involvement during procurement. After the decision had been narrowed to two infusion pumps, human factors engineers conducted comparison usability testing with the goal of gathering data to help determine which pump better promoted safe and effective use. This included collection of crucial data obtained through nurse performance of potential high-risk tasks in a simulated setting. The data from the testing demonstrated that one pump had three potentially serious safety flaws, leading to the purchase of the safer device. This result wouldn't have been possible without the data collected from nurse participation.

## 3 Device hazard analysis

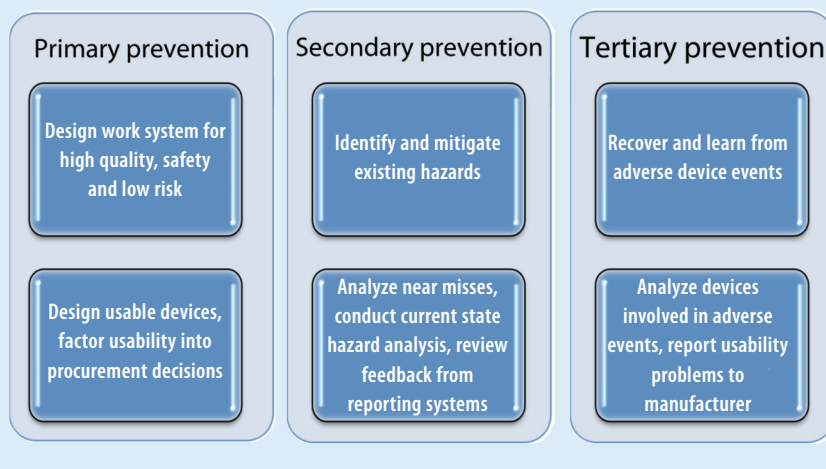
Unfortunately, we can't always pre-

vent risky or unusable devices from getting into healthcare environments, so sometimes we have to rely on secondary and tertiary methods to improve safety. (See *Quality and safety transformational model*.)

You can use several techniques to identify usability issues that may contribute to adverse events or safety hazards. By assessing a device based on human factors heuristics (known standards), you can generate solutions to keep an unusable device from causing harm. For example, if a device interface generates an error message that doesn't identify the problem, it's violating the "Good Error Message" standard, and an update to the message wording should be considered. (See *Medical device heuristics*.)

## Quality and safety transformational model

This model for risk reduction developed by MedStar Health National Center for Human Factors in Healthcare illustrates how usability should be considered during each prevention phase. Primary prevention focuses on designing usable devices and incorporating well-designed devices into the work system, while secondary and tertiary prevention techniques are used when poorly designed devices already exist.



You may need to take initiative to have your voice heard.

Devices are used within complex work systems composed of multiple components that alone or collectively affect device usage and safety. The Systems Engineering Initiative for Patient Safety model breaks the work system into five interacting components:

- person—for example, device users (including their physical and psychological characteristics, skills, and education), biomedical staff, and families
- tools and technology—for example, electronic health records, medical devices and accessories, and interoperability
- tasks—for example, step-by-step procedures, common and unique usage scenarios, workflow, and workload
- environment—for example, space layout, location of equipment, noise, and temperature
- organizational factors—for example, policies and procedures, protocols, training, work culture, and teamwork.

Device usability issues affect not only the device, but also other areas of the work system. In turn, work system elements can have a detrimental effect on successful device use. For example, a poorly lit

## Medical device heuristics

Applying human factors heuristics to medical device design can help identify potential usability problems. These 14 heuristics were created specifically to assess medical device interfaces.

Consistency and standards	Devices should maintain consistency with use of words, situations, and actions, and follow conventions of product design.
Visibility of system state	Appropriate feedback and display of information ensures users stay informed about what's happening with the system.
Match between system and world	The image of the system perceived by users should match the model the users have.
Minimalism	Extraneous information is a distraction and can cause slowdowns.
Minimize memory load	Task completion shouldn't require excessive memorization.
Informative feedback	User actions should trigger prompt, informative feedback.
Flexibility and efficiency	Flexibility allows users to create customization and shortcuts to accelerate performance.
Good error messages	Informative error messages help users understand the nature of errors, learn from them, and recover quickly.
Prevent errors	Appropriately designed user interfaces prevent errors from happening in the first place.
Clear closure	Task completion should be clearly communicated to users.
Reversible actions	Reversible actions allow users to recover from errors and also encourage exploratory learning.
Use users' language	Device language should be understood by the intended users.
Users in control	Users should not feel that they are controlled by the systems.
Help and documentation	Always provide help when needed.

Adapted from Zhang J, Johnson TR, Patel VL, Paige DL, Kubose T. Using usability heuristics to evaluate patient safety of medical devices. *J Biomed Inform.* 2003;36(1-2):23-30.

device interface might function well in a daytime environment but can become a safety hazard when used in low lighting. Just as considering these factors during device design can result in products that fit better into the expected work systems, you can think about the system components when analyzing your work environment for potential usability hazards.

### How to get involved

You can take several routes to get involved in helping develop and evaluate the devices that may be introduced into your work environment. Some healthcare systems employ usability engineers who work

with device manufacturers during development. MedStar Health National Center for Human Factors in Healthcare, for example, conducts usability activities during all development phases and places a high value on nursing involvement. Nurses at MedStar can reach out directly to the human factors team to participate. If your healthcare system doesn't have these capabilities, you will find that many usability firms welcome your participation.

In your organization, ask your managers how you can have input on new purchases. If formal usability studies aren't being conducted, use some of the approaches mentioned in this article to assess de-

vices through a human factors lens and consider how the new device might affect the work system. For instance, walk through tasks that might be risky or present problems when performed in your daily work and apply heuristics to detect potential use problems.

If a poorly designed device already exists within your system, examine current hazards and near misses from a systems perspective to generate potential solutions. Use heuristics as a guide or a checklist to evaluate current devices and determine how they might be modified to better fit your needs. This same approach can be used after serious safety events to determine if poor usability was a factor. If you find critical usability problems, talk to management about communicating with the device manufacturer so they can incorporate that information into their next design and create workarounds as appropriate.

Your input can help not only to mitigate hazards in your current environment, but also to develop the next generation of safer, more usable products. ★

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## Leading patient safety efforts

Are you responsible for leading safety efforts in your organization? If so, don't miss "Leading a Culture of Safety: A Blueprint for Success," an evidence-based resource developed by the American College of Healthcare Executives and the National Patient Safety Foundation's Lucian Leape Institute. You'll find tools and proven strategies for creating a culture of safety—an essential first step for eliminating harm to patients, families, and staff.

The resource is organized into six leadership domains, including foundational and sustaining strategies. Although geared for executive leaders, this document contains a wealth of information for leaders in other positions, too.



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