Online Supplement to "Assessing Equipment, Supplies, and Devices for Patient Safety Issues"

This supplementary material has been provided by the authors to give readers additional information about their work.

Appendix A. Patient Safety Procurement Assessment Tool

Purpose: Healthcare facilities are often presented with numerous options when purchasing equipment, supplies, or devices (ESDs). Assessing the safety and usability of a product, in addition to other factors, such as cost and availability, is critical to identifying ESDs that work best for healthcare workers and patients. The purpose of this patient safety procurement assessment tool is to provide an easy-to-use resource for healthcare facilities to assess products they are considering for purchase. The tool is intended to require few resources and does not require deep domain expertise in safety or usability. This tool is focused on assessing two aspects of ESDs: usability and malfunctions. Usability, which is the extent to which a product can be used efficiently, effectively, and satisfactorily, is assessed through a heuristic evaluation process. Malfunctions, which are instances in which the ESD does not function as intended, can be assessed through analysis of a product's malfunction history and current use.

How to Use the Tool: This tool is recommended for use during the procurement process to assess multiple products being considered by your facility. Both the usability heuristic evaluation and malfunction checklist can be completed on each product and results can be compared to provide additional information for consideration during procurement.

Usability Heuristic Evaluation: This tool can be used to assess the usability of any ESD and does not require usability domain knowledge. For each of the 10 heuristics which are based on previous usability research,[26] an evaluator should follow the instructions outlined in the table below. To assess and compare the usability of similar products from different manufacturers or similar products from the same manufacturer, the usability heuristic evaluation template provided as part of this tool can be a quick way to do a high-level analysis.

Usability Heuristic Evaluation Instructions and Examples

Instructions	Example: Facility is considering new pulse oximeters
1. Identify 1–3 common tasks performed with the products being considered.	Obtain a pulse oximetry reading on a patient.
2. List the typical steps required to complete the identified tasks.	• Get pulse oximeter. • Turn on pulse oximeter. • Place pulse oximeter on patient's finger. • Wait. • Read results. • Record results.
3. Perform each step of each task, in an environment that closely mimics real-world use, and evaluate each step of each task using the Usability Heuristic Evaluation Template.	When assessing a pulse oximetry device, turn the device on and place it on the finger of a person in the emergency department to see how it works in that environment with noise and other distractions.
4. For each step, review the 10 heuristics to identify which ones are relevant. It may be the case that not every heuristic will be applicable to every ESD, task, or step. For example, when testing the ESD, if there are no error messages, you may not use the "Recognize, Diagnose, and Recover from Errors" heuristic.	After the pulse oximeter is turned on and placed on the finger, see what happens next. If there is no visual indication that the device is on, that it is calculating the blood oxygen saturation level, or that it is clear what the device is doing, the heuristics of "Visibility of System Status" would be applicable.

5. Score each task step based on whether the heuristic results in catastrophic problems that prevent use, major problems that make use difficult, minor problems that are an annoyance, cosmetic issues that do not impact use, or no problems at all. The scoring is as follows:
    0 points: catastrophic problems that prevent use
    1 point: major problems that make use difficult
    2 points: minor problems that are an annoyance
    3 points: cosmetic issues that do not impact use
    4 points: no notable problems
 	
Record this information in the template for each step by identifying the heuristic(s) violated for that step, recording the task step number in the "Task Step" column and recording the score in the appropriate "Usability Rating" column.
	If it is unclear what the device is doing when it is calculating the blood oxygen saturation level and "Visibility of System Status" is selected, a score of 1 would be selected.

6. Perform this evaluation for each step required to use the device being evaluated.	
7. Repeat 1–6 with additional devices being assessed.	
8. Take the sum of scores for each product across all tasks that it was tested against and the product with lowest score likely has more optimal usability for the set of tasks it was tested against, compared to the other products. Note that all tasks should be performed with all products being considered to ensure appropriate comparisons.	

Usability Heuristic Evaluation Template

Heuristic	Definition	Task Step	Device 1 Usability Rating	Device 2 Usability Rating	Device 3 Usability Rating	Recommendation/ Comment
Visibility of System Status	The equipment, supply, or device (ESD) should keep users informed about what is going on, through appropriate, timely feedback. For example, an automatic blood pressure cuff keeps the user informed that the cuff is inflating and deflating/measuring the blood pressure by showing the numbers increasing and decreasing.					
Match Between the System and the Real World	The ESD should use words, phrases, and concepts familiar to the user, rather than internal jargon. For example, all symbols on the ESD should be universally known and quickly understood by any user.					
User Control and Freedom	Users often perform actions by mistake. The ESD should provide a clearly marked "emergency exit" to leave the unwanted action. For example, the user should be able to stop the blood pressure cuff once it has started.					
Consistency and Standards	Users should not have to wonder whether different words and/or symbols mean the same thing. In different situations the same actions should lead to similar expected outcomes. For example, critical situations should always alert the user with similar sounds or colors.					
Error Prevention	The ESD should provide informative error messages. Ideally, the ESD should be designed to carefully prevent problems from occurring in the first place.					
Recognition Rather Than Recall	The ESD should minimize the user's memory load by making elements, actions, and options visible. For example, a dropdown list gives someone a choice (recognition) versus having to recall a specific item.					

Flexibility and Efficiency of Use	The ESD should provide shortcuts to support expert users, while also being designed for novices.
Aesthetic and Minimalist Design	Interfaces should not contain information which is irrelevant and does not add value to the user. Every extra unit of information in an interface competes with the relevant units of information.
Recognize, Diagnose, and Recover From Errors	Error messages should be expressed in plain language (no error codes), precisely indicate the problem, and constructively suggest a solution.
Help and Documentation	Ideally, the ESD can be used without the need to refer to a user manual. The user should not need any instructions, or as few instructions as possible, to use the ESD.

Other Usability Issues Not Captured Above

Malfunction Assessment: ESD malfunctions can have serious patient safety consequences. While malfunctions can be difficult to identify during procurement, a deliberate assessment process can serve to help identify products that may have malfunction issues. We suggest the following:

- Search publicly available databases that contain reports about patient safety issues associated with ESDs. For example, the FDA's MAUDE database contains reports on safety issues associated with medical devices.[19] These databases can provide insights on the types of malfunctions, or other issues, that have been reported about the ESD under consideration.
- Ask the ESD manufacturer for malfunction rates and whether any issues have been reported by users of the product.
- Consider contacting other facilities that have already adopted the ESD being considered and ask the facility about malfunctions and other issues they may have experienced.

The table below is provided to assist with the tracking of the malfunction assessment process (Database, Manufacturer and Other Facility ESD Information).

Database, Manufacturer, and Other Facility ESD Information

	Device 1 Comments	Device 2 Comments	Device 3 Comments
Database Searches			
Was the ESD found in the FDA MAUDE or other available data-bases?*			
If so, what malfunctions or safety issues are mentioned in the FDA MAUDE or other databases?			
Manufacturer Queries			
Does the manufacturer have malfunction rates or other data available for the ESD? If so, what are they?			
What, if any, safety issues or malfunction issues have been reported to the manufacturer?			
Other Healthcare Facilities			
What safety, malfunction, or other issues, if any, have other healthcare facilities experienced with the ESD?			

*Note that a lack of reports found in a database does not indicate there are no safety issues associated with the ESD.

References

19. Food and Drug Administration. Manufacturer and User Facility Device Experience (MAUDE) Database. FDA. https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude. Accessed September 22, 2022.

26. Nielsen J. Enhancing the Explanatory Power of Usability Heuristics. *Proceedings of the SIGHI Conference on Human Factors in Computing Systems*. 1994:152-158.