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Designing the design phase of critical care devices: a cognitive approach

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Abstract

In this study, we show how medical devices used for patient care can be made safer if various cognitive factors involved in patient management are taken into consideration during the design phase. The objective of this paper is to describe a methodology for obtaining insights into patient safety features—derived from investigations of institutional decision making—that could be incorporated into medical devices by their designers. The design cycle of a product, be it a medical device, software, or any kind of equipment, is similar in concept, and course. Through a series of steps we obtained information related to medical errors and patient safety. These were then utilized to customize the generic device design cycle in ways that would improve the production of critical care devices. First, we provided individuals with different levels of expertise in the clinical, administrative, and engineering domains of a large hospital setting with hypothetical clinical scenarios, each of which described a medical error event involving health professionals and medical devices. Then, we asked our subjects to "think-aloud" as they read through each scenario. Using a set of questions as probes, we then asked our subjects to identify key errors and attribute them to various players. We recorded and transcribed the responses and conducted a cognitive task analysis of each scenario to identify different entities as "constant," "partially modifiable," or "modifiable." We compared our subjects' responses to the results of the task analysis and then mapped them to the modifiable entities. Lastly, we coded the relationships of these entities to the errors in medical devices. We propose that the incorporation of these modifiable entities into the device design cycle could improve the device end product for better patient safety management.

Keywords: Decision making; Devices; Device engineering; Critical care; Patient safety; Task analysis; Institutional decision making

1. Introduction

"Don't blame me for the article; blame the typewriter that printed it!"—Anonymous.

Even if the above statement were true, when the question of errors in clinical settings arises, assigning the blame does not help solve the problem. The individual with closest proximity (the operator) to the device most often bears the brunt of blame [1]. The critical care setting is a high-tension environment with a large number of users interacting with an even larger number of devices. Errors related to devices or users in the healthcare setup are drawing increased attention towards them as their recognition and reporting has improved [2,3]. We need to analyze these errors to devise measures that will help prevent them in future.

The use of devices in medical care was introduced for many reasons, the primary ones being related patient monitoring and automation of procedures in order to save time and increase accuracy. The devices were not intended to replace human caregivers but to supplement their tasks. The effectiveness of these devices relied

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largely on how well the user operated them. The concept of including patient safety measures in medical devices slowly evolved as the impact of errors due to the improper design, implementation, and use, of medical devices started being recognized. In addition to introducing medical errors, the newly acquired devices raised other issues, including the disruption of organizational culture and concern among physicians regarding the changes in their professional relationships and established workflow routines [4].

1.1. Evolution of the medical device safety net

From a general standpoint, when a new device is invented, the primary concern at the time is to achieve the desired functionality. With constant use, shortcomings or possible improvements for the device become evident; with modifications, subsequent generations of the device evolve into much better contraptions. Similarly medical devices and instruments have evolved in functionality by incorporation of more and more features and automaticity. With development of more programmable and independently operating devices, it became imperative that they not compromise patient safety in any way. Fig. 1 illustrates the "Evolution of the Patient Safety Net," delineating how different generations of medical devices evolved to provide safety along with their intended functionality.

The first generation of medical devices was patient safety naïve because their primary aim was to achieve a certain functionality. The need for safety features was unrecognized until a medical error or error in the making was observed. The earliest safety features included alarms, constraints, input confirmations and reconfirmations, but their scope was limited to the immediate domain of device interface and operation.

Considering the fact that medical devices do not work in isolation, but interact with various other entities and personnel working in the same setting, the next evolutionary stage in terms of patient safety measures should account for these factors as well. From the time a clinician decides a plan of action to the actual execution of this plan, a number of cognitive processes and sequential events occur. The communication cascade triggered by this situation is mostly concentrated around nurses and physicians [5]. Performing a cognitive task analysis

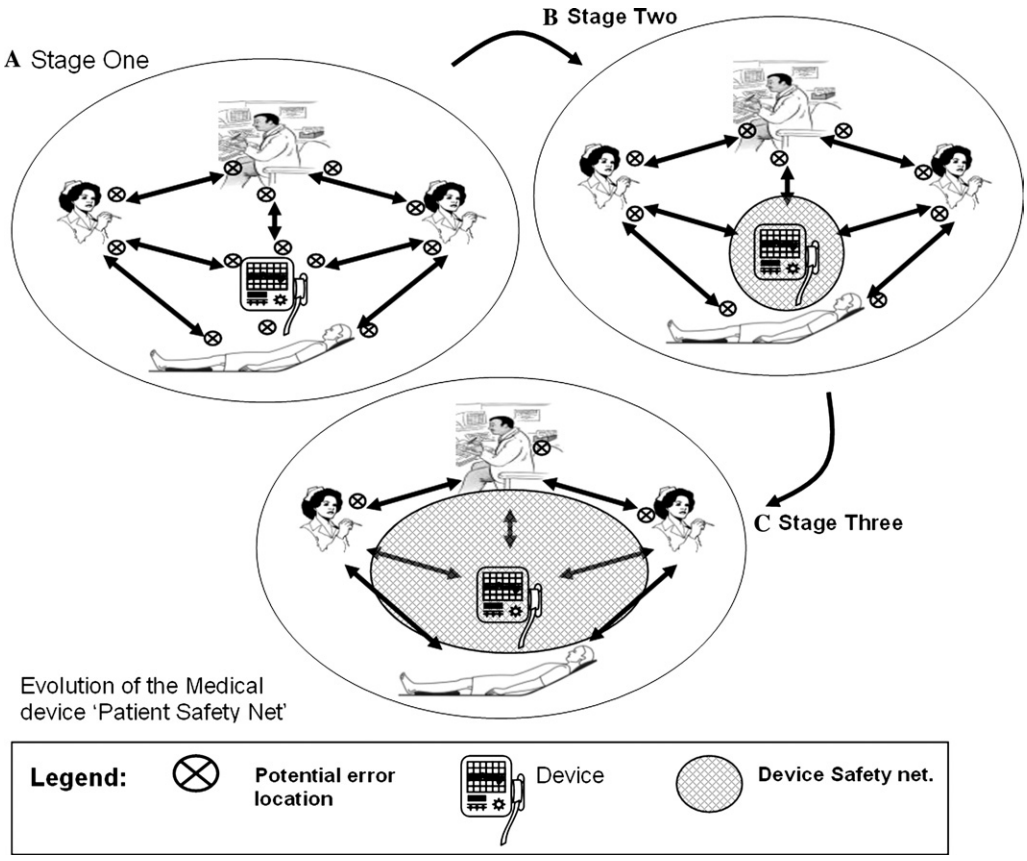

Fig. 1. Evolution of the device safety net. (A) Stage one: medical devices with no patient safety features. (B) Stage two: medical devices with patient safety features limited to the device. Features such as inbuilt alerts and alarms were included. (C) Stage three: medical devices with extended patient safety features. Features that take into account the setting of operation and the involved workflow as well as the boundaries of human errors. Patient safety administered by the device extended to the interactions between the various role players and their usage of medical devices.