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Safety-oriented usability test of a semi-automated Unit Dose System: Role of task allocation between Human and Machine

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Abstract. The distribution of tasks between humans and machines in the design of healthcare systems is an important issue for patient safety. This paper presents a usability test performed to compare a semi-automated unit dose system (UDS) with the usual/manual preparation procedure for preparing and administering drugs. The results show that the UDS prevents the frequent administration errors encountered with the usual cabinets and produces a better performance in terms of time for filling the pill dispensers (6.52 sec ± 1.1 vs. 8.5 sec ± 1.5 ($t_{9,16} = 3.12$, $p < .007$)). But the results also stress that the UDS takes entire control of the preparation and administration tasks, thus leading to a loss of control of the process by nurses (difficulties experienced by them in resuming their actions, difficulties in memorizing drugs, lack of confidence in the UDS while they "blindly" rely on it). The distribution of tasks between the nurses and the UDS should be modified to give back control to the nurses. Design suggestions were provided in this way. For instance, the UDS may guide the nurses for the drugs localization in the cabinet but leaves the validation of the drugs to the nurses.

Keywords. Human Engineering, Evaluation Studies, Patient Safety, Automation, Usability

Introduction

Safety is a fundamental principle of patient care and a critical component of quality management. Its improvement demands to make evolve a complex health system and involves a large range of measures. Automation of hospital processes may result in a reduction of errors [1], but the integration of new technologies into hospital practices may also introduce new types of errors and also involves investigation of any possible errors this could entail [2]. System (latent) failures pose the greatest risk to patient safety as they lead professionals into causing many types of errors [3].

This study focuses on the prevention of errors within the hospital medication process for the preparation of oral route drugs by nurses in the wards. Today the most common organization of the process in France is the following [4]: at some point in the

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24hr period a nurse prepares the pill dispensers (PD) for all the patients on the ward. This preparation takes place in the room where the ward medication cabinet is located, usually the nursing room. In the ward stock, drugs are stored in their packaging or only in their blisters, this in alphabetic order or according to therapeutic classification. From each patient's prescription, the nurse chooses the drug in the cabinet, cuts up the blister to get the required number of pills and puts them in the PD. This is a repetitive task, which requires a great deal of concentration and memory. Most studies published about medication-related safety stress the numerous errors occurring during this step of preparation [5]: (i) the confusion of drugs similar in form or name, (ii) the cutting of the blisters which deletes critical information such as the expiration date or the name of the drug, (iii) the manual management of the stock and expired drugs.

Many unit dose devices with different degrees of automation have been developed, including robot systems, which offer useful technology to facilitate this work, reducing the filling time and errors and facilitating information management. These systems execute part of drugs preparation activities, alleviating the nurses' workload (e.g. cutting of blisters or filling the PD). The distribution of tasks between humans and machines is an important issue in the design of such safety-critical systems. It doesn't simply consist of breaking down the process into elementary tasks that will be assigned to humans or machines, because this may "parcel out" the process while certain tasks are highly interdependent [6].

The aim of this paper is to show the impact of the distribution of tasks between human and machine on the performance and the safety of a medication unit dose system. To do so, a usability test was performed to compare a semi-automated UDS with the usual/manual preparation procedure of filling the PD.

1. Methods

1.1. Description of the Unit Dose System

The semi-automated UDS for medication was designed by a French start-up company of two persons at the time of the study. The prototype consists of a metal cabinet and a specific PD which allows the storage of drugs and facilitates their preparation and administration through the Pick to Light technique[2].

The cabinet: It has a variable number of racks holding ID (IDentity) cards. Each ID card holds one pill labeled with the drug name, dose and expiration date. There is no longer a need to cut the blisters. One rack corresponds to all the ID cards for a given drug (e.g. Paracetamol® 500mg).

The Pick to Light: To begin filling the PD, the prescription is directly retrieved from any Computerized Physician Order Entry (CPOE) system. The position of the drug is indicated by an illuminated light just above the corresponding rack. After each pick of an ID card/drug, the nurse has to press the illuminated light to validate his/her action. If several pills of a drug are to be taken, then the light is orange. When only one pill is to be taken, then the light is green.

The pill dispenser: This consists of a spiral notebook with four rings corresponding to the time of drugs administration (morning, noon, afternoon, evening). The ring

[2] The Pick to Light is a sorting technique that uses light displays to assist operators in preparing items for an order.

corresponding to the administration time of the drug just picked in the cabinet lights up when the nurse validates his/her action (pressing the light in the cabinet). Figure 1 describes in detail the intended procedure with the UDS.

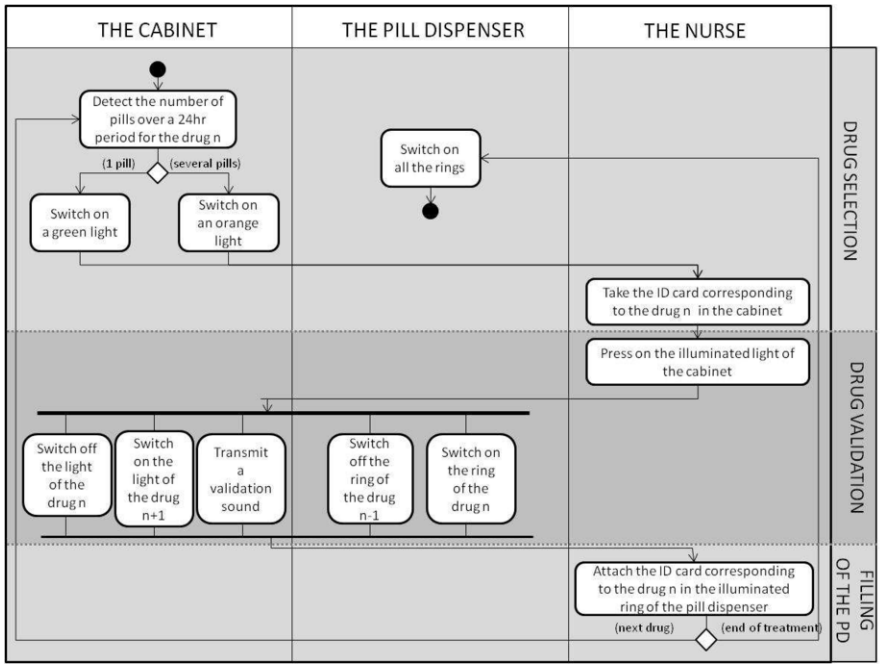

Figure 1. Description of the intended preparation procedure with the UDS prototype

1.2. Participants

Geriatric departments were selected by the clinical research department of a 3,600 bed academic teaching hospital to be the pilot sites for the study. The study was presented during a meeting of head nurses, who selected two wards. The study was then presented in these two wards. Nine nurses voluntarily consented to participate in the study. They averaged 5.5 years ± 4.5 of clinical experience and 3.2 years ± 3.6 of clinical experience in the given departments.

1.3. Study setting

Task analysis: A brief task analysis was conducted to prepare the usability test to be as close as possible to real working conditions. Three sessions of field observation of the tasks were performed in each department with three different nurses and were combined with interviews in order to identify habits of work and task specificities, in accordance with the methodology provided in the ISO 9241-210:2010 [7].

Tasks: Prescriptions were given to participants who were asked to perform the preparation of the PD and the fake administration to the patient (to verify that a last check was done to identify errors). Three prescriptions were prepared by each nurse counterbalancing the order of presentation: one with the usual cabinet and two with the UDS, this for an equivalent number of drugs for the two systems. Participants were

asked to think aloud. At the end of each administration, a free recall task of the drugs was given. At the end of each session, a debriefing was performed along with a usability satisfaction rating by means of the System Usability Scale (SUS). The entire session was filmed/ recorded, transcribed and analyzed.

Prescriptions: The prescriptions were real prescriptions retrieved from the two departments to ensure that the nurses were familiar with the drugs. They were adapted with a clinician to (i) remove drugs unsupported by the UDS (e.g. syrup) and (ii) introduce confounding variables to test the impact of the systems on errors management. Two frequent errors were met in the departments: confusion between two drugs similar in form (previscan® 20 mg/linisopril® 20 mg) and in packaging (seropram® 20 mg/seroplex® 10 mg). These drugs were introduced side by side in the two systems.

Dependent variables: The measurements included task completion time, verbal comments, measurement of user satisfaction, number of drugs recalled/total number of drugs and significant errors.

2. Results

2.1. Task completion time

From a performance point of view, the mean time of drugs preparation was lower with the UDS as compared to the usual cabinet (6.52 sec; SD=1.1 vs. 8.5 sec; SD=1.5 ($t_{9, 16}$ = 3.12, p <.007)), since there was no cutting of blisters. But the administration mean time was higher with the UDS as compared to the usual cabinet (6.86 sec; SD=2.49 vs. 3.47 sec; SD=0.77 ($t_{9, 16}$ = -3.4, p <.01)), since nurses weren't used to handling ID cards.

2.2. Significant errors

Usual cabinet: As part of the thinking aloud, six out of the nine nurses spontaneously expressed the need to be very careful with the Previscan®, nevertheless one out of those six committed an error with the drug (Table 1). We also observed an omission of a pill.

Table 1. Number and type of errors occurring during the usability testing

	Error rate	Error type	Stage of error	Error description
Classical cabinet	1/9	Wrong drug	Selection of the blister from the cabinet	Lisinopril® instead of Previscan®
	1/9	Omission	Filling the PD	1 Risperidone® pill instead of 2
UDS	3/9	Wrong time over a 24hr period	Validation error	Pressed the illuminated light after attachment to the ring of the PD
	2/9	Wrong time over a 24hr period	Validation error	Double validations of the same pill (before and after attachment to the ring of the PD)

UDS: Errors mainly reflect problems with validation management. A specific procedure should be respected with a fixed order of actions. For instance, the nurse has to (i) pick the ID card from the cabinet, (ii) validate the picking by pressing the light which switches on the correct ring on the PD and (iii) then attach the ID card to the correct ring (Figure 1). If not, errors may appear. During the test, three nurses (i) picked the ID card from the cabinet, (ii) attached the ID card to the ring of the PD and then (iii) validated the action by pressing the light of the cabinet (Figure 2). As they validated their action after the attachment of the ID card to the PD ring, the illuminated ring corresponded to the previous drug. They should have validated before attachment to update the rings lighting up in the PD

Moreover, many of them (6/9) verbalized "*the need to focus to be sure to do what is necessary when needed*". During the test, three nurses were distracted from their task because they started commenting on the system. But then they had difficulties in resuming their task: "*how do I know what I've already done or not?*"

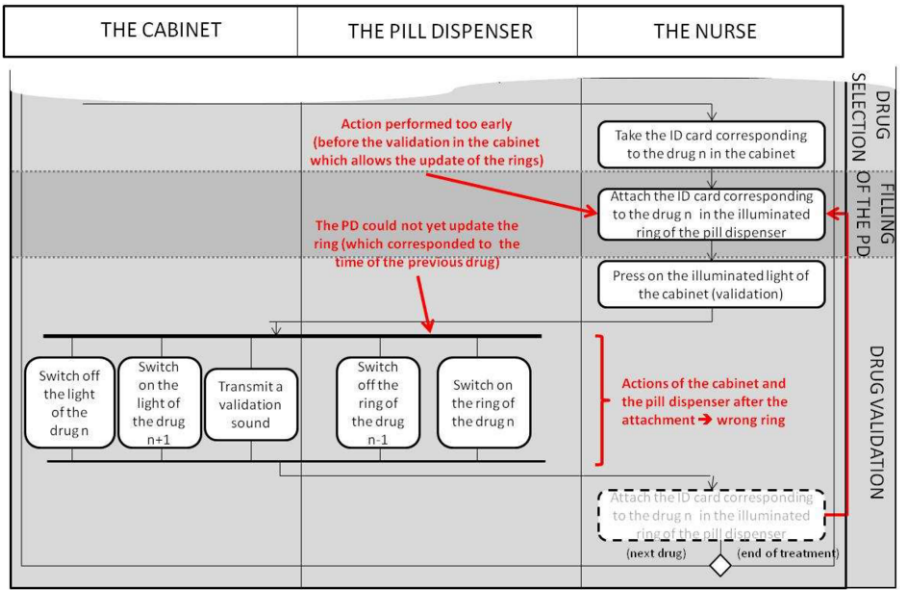

Figure 2. Focus on the risk zone of the UDS: example of an error of validation of the drug

2.3. Number of drugs recalled / total drugs

The mean number of drugs correctly remembered was significantly lower with the UDS as compared with the usual cabinet 2.4 (SD=1.3) vs. 8.3 (SD=1.7).

2.4. User satisfaction and verbal comments

Nurse satisfaction was good (SUS=76/100). They appreciated the pick to light system and the innovative PD; they were ready to use the UDS in their daily practice: "*it would make things easier"*, "*I just have to do what the machine says*". Only one negative aspect was highlighted by five out of the nine nurses: they didn't feel confident with the UDS, "*It's a little too convenient, because we do things a little too mechanically*".

3. Discussion

The study actually shows that the UDS prevents most of the preparation and administration errors encountered with the usual cabinets which are of a risky nature for the patient (wrong drug or quantity). The UDS also produces a better performance in terms of task completion time for the preparation task. But although there are fewer risks for the patient as compared to the risks with the usual cabinet, the study also stresses the emergence of risks of new errors e.g. giving the drug at a wrong time within a 24hr period. The problem is due to a too rigidly implemented model of the UDS. First, it doesn't correspond to the order of actions inherently performed by nurses (tendency to confirm an action after completion). Second, the UDS model is structured pill by pill while nurses tend to naturally work drug by drug (tendency to confirm once all the pills of a drug are in the PD).

The new task allocation to the UDS (blister cutting while keeping pill information) seems to improve patient safety and performance. While there were more errors with the UDS as compared to the usual cabinet, the errors committed were potentially less dangerous for the patients. But the UDS creates new risks of errors. Apart from the problem of an order of actions incompatible with that of nurses, the UDS takes entire control of the preparation tasks, thus leading to a loss of control of the process by the nurses. This explains why (i) some nurses have difficulties in resuming their actions if interrupted/distracted (which occurs frequently in their work), (ii) the lack of confidence in the UDS expressed by nurses and (iii) the small number of drugs recalled when working with the UDS as compared with the usual/manual cabinet. Nurses are forced to "blindly" rely on the UDS although they are aware of its limits; this is a well-known risk in the domain of automation called "risk of complacency" [8].

There was then a need to give back control to nurses through the reallocation of tasks between human and machine. One of the design recommendations was to design a UDS guiding for the drugs localization in the cabinet and requiring a validation *drug by drug after the attachment* of the last pill to the PD. This way, nurses keep control as they must check the number of pills for each drug themselves. This suggestion was implemented thereafter and seems to avoid the occurrence of time errors related to wrong administration. Its potential impact on hospital practices has now to be evaluated.

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