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Human Factors Based Recommendations for the Design of Medication Related Clinical Decision Support Systems (CDSS)

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Abstract. This study is part of a research project aiming at developing advanced functions of medication related CDSS to support the monitoring of patients' therapeutic treatments based mainly on corresponding lab values. We adopted a user-centred approach to the design of these advanced CDSS functions. We collected existing recommendations in the literature and completed previous Human Factors (HF) field studies and analyses by focused observations and modeling. We present resulting HF based recommendations for the design of such advanced medication CDSS and focus more specifically on two innovative high level recommendations completing those already existing in the literature. For illustration purposes, an example of the operationalization of one of the recommendation is presented.

Keywords. Adverse drug event, Clinical Decision Support Systems, Software design, Monitoring and clinical context, Human factors

1. Introduction

Medication related CDSS have been found to be beneficial in improving the quality of clinicians' prescriptions, reducing medication errors and ultimately preventing Adverse Drug Events (ADE) [1]. These systems support clinicians' therapeutic decision by a real-time checking of the orders through a medication knowledge base providing alerts to the prescribers. In spite of their known positive impact, they remain difficult to implement [2]. These difficulties are partly due to compatibility problems between users' cognitive characteristics and organisation of work on the one hand, and the model implemented in a given application on the other hand. Thus, alerts do not respect the collective aspects of the healthcare work situations [3]. The medication use process involves different professionals with cumulative roles: physicians monitor the treatment of the patient, pharmacists and nurses are in charge of controlling and executing the therapeutic orders. But alerts are very often, if not always, designed exclusively for the physicians. Additionally, alerts are too often disruptive of the cognitive processes inherent to decision making, due to wrong timing, wrong display mode and wrong/weak content of the information delivered. For example, it is not wise

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to suggest to the physician an action s/he is just about to carry out, or to alert him/her on a potentially dangerous situation for which s/he has just taken action.

Medication related CDSS have been in use for long enough to allow publishing a number of review papers which have tried to (i) identify the key features which should ensure their success and (ii) provide recommendations for the design of applications [4]. The analysis of these key papers allows drawing an overview of the current state of the art for designing acceptable, usable and efficient CDSS. Authors agree on the current limitations of existing CDSS and there is a consensus on a number of recommendations for the design of CDSS: provide decision support automatically as part of clinician workflow and deliver decision support at the time and location of decision making [5], provide justifications for the suggestion and require provider's documentation of the reason for not following it [6], integrate the CDSS with the Electronic Healthcare Record (EHR) and automatically retrieve data from it [7].

The design of such CDSS requires a perfect understanding and appropriation of the work environment and of its key elements. A lot of studies have already provided valuable insights on the intangible characteristics of the activities within the medication use process. The results emphasize the fact that the therapeutic decision making process is a dynamic process [8]: the patient's condition evolves depending on the healthcare professionals' actions but also spontaneously by itself. At each encounter with the patient, clinicians have then to update their knowledge about the patient's status and his/her evolution, especially as regards new elements in the situation that must be known, *e.g.* new lab results, unexpected clinical evolution of the patient or actions already undertaken for the patient. Moreover, the medication use process may be characterized as a complex distributed work situation: the information is distributed across the media, such as the EHR or the CDSS but also across the minds of the members of the clinical team. This distribution of the work processes supposes team situation awareness, *i.e.* a shared understanding of the situation where each professional has a complete vision of the situation allowing the decisions to be adjusted according to the information of the others.

The present study is part of the European project entitled "Patient Safety through Intelligent Procedures in medication" (PSIP). One of the major goals of the project is to design CDSS functions and to integrate them into different EHR/CPOE (Computerized Physician Order Entry) systems, so that the resulting CDSS corresponds to the users needs and fits clinical workflows and cognitive processes. We have capitalized on existing knowledge of the medication use process work situations and of the current limitations of the existing CDSS to provide HF based recommendations for the design of medication related CDSS along with clues for the operationalization of the existing recommendations. We completed previous field studies and analyses by focused observations and modelling of the monitoring process of patients' therapeutic treatments based mainly on corresponding lab values. This paper presents two innovative recommendations complementing those already existing in the literature. An example of operationalization is given to illustrate the adopted approach.

2. Methods

2.1. Study Site

The study took place in the Hospital Center of Denain in northern France. The hospital

has a Patient Care Information system (PCIS) including an Electronic Health Record (EHR) equipped with a CPOE which in this version has very limited CDSS functions (e.g. alerts in case of doubletons). The PCIS is interfaced with a pharmacy system, which allows the pharmacists to check the medication orders and send physicians alerts. The analyses were carried out in two medicine departments: the “cardiology” department and the “internal medicine and infectious diseases” department.

2.2. HFE Methods

Over a period of one month, four Human Factors experts observed all tasks related to the medication process carried out by 4 physicians, 6 nurses, 2 pharmacists and 2 assistant pharmacists, with a special focus on all actions related to lab values monitoring. Observation time amounted to 53 hours and concerned 101 patients. It was completed with debriefings and semi-structured interviews. The list of recommendations obtained during the analysis has been submitted for feasibility assessment to all PSIP project’s partners, including two CPOE vendors in charge of integrating the PSIP CDSS in their CPOE, the company in charge of ensuring the connectivity of the system, the designers of the knowledge based system and the designers of the PSIP standalone CDSS.

3. Results

The two critical recommendations for the design of medication related CDSS summarize what a CDSS should be, i.e. a teamplayer and a partner to clinicians.

3.1. Make the System a Team Player

The system should be a team player to be able to support the elaboration and maintenance of a team situation awareness for the healthcare professionals in charge of the patient. That means the system should (i) provide an indication for all the professionals of the availability of an information; the designers may choose the most appropriate way of indicating the information in the interface, (ii) incorporate functions to support the team awareness about the alert management and its evolution over time (e.g. visible access to how the alert was handled and to the reasons for alert override or rule deactivation if any has been documented), (iii) have the same display of basic CDS information for the case at hand for all professionals and (iv) give access upon request to extended information (justification of the rule, attached scientific documentation, etc.) that should be structured depending on the user profile.

3.2. Make the System a Clinicians’ Partner

The clinicians have a critical role since they are the decision makers and those handling the alerts (acknowledgement, deactivation and so on). But the existing CDSS are not able yet to catch elements of the work situation to provide relevant information to clinicians. The CDSS should act as a partner by (i) adapting its behaviour according to a subset of relevant actions taken by clinicians, (ii) adapting its behaviour to the evolution of the outcome at risk over time (i.e. take into account the evolution of the

targeted lab values to filter the rules and adapt its severity) and (iii) incorporating functions supporting the dialog between the CDSS and the clinician (e.g. acknowledgment / de-activation of the CDSS alert).

For illustration purposes of these recommendations, we provide a Unified Modelling Language (UML) model describing the classification process to be performed by a CDSS to catch the monitoring and clinical context of patients identified by the system as being at risk of an ADE (Figure 1). We identified eight typical situations characterizing the current status of drug monitoring. They result from the combination of the status of the lab tests orders on the one hand and the validity and normality of the available lab values on the other hand. For each typical situation we can identify whether the monitoring procedure is appropriate or not, and whether the patient’s clinical status, assessed by the lab value, is alarming or not.

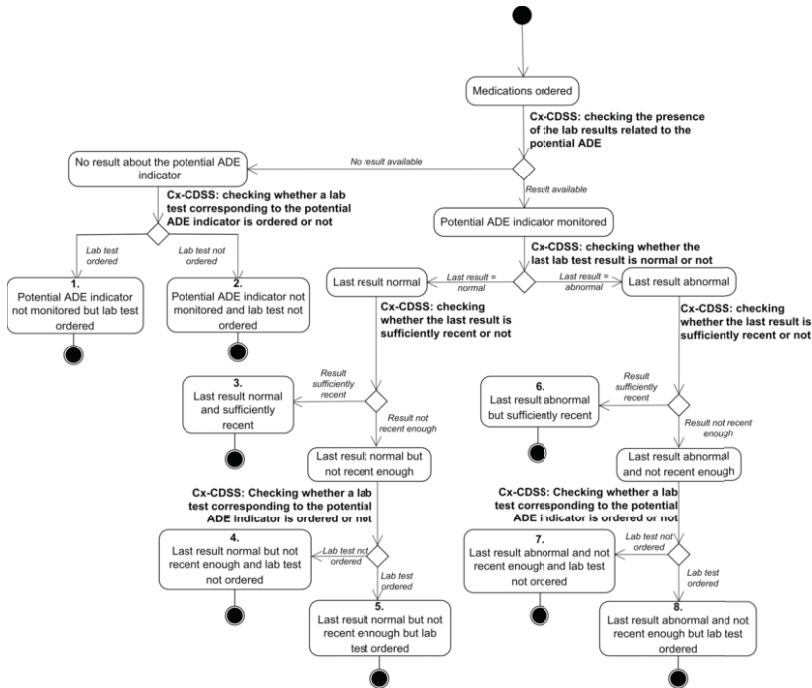


Figure 1. UML model supporting the classification of the situations.

Making the system able to catch the monitoring and clinical contexts opens interesting opportunities for the design of the CDS information content and display mode. For each situation the system displays the rule leading to the identification of the case as being at risk of ADE. But this basic information may be extended or particularized depending on the context. For instance, in contexts 2, 4 and 7 which correspond to situations that are not properly monitored, the CDS could suggest that the clinician order the required lab test and eventually propose a short cut to the lab tests ordering page. On the contrary in context 6, in which a new (recent and valid) lab value came in abnormal, the system could alert the physician on the increasing negative side effect of the drug and invite him/her to reassess the cost benefit ratio of the incriminated drug(s).

4. Discussion and Conclusion

This paper has presented two high-level recommendations for the design of medication CDSS, so that the resulting system correspond to the users needs and fit clinical workflows and cognitive processes. Due to limited space it was not possible to present the entire set of recommendations. These recommendations look promising for improving the capacity of the system to catch the monitoring and clinical context which in turn opens interesting design possibilities. However it is important to assess the technical feasibility of such a set of recommendations. In the PSIP context, all partners have rated the feasibility of the proposed recommendations and unanimously confirmed that most of the recommendations are possible to implement. This attests to their technical feasibility and also to their relevance for the design of advanced medication CDS functions. Those recommendations are quite innovative in the domain of the design of CDSS. For instance, a lot of studies emphasize the inherently collaborative characteristics of the medication use process and the importance to support them efficiently, but to our knowledge, none provides recommendations for the design of a teamplayer CDSS supporting shared awareness of potential ADEs and of the actions taken to prevent them. Similarly, it would be a significant progress for these systems to better catch the monitoring and clinical context.

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