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Development of a Clinical Decision Support System in Intensive Care

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Abstract. Background: Intensive care is confronted with an increasing complexity and large amounts of data provided by new technological tools. One way of assisting health care professionals is providing effective clinical decision support (CDS) systems. Objectives: The aim is to develop a tailored model for the sustainable development of a clinical decision support system in intensive care. Methods: The model consists of two parts. The first part includes the interaction of the following partners: science industry and HCP. The second part comprises a three-phase process consisting of (1) the identification of clinical needs, (2) modeling and prototyping, and (3) implementation. Results: By July 2015, a government funded CDS development project started in Graz, Austria. After assigning a multi-professional and interdisciplinary team, a clinical need statement was formulated within the first six months. A prototype was developed by end of 2016 and verified using a clinical dataset. Conclusion: The developed model proofed to be feasible regarding the first two phases. Additional progress needs to made to assess the performance of the model in the implementation phase.

Keywords. Intensive Care, Clinical Decision Support, Technology Development.

1. Introduction

Modern medicine is moving towards a growing recognition of personalized and precision medicine. This reflects the emergence of a rapidly accelerating field that will leave a major imprint on the practice of medicine [1]. New technological tools have the potential to collect large amounts of digital data from different perspectives. Together with the increasing availability of molecular information [2] and the usage of advanced sensors for physiological parameter registrations, new prospects are offered to researchers and scientists in healthcare. Consequently, health care professionals (HCP) ultimately need new electronic systems processing clinical data for daily practice.

Research in intensive care has been increasing strongly since the 1980's. Figure 1 depicts the number of publications per year over time for the keywords "intensive care" and "critical care" in PubMed showing an exponential increase over time. Thus, it has become more and more difficult for clinicians to keep an overview of state-of-the-art knowledge regarding diagnosis and treatments.

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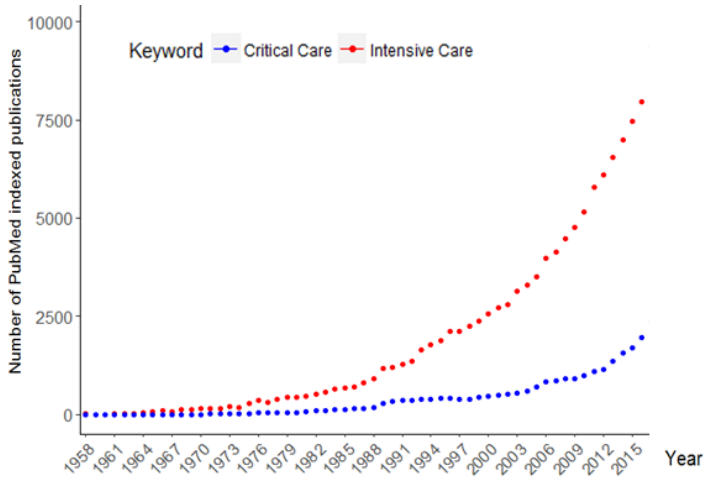

Figure 1. Yearly number of PubMed indexed publications from 1956 to 2017 for the keywords "Critical Care" and "Intensive Care" in title and abstract (TIAB search pattern).

One way to assist clinicians in their daily practice and thus improve the quality of medical care in hospitals is the use of clinical decision support systems [3]. The term "Clinical Decision Support" (CDS) as used from hereon is defined as a system "providing clinicians, patients or individuals with knowledge and person-specific or population information, intelligently filtered or presented at appropriate times, to foster better health processes, better individual patient care, and better population health" [4]. This definition refers to the consensus published along with the national roadmap on clinical decision support in 2007 in the United States.

1.1. Types of Clinical Decision Support

When approaching the different applications of CDS, it is crucial to narrow it down to the relevant types in each setting. One way of classifying decision support is to divide it into four phases [5]. Therein, CDS (1) may act as a single system, (2) be integrated into clinical systems, (3) use standards for sharing content and (4) provide service models. A more precise way is to cluster CDS systems according to their capabilities [6]. Table 1 gives an overview of the taxonomy of the systems, based on various capabilities.

Table 1. Clinical decision support taxonomy based and modified on [6].

Decision support capability	Related types
Medication dosing support	Functions for e.g. adjustment, range of dose, maximum dose or indication-based dosing.
Order facilitators	Indication-based, protocol-based or condition based ordering.
Point-of-care alerts/reminders	Drug interactions, care planning, physiological parameters, critical values
Relevant information display	Context-sensitive information retrieval, patient-specific data displays, medication cost display or context-sensitive interfaces.
Expert systems	Support functions, e.g. interpretation of sensor data and information systems, diagnostic support, treatment planning, risk assessment, prediction or interpretation.
Workflow support	Reconciliation of medication, order routing and approval, assistance in documentation.

Depending on the type of capability, CDS may range from simple methods such as dose range checking for medication, to complex ones like prognostic tools used in expert systems. The approach proposed in this paper refers to the development of expert systems. In general, CDS is able to improve the performance of HCP. A systematic review including one hundred studies showed that in 64% of the studies the practitioner performance improved by using CDS [7]. Studies included in the review assessed diagnostic, reminder, disease management and drug-dosing or prescribing systems. Regarding patient outcome, another analysis showed that a positive impact was present in 25 out of 82 studies included in systematic reviews [8].

1.2. Clinical Decision Support in Intensive Care

Treatment in intensive care units (ICU) is different from standard wards. Resources, time, workload and staffing are limited and crucial in the treatment of critically ill. Benefits for the use of CDS in intensive care have been demonstrated. One prospective controlled intervention cohort study was able to show a reduction in the incident of drug-drug interactions and related adverse events due to the use of CDS [9]. A randomized controlled trial (RCT) conducted in three different ICU across Europe demonstrated that a fully automated algorithm for tight glycemic control is safe and effective in the treatment of critically ill patients [10]. Regarding argument-based recommendations for diagnosis, a computer-interpretable guideline model for hyponatremia improved agreement with expert consensus in comparison to a paper algorithm [11]. Thus, CDS in intensive care represents a suitable option in assisting clinicians in their daily practice.

1.3. Challenges in Clinical Decision Support

The following efforts and challenges need to be considered when developing a CDS due to user and market adoption and particularly to the diversity of stakeholders involved:

- Clinical need: Early consultation of health care professionals is essential for identifying a clear clinical need [12]. Assessing the currently unmet requirements and not losing sight of them represents one of the top priorities.
- Continuous involvement of HCP: Integration starting with the beginning of the development, but also maintained longitudinally across the whole process. Including HCP in sprints or loops may lead to the reconsideration of function and application fostering sustainability.
- Interaction with existing systems: A high number of electronic systems exist in intensive care bedsides. These include hospital information and patient data management systems. In order to ensure an easy installation of the CDS system and to enable communication within a diverse technological environment, standards and state-of-the-art interfaces should be implemented.
- Availability of technology and devices: Any new device, sensor or machine, as well as any upgrade is related to monetary investments. Moreover, new systems often require additional electronic interfaces for processing data.
- Meeting the patients' need: CDS systems should also contribute to a safe and comfortable environment allowing the patients to recover. In intensive care, several physical and psychological factors represent stressors for patients [13]. Among the five greatest stressors are noise and invasive actions (such as tubes) [14]. New systems should aim at improving patient quality by using minimally

invasive methods and intelligent alarms. Alarms in general may lead to alarm fatigue by the users, which in turn affects patient safety [1516]. Prompts and alarms need to be tailored to fit patient and user needs [17].

These first discussion points do not provide an entire overview regarding challenges in CDS (see [18] for a detailed analysis).

1.4. Aims

The main aim of our approach was to propose a tailored model for the sustainable development of a CDS system in intensive care. In contrast to normal wards, the field of intensive care represents a high-reliability environment [19], bringing along a whole set of crucial requirements. Secondly, the model has to relate to the various challenges associated with CDS described under 1.3. In summary, following the model shall foster the development of a viable system, independent of the addressed type of CDS.

2. Methods

We consider two aspects vital for an integrated development approach. First, a pool of key partners need to be included by taking into account the multi-professional and interdisciplinary environment in intensive care, representing the cornerstones of the model. The second aspect of importance represents the process of developing the system. This may include different phases or iterative loops, from ideation until market entry. Regarding medical technologies, a step-by-step model is provided by the Stanford Biodesign [20], consisting of three distinct phases: "identify, invent and implement". The process model we propose has familiarities, whereas it focuses more on the developmental approach, not taking into account the economic and legal perspective.

2.1. Interaction of partners

Our model includes scientific partners, health care professionals and industrial partners. Figure 2 depicts their interactions, with a common interaction area in the center of the model. All three different fields are to cooperate within the development of the CDS. HCP provide insight into daily practice. This is necessary to hit the clinical need when starting to identify the field of action. Their continuous involvement throughout the whole process guarantees practical gains for the clinical applicability and reliefs common problems. The scientific partner develops the models required for the expert system, specifically designed and tailored to the needs of the HCP. Finally, the industrial partner provides the framework for technological feasibility and implementation.

(1) Interaction between the scientific and the industrial partner. Focusing on evidence-based fundamentals, the scientific partner provides knowledge required by the industrial partner for technically developing the CDS. Relevant data needed for developing models can be provided by conducting clinical trials.

(2) Interaction between the scientific partner and health care professionals. The dialogue between the scientific partner and HCP is particularly important for proofing the applicability of concepts and models. HCP can pinpoint problems in clinical practice and feedback on the effectiveness and efficiency of a conceptual model, thereby fitting it to their needs. Moreover, the scientific partner can be invited to join providers in their daily work by carrying out walkthroughs to identify problems.

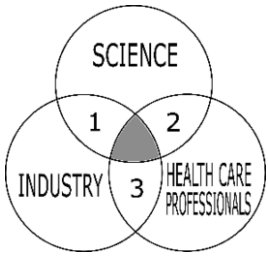

Figure 2. Interaction of partners for CDS development. (1), (2) and (3) showing overlaps for cooperation.

(3) Interaction between health care professionals and industry. Along the progress of developing the technology for the CDS, HCP can assist the industrial partner in regularly testing usability and design. By integrating HCP in a very early phase, time and effort spent on otherwise later tests will lead to a quicker development.

2.2. Process model

The process used for CDS development consists of three distinct phases (see Figure 3). At first, identifying the clinical needs is of fundamental importance for the whole process as it already relates directly to daily clinical practice. Secondly, the model for the CDS expert system is set up, accompanied by a simultaneous and quick prototyping, integrating HCP in feedback loops. In the third phase, the implementation takes place.

Throughout every phase, the plan-do-study-act (PDSA) cycle [21] is used. The hypothesis of each phase is tested and adapted due to the results obtained using the PDSA cycle. This allows a profound development along each phase, which may reject, restate or fine-tune the underlying hypothesis used for CDS development.

(1) Identification of clinical needs. The scientific partner is cooperating on a close basis with HCP. Underlying problems in the clinical setting are analyzed and structured, e.g. by qualitative interviews or walkthroughs. Additionally, current scientific literature and latest publications are screened for understanding the context of the problem field. A justification of the identified problem has to be formulated in order to have a firm basis for further investigation. Planning clinical trials at the end of this phase may assist if there is a need for more or additional data or information, respectively.

(2) Modeling and prototyping. After having formulated the clinical need, a conceptual CDS model is set up. The scientific and industrial partner work together to develop a first prototype, without functionality towards the patient, but providing a tool to assess its applicability together with HCP. Advantages of such a non-functional prototype are the early availability for testing and receiving feedback of HCP, saving costs and time instead of long development runs and a quick adaption and integration of changes based on expert input. Clinical trials provide data and information for the

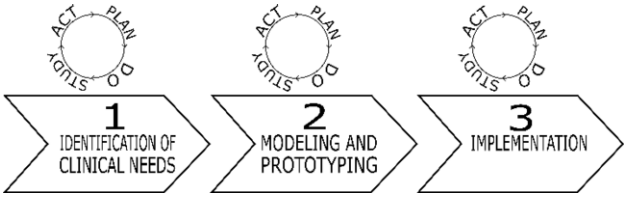

Figure 3. Process model for the CDS development.

development of the underlying model, taking place in parallel to usability tests of the non-functional prototype. Data sources may include the hospital information system, electronic health record or patient data management systems.

(3) Implementation. The main focus lies on directly translating the prototype including the model into a functional product. Existing sensors and devices are considered to reduce invasiveness and additional connections towards the patient. Together with the scientific partner and HCP, the industrial partner is able to conduct clinical trials for means of evaluation. Planning for such trials can start in parallel to the implementation, increasing efficiency in comparison to traditional approaches.

3. Results

By July 2015 a CDS project was started in the framework of the government funded COMET-K1 Centre, Center for Biomarker Research in Medicine (CBmed) in Graz, Austria. With CBmed as lead, B.Braun Melsungen AG as industrial, Medical University of Graz (MUG) and Graz University of Technology as scientific partners have joined the project. A multi-professional and interdisciplinary team consisting of biomedical engineers (1.75 full time equivalents (FTE)), intensivists (available at MUG), nurses (0.125 FTE and available at MUG), molecular biologists (0.75 FTE) and clinical trial experts (0.5 FTE) has been assigned to the project. The FTE refer to the employment at CBmed. Personnel of industrial and scientific partners join based on pre-specified in-kind contributions. The core team holds representatives of each partner (one per partner), setting the stage for close cooperation within every phase. All team members work within the MUG Campus. Arranging regular meetings and jour fixes over short time spans, every partner involved is up to date about the progress of each other. The core project team jour fixe takes place weekly, whereas coordination with the industrial partner takes place in a bi-weekly meeting schedule. Medical advisors such as intensivists or nurses are kept up to date on a monthly basis or are invited to the core project team jour fixe on demand.

The identification of clinical needs was carried out within the first six months, mainly by multi-site quality interviews conducted with intensivists and nurses. A total number of 12 HCP were interviewed in two different Austrian hospitals. Using these results, a robust justification report was created wherein the clinical need statement was related to the specified area of research. Modeling and prototyping started by beginning of 2016. A prospective monocentric observational clinical trial (Clinibil, clinicaltrials.gov identifier NCT02914782) was planned and started in September 2016 at an intensive care unit of MUG to provide extensive clinical data needed for the model. The trial includes electronic data about patient demographics, individual data of medical sensors during the ICU stay (i.e. heart rate, blood pressure, invasive circulation monitoring parameters, ventilation parameters, lab test results for serum and urine including electrolytes) and information about the medical treatment (i.e. administration of drugs and fluids, invasive interventions). Additionally, biosamples of the patients were acquired and aliquots stored at BioBank Graz for later in-depth analysis. By end of 2016, a first non-functional prototype was available. In 2017, the prototype was tested in further multi-site qualitative interviews with intensivists and nurses of the first interview round. In parallel, the development of a mathematical model for the analysis of the clinical course of selected parameters including fluid and electrolyte management started. Data acquired in Clinibil for 52 patients was used for early verification of the developed model

by end of 2017. Verification was carried out by electronically comparing the predicted results of the model to the data of the clinical course of each patient included in Clinibil at specified time points and timeframes. Next steps for enhancing the model and validating its applicability by a second trial including more than 2000 patients are planned to finish the second phase by end of 2018. This includes combining the user interface of the non-functional prototype together with the validated model. The project can then transit to the implementation phase for the finalization of a new medical device including necessary evaluations in situ.

4. Discussion

The increased amount of scientific work published in the field of intensive care together with the growing share of electronic systems and devices makes it necessary to adapt the way CDS systems are developed. Traditional ways of research and development (R&D), starting in R&D divisions without an early involvement of HCP, may hamper the development of devices and systems that tackle problems of daily practice and take into account the clinical needs. The approach for CDS development proposed in this paper tries to consider these needs by integrating a multi-professional and interdisciplinary partnership model into a three-phase process. The early identification of clinical needs makes it possible to avoid unnecessary development iterations. Moreover, continuous feedback and evaluation by HCP provide the possibility to take into account the applicability of the CDS in comparison to already used systems, tailoring it specifically to specified problems of clinical practice.

The results show that the approach for CDS development is feasible. Regarding the time span of the various phases, it has to be highlighted that formulating a clinical needs statement is possible within a rather short time span as of six months. Therefore, modeling and prototyping can start early. Moreover, the availability of clinical data from the conducted trials provide tailored data for development of the CDS model. However, as the project has not yet begun with the implementation phase, no statement about efficacy in terms of a final CDS system is possible. Saving of time and resources by constantly involving HCP can only be evaluated after project end. Concerning the mode of cooperation between the partners, mutual understanding has been set up between the various and different professions involved. This is supported by the rather high frequency of meetings and jour fixes, thereby constantly keeping track with each project partner, possibly proofing beneficial in respect to the sustainability of the new system.

In clinical practice, CDS will definitely become more important within the next decade. Electronic systems will not only support, but also routinely provide services especially in settings with high workload, such as intensive care. Therefore, these systems have to fulfill the needs of HCP and patients. The described approach for CDS development is one way of integrating different partners to accomplish such goals.

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