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Towards a PropeR combination of patient records and protocols

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Abstract. The combination of a computer-based patient record system with a decision support system may give physicians the decisive push they need to accept such systems. In the PropeR-project we determine the requirements for a generic interface between both such systems and measure its potential impact on patient care. In this overview we describe the objectives, the experimental approach, and the current state of the PropeR-project. We also discuss the original positions behind the project.

1. Introduction

A CPR system is only acceptable to the physician if (s)he sees direct advantages for daily practice. The combination of a CPR system with a decision-support (DS) system may give the advantages the physicians are looking for [1, 2]. DS-systems are often based on protocols (guidelines). Protocols are standards of best practice developed by consensus conferences, evidence-based approaches, or other approaches [3]. The aim of a protocol is to reduce rates of inappropriate care by decreasing physicians' uncertainty, while reducing health-care costs [4]. However, what is best for patients overall, may be inappropriate, and even harmful, for individuals. When rigidly used, protocols may lead to cookbook-medicine [5]. A useful clinical guideline should allow the user to deviate from the protocol when (s)he has a valid reason. In that case, an explicit justification of his non-adherence may provide useful information for others. Another key component of a useful clinical guideline is an adequate presentation of evidence and recommendations to the user [6]. Computer-based protocols can be presented to the user in various ways: as a reference, as pro-active reminders (guide, advisor), or as re-active reminders (critique).

2. Objectives and research questions

The PropeR-project aims at investigating the added value of a combination of a CPR- and a DS-system, with a focus on the advantages for daily practice. Key issues of the Proper-project are (a) the presentation of protocols, and (b) the recording of justification for deviating from the protocol. The objectives of the PropeR project are:

1. To determine the requirements for a combination of a CPR- and DS-system that can successfully support physicians and other health-care professionals in managing their patients according to the protocol, but also in providing the means to justify (motivate) deviations from the protocol. The focus is on usability ("Is it a proper tool?") and satisfaction ("Does it provide the user with proper support?").

2. To evaluate the impact of such combination on patient care. Here the focus is on protocol adherence ("Does it lead to proper decisions?") and interdisciplinary collaboration ("Does it lead to proper care?").

To this end, we are developing a prototype implementation of a CPR-DS-interface that supports proactive and reactive reminders and try it out in two medical domains. For each domain a PhD-study is running.

3. Two medical domains

Two typical domains with experience in using paper-based protocols are inpatient hematology and transmural (shared) stroke revalidation. In both domains, non-adherence to the protocol is a serious problem, but for different reasons.

The treatment of haematological patients is complex from the medical perspective. Non-adherence may be due to difficulties with finding patient data that are relevant for the protocol [7]. Hematology is a well-structured medical domain with complex therapies. Hence, in this PhD-study we focus on the medical aspects of the care process. The base study centre will be the Maastricht University Hospital (azM).

The transmural revalidation of stroke patients is difficult from the organisational perspective. Non-adherence may result in ineffective collaboration, or vice versa. Compared to hematology, the domain of transmural stroke care is far less structured. Each discipline involved is using or developing its own guidelines, but a constant tuning of tasks between disciplines remains necessary. Therefore, in this PhD-study we pay more attention to organisational aspects of the care process. For this study there are two base centres: the home-care centre GKH at Maastricht and the revalidation centre IRV at Hoensbroek. At GKH a shared paper patient record has been introduced for communication purposes, which does not work however. We will replace this paper version with a CPR-system.

4. Experimental approach

In the domain of hematology, we use three treatment protocols: acute myeloid leukaemia (AML), acute lymphatic leukaemia (ALL), and non-Hodgkin lymphoma (NHL). In the domain of transmural care, we study the care for stroke patients after discharge from the hospital. The main lines of our experimental approach are:

a. **Analysis** of the current situation in daily practice (protocol use, communication) and review of the scientific literature concerning protocol use, CPR- and DS-systems in the domains under study, and the integration of CPR- and DS-systems in general. The current process of protocol-based care at the base centres under study has been described in detail. To this end, the protocols and medical records were analysed and compared, the working floor was observed, and interviews were held with representative samples of health-care professionals involved.

b. **Design and development** of a generic interface between a DS- and CPR-system. Before an interface module will be specified, we must have working versions of a CPR-system and a DS-system. The base centre of hematology will use a commercially available CPR-system Mirador (a product of Hiscom), which in the near future will be implemented in all inpatient clinics of the Maastricht University Hospital. For our base centre of transmural care we are developing a new CPR-system based on open standards. As DS-system in both domains we will use Gaston, an expert-system shell that reasons with protocol knowledge [8]. The interface between CPR- and DS-system will be developed as a separate component that can easily be replaced by a future standard. It will contain functions for recording and

motivating deviations from the protocol and for switching between proactive and reactive reminders. The problem of matching terminologies between both systems will not be addressed in this project. This problem is subject of study of other research groups [9].

c. **Intervention study** to evaluate of the effect of the system. We will ask a number of health-care professionals to use the system in daily practice. The aspects of evaluation will be (a) user satisfaction, (b) protocol adherence and justification for non-adherence, (c) accessibility of clinical data and protocol knowledge, and (d) changes in the health-care process. In the hematology study we will use a before-after design with triangulation of qualitative evaluation methods (e.g., in depth-interviews). In the stroke revalidation study we will perform a controlled trial with cross-over design, again with triangulation.

5. Results so far

In both domains, protocol use and information needs of health-care professionals were analysed and been reported in UML use cases and class diagrams (not published). In the stroke-revalidation study a literature survey concerning the problems with shared care was performed. This survey approved our assumption that that collaboration problems in shared care are mainly due to insufficient communication, and that shared paper patient records did not work (neither in our own base centre, nor elsewhere). The survey also revealed that a combination of of EPR- and DS-system, advocated by many as the solution for this problem, was successful in other domains but not yet tried out in shared care [10]. The development of a shared EPR-system for stroke revalidation is in progress and will be described elsewhere [11].

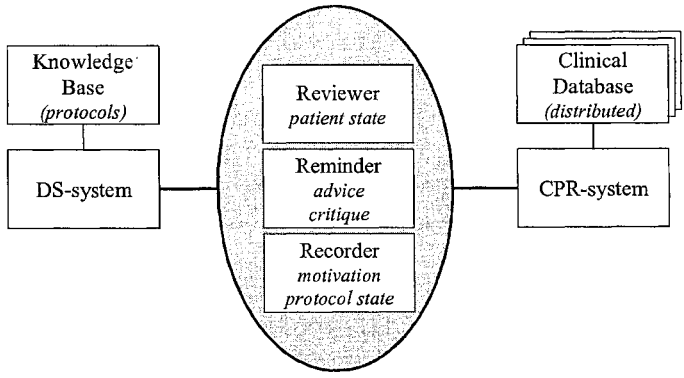

Figure 1: Potential architecture of a CPR-DS interface.

6. Future planning

At the moment of writing, the first hematology protocol is being entered in the DS-system and a baseline study concerning protocol adherence is in preparation. The stroke-revalidation guidelines have to be structured yet, before they can be entered. If complete structuring is not possible, we consider a hybrid of textual and formal representation, as is studied by others [12]. The generic interface will be specified when we have working (prototype) systems on both sides. We think of a EPR-DS-interface that consists of three components (

Figure). The Reviewer deals with the past. Its function is to query patient data in the EPR-system, triggered either by a user action (reactive) or by the state of the protocol (proactive). The Reminder deals with the present. Its function is to present reminders to the user, in the form of critique (reactive) or advice (proactive). The Reporter deals with the future. Its function is to remember the temporal state of the protocol (where are we?) and to capture the user's justification of non-adherence. We expect to implement the combination of systems in daily practice begin 2003 and evaluate its use and impact late 2003/2004.

7. Discussion

The PropeR-project is half way now and is generating its first products this year. These will be published and discussed in future papers. In this discussion we concentrate on the innovative elements of the PropeR-project.

The combination of different ways of decision support. One of the key components of a useful clinical guideline is an adequate presentation of evidence and recommendations to the user [6]. This can be in a passive or active way. Examples of passive support are reference systems [13] and systems that provide solicited advice [14, 15]. Examples of active support are systems that guide the user by dynamic data entry [16, 17], and systems that provide unsolicited advice, alerts, reminders [18, 19], or critique [20, 21]. Which way of decision support is best depends on the situation. Existing DS-systems usually provide only one way of support. Combining different ways of decision support in one system is a research challenge.

The justification of non-adherence. A protocol is simply a reference tool. What is best for patients overall, may be inappropriate, and even harmful, for individuals. When rigidly used, protocols may lead to cookbook-medicine [5]. The physician (or other health-care professional) is responsible for matching the protocol to the needs of a specific patient. Thus, he may have a valid reason for deviating from the protocol. In that case an explicit justification of his non-adherence may provide useful information for the other professionals involved. Reasons for non-adherence can also be used for medical-audit purposes and for improvements of the protocol itself. However, physicians will not be inclined to record their considerations when it takes too much effort. Likewise, it must be easy for colleagues to take notice of this justification. Therefore, it is a challenge to determine the requirements for an adequate user interface for this functionality and to study its added value.

Open links between CPR- and DS-system. Most DS-systems are autonomous systems and need explicit data entry, which is a barrier for the acceptance of those systems. On the other hand, there are some excellent examples of DS-system fully integrated with a CPR-system [18, 22, 23]. However, these fully integrated systems are usually proprietary systems that cannot easily make use of other knowledge sources and cannot easily be combined with systems from other vendors. A current research challenge is the development of standards for open links between CPR- and DS-system [24]. In our

approach, we will anticipate on this development by designing the interface between DS-system and both CPR-systems as a separate component that can easily be replaced by a future standard.

8. Epilogue

The two PhD studies must reveal enough information to specify a generic interface between EPR-system and DS-system. This interface must be indepedent from both systems. Hospitals and other health-care organisations must be able to implement this concept without much trouble. For a medical informatician, it is both the art and fun to develop a generic model that fits anyone.

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