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Factors Influencing the Implementation and Distribution of Clinical Decision Support Systems (CDSS)

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Abstract. Clinical Decision Support Systems (CDSS) can have positive effects on quality of care measures, yet have not gained widespread traction in healthcare. This study sought to determine and evaluate barriers and facilitators to CDSS implementation and distribution. Based on 768 systems identified in a literature review we conducted semi-structured telephone interviews with 54 system developers in 16 countries. Qualitative analysis led to the identification of 66 key factors influencing implementation. Central issues evolved around CDSS properties, quality and integration, as well as usability, user related factors, internal marketing, resource issues and collaborations with emphasis partly on topics differing from existing research. Additionally, evidence pointed to regional differences regarding implementation hurdles. Recent regulatory requirements were deemed less of a barrier to system adoption than expected, even though lacking expertise in this area was surprisingly common among interview partners.

Keywords. Clinical Decision Support Systems, Health Information Systems, Barrier, Medical Devices, Medical Device Legislations

1. Introduction

The growing complexity of medical care contributes to a high number of preventable adverse events in patient care worldwide [1]. Great efforts have been made in recent years, with varying success, to improve patient safety and promote evidence based medicine [2]. Computer systems that assist with clinical decision making (CDSS) have repeatedly proven their ability to have a positive impact on quality of care measures [3]. Governments and legislators in various countries strive to advance the use of CDSS. Yet as of today these systems have failed to gain widespread traction in healthcare [4].

A large body of literature exists that cites hurdles and facilitators for the implementation of Health Information Technology (HIT) and specifically CDSS. These include various models for the adoption of new technologies [5], systematic reviews of case reports [6], Delphi studies [7] and other surveys of experts [8], as well as field work [9] and user surveys [10]. Limitations of current research include a strong focus on Anglo-American studies [11] in a domain that is very much influenced by cultural

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factors, methodical inadequacies of many systematic reviews [11] and a general pronounced fragmentation in this field of research [12]. Additionally, the impact of potential implementation barriers like recent regulatory requirements regarding the classification of software as a medical device, have not been studied systematically. This study therefore sought to identify and evaluate obstacles and facilitators to the implementation and distribution of CDSS in a comprehensive multinational study.

2. Methods

We conducted semi-structured telephone interviews with CDSS developers, who have published papers on their systems between 2002 and 2012. Potential interview partners were identified using a Medline search based on proven search strategies. 768 CDSS were identified after reviewing more than 70,000 titles. Owing to language barriers, we focused on developers situated in Europe and North America. 150 potential interview partners were contacted via E-Mail. Acknowledging the aforementioned dominance of Anglo-American studies on CDSS implementation hurdles, 120 (80%) of the contacted developers were based in Europe. Researchers in both regions were selected randomly.

Interviewees were queried on their CDSS implementation experiences and factors aiding or hindering that process using open questions (Table 1). Additionally, we collected data on three often-cited barriers, namely requirements imposed by legislators, issues regarding knowledge management, as well as challenges concerning lacking standards for sharing CDSS content. Developers were also questioned on the current implementation status of their projects, resources consumed by the development, their role in the development process and their professional background. Interviews were conducted in either German or English. All interviews were fully transcribed. For evaluation, we resorted to qualitative methods developed by Mayring [13], which combine both deductive techniques and practices rooted in grounded theory.

3. Results

3.1. Response Rate and Descriptive Statistics

136 out of 150 (90%) E-Mails reached their recipients. 63 (46%) developers replied to our invitation for an interview. In total 54 interviews were conducted between August and December 2014. The average interview time amounted to 16 minutes. Nine experts replied late (3), deemed themselves non-specialists (2) or were not able to find time for an interview (4). Interviews were conducted with experts from 16 different countries, with the majority based in Germany (13), the Netherlands (7), the US (7), Italy (6) and Canada (6). 42 (78%) of the interview partners were male. Most experts possess either a medical degree (28) or work as computer scientists (16). On average, the developers looked back on 22 years of working experience and 17 years of experience with HIT. A vast majority of the developed CDSS were knowledge-based systems (48 or 89%). The sample included CDSS that provided guidance in therapeutic decisions (24 or 44%), drug prescription (13 or 24%), diagnosis (13 or 24%) and prevention (3 or 6%) in a variety of different medical specialties. The majority of CDSS was developed or deployed in teaching hospitals (36 or 67%). 21 (39%) of all systems were integrated with existing HIT. 54% of the selected systems (29) required data input by medical personal.

7 (13%) of the CDSS generated actionable output. 19 (35%) of the systems had undergone evaluation. The implementation rate amounted to 50% at the time of the respective CDSS publications (27) and had dropped to 41% at the time of the interviews (22) with eight new installations and 13 out of 27 systems that had ceased operation. 19 (35%) of the developers had plans to implement their system again in the future.

3.2. Qualitative Analysis

Table 1 aggregates the main factors influencing CDSS implementation and distribution according to the interviewed developers. The cited barriers and facilitators to implementation were pooled, as a majority perceived these to be two sides of a coin.

Table 1. Factors with an influence on successful CDSS implementation

Category	Influencing Factor
System (83*)	Quality (16), properties (15), workflow integration (12), usability (12), EMR integration (8), transparency (7), maintenance (3), availability (3), updates (2), security (2), scalability (2), performance (1)
User (46)	Time (9), project involvement (9), motivation (5) , relevance (5), loss of influence & control (4), output acceptance (3), IT know-how (2), job security (2), information overload (2), resistance to change (1), incentives (1), expectations (1), utility (1), general acceptance (1)
Management/ decision makers (26)	Internal marketing (16), organization (3), external marketing (3), HR planning (1), economic benefit (1), hierarchies (1), implementation (1)
External partners (13)	Collaboration (10), external funds (1), investors (1), marketing (1)
Resources (13)	Funding (10), data (1), know how (1), human resources (1)
Politics/Legal framework (13)	Regulation (8), funding (3), liability (1), patents (1)
Existing IT (12)	Performance (3), data availability (3), interfaces (2), standards (2), standards regarding data structures (1), general conditions (1)
Scientific community (11)	Evaluation (5), grants (3), publications (2), guideline development (1)
Project team (10)	Interdisciplinarity (5), training (3), preferences (2)
Public (4)	NGOs (2), patients (2)
Competition (1)	Collaborations (1)

* Number of supporting statements

Looking at regional differences in adoption barriers, management related factors are quoted more often by developers in the US than in Western Europe. Here, system related aspects like quality and CDSS properties are deemed relatively more important. Furthermore, regulatory aspects are mentioned solely by interviewees from Northern and Western Europe. A specific inquiry into this topical issue reveals that only 33% of the developers see regulation as a barrier for the implementation of their system with a larger number acknowledging a challenge for CDSS adoption in general. 30% of the queried experts could not comment on the issue, as they were not familiar with current regulatory practice. Reasons for not being personally affected by regulation included CDSS developments before the passing of current legislation (6), systems that allegedly do not meet the definition of a medical device (6), CDSS that are still in a development stage (5) and missing relevant national laws (1). In the EU, software has to be certified as an active medical device, if the developer intends its use for the diagnosis, therapy, prevention or monitoring of diseases. Nonetheless, only 5% of the sampled systems have received certification. 85% of the interviewees have no plans to this end. Another often-mentioned barrier to long-term implementation is the maintenance of the CDSS knowledge base. However, 69% of the developers do not perceive this as a prob-

lem. They cite CDSS in small and static domains, along with maintenance work as part of the general internal guideline development process in hospitals as reasons.

4. Discussion

As part of this survey a wide range of factors influencing successful CDSS implementation were identified. Low adoption rates among interviewees show the need for detailed knowledge regarding CDSS adoption challenges. System quality is seen as one of the key elements for effective implementation. On that score, it became apparent that frequently the depiction of complex medical decision processes still presents a major challenge for developers. Common over-alerting and the realization that CDSS can potentially also do harm, add to the picture of a domain that still has to overcome substantial challenges. System properties are deemed almost equally important for successful adoption. In this regard, conflicting goals exist between small and simple CDSS in clearly defined domains that are easy to develop and maintain and the user demand for complex integrated solutions. The inadequate focus on the respective target groups by developers stands in close connection to calls for early user involvement in the CDSS development process. In this context, the interview partners see usability, transparency and time investment by the client as the key factors for user acceptance of the system. Many developers described barriers within the organization and the considerable resources needed to convince decision makers of a CDSS project. This is aggravated by the fact that these are often not one time investments by the developers, but rather part of a constant effort, where the raison d'être of a system has to be constantly explained and demonstrated in a dynamic organization. The majority of the interviewees develop CDSS in a university setting. In this context, collaboration with industry partners is often vital for implementation and distribution due to monetary constraints and limited legal and marketing expertise. Especially European scientists point out that system distribution and migration regularly exceeds both the resources and the goals of university research groups. This problem is somewhat less pronounced in the US, where CDSS development often occurs within health maintenance organization that migrate systems into their own clinics. Higher implementation rates in the US fit into this picture. Regulatory issues are among the most frequently cited implementation factors, though they are actively mentioned only by European developers, which can in part be attributed to currently unclear regulation intents by the FDA in the US. Overall, low concern about regulatory issues comes as a surprise given the potential consequences of a classification of software as a medical device, but can partly be explained by low overall adoption rates and plans for implementation.

Strengths of this study include its wide scope with interview partners from more than a dozen countries with often significant differences with regard to cultural and socioeconomic factors and the design of their healthcare systems. The sample was drawn from a comprehensive literature review. Despite a satisfactory response rate of 40%, a non-response-bias is likely. The qualitative methods used for data classification are highly formalized and allow for a standardized treatment of the data. At the same time the transfer of complex information into a rigid system of categories may have led to a loss in both meaning and context. Similarly, when conversing with non-native speakers, language barriers could have produced suboptimal data. Compared to existing literature, this study in part emphasizes different aspects with regard to CDSS implementation hurdles, for the first time adding the unique perspective of system devel-

opers in an international survey. Spreckelsen et al. report similar barriers, albeit with emphasis on user related and technical issues. [13] Paré et al. focus more on usability and project-based aspects compared to this study. [14] Partly differing barriers were also identified by Ash et al. [9], Moxey et al. [6] and Brenders et al. [7] The cited differences may in part be explained by input from experts with different backgrounds, a change in implementation barriers over time, regional differences with regard to adoption factors, a focus on different HIT, as well as differing qualitative methods.

5. Conclusion

Successful CDSS implementation depends on a wide variety of complex factors with potentially relevant regional differences. Surprisingly, regulatory aspects as a potential key barrier to the uptake of CDSS are currently not given much consideration by many developers. In light of the forthcoming profound changes in the EU with the planned passing of the Medical Device Regulation in 2017, European CDSS projects are likely going to face additional implementation challenges in the future.

6. Conflict of Interest

The authors state that they have no conflict of interests. The data is part of the doctoral thesis of BRK.

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