THE MULTI-LEVEL IMPACT OF CLINICAL DECISION SUPPORT SYSTEM: A FRAMEWORK AND A CALL FOR MIXED METHODS EVALUATION

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Abstract

Clinical decision support systems are important healthcare systems that help in improving healthcare quality and in reducing cost. These systems have multiple levels of outcomes on the individual, group, organization, and society levels. However, despite the abundant studies conducted to evaluate CDSS, most of these studies failed to recognize these multiple levels of impact and mostly focused on the clinical efficacy of these systems using randomized controlled trials (RCT) designs. In this paper, we propose that CDSS evaluation is a complex task that cannot be accomplished using a single research methodology. We propose a framework that identifies the multiple levels impacted by CDSS and the appropriate methodologies that can be used to evaluate these impacts. We also provide an example of using this framework to evaluate a pain management CDSS. This study informs future evaluation studies on what and how to evaluate at different levels of CDSS interventions.

Keywords: Clinical Decision Support Systems, CDSS, E-health, multi method Evaluation, levels of impact
1 INTRODUCTION

Healthcare is one of the fundamental and most important services in any society. The importance of healthcare stems from its direct relation to the wellness of society and the wellbeing of its members. This importance is evident in the huge budgets governments allocate for healthcare. For example, USA spent over 6 trillion dollars ($8300 per person) on healthcare in 2012. Despite its huge budget, Healthcare continues to suffer from medical errors and poor quality control materializing in adverse drug effects, and diagnosis errors (Piontek et al., 2010).

The use of information systems (IS) in healthcare decision making started with the start of computer age, specifically the use of IS to improve healthcare decision making (Ledley & Lusted, 1959). However, attention to the importance of using IS in healthcare grew with the huge increases in healthcare costs and the call for quality improvements at the end of last century (America, 2001). IS was perceived as a means to reduce errors, improve quality, and reduce the growing healthcare costs.

Clinical decision support systems (CDSS) have been widely used in healthcare specifically in diagnosis, drug prescription, and in improving clinical efficiency. Because of the importance of these systems and the wide context of their use, abundant evaluation studies using randomized controlled trials (RCT) attempting to assess their effectiveness have been conducted and indeed these studies found CDSS useful in improving patient outcome and clinicians’ performance (Monique WM Jaspers, Marian Smeeuers, Hester Vermeulen, & Linda W Peute, 2011; Johnston, Langton, Haynes, & Mathieu, 1994). Surprisingly, despite the usefulness of CDSS in improving clinical outcomes, CDSS suffered from adoption problems (Cabana et al., 1999) and RCT based evaluations failed to provide explanation for this discrepancy because of their failure to account for contextual and environmental factors affecting CDSS use (B Kaplan & Shaw, 2004).

Because of the shortcomings of RCT designs, researchers called to use other methodologies to compensate for these shortcomings such as simulations, field studies, and qualitative designs (Bonnie Kaplan, 2001b). Despite these repetitive calls, RCT still dominates the CDSS evaluation literature. Moreover, even if different evaluation designs were employed, they focused on the effects of implementing CDSS on performance, workflow, and other healthcare outcomes and contexts and ignored how these contexts mutually influence CDSS implementation. For example, the effects of using CDSS on improving clinician-patient communications have been repeatedly examined (Black et al., 2011), while the influence of clinician-patient communications on clinician’s use of CDSS has rarely been studied. At organizational level, the effects of CDSS on workflow have been examined in several studies (Hine, Farion, Michalowski, & Wilk, 2009) while how existing workflows influence CDSS use has seldom been studied. This gap in studying the mutual effects between CDSS and healthcare contexts limits our understanding of why many CDSS implementation fail despite their proven clinical benefits.

In this paper, we aim to develop a framework for evaluating CDSS. This framework is expected to identify the different levels at which CDSS should be evaluated and the possible CDSS outcomes at these levels. The framework also signifies the mutual influence between CDSS and healthcare contexts. Moreover, our proposed framework will provide guidelines on the design of studies for different levels of CDSS evaluation. Our aim of this framework is to provide guidelines to inform future evaluation studies about the levels of CDSS evaluations and how to conduct these evaluations effectively, and to emphasize the need to use mixed methods in evaluating CDSS.

This paper is organized as follows. We start by describing the evolution of CDSS with focus on their impact on individual, group, organizational, and societal levels. Then, we discuss the different methodologies used to evaluate CDSS, their benefits and their shortcomings. Next, we suggest a need to use mixed methods to evaluate CDSS and provide a framework to evaluate CDSS on multiple levels.
Finally, we use our framework to design a study to evaluate a pain management CDSS. We conclude by summarizing the outcome of this study, its limitations, and its impacts on future research.

2 EVOLUTION OF CDSS

Computerized clinical decision support systems (CDSS) can be defined as information and communication systems that provide clinicians or patients with timely, accurate and appropriate knowledge to enhance patient care (Osheroff, Pifer, & JM, 2005). Based on this definition, there are two basic features that apply to CDSS systems: (1) CDSS users include clinicians such as physician and nurses as well as patients. (2) The goals of CDSS are to provide access to patient information and to enable users to make informed and optimized decisions.

Although the previous definition differentiates CDSS from expert systems which aim to emulate human decision making instead of only providing the knowledge necessary to do so (Seto et al., 2012), the evolution of CDSS shows that this has not always been the case. Ever since the introduction of computerized clinical support more than fifty years ago, researchers attempted to use the (new) computer power to facilitate, and even make, decisions on treatment options and diagnosis (Greenes, 2011). For example, one of the earliest papers on CDSS discussed selecting among treatment alternatives (Ledley & Lusted, 1959). Diagnostic CDSS prevailed during the first two decades of CDSS use and they actually offered little benefits to physicians because they lacked the ability to transform clinicians’ tacit knowledge into explicit knowledge that can be coded into CDSS, and because they lacked appropriate guidelines to make clinical decisions (Berner & La Lande, 2007). The development of evidence based medicine (EBM) in the early nineties (Guyatt, Sackett, Cook, & Group, 1993) represented a landmark for CDSS. EBM enabled the coding of best practices in guidelines that can be used by physicians to make diagnostic and treatment decisions (Chalmers, 1993). The development of EBM in addition to the development of appropriate protocols for guidelines exchange such as GLIF (Peleg et al., 2000) enabled CDSS to incorporate these guidelines in the decision making process which enhanced their effectiveness as diagnosis and treatment support tools (Greenes, 2011).

In addition to the use of CDSS as a diagnostic tool, several other uses of CDSS evolved. For example, one of the important roles of CDSS is to monitor user’s input, evaluate them and trigger events associated with these inputs (Kawamoto, Houlihan, Balas, & Lobach, 2005). For example, CDSS can be integrated with computerized physician order entry (CPOE) systems to alert physicians if they provide a medication overdose, or if the patient is allergic to some drug. CDSS have also been used to provide reminders to clinicians regarding patient care. For example, CDSS can be integrated with electronic health records (EHR) to remind physicians of necessary lab tests or prescription renewals.

Technological, societal, and healthcare related factors significantly affected CDSS evolution. CDSS have gained momentum and acceptance from healthcare industry over time. There are several motivations behind this wide adoption of CDSS. First, technology advances and the development of other types of health information systems such as EHR and CPOE systems enhanced the role and effectiveness of CDSS. This is mainly because these systems provided a context where the benefits of CDSS can be realized as well as knowledge which CDSS can use to facilitate decision making (Kawamoto et al., 2005). Moreover, the developments in data mining and data analytics enhanced the efficiency of CDSS and their capability to form decisions. Second, the development of health information systems resulted in an explosion of information that overwhelmed physicians and made it necessary to find ways to filter this information and find the information most relevant to the situation especially with the emerging trend in using genetic data to personalize treatments. For example, a patient personal health record (PHR) can have a lot of information such as diet and activity details which may not be needed in patient treatment. CDSS can be used to filter this information and provide the physician with only relevant information. Third, in the past twenty years, healthcare quality gained strong interest from society (America, 2001). One of the causes of this interest was the role of medical errors in increasing preventable mortalities and healthcare costs. For example, preventable deaths because of
medication errors were estimated to be ninety eight thousands in the United States (Pham et al., 2012), and twenty four thousands in Canada (Baker et al., 2004). The use of CDSS, especially for alarming physicians about possible adverse effects of over doses, can play an important role in enhancing quality and reducing medication errors (Singer & Vogus, 2013). Fourth, the aging population in developed countries, the chronic diseases associated with aging, and the increasing cost of managing these diseases as well as the increasing healthcare cost in general created a need to enhance the efficiency of healthcare in terms of hospital visits, medication, and disease management. Using CDSS can enhance efficiency by, for example, providing physicians with guidelines to best practices in managing diseases, and providing a standard for treatment. Finally, the recent direction of patient-centered care has a significant effect on CDSS. Patient-centered care calls for the involvement of patients in their own treatment and has resulted in the development of PHR systems that enable patients to communicate with care providers and to take part in the decision making process (Barry & Edgman-Leviton, 2012). Therefore, new CDSS, which where traditionally oriented towards clinicians, were developed to allow for the shared decision making between physicians and patients. For example, CDSS can be used to inform patients about treatment options and risks associated with these options and elicit their preferences (Ruland, 2004).

The factors that influenced CDSS adoption by the healthcare industry demonstrate the potential benefits of CDSS to individuals, groups, organizations, and to the society at large. For individuals, CDSS affects both physicians and patients. For physicians, CDSS enhance their decision making capability, increase their efficiency, and reduce the errors they may commit due to pressure, lack of resources, or overwhelming information. For patients, CDSS encourage patients’ involvement in their own treatment (especially when integrated with PHR systems). CDSS enhance patient safety by reducing medication errors, increase the effectiveness of disease management, and improve patients’ satisfaction with treatment. For groups, the adoption and use of CDSS may be affected by group dynamics and group leaders’ influence. CDSS may interfere with workflows in hospitals’ departments. For example, Pope et al. (2013) discussed the effects of implementing CDSS in emergency departments and how CDSS impact workflow there. Groups also include clinicians and patients’ groups. For example, physicians as a group may perceive CDSS differently from hospital administration because of their habitual decision autonomy and resistance for change. For patients, elderly patients may be less receptive of CDSS systems than younger patients because of their learning disabilities (Archer, Fevrier-Thomas, Lokker, McKibben, & Straus, 2011). On the organizational level, there are different organizations that may be affected by decision support systems such as hospitals and payers. For example, the implementation of CDSS in a hospital can impact its overall efficiency and cost savings. Moreover, it can lead to changes in the hospital organizational structure and workflows. For payers, CDSS represent a way to standardize decision making and treatment options which may enable them to predict health insurance costs accurately and accelerate their claim processing. Finally, the reduction in medical errors, reduction in healthcare cost, and improvement in healthcare quality which result from implementing CDSS have direct impact on the society. These benefits increase individuals’ trust in the healthcare system and improve the efficiency of health expenditure. Table 1 summarizes how the use of CDSS can address healthcare stakeholders concerns and the level of CDSS effects. In addition to the impacts of CDSS on different levels, CDSS affect the interaction between these levels. For example, the use of CDSS for shared decision making between patients and physicians is likely to affect the quality of the interaction between them as well as patient satisfaction with this interaction.
### Table 1. Levels and impacts of CDSS use

<table>
<thead>
<tr>
<th>Healthcare Concerns</th>
<th>Level of Impact</th>
<th>Description of Impact</th>
</tr>
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<tbody>
<tr>
<td>Technological advancement</td>
<td>Patients Clinicians Groups</td>
<td>Involvement in the decision making process Optimized decision making, alerts, and reminders Improvements in departmental workflows</td>
</tr>
<tr>
<td>Information explosion</td>
<td>Physicians</td>
<td>Providing physicians with tools to filter information and use only relevant information</td>
</tr>
<tr>
<td>Healthcare quality</td>
<td>Clinicians Patients Organization Society</td>
<td>Less errors committed because of time and resource pressure Better treatment and care quality Overall efficiency/cost reductions/ satisfaction Reduced healthcare costs, society wellness/ satisfaction</td>
</tr>
<tr>
<td>Aging population</td>
<td>Patients Groups Society</td>
<td>cost savings can be used to improve overall healthcare Better management of chronic diseases associated with age Improved healthcare/cost savings/people’s satisfaction</td>
</tr>
<tr>
<td>Increasing cost</td>
<td>Clinicians Organization Society</td>
<td>Time savings/less pressure Standardized decision making/ cost reductions Healthcare cost reductions</td>
</tr>
<tr>
<td>Patient-centered care</td>
<td>Patients Physicians Organization Society</td>
<td>Engagement in treatment/better adherence Patient adherence to treatment/ time savings Less hospitalization and hospital visits Reduced cost/ enhanced healthcare quality</td>
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The above discussion suggests that CDSS success depends on a multitude of personal, organizational and societal factors, and at the same time, CDSS influence these factors. For example, while the technological culture of a hospital may encourage it to adopt a CDSS system, this adoption is likely to impact workflows and operating procedures within this hospital. Hence, evaluating CDSS on different levels and taking mutual relationships into consideration is essential to assess the usefulness of these systems and their impacts on individuals, groups, organizations and society. Without such a comprehensive evaluation, we will not be able to fully understand how the interaction between these levels can influence the adoption and use of CDSS (B Kaplan & Shaw, 2004). Unfortunately, CDSS evaluations have been greatly limited to evaluating their effects on clinical outcomes and physicians’ performance (Bright et al., 2012; Bonnie Kaplan, 2001a). This limitation in evaluation studies reduced our ability to understand how CDSS influence and are influenced by other levels such as groups and organizations, and to understand the discrepancies between the efficacy of CDSS and their actual use (B Kaplan & Shaw, 2004). One of the main reasons behind this research limitations is the dominance of randomized controlled trials (RCT) in CDSS evaluation studies and the restrictions imposed by RCT designs (Bonnie Kaplan, 2001b; Shcherbatykh, Holbrook, Thabane, & Dolovich, 2008). In the next section we discuss the methodological issues related to CDSS evaluation and their impact on our understanding of CDSS.

### 3 METHODOLOGICAL ISSUES IN CDSS EVALUATION

In its simplest form, RCT design is one of the most powerful medical research designs where participants are randomly allocated to receive one of several interventions (Jadad, 1998). RCT has been the most frequently used design in CDSS evaluation studies (Bonnie Kaplan, 2001a). The prevailing role of RCT can be observed by considering systematic reviews of CDSS evaluation since the 1990s (M. W. Jaspers, M. Smeulers, H. Vermeulen, & L. W. Peute, 2011; Johnston et al., 1994; Pearson et al., 2009) which show the great number of RCT based evaluation as opposed to other designs. This dominant role is an extension to the role of RCT in clinical research where RCT is considered the “gold standard” of research designs (Balas & Boren, 2007; Bonnie Kaplan, 2001b). This is mainly because RCT provides the strongest internal validity, and reduces allocation bias (Shcherbatykh et al., 2008; Stolberg, Norman, & Trop, 2004). Another reason behind the dominance of RCT in CDSS evaluation is that other forms of
research designs (e.g. qualitative designs) are usually considered of lower quality and are often excluded in CDSS evaluation systematic reviews (M. W. Jaspers et al., 2011). One of the benefits of RCT in CDSS evaluation is demonstrating the effectiveness of CDSS in improving both patient outcomes and clinician performance (Garg et al., 2005; Hunt, Haynes, Hanna, & Smith, 1998; M. W. Jaspers et al., 2011; Randell, Mitchell, Dowding, Cullum, & Thompson, 2007) as well as in improving quality (Wu et al., 2006). However, RCT failed to provide significant contribution in other evaluation areas such as user acceptance, organizational and societal effects and barriers to adopt. This failure is both because of the complexity of CDSS interventions which make it difficult to manage RCT trials (Ammenwerth, Gräber, Herrmann, Bürkle, & König, 2003) as well as RCT limitations which include: (1) the controlled and idealized environment which limits our understanding of the effectiveness of CDSS in real-life situations (Bonnie Kaplan, 2001b), (2) focus on quantitative analysis and lack of context which prevent us from understanding the behavioral and social aspects of CDSS use such as effects of organizational politics on the adoption of CDSS, or how physicians perceive the effects of CDSS on their autonomy (B Kaplan & Shaw, 2004), and (3) the quantitative nature of RCT trials enable us to assess the causal relationship between constructs but do not allow us to understand why these relationships exist or their impact on CDSS use. For example, RCT can inform us that physicians agree with a CDSS system recommendation 96% of time, but it does not explain why these physicians refuse to follow CDSS recommendations in the other 4% (Cabana et al., 1999).

RCT limitations stem from its nature as a postpositivism research paradigm. Postpositivism research paradigm takes an objective view of the world in which causes determine effects. Hence, postpositivism researchers seek to assess relationships between cause and effect thus adopting a reductionist approach where relationships are reduced to a set of hypotheses to be tested. Postpositivism adopts quantitative methodologies including experimental designs (e.g. RCT) and non-experimental designs (e.g. surveys) to measure the objective truth (Creswell, 2013). Therefore, postpositivism research, including RCT, does not recognize the meaning people attach to social phenomena and does not acknowledge the effects of social processes (Ponterotto, 2005). This explains both the strength of RCT in using randomized design to assess relationships while eliminating bias, and the weakness of RCT which fails to recognize the effects of social processes on the acceptance and use of CDSS.

One final point regarding quantitative research in CDSS evaluation is the lack of quantitative studies in real-life environments (B Kaplan & Shaw, 2004). Although this type of research is essential to understand CDSS in the complex clinical environment, few studies such as (Zheng, Padman, Johnson, & Diamond, 2005) use quantitative research in a clinical environment. One of the reasons for this lack of quantitative research is that it is viewed as inferior to RCT trials (M. W. Jaspers et al., 2011; Wu et al., 2006), and because of the complexity and prolonged time requirements for this type of research (Ammenwerth et al., 2003).

Social Constructivism, on the other hand, takes a subjective view of the world in which people seek to understand their world and develop subjective views of their experiences. Thus, social constructionists seek to understand individuals’ view of their world instead of reducing the world into a set of relationships. Researchers depend on eliciting individuals’ views about an object or a situation by using qualitative methods such as interviews, open-ended questions, and observations through numerous research designs such as ethnography, grounded theory, and case studies (Creswell, 2013; Easterby-Smith, Thorpe, & Jackson, 2012). Therefore, the qualitative methodologies of social constructivism are ideal to understand social processes and individuals’ perceptions (Ponterotto, 2005). Despite its power to explain social interactions. Qualitative methods are difficult to conduct because of the lengthy time required to collect data, complexity of analysis, the bias that may be introduced to research because of researcher’s involvement with research participants, and the view that qualitative research is less rigorous than quantitative research (Easterby-Smith et al., 2012).

In the context of CDSS evaluation, the use of qualitative research has been limited because of the clinical care researchers’ inherent belief of its low quality and the perception that it provides unreliable results
(M. W. Jaspers et al., 2011; Tierney, Overhage, & McDonald, 1994). However, several researchers have called for the inclusion of qualitative methods in evaluating CDSS (B Kaplan & Shaw, 2004; Bonnie Kaplan, 2001a; Pearson et al., 2009) to understand issues related to social processes such as adoption, use, organizational political factors, and barriers to adoption. Recently, several researchers used qualitative research in evaluating the use of CDSS such as using “think-aloud” analysis to study physicians’ acceptance of CDSS (Li et al., 2012) and evaluating the use of CDSS in nursing homes using interviews (M. Fossum, M. Ehnfors, A. Fruhling, & A. Ehrenberg, 2011). However, Qualitative studies cannot be used alone to evaluate CDSS because although they can examine social and contextual factors that influence CDSS, they are not able to identify the concrete benefits of CDSS in terms of outcomes and cost savings.

In order to evaluate CDSS from different angles we need a more comprehensive paradigm than only postpositivism or social constructivism. One of the most viable paradigms for this task is pragmatism. Pragmatism focuses on the problem and on the applications that can successfully solve this problem. As such, pragmatists are not concerned with specific methodologies but with methodologies that are able to solve the problem at hand (Easterby-Smith et al., 2012). Pragmatism is considered the root of mixed methods research (Creswell, 2013).

To conclude, we believe that there is not a single methodology to evaluate CDSS benefits and use. Instead, a mix of methods that involve RCT, quantitative field studies, and qualitative studies should be combined to provide a comprehensive understanding of CDSS role for individuals, groups, organizations and the society. They should be viewed as complementary rather than focusing on a single research methodology.

4 A FRAMEWORK FOR EVALUATING CDSS

The call for mixed methods evaluation of CDSS has been growing in recent years (Chiasson, Reddy, Kaplan, & Davidson, 2007; Delpierre et al., 2004; B Kaplan & Shaw, 2004; Bonnie Kaplan, 2001b; Rahimi & Vimarlund, 2007; Stoop & Berg, 2003) because of the emerging need to understand not only the effectiveness of CDSS in improving clinicians’ performance and patient’s outcomes but also the contextual, social, and organizational factors that influence the adoption of these systems. This need for mixed methods evaluation is further emphasized by the multiple levels of CDSS effects. CDSS does not only affect clinicians, patients, and their relationship. CDSS influence and are influenced by organizational factors such as policy and quality as well as societal factors such as regulations and legalizations. In order to appreciate the effects of CDSS on multiple levels and the need for mixed methods to evaluate these different effects, it is necessary to develop a CDSS evaluation framework that combines effects and methods together.

The idea of developing a framework for health information systems (HIS) evaluation is not a new one. Several frameworks have been proposed in information systems and healthcare literature that try to determine the different impacts of HIS on individual and organizational level (Yusof, Papazafeiropoulou, Paul, & Stergioulas, 2008). However, these frameworks failed to provide a comprehensive view of CDSS influences because of several factors including: (1) Most of these frameworks focused on the individual level (patients and clinicians) of CDSS effects (Clarke et al., 1994; Dixon, 1999). (2) Even those frameworks that extended evaluation to organizational level did not consider group or societal levels (Yusof, Kuljis, Papazafeiropoulou, & Stergioulas, 2008). (3) Previous CDSS evaluation models did not attempt to associate levels of evaluation with appropriate methodologies to guide the design of future evaluation studies. We propose that a multi-level framework for evaluating CDSS that supports the use of mixed methods will be useful in guiding future evaluation research and emphasizing the complementary roles of different research methodologies. We propose the framework in figure 1 as an example of such a CDSS evaluation multi-level framework.
The proposed framework suggest the following levels of Evaluation:

4.1 Individual Level

CDSS evaluation on the individual level is related to the effects of CDSS on clinicians, patients, and on the interaction between them. Examples of the possible types of evaluations here include evaluating objective measurements such as reduction in medical errors, efficiency improvement, and number of visits (Aron, Dutta, Janakiraman, & Pathak, 2011; M. W. Jaspers et al., 2011). These endpoints are best evaluated using RCT research designs to make sure changes in these variables result from CDSS effects (Shcherbatyk et al., 2008). This level also includes subjective measurements such as patient satisfaction with the system, system usability, and physician intention to use the system. Barriers to adopt CDSS can be also evaluated at this level. Quantitative methods such as surveys may be used to measure patients and clinicians’ attitudes, while qualitative methods are inevitable to understand barriers to adoption as well as the most important features to the users (Mariann Fossum, Margareta Ehnfors, Ann Fruhling, & Anna Ehrenberg, 2011).

4.2 Group Level

On the group level, the focus should be on evaluating the aggregated effects of CDSS on groups. For healthcare organization departments, quantitative studies (e.g. RCT) can be used to assess efficiency improvement at departmental levels such as emergency departments (Hine et al., 2009). On the other hand, qualitative studies can be used to assess the effects of CDSS on workflows and clinicians’ job performance (Pope et al., 2013). For patients, the influence of patient groups’ characteristics on the adoption of CDSS can be investigated using qualitative methods such as interviews and observations.
For example, elderly patients were found not to adopt e-health systems because of cognition and learning problems (Archer et al., 2011).

4.3 Organizational Level

Healthcare organizations represent the environment where clinicians work and interact with patients. Previous research on the healthcare organization effort focused on the cost savings for the organization and quality improvements (e.g. adverse effects decrease) (B Kaplan & Shaw, 2004) using RCT designs. However, other important aspects of evaluation have been neglected such as patients’ satisfaction with the hospital and patients’ perceived quality of service. These aspects are important in assessing the outcome of using CDSS system and they can best be measured by qualitative methods that seek to understand patients’ perceptions of hospital service.

4.4 Societal Level

Despite the importance of the impact of healthcare on society, CDSS evaluation on societal level has been very much limited. This lack of societal evaluation may be because of the complexity of conducting such a research and the resources required to complete it. Nevertheless, it is necessary to evaluate CDSS impact on societal level because it is the society that pays for CDSS through taxes and donations. Therefore, members of society need to know the impact of their expenditure on these systems. Moreover, e-health applications are influenced by government regulations and legalizations such as the EHR meaningful use act in the United States (Blumenthal & Tavenner, 2010), therefore, it is important to evaluate the effectiveness and benefits of such regulations by evaluating e-health systems. For CDSS, Societal evaluation criteria include cost savings due to CDSS use, and overall healthcare quality improvements. Both these benefits can be used by quantitative methods that aggregate savings and improvements across different healthcare organizations. Qualitative studies can be used to assess the healthcare cultural change due to the use of patient-oriented CDSS systems. For example, individuals now are not usually satisfied with their physician opinion and they seek advice through other sources including the Internet (Gaglio et al., 2012).

4.5 Influences of Interactions among Levels

As figure 1 shows, evaluations levels are not independent of one another. Instead, there are significant interactions among these levels that influence the adoption and use of CDSS.

For example, on the individual level, the relationship between clinicians and patients is likely to play an important role in the adoption of CDSS especially by patients. This influence is supported by studies that show and improvement in patient adherence to treatment because of enhanced patient-physician relationship (Cameron, 1996; Griffith, 1990). The level of communication between physicians and patients is also likely to affect the outcomes of using CDSS system (Holroyd-Leduc, Lorenzetti, Straus, Sykes, & Quan, 2011). One the group level, the group dynamics such as decision making process and adoption by respectful members of the clinical community can influence the adoption of CDSS by clinicians (Yi, Jackson, Park, & Probst, 2006). On the organizational level, several researchers proposed that organizational factors such as politics, power, and social interactions influence technology adoption in organizations in general (Silva & Hirschheim, 2007) and healthcare organizations in particular (Davidson & Chismar, 2007; Kim & Michelman, 1990). This implies the need to examine the role of organizational factors on the use of CDSS. Finally, on the societal level, regulations, legalizations, and population demand can impact the adoption of CDSS by healthcare organizations. For example, in the United States, the meaningful use act for EHR systems increased the adoption rate of such systems (Hsiao, Hing, Socey, & Cai, 2012). It is likely that these forces will encourage the use of CDSS as well since they depend on many cases on EHR systems to get relevant data.
Because the interactions among different levels represent social and political processes that influence the adoption of CDSS, qualitative methods represent the most appropriate designs to address these interactions. For example, observations can be used to understand the effects of organizational forces on CDSS adoption, while interviews may be used to understand group dynamics and societal influences.

5 APPLYING THE CDSS EVALUATION- A PAIN MANAGEMENT PROGRAM EXAMPLE

In order to demonstrate the applicability of our model, we attempt to use it to develop an evaluation program for a pain management CDSS. Pain management has been an important clinical research topic that received a lot of attention (Goldberg & Morrison, 2007). This is mainly because of the severe effect of pain, especially chronic pain, on quality of life and healthcare costs (Fritz, Childs, Wainner, & Flynn, 2012). In primary care settings, CDSS can play an important role in pain management because of lack of pain management expertise for primary care practitioners (Smith, DePue, & Rini, 2007). CDSS provide primary care physicians with pain management guidelines and how to best apply these guidelines to manage patients’ pain (Smith et al., 2007). McMaster primary care pain program is an example of developing a pain management CDSS and integrating it with OSCAR EMR (Daglish & Archer, 2009) where all primary clinics using OSACR can access and use the CDSS. One of the advantages of this program is utilizing OSCAR which will enhance both usability and access to patients’ information. Such a program is likely to create positive outcome on the patient, physician, as well as organizational and societal levels.

To get a complete picture of the effectiveness of such a program, we start by identifying the possible outcomes of the project, as well as the possible factors that may influence its success, then we will propose an evaluation program to assess these outcomes and factors.

5.1 Expected Program Outcomes

In the design of the McMaster Pain Management CDSS, the main concern was the individual level, specifically, the role of the system in enhancing physician awareness of pain management guidelines, their adherence to guidelines, and patients’ improvement and satisfaction because of system use. For physicians, the pain management CDSS is expected to enhance efficiency and improve adherence to pain management guidelines. The system is expected to overcome physicians’ lack of expertise and enhance their communications with chronic pain patients. The system usability, physician satisfaction with the system, and their willingness to continue using the system are also important factors that need to be assessed because these outcomes would help us understand how to enhance CDSS acceptance and use. Finally, the active ingredients of the system (important features) that are most useful to the physicians need to be identified and studied. For patients, improvement in patients’ perception of pain is the most important effect to measure, as well as patients’ perception of improvement in communications with physicians. These improvements are expected from adherence to CDSS guidelines and communicating them to patients. Pain management is a collaborative physician-patient work (Bertakis, Azari, & Callahan, 2003), therefore, patient satisfaction with the program and their engagement should also be assessed using appropriate methodologies.

To further enhance the study, group level factors and outcomes are studied, these factors include the influence of patients’ age and disease groups on satisfaction with the system outcomes. For example, cancer patients’ quality of life is severely degraded by pain that affects 52% to 81% of patients (Bertsche et al., 2009). Therefore, these patients may perceive the outcome of the CDSS as the most useful. Another group level factors that may influence system use is residents versus experienced physicians with residents expected to show a more positive attitude towards using the system (Dreiseitl & Binder, 2005).
At an organizational level, the overall effect of the program on the efficiency and quality of care in the hospital is assessed in addition to changes in the hospital’s workflows (e.g. admission) to accommodate the program requirements.

Finally, at a societal level, it is estimated that 9% of population in North America suffers from chronic pain and half of them seek treatment to their pain (Glajchen, 2001). Hence, improvement in pain management is expected to positively affect the quality of life and healthcare cost in society. To assess the societal impact of the system, the change in pain management cost is measured and propagated to national levels to estimate the effects on overall healthcare cost. Moreover, patient’s facets of improvement are studied to examine the effect on enhanced pain management on the wellbeing of society.

5.2 Program Evaluation Design

The design of the evaluation study of the pain management system represented a unique tension between the popular and well accepted medical research study designs which adopt direct measurements of intervention efficacy and the use of clinical trial, and information systems approach of using multiple-items constructs, and qualitative methods to evaluate physicians and patients’ behavior towards the system. This tension resulted in many debates among research team leading to improvements in the rigorousness and effectiveness of the study design.

To evaluate the different outcomes of the program and the different factors influencing its effectiveness, we take a pragmatic view and apply mixed evaluation methodologies.

First, RCT design is employed to measure the effectiveness of the CDSS on physician performance, patient outcomes, as well as improvement in communications between physicians and patients. On the group level, RCT can be used to evaluate effectiveness on departmental level as well as improvements on specific patients’ groups such as cancer patients or the elderly. There are few things that need to be noted here. First, ethical considerations are very important and will influence the design of RCT. It is unethical not to provide patient management for patients in the control group (no treatment option), hence alternative pain management solution should be provided to them (e.g. normal pain treatment) and then compared to CDSS intervention. Second, there should be several groups in the RCT to control for factors such as training and awareness programs. Finally, the selected groups should be representative of different patient groups including for example cancer patients and elderly patients as well as different departments.

Other quantitative methods such as surveys are used to measure patients and physicians’ satisfaction with the system and its outcomes, perceived pain levels, and improvement in hospital quality. Improvement in healthcare cost and healthcare utilization are assessed by reviewing patients’ charts and identifying the changes in radiology orders and medication prescription and then translating those changes into cost and propagating the cost to national level. Physicians’ adherence to CDSS use is also accomplished by examining patients’ charts and deciding whether physicians are adhering to guidelines in pain management.

Qualitative methods are used extensively in such a program to evaluate patients’ engagement in the program, CDSS most important features, and an auxiliary method to evaluate improvement in communications between patients and physicians. We recommend patient and physician interviews as well as physicians focus groups as a formative research to inform the design of the CDSS system. The role of group dynamics and social influence in using the system and other political and social factors influencing system use are assessed using interviews and observation. For qualitative evaluation, special care should be given to estimating the time frame of the study which can be prolonged by using qualitative studies, the cost of the study, as well as the validity and reliability of the results.
5.3 Results and Discussion

While the pain management CDSS is in its first stage of implementation, with only a limited set of quantitative and qualitative results. These limited and preliminary results clarify the significance and applicability of our suggested evaluation model. So far, we obtained qualitative results through focus groups conducted before the system was implemented, a survey, in pilot test stage, that explains the relationship between information quality, system quality, trust in the system, and intention to use the pain management CDSS. In our studies, we studied the difference in use between experienced physicians and residents; as well as between the use of the system in academic and non-academic healthcare organizations.

The focus groups emphasized the relationship between physician’s requirements in the system, and how they would use this system. As an outcome of these groups, the system was integrated with OSCAR EHR system, and provided a similar interface to this widely used EHR. These groups also showed that physicians were mainly interested in lower back pain and neuropathic pain where they lack the necessary care skills most. Therefore, the pain management CDSS focused on the guidelines related to these two types of pain. These results signifies the importance of the relationship between system-level and individual-level components of the model where system attributes influence individuals’ behaviour.

The quantitative component of our study employed a physician questionnaire that examined the relationship between system quality, information quality, trust in the system, and intention to use the system. The survey was distributed on physicians and residents in academic and non-academic organizations. The outcome of the pilot test of the questionnaire shows that indeed the quality of the information produced by the system and the quality of the system itself influence trust in the pain management CDSS which in turns influence intention to use the system. This results again relates to the relationship between system-level and individual-level interactions in the above model. More significantly, however, is the difference between physicians and residents use of the system. The initial results show that residents are more willing to depend on the system and use it than experienced physician which shows the relationship between group-level and individual level use of the system. Moreover, physicians in academic healthcare organizations are more willing to use the system than those in non-academic organizations which emphasizes the effects of healthcare organizational culture on physicians’ behaviour.

The above results, although still preliminary, show that the different levels in the proposed evaluation model influence each other, and this influence affect how the system is used and the outcome of this use.

Later stages of the study will include the wide distribution of the questionnaire, and measuring the effects of using CDSS on patients, and on cost savings.

6 CONCLUSION

CDSS are important healthcare systems that can benefit clinicians, patients, healthcare organizations, and the society especially with the gigantic increase in available medical data and the development of new interventions such as personalized genetic interventions and PHR systems. The importance of CDSS has been acknowledged through the high volume of research focusing on the evaluation of CDSS systems. Our research shows that, despite the several calls to use qualitative research in CDSS evaluation, RCT studies still dominate this area of research. This is mainly due to the dominance of RCT design in clinical interventions and the methodological quality RCT designs provide. However, RCT designs are not enough to fully understand the impact of CDSS on individual, group, organization, and society level because of the complexity of CDSS interventions and the involvement of numerous social processes in the use and adoption of CDSS.
In this paper, we proposed that CDSS should be evaluated on multiple levels and we provided an example of a possible multi-level framework for evaluating CDSS. We also agreed with previous researchers (Bonnie Kaplan, 2001b) on the need for a pragmatic view and mixed method approach to evaluate CDSS. Finally, we presented a case to show how our proposed framework and the evaluation methodologies associated with it can be practically implemented by using a pain management CDSS for primary care practitioners.

The contribution of this paper is two folds. First, it demonstrates the wide and deep effects of CDSS on different levels including individual, group, organizational, and societal level. Specifically, the group and societal level have rarely been discussed in CDSS evaluation literature and therefore should receive more focus in the future. Second, we provided a framework that associates different evaluation levels with different methodologies.

The outcome of this study should inform future evaluation studies on the different levels of CDSS evaluations and the influence of interactions between these levels on CDSS use. The research also calls for the use of mixed methods to evaluate CDSS and provides guidance to how these methods can be applied at different evaluation levels. In multi-disciplinary studies, special care must be given to the differences in research “habits” between healthcare researchers and information systems (or in general, social sciences) researchers.

Limitations of this study include that the proposed framework is not a comprehensive one but rather one of several possible frameworks that can be developed. Indeed it is neither possible nor desirable to develop one framework for all CDSS interventions but the idiosyncrasies of each intervention should be considered such as the environment and context of intervention. Future research should attempt to focus on developing research designs that reflect the complexity of CDSS interventions and the need for mixed methods and multi-levels evaluation.

References


