Social, organizational, and contextual characteristics of clinical decision support systems for intensive insulin therapy: A literature review and case study

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ABSTRACT

Introduction: Evaluations of computerized clinical decision support systems (CDSS) typically focus on clinical performance changes and do not include social, organizational, and contextual characteristics explaining use and effectiveness. Studies of CDSS for intensive insulin therapy (IIT) are no exception, and the literature lacks an understanding of effective computer-based IIT implementation and operation.

Results: This paper presents (1) a literature review of computer-based IIT evaluations through the lens of institutional theory, a discipline from sociology and organization studies, to demonstrate the inconsistent reporting of workflow and care process execution and (2) a single-site case study to illustrate how computer-based IIT requires substantial organizational change and creates additional complexity with unintended consequences including error.

Discussion: Computer-based IIT requires organizational commitment and attention to site-specific technology, workflow, and care processes to achieve intensive insulin therapy goals. The complex interaction between clinicians, blood glucose testing devices, and CDSS may contribute to workflow inefficiency and error. Evaluations rarely focus on the perspective of nurses, the primary users of computer-based IIT whose knowledge can potentially lead to process and care improvements.

Conclusion: This paper addresses a gap in the literature concerning the social, organizational, and contextual characteristics of CDSS in general and for intensive insulin therapy specifically. Additionally, this paper identifies areas for future research to define optimal computer-based IIT process execution: the frequency and effect of manual data entry error of blood glucose values, the frequency and effect of nurse overrides of CDSS insulin dosing recommendations, and comprehensive ethnographic study of CDSS for IIT.

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1.   Introduction

The U.S. National Research Council recently endorsed the use of clinical decision support systems (CDSS) and "organizational systems-level research" of health information technology to help drive healthcare transformation [1]. Historically evaluations of CDSS have focused on practitioner performance [2] rather than social, organizational, and contextual factors [3,4]. Kaplan noted that CDSS evaluation studies measure CDSS effects on clinical performance, use experimental study designs or randomized controlled trials, disregard naturalistic study methods, ignore contextual issues surrounding system usage, investigate the perspectives of physicians rather than other clinical roles, and consider only the CDSS intervention, not other clinical information systems in use [3]. The reporting of findings in the literature reflects a rationalist scientific orientation [3] and shows clinical and medical informatics investigators' preferences toward objectivist rather than subjectivist approaches to evaluation [5]. Although subsequent reviews have identified dimensions of workflow integration as critical to CDSS success [6], researchers have yet to fully embrace the National Research Council's directives or address the gaps identified by Kaplan.

Studies of clinical decision support systems for intensive insulin therapy (IIT), a treatment combining frequent blood glucose monitoring and insulin drip adjustments to maintain tight glucose control [7], follow the general CDSS evaluation trend. Investigations using experimental designs have demonstrated improved clinician protocol adherence and achievement of target glucose levels using computer-based IIT protocols instead of paper-based versions [8–19]. However, these evaluations have paid little attention to the context of interventions, including the complex interaction between staff, testing devices, and computers that may result in inefficiency and error. Nurses use computer-based IIT advisors to document care and calculate insulin doses, but investigations mostly rely on anecdotal feedback to understand nurse perspectives of CDSS and rarely consider CDSS usage with respect to other care processes and clinical information systems. The literature describes paper-based IIT protocol implementation barriers [20] and effects on nurse work [21] but does not explore the complexity and organizational change related to computer-based IIT approaches.

Understanding the mechanisms of effective intensive insulin therapy CDSS is important because IIT is the standard of care for critically ill patients [22]. In 2001 the Leuven study demonstrated morbidity and mortality improvements through an intensive insulin therapy protocol [7], and subsequent studies at other institutions have produced similar results [23,24]. However, a 2008 meta-analysis of randomized trials raised concerns about the therapy's mortality benefit and safety [25]. Differences in care protocols ranging from nutrition provisions [26] to target blood glucose ranges [26,27], insulin administration [28], and intended patient populations [29] may explain variation in IIT outcomes, but researchers have not determined comprehensive solutions, especially ones that address computer-based approaches.

Although care protocols define the decision-making behavior clinicians should exhibit under certain conditions [30] and

represent the evidence-based, formal structure of healthcare organizations, actual work activities usually differ from official practice definitions [31]. In patients treated with computer-based intensive insulin therapy in the surgical intensive care unit at Vanderbilt University Hospital, researchers found fourteen percent of blood glucose measurements were not taken on time [32]. Significant relationships between late blood glucose measurements and episodes of hyper- and hypoglycemia [32] as well as blood glucose variability and mortality [33] suggest that workflow may be a factor in computer-based IIT performance and patient outcomes [32]. In sociology and organizational studies, institutional theory [31,34–38] examines the way rules, policies, and procedures affect and are affected by "assumptions, norms, values, choices, and interactions" [36]. This approach has informed investigations of information technology in law [39], banking [40], and research workplaces [41], and informatics researchers have focused on similar issues to influence system design [42–44]. To improve intensive insulin therapy protocol performance and patient outcomes, researchers and practitioners can use institutional theory to address care process execution issues related to human behavior.

This paper takes a subjectivist approach [4] to the study of computer-based intensive insulin therapy and illustrates the need for additional research in two parts: (1) a literature review, which uses institutional theory to take inventory of formal structure and social organization [35] reported in computer-based IIT evaluations, and (2) a case study that builds on the literature review and emphasizes social, organizational, and contextual aspects typically absent from computer-based IIT evaluations. The literature review can potentially serve as a source for other CDSS evaluators interested in social, organizational, and contextual elements, and the case study shares the experience of computer-based IIT at one institution so other institutions can make informed decisions. Overall the analysis shows a gap in the computer-based IIT literature concerning complexity of protocol execution, opportunity for error in staff-device–CDSS interaction, effects on other workflow and care processes, and the magnitude of organizational change necessary for implementation.

2.   Literature review of computer-based intensive insulin therapy evaluations

In May 2008 we searched ISI Web of Science for articles citing the Leuven study (1783 articles) and containing the keyword "protocol" (129 articles). Because the Leuven study played a significant role in IIT protocols becoming the standard of critical care, we used it to focus our search. From the "protocol" corpus we identified fifteen evaluations of computer-based IIT protocols. Fourteen evaluations used experimental designs or randomized trials, and one was a practice report. The studies examined eighteen intensive care units in twelve healthcare organizations excluding the hundreds of sites evaluated in a longitudinal study of a commercial product [10].

One of the authors (TRC) reviewed the studies through the lens of institutional theory [31,34–38] to identify aspects of computer-based intensive insulin therapy's formal structure—*the prescribed, written policies established to govern and*