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Integrating usability testing and think-aloud protocol analysis with "near-live" clinical simulations in evaluating clinical decision support

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ABSTRACT

Purpose: Usability evaluations can improve the usability and workflow integration of clinical decision support (CDS). Traditional usability testing using scripted scenarios with think-aloud protocol analysis provide a useful but incomplete assessment of how new CDS tools interact with users and clinical workflow. "Near-live" clinical simulations are a newer usability evaluation tool that more closely mimics clinical workflow and that allows for a complementary evaluation of CDS usability as well as impact on workflow.

Methods: This study employed two phases of testing a new CDS tool that embedded clinical prediction rules (an evidence-based medicine tool) into primary care workflow within a commercial electronic health record. Phase I applied usability testing involving "think-aloud" protocol analysis of 8 primary care providers encountering several scripted clinical scenarios. Phase II used "near-live" clinical simulations of 8 providers interacting with video clips of standardized trained patient actors enacting the clinical scenario. In both phases, all sessions were audiotaped and had screen-capture software activated for onscreen recordings. Transcripts were coded using qualitative analysis methods.

Results: In Phase I, the impact of the CDS on navigation and workflow were associated with the largest volume of negative comments (accounting for over 90% of user raised issues) while the overall usability and the content of the CDS were associated with the most positive comments. However, usability had a positive-to-negative comment ratio of only 0.93 reflecting mixed perceptions about the usability of the CDS. In Phase II, the duration of encounters with simulated patients was approximately 12 min with 71% of the clinical prediction rules being activated after half of the visit had already elapsed. Upon activation, providers accepted the CDS tool pathway 82% of times offered and completed all of its elements in 53% of all simulation cases. Only 12.2% of encounter time was spent using the CDS tool. Two predominant clinical workflows, accounting for 75% of all cases simulations, were identified that characterized the sequence of provider interactions with the CDS. These workflows demonstrated a significant variation in temporal sequence of potential activation of the CDS.

Conclusions: This study successfully combined "think-aloud" protocol analysis with "near-live" clinical simulations in a usability evaluation of a new primary care CDS tool. Each phase

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of the study provided complementary observations on problems with the new onscreen tool and was used to refine both its usability and workflow integration. Synergistic use of "think-aloud" protocol analysis and "near-live" clinical simulations provide a robust assessment of how CDS tools would interact in live clinical environments and allows for enhanced early redesign to augment clinician utilization. The findings suggest the importance of using complementary testing methods before releasing CDS for live use.

1. Introduction

Worldwide healthcare organizations are moving towards implementation of electronic health records (EHRs) and clinical decision support systems (CDSS) to improve the efficiency and safety of healthcare. In the United States, with $19 billion from the American Recovery and Reinvestment Act (ARRA) of 2009, incentives to adopt EHRs into clinical practice are securely in place [1,2]. CDSS are an important part of every EHR system; they computerize information to allow for delivery of clinical decision support (CDS) tools to providers during the clinical decision-making process. CDSS promise to bring evidence-based medicine (EBM) to the point-of-care and guide clinicians in their effort to deliver more efficient and effective healthcare [3]. Ideally, they provide patient specific recommendations by using individual patient data, a rules-based engine, and a medical knowledge base [4,5]. However the results to date have been mixed in ambulatory EHRs [6–9]. Given the increasingly chaotic and time pressed nature of patient visits, it is not surprising that CDSS have had limited impact on the delivery of point-of-care EBM—a reflection of poor provider acceptance [8,10]. Critical factors for effective design of CDSS include integration with provider workflow, anticipation of provider needs, and a need to study and to assess the usability of these systems [10–15]. An increasingly important potential solution to improving the adoption of CDSS during patient care includes conducting usability testing of CDSS interventions prior to widespread implementation.

Formal usability testing has begun to be considered critical to the EHR adoption and implementation lifecycle; and this clearly applies to CDSS [10,16]. Discussions and observations of usability with care providers have provided a large volume of evidence to suggest optimal system use and outcomes depend on improved usability during the EHR design process [14,17]. Current best practices promote utilization of cognitive approaches to assess human–computer interactions within the EHR system [17,18]. A variety of both summative and formative user-based approaches have been employed to evaluate EHRs including "think aloud" usability testing, cognitive task analysis, and surveys [19–21]. The "think-aloud" formative usability approach, in which users verbalize their thoughts while performing pre-specified tasks within CDSS, is particularly well-suited for identifying barriers to adoption. It integrates qualitative and quantitative analyses of direct observations of scripted provider–CDSS interactions to identify surface level usability issues [22]. However, this approach limits the amount of unrestricted interactions providers have with the CDSS and the underlying EHR system. Therefore, some groups have employed studies that measure the time to completion of set tasks as measures of usability and learnability of CDSS [10]. However, even these more unrestricted studies have limited correspondence to live patient encounters. In this study, we describe an evaluation approach combining think-aloud protocol analysis from usability testing with "near-live" clinical simulations to document and assess provider–CDSS interactions of a newly developed CDSS [23,24].

Through a process involving two usability studies, we attempted to improve the usability of a CDS prototype for two integrated clinical prediction rules (CPRs): the Walsh rule for Streptococcal pharyngitis (Strep rule) [25,26] and the Heckerling rule for Pneumonia [27] within a commercial EHR (EpicCare©). CPRs are well-validated EBM tools that, if used as frontline decisional aids, can help physicians make evidence based, cost-effective decisions. These rules use objective findings in patient history, physical, and/or labs to help risk stratify the disease condition and to determine whether further investigative or treatment efforts are necessary. We selected these two clinical prediction rules as they are familiar to healthcare providers and deal with highly prevalent ambulatory care conditions.

This paper describe the two phases of evaluation that we conducted prior to widespread deployment of the integrated clinical prediction rules clinical decision support tool which we will refer to as the iCPR CDS. Phase I involved usability testing in conjunction with "think-aloud" protocol analysis to assess human–computer interaction as the healthcare providers performed specific tasks following a script for invoking the iCPR CDS [28,29]. Phase II involved a "near-live" clinical simulation to assess how providers interact with the iCPR CDS while interviewing a simulated patient [30]. We hypothesize that both forms of testing provide disparate, informative insights that are critical to the successful development and integration of CDS in EHRs.

2. Methods

The actual design of the iCPR CDS prototype is described in detail in a previous publication [31]. The purpose of the usability phase of the software development cycle was to identify barriers to use prior to the implementation of a randomized controlled trial of iCPR. The two phases of evaluation were conducted in series (see below). Between each phase, a period of analysis and prototype revision was conducted to allow for iterative improvements. All human–computer interactions were captured on a standard clinical workstation running Hypercam® screen recording software.

Built into the CDS is an algorithm that evaluates provider EHR inputs during live patient encounters to assess the clinical relevancy of activating the iCPR CDS for that specific