

Live Usability Testing of Two Complex Clinical Decision Support Tools

Safiya Richardson, David Feldstein, Thomas McGinn, Linda S Park, Sundas Khan, Rachel Hess, Paul D Smith, Rebecca Grochow Mishuris, Lauren McCullagh, Devin Mann

Submitted to: JMIR Human Factors
on: October 16, 2018

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript.....	5
---------------------------------	----------

Preprint
JMIR Publications

Live Usability Testing of Two Complex Clinical Decision Support Tools

Safiya Richardson¹ MPH, MD; David Feldstein² MD; Thomas McGinn¹ MPH, MD; Linda S Park² PhD; Sundas Khan¹ MD; Rachel Hess³ MS, MD; Paul D Smith² MD; Rebecca Grochow Mishuris⁴ MS, MPH, MD; Lauren McCullagh¹ MPH; Devin Mann⁵ MS, MD

¹Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Hempstead US

²University of Wisconsin School of Medicine and Public Health Madison US

³School of Medicine University of Utah Salt Lake City US

⁴Section of General Internal Medicine Department of Medicine Boston University School of Medicine Boston US

⁵Department of Medicine NYU Grossman School of Medicine New York US

Corresponding Author:

Safiya Richardson MPH, MD

Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

500 Hofstra University

Hempstead

US

Abstract

Background: The potential of the electronic health record (EHR) and clinical decision support (CDS) to improve the practice of medicine have been significantly tempered by poor design and the resulting burden they place on health care providers. CDS is rarely tested in the real clinical environment. As a result many tools are hard to use, placing strain on providers and resulting in low adoption rates. The existing CDS usability literature relies primarily on expert opinion and provider feedback via survey.

Objective: This is the first study to evaluate CDS usability and the provider-computer-patient interaction with complex CDS in the real clinical environment. The objective of this study was to further understand barriers and facilitators of meaningful CDS usage within a real clinical context.

Methods: This qualitative observational study was conducted with three primary care providers during a total of six patient care sessions. In patients with the chief complaint of sore throat a CDS tool built with the Centor Score was used to stratify the risk of group A strep pharyngitis. In patients with a chief complaint of cough or upper respiratory infection a CDS tool built with the Heckerling Rule was used to stratify the risk of pneumonia. During usability testing all human-computer interactions, including audio and continuous screen capture, were recorded using Camtasia® software. Participants' comments and interactions with the tool during patient care sessions and participant comments during a post-session brief interview were placed into coding categories and analyzed for generalizable themes

Results: In the 6 encounters observed, primary care providers toggled between addressing either the computer or the patient during the visit. Minimal time was spent listening to the patient without engaging the EHR. Participants almost always used the CDS tool with the patient, asking questions to populate the calculator and discussing the results of the risk assessment; they reported the ability to do this as the major benefit of the tool. All primary care providers were interrupted during their use of the CDS tool by the need to refer to other sections of the chart. In half of the visits, patient's clinical symptoms challenged the applicability of the tool to calculate the risk of bacterial infection. Primary care providers rarely used the incorporated incentives for CDS usage, including progress notes and patient instructions/documentation

Conclusions: Live usability testing of these CDS tools generated insights about their role in the patient-provider interaction. CDS may contribute to the interaction by being simultaneously viewed by provider and patient. CDS can improve usability and lessen the strain it places on providers by being short, flexible and customizable to unique provider workflow. A useful component of CDS is being as widely applicable as possible and ensuring that its functions represent the fastest way to perform a particular task. Clinical Trial: Live usability testing of these CDS tools generated insights about their role in the patient-provider interaction. CDS may contribute to the interaction by being simultaneously viewed by provider and patient. CDS can improve usability and lessen the strain it places on providers by being short, flexible and customizable to unique provider workflow. A useful component of CDS is being as widely applicable as possible and ensuring that its functions represent the fastest way to perform a particular task.

(JMIR Preprints 16/10/2018:12471)

DOI: <https://doi.org/10.2196/preprints.12471>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in [JMIR Publications](#)

Original Manuscript

Live Usability Testing of Two Complex Clinical Decision Support Tools

Safiya Richardson, David Feldstein, Thomas McGinn, Linda Park, Sundas Khan, Rachel Hess, Paul Smith, Rebecca Mishuris, Lauren McCullagh, Devin Mann

The paper type is an original research.

Corresponding Author:

Safiya Richardson, MD, MPH

Assistant Professor

Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

500 Hofstra University

Hempstead, NY, USA

Phone: 404-695-7883

Fax: 516-600-1756

srichard12@northwell.edu

David Feldstein, MD

Associate Professor of Medicine

University of Wisconsin School of Medicine and Public Health

Madison, WI, USA

Thomas McGinn, MD, MPH

Professor of Medicine

Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

Hempstead, NY, USA

Linda S. Park, PhD

Research Coordinator

University of Wisconsin School of Medicine and Public Health

Madison, WI, USA

Sundas Khan, MD

Administrative Manager - Research

Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

Hempstead, NY, USA

Rachel Hess, MD, MS

Professor of Population Health Sciences and Internal Medicine

University of Utah, School of Medicine

Salt Lake City, UT, USA

Paul D. Smith, MD

Professor

University of Wisconsin-Madison

1100 Delaplaine Ct

Madison, WI, USA

Rebecca Mishuris, MD, MPH
Associate Chief Medical Information Officer/Assistant Professor
Boston University School of Medicine
Boston, MA, USA

Lauren McCullagh, MPH
AVP – Clinical Research
Donald and Barbara Zucker School of Medicine at Hofstra/Northwell
Hempstead, NY, USA

Devin Mann, MD, MS
Associate Professor, Department of Population Health
NYU School of Medicine
New York, NY, USA

Live Usability Testing of Two Complex Clinical Decision Support Tools

ABSTRACT

Objectives: The potential of the electronic health record (EHR) and clinical decision support (CDS) to improve the practice of medicine have been significantly tempered by poor design and the resulting burden they place on health care providers. CDS is rarely tested in the real clinical environment. As a result many tools are hard to use, placing strain on providers and resulting in low adoption rates. The existing CDS usability literature relies primarily on expert opinion and provider feedback via survey. This is the first study to evaluate CDS usability and the provider-computer-patient interaction with complex CDS in the real clinical environment. The objective of this study was to further understand barriers and facilitators of meaningful CDS usage within a real clinical context.

Methods: This qualitative observational study was conducted with three primary care providers during a total of six patient care sessions. In patients with the chief complaint of sore throat a CDS tool built with the Centor Score was used to stratify the risk of group A strep pharyngitis. In patients with a chief complaint of cough or upper respiratory infection a CDS tool built with the Heckerling Rule was used to stratify the risk of pneumonia. During usability testing all human-computer interactions, including audio and continuous screen capture, were recorded using Camtasia® software. Participants' comments and interactions with the tool during patient care sessions and participant comments during a post-session brief interview were placed into coding categories and analyzed for generalizable themes.

Results: In the 6 encounters observed, primary care providers toggled between addressing either the computer or the patient during the visit. Minimal time was spent listening to the patient without engaging the EHR. Participants almost always used the CDS tool with the patient, asking questions to populate the calculator and discussing the results of the risk assessment; they reported the ability to do this as the major benefit of the tool. All primary care providers were interrupted during their use of the CDS tool by the need to refer to other sections of the chart. In half of the visits, patient's clinical symptoms challenged the applicability of the tool to calculate the risk of bacterial infection. Primary care providers rarely used the incorporated incentives for CDS usage, including progress notes and patient instructions/documentation.

Conclusions: Live usability testing of these CDS tools generated insights about their role in the patient-provider interaction. CDS may contribute to the interaction by being simultaneously viewed by provider and patient. CDS can improve usability and lessen the strain it places on providers by being short, flexible and customizable to unique provider workflow. A useful component of CDS is being as widely applicable as possible and ensuring that its functions represent the fastest way to perform a particular task.

Keywords: usability, usability testing, user experience, clinical decision support, health informatics, provider adoption, workflow, live usability, clinical prediction rules

BACKGROUND

The landmark Institute of Medicine report "To Err Is Human", sparked an increased focus on the prevention of medical errors.[1] Computerized clinical decision support (CDS) aids providers in

clinical decision-making for individual patients[2] and was proposed as a key tool to improve quality of care by providers, policymakers, experts, and consumers.[1, 3, 4] In the United States, unprecedented resources were committed to support the adoption and use of electronic health records (EHRs) through the Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009 including incentive payments by the federal government totaling up to \$27 billion over 10 years.[5] EHR adoption in eligible hospitals and practices grew from less than 10% in 2008 to over 80% in 2015.[6] One of the HITECH requirements, to meaningful use of EHRs, included criteria to implement CDS at every stage.

CDS can improve quality by improving diagnosis, treatment, and preventative care services [7-21] but it now contributes to the increasing complexity of clinical practice. Murphy, et al. reported primary care doctors received 77 notifications in the EHR per day[22] and spend nearly two hours on the EHR and desk work for every hour of face to face time with their patients [23]. Poor EHR usability is a major driver of declining career satisfaction among providers.[24] CDS is almost never tested in real clinical care sessions that have real-time pressure and patient-case complexity. As a result, many tools that appear usable and useful during development and usability testing are cumbersome within workflow, are poorly adopted, and fail to deliver on their promise of improved care.[21]

There is an extensive literature detailing the features of highly usable CDS. The foundational article “Ten Commandments for Effective Clinical Decision Support” specifies the importance of creating CDS that is fast, anticipates provider needs, fits into user workflow, provides a change in practice as opposed to a stop, is simple with few user inputs and adaptive.[25] A comprehensive literature review of studies evaluating barriers to and facilitators of CDS usage details similar CDS specific usability issues, including minimal mouse clicks and workflow integration.[26] These works and many others[27-34] are important but primarily based on expert opinion and provider feedback given via surveys, interviews and simulated usability testing. Few have objectively observed providers during a real clinical session and none have observed the provider interaction with complex CDS.

The objective of this study was to further understand the barriers to and facilitators of meaningful CDS tool usage within a real clinical context. Usability testing of two CDS tools was conducted as a part of the study “Integrated Clinical Prediction Rules: Bringing Evidence to Diverse Primary Care Settings (iCPR2)”, a randomized controlled trial evaluating the tools’ effect on antibiotic ordering. [35] The CDS tools were composed of an alert, a clinical prediction rule (Centor Score, and Heckerling Rule) estimating risk of either group A Streptococcus (GAS) pharyngitis or pneumonia, and an automatic order set based on risk.

METHODS

This was a qualitative observational study done in January of 2017 at the University of Wisconsin-Madison, School of Medicine, a large academic health care center, where the parent study was being conducted. Testing was completed with a convenience sample of three volunteer primary care providers during a total of six patient care sessions. Inclusion criteria required that participants: 1) worked in Family Medicine or Internal Medicine clinics; 2) spent at least half of their time providing clinical care; and 3) were randomized to the intervention arm of the larger iCPR2 study with the CDS embedded in their EHR system. The sample size was typical for usability studies and is considered sufficient to elicit the vast majority of usability issues.[36-38] The sample size was considered to be six, for each patient care session, as each was a complex and unique interaction between patient, provider and clinical decision support tool. A typical sample size for usability studies is five.

The two CDS tools tested in the parent study used clinical prediction rules to evaluate the risk of

GAS pharyngitis in patients presenting with sore throat (the Centor Score) and the risk of pneumonia in patients presenting with cough or upper respiratory tract infection (the Heckerling Rule). The tools were both built in the EpicCare ambulatory EHR (Epic Corp. Verona, Wisconsin). The tools were triggered by a reason for visit of sore throat, cough, or upper respiratory tract infection. When triggered, the provider was presented with an alert offering the CDS tool upon opening the chart. If accepted, the provider was taken to a calculator with a list of clinical questions, each of which contributes to a total risk score (**Figure 1**). After calculator completion, the provider was shown a risk score, identifying the patient as low, intermediate, or high risk for the condition, as well as offered an order set tailored to the calculated risk. These order sets included documentation for progress notes, laboratory orders, prescription orders, diagnoses, patient instructions, and level of service (**Figure 2**).

Live usability testing was conducted in a clinical office setting. Written informed consent was obtained from all participating providers the day before the study observations. At that time, the study procedures were reviewed with the providers and their staff. Testing was performed for one day for each of the providers. On the day of live usability testing, the providers' receptionist handed out a flyer with details about the study to all of the participating providers' patients. Study staff approached these patients to ask if they were being seen for a cough, sore throat, or upper respiratory tract infection. Patients with these symptoms were provided with an explanation of the study and verbal consent was obtained.

All human-computer interactions, including audio and continuous screen capture, were recorded using Camtasia® (TechSmith, Okemos, MI, USA) software. Before the start of the patient care session the usability testing software was set to record. It was paused if patients left the room for testing and stopped at the end of the visit. After the provider's care sessions were completed, they were briefly interviewed about their general attitudes towards the tool. These interviews were recorded using a digital voice recorder.

All provider and patient verbalizations from the visits and the interviews were transcribed verbatim. The video from the visits, audio from the interviews, and the transcriptions of both underwent thematic analysis and were coded using the following process: Two coders used a triangulation approach involving iteratively watching the videos, listening to the interviews and reading the transcriptions. This allowed a broader and more complex understanding of the data attained. Those two coders then undertook development of a codebook reflecting the emerging themes with no a-priori codes used. Using the constant comparative method, additional readings of the transcription lead to the consolidation of these coding schemes until no further refinement was required. The primary themes identified were: Tool Interruptions, Workflow, Tool Applicability, Patient-Tool interaction, Provider-Computer-Patient Interaction, Ease of Use and Missed Opportunities. Transcribed audio from the visit and the interview along with observed participant interaction with the tool were coded by hand and were categorized under each code by two independent coders and analyzed for themes that would be generalizable to most CDS. The themes were reviewed together by the coders and all discrepancies were resolved by discussion to achieve a consensus leading to 100% agreement between the coders. This was formative as opposed to summative usability testing. We did not measure task times, completion rates or satisfaction scores. The Institutional Review Board at the University of Wisconsin approved the research protocol."

RESULTS

The three participants were all primary care providers; two nurse practitioners and one medical doctor. There were a total of six patient encounters. Five of these were acute or follow up visits which lasted about 15 minutes each, and one was a complete physical exam which was about 30 minutes in length. In half of the visits the patients presented with a the chief complaint of sore throat

and the CDS tool built with the Centor Score was used to stratify the risk of group A strep pharyngitis. In the other half of the visits the patients presented with a chief complaint of cough or upper respiratory infection and the CDS tool built with the Heckerling Rule was used to stratify the risk of pneumonia. Because the tools were so similar, with the exception of clinical content, they were analyzed together. Example visit quotes, participant actions, and participant interview quotes are included in **Table 1** by coding category along with a summary and recommendations for future CDS.

Coding Categories

Tool Interruptions

While the tool was built to be completed sequentially and without interruption (**Figure 3**), every participant was interrupted during their use of the CDS tool. Participants were typically triggered to navigate away from the CDS tool by questions that came up during the encounter about patient's previous medical history (e.g., vaccine record, laboratory test results). Each of these deviations required the participant to remember to navigate back to the CDS tool and to know how to do this.

Workflow

Upon opening the chart, every participant was taken to an alert for the CDS tool. At the start of each patient session, the provider navigated away from the alert to the progress note and began taking the history of present illness. During most patient sessions, the provider then completed the physical exam, brought the patient back to the computer and engaged with the CDS tool. The progress note served as the center point of the participant interaction with more than 95% of visit time spent with the progress note feature open in half of the sessions.

Tool Applicability

In half of the patient visits, patients reported some piece of information, typically as a part of the history of present illness that raised a question for the coders of whether the tool was applicable to their clinical condition. For example, two of the patient encounters were for complaints consistent with sinusitis and one patient with cough had been previously treated. All of the providers in the post-session brief interviews mentioned the value of a more broadly applicable tool that included CDS for bacterial sinusitis. They felt that this addition would allow them to use the tool more often.

Patient-Tool Interaction

A majority of the providers used the tool to assess risk by showing the patients the tool while they completed it and explained the results of the calculator to the patient. They all reported that the ability to show the patient their risk of a bacterial infection was the strongest feature of the tool. Providers reported using the tool to educate patients about their risk and manage patient expectations more than using it to discover the patient's risk of bacterial infection.

Provider-Computer-Patient Interaction

Providers spent most of the visit either talking to the patient or interacting with the EHR. They spent between 0-3% of their time listening to the patient without engaging the EHR. For example, to gather the history of present illness providers typically started with an open-ended question. As the patient began talking they shifted their focus to the EHR to begin typing the progress note. They took the opportunity to review the chart if the patient began talking about unrelated topics. At times when the patient was not speaking but the provider needed to interact with the EHR (e.g., completing orders at the end of the visit) there would be silence.

Ease of Use

Providers commented on the tools brevity as being a significant strength, making it easier to use.

They spent about one minute of the patient visit completing the tool. Hard stops and fixed elements within the tool led to frustrations. For example, after a verbal communication about a positive rapid GAS pharyngitis result, the provider could not continue to the automatic order set until the result was properly registered by the lab, requiring the provider to leave the patient, go back to the lab, and resolve the issue before continuing with the patient visit.

Missed Opportunities

Although the tool was designed to automatically generate visit documentation as an incentive for tool completion, every provider started writing their note at the beginning of the visit. Each provider used short cuts to template their notes, which increased the comparative ease of use of typing their note without using the tools feature. While the tools automatic order-set was also designed as an incentive for use, participants described it being easier to order antibiotics and tests outside of it.

DISCUSSION

This study contributes to our growing understanding of how to develop usable and useful CDS tools, particularly considering the provider-computer-patient interaction. This study builds on our previous work analyzing results from the “Think Aloud” and “Near Live” usability testing of these two CDS tools.[39] Each of these three types of usability testing generated unique and generalizable insights. As testing increasingly approached reality, additional types of barriers to and facilitators of CDS usage were found. During “Think Aloud” testing providers were presented with a written clinical case while interacting with the tool. Commentary focused on improving the ease of use of the tool. During “Near Live” testing providers interacted with a patient actor and commentary addressed ease of use of the tool with an added, more focused evaluation of its usefulness. Previous studies have also found that as usability testing approaches reality, themes and insights shift from mostly surface level ease of use issues to higher level usefulness and workflow issues.[29] Live usability testing provided insights on the tools’ ease of use, usefulness and its impact on the patient-provider interaction that were not evident in previous usability testing.

Provider-Computer-Patient Interaction + Patient-Tool Interaction

Our observation of the minimal time providers spent listening to the patient without simultaneously interacting with the computer speaks to the growing demands of the EHR. Each of these demands must take the place of some part of what was already a full visit. In a typical encounter a provider listens to the patient, examines the patient and talks to the patient. The pressure to “multi-task” using the EHR is easiest while listening to the patient. Notably however, there is evidence that providers are doing this without decreasing patient satisfaction or diminishing the patient-provider relationship. [20] The use of EHRs in the ambulatory setting also does not seem to decrease quality of care.[40] However, the EHR contains a wealth of information that has the potential to positively impact care. The simple, intuitive and informational design of this tool allowed providers to use it with their patients, allowing the EHR to provide important information while reconnecting the patient and the provider.

CDS designers have largely focused on these tools’ contribution to medical decision making without considering its collaborative nature. To varying degrees, every medical decision is a shared decision. CDS tools that are built to engage both patient and provider target both decision makers. Every provider in this study cited the ability to share the tool’s results with the patient as its greatest strength. These providers did not need a better understanding of patient’s risk of bacterial infection as much as they needed a better way to communicate this information to the patient. CDS that accounts for the patient’s role in decision making may be used to facilitate shared decision making, which may improve usability, increase adoption rates resulting in improved quality of care.

Tool Interruptions + Usability + Workflow

The expected workflow for the tool was not observed in any encounter and providers did not use the tool at the time it triggered. Additionally, when the tool was used they were unable to flow from alert to calculator to automatic order set as it was designed to be used. These findings point to the existence of significant provider workflow variability. Primary care provider workflow is not pre-specified and emerges based on the unique interaction between the patient and the provider's agendas.[41] Our study points to a short, flexible and customizable CDS tool as more usable. Locating the CDS inside of the progress note may help to address tool interruptions and improve usability and workflow. The progress note seems to be the center point of provider interaction with the computer. For many providers, this would make the tool available at the time of decision making and present while they use the split screen to refer back to the chart when necessary.

Missed Opportunities + Tool Applicability

The ability to use the tool in as many clinical situations as possible increases its usefulness. Every provider commented on the utility of adding a tool addressing risk of bacterial sinusitis. This addition would allow providers to apply these tools to almost any symptoms of upper respiratory infection. The more broadly these tools apply the more valuable they may be to providers. In half of the visits, patient history challenged the validity of the clinical prediction rule used to calculate the risk of bacterial infection. Usefulness was addressed as well with providers' lack of use of the incorporated incentives. Elements that are incorporated into CDS tools as incentives should save the provider time or effort when compared to their usual workflow. The lack of order set use can also limit the ability of the CDS to improve evidence-based patient care and influence the type of antibiotics ordered.

Usability testing of CDS helps to close the gap between its current and its potential impact on providers, their interactions with patients, and the quality of care they give. Although the EHR's poor usability and interference with face-to-face patient care are prominent sources of professional dissatisfaction, providers still believe in the potential of this technology.[24] The concept of evidence based clinical care revolutionized medicine by demanding that interventions be formally evaluated. We must evaluate CDS with this same rigorous approach; usability tested and refined CDS can address unforeseen consequences, decrease strain on the provider and the patient-provider interaction, and garner the adoption rates required to have a meaningful positive impact.

Limitations

As typical for usability studies, participants were a convenience sample of volunteers rather than a representative sample. They were identified based on their higher than average use of this CDS tool. This was done to ensure tool usage on the day of testing. These providers may have a more positive opinion of it or use it in a way that is fundamentally different than the average provider. Even in this subset of providers predisposed to high CDS use, the tool was not used as designed and created work-flow frustration. These providers may also use the EHR more during patient encounters than average. The sample size for this study was small as a result of the inherent logistical difficulty of live usability testing in the real clinical environment. However, usability testing is typically performed in just five sessions as thematic saturation begins to occur at this point.[36-38] We reached thematic saturation during our study, observing consistent and recurring themes across all of our recorded sessions. During testing, participants were aware that they were being recorded and may have changed their behavior and reported observations as a result of being observed (the Hawthorne effect). This testing was done with just one EHR, EpicCare, which may limit generalizability. However, this is the most widely used EHR in the United States. All of these limitations are inherent to usability studies and represent standard practice.

CONCLUSION

Live usability testing of this CDS tool provided insights on its ease of use, usefulness and its impact on the patient-provider interaction that were not evident in previous usability testing. This highlights the importance of incorporating live usability testing into CDS tool development. Our study suggests that short, flexible and customizable CDS tools may be more usable, addressing the challenges of the highly variable provider workflow. The progress note seems to be the center point of provider interaction with the EHR. Locating the CDS tool inside of the progress note may help to address tool interruptions and ensure that the tool is available at the time of decision making and present when providers refer back to the chart when necessary. The tool was designed to be used sequentially and this contributed to providers not finishing the tool once they deviated from the intended workflow.

The more broadly these tools apply the more valuable they are to providers. Elements that are incorporated into CDS tools as incentives must be useful, saving the provider time or effort when compared to their usual workflow. Live usability testing of these tools also generated insights about their impact on the patient-provider interaction. The simple, intuitive, and informational design of the tool allowed providers to use it with their patients. CDS can contribute to the patient-provider interaction by being built to be simultaneously viewed by provider and patient. The use of the calculator to engage the patient in the decision making as a driver for the use of the CDS tool needs further study. This allows the EHR to provide important information while reconnecting patient and provider.

ACKNOWLEDGEMENTS

This project was funded by the National Institutes of Health, National institute of Allergy and Infectious Diseases, under grant #5R01 AI108680-03. The funding body had no role in the design of the study or the collection, analysis, or interpretation of data.

REFERENCES

1. Donaldson, M.S., J.M. Corrigan, and L.T. Kohn, *To err is human: building a safer health system*. Vol. 6. 2000: National Academies Press.
2. Connelly, D.P., et al., *Knowledge resource preferences of family physicians*. J Fam Pract, 1990. **30**(3): p. 353-9.
3. Baker, A., *Crossing the quality chasm: a new health system for the 21st century*. BMJ: British Medical Journal, 2001. **323**(7322): p. 1192.
4. Asch, S.M., et al., *Comparison of quality of care for patients in the Veterans Health Administration and patients in a national sample*. Annals of internal medicine, 2004. **141**(12): p. 938-945.
5. Blumenthal, D. and M. Tavenner, *The "meaningful use" regulation for electronic health records*. N Engl J Med, 2010. **2010**(363): p. 501-504.
6. Adler-Milstein, J. and A.K. Jha, *HITECH Act Drove Large Gains In Hospital Electronic Health Record Adoption*. Health Affairs, 2017. **36**(8): p. 1416-1422.
7. Bernstein, S.L., et al., *An electronic chart prompt to decrease proprietary antibiotic prescription to self-pay patients*. Acad Emerg Med, 2005. **12**(3): p. 225-31.
8. Garthwaite, E.A., et al., *Patient-specific prompts in the cholesterol management of renal transplant outpatients: results and analysis of underperformance*. Transplantation, 2004. **78**(7): p. 1042-7.
9. Gaikwad, R., et al., *Evaluation of accuracy of drug interaction alerts triggered by two electronic medical record systems in primary healthcare*. Health Informatics J, 2007. **13**(3): p. 163-77.
10. Seidling, H.M., et al., *Patient-specific electronic decision support reduces prescription of excessive doses*. Qual Saf Health Care, 2010. **19**(5): p. e15.
11. Shah, N.R., et al., *Improving acceptance of computerized prescribing alerts in ambulatory care*. J Am Med Inform Assoc, 2006. **13**(1): p. 5-11.
12. Smith, D.H., et al., *The impact of prescribing safety alerts for elderly persons in an electronic medical record: an interrupted time series evaluation*. Arch Intern Med, 2006. **166**(10): p. 1098-104.
13. Tamblyn, R., et al., *The medical office of the 21st century (MOXXI): effectiveness of computerized decision-making support in reducing inappropriate prescribing in primary care*. CMAJ, 2003. **169**(6): p. 549-56.
14. Bright, T.J., et al., *Effect of clinical decision-support systems: a systematic review*. Ann Intern Med, 2012. **157**(1): p. 29-43.
15. Kaushal, R., K.G. Shojania, and D.W. Bates, *Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review*. Archives of internal medicine, 2003. **163**(12): p. 1409-1416.
16. Bonnbaby, P., et al., *A risk analysis method to evaluate the impact of a computerized provider order entry system on patient safety*. Journal of the American Medical Informatics Association, 2008. **15**(4): p. 453-460.
17. Roshanov, P.S., et al., *Features of effective computerised clinical decision support systems: meta-regression of 162 randomised trials*. Bmj, 2013. **346**: p. f657.
18. Souza, N.M., et al., *Computerized clinical decision support systems for primary preventive care: a decision-maker-researcher partnership systematic review of effects on process of care and patient outcomes*. Implement Sci, 2011. **6**(1): p. 87-99.
19. McGinn, T.G., et al., *Efficacy of an evidence-based clinical decision support in primary care practices: a randomized clinical trial*. JAMA internal medicine, 2013. **173**(17): p. 1584-1591.

20. Chaudhry, B., et al., *Systematic review: impact of health information technology on quality, efficiency, and costs of medical care*. Annals of internal medicine, 2006. **144**(10): p. 742-752.
21. Bright, T.J., et al., *Effect of clinical decision-support systems: a systematic review*. Annals of internal medicine, 2012. **157**(1): p. 29-43.
22. Murphy, D.R., et al., *The Burden of Inbox Notifications in Commercial Electronic Health Records*. JAMA internal medicine, 2016. **176**(4): p. 559-560.
23. Sinsky, C., et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties*. Annals of Internal Medicine, 2016.
24. Friedberg, M.W., et al., *Factors affecting physician professional satisfaction and their implications for patient care, health systems, and health policy*. Rand health quarterly, 2014. **3**(4).
25. Bates, D.W., et al., *Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality*. J Am Med Inform Assoc, 2003. **10**(6): p. 523-30.
26. Moxey, A., et al., *Computerized clinical decision support for prescribing: provision does not guarantee uptake*. Journal of the American Medical Informatics Association, 2010. **17**(1): p. 25-33.
27. Graham, T.A., et al. *How usability of a web-based clinical decision support system has the potential to contribute to adverse medical events*. in AMIA annual symposium proceedings. 2008. American Medical Informatics Association.
28. Payne, T.H., et al., *Recommendations to improve the usability of drug-drug interaction clinical decision support alerts*. Journal of the American Medical Informatics Association, 2015. **22**(6): p. 1243-1250.
29. Li, A.C., et al., *Integrating usability testing and think-aloud protocol analysis with "near-live" clinical simulations in evaluating clinical decision support*. International journal of medical informatics, 2012. **81**(11): p. 761-772.
30. Devine, E.B., et al., *Usability evaluation of pharmacogenomics clinical decision support aids and clinical knowledge resources in a computerized provider order entry system: a mixed methods approach*. International journal of medical informatics, 2014. **83**(7): p. 473-483.
31. Kastner, M., et al., *Usability evaluation of a clinical decision support tool for osteoporosis disease management*. Implementation Science, 2010. **5**(1): p. 96.
32. Horsky, J., et al., *Interface design principles for usable decision support: a targeted review of best practices for clinical prescribing interventions*. Journal of biomedical informatics, 2012. **45**(6): p. 1202-1216.
33. Fossum, M., et al., *An evaluation of the usability of a computerized decision support system for nursing homes*. Applied clinical informatics, 2011. **2**(04): p. 420-436.
34. Kortteisto, T., et al., *Clinical decision support must be useful, functional is not enough: a qualitative study of computer-based clinical decision support in primary care*. BMC health services research, 2012. **12**(1): p. 349.
35. Feldstein, D.A., et al., *Design and implementation of electronic health record integrated clinical prediction rules (iCPR): a randomized trial in diverse primary care settings*. Implementation Science, 2017. **12**(1): p. 37.
36. Nielsen, J., *Estimating the number of subjects needed for a thinking aloud test*. International journal of human-computer studies, 1994. **41**(3): p. 385-397.
37. Virzi, R.A., *Refining the test phase of usability evaluation: How many subjects is enough?* Human Factors: The Journal of the Human Factors and Ergonomics Society, 1992. **34**(4): p. 457-468.

38. Nielsen, J., *How many test users in a usability study*. Nielsen Norman Group, 2012. **4**(06).
39. Richardson, S., et al., *"Think aloud" and "Near live" usability testing of two complex clinical decision support tools*. International Journal of Medical Informatics, 2017. **106**: p. 1-8.
40. Linder, J.A., et al., *Electronic health record use and the quality of ambulatory care in the United States*. Archives of internal medicine, 2007. **167**(13): p. 1400-1405.
41. Holman, G.T., et al., *The myth of standardized workflow in primary care*. Journal of the American Medical Informatics Association, 2015. **23**(1): p. 29-37.

Preprint
JMIR Publications

Table 1. Live Usability Testing Results		
Coding Category	Example Comments / Actions	Summary / Recommendation
Tool Interruptions	Patient: "Was it last year or the year before - didn't I have to get a pneumonia shot?" <i>Provider navigates away from automatic order set immediately after opening</i>	During every testing session the provider was interrupted during their use of the CDS tool by the need to refer to other sections of
	Provider: "Have you had a chest X-ray anytime recently?" <i>Provider clicks away from automatic order set to review results of last CXR.</i>	Recommendation: Complex CDS should be built for disrupted workflow, with easy and obvious re-entry points.
Workflow	<i>Provider opens chart, clicks away from alert, to progress notes.</i>	During every testing session the progress note served as the center point of the provider interaction with the EHR.
	"It's the first thing that comes up ...but you have to get all that info from the patient first. So that's what I mean by clunky."	
	<i>At the start of visit all providers navigate immediately to the progress note. Half spent > 95% of the visit with this function open and only one spent < 40% of the visit time with it open.</i>	Recommendation: CDS tools that exist within the progress note may have higher adoption rates because it would be more likely they were present at the time of decision making.
Tool Applicability	Provider: "So I read your chart; it says that you've been having symptoms since deer season?"	In half of the sessions, patient history challenged the validity of the clinical prediction rule used to calculate risk.
	Patient: "I actually called in and Dr. [name] gave me a prescription..."	
	"sometimes... something in your clinical encounter still says, 'get the X-ray or still treat,' you know, maybe you saw them before"	Recommendation: CDS tools should be as broadly applicable as possible with clear indications for use.
Patient - Tool Interaction	Provider: "OK, so our little risk calculator here is recommending that we would swab you for strep throat, and I agree with that."	In every session in which the tool was used to assess risk, the provider completed the calculator with the patient.
	Provider: "But your heart is beating kinda fast, you've had a fever last night ...the recommendation would be to get a chest x-ray today."	
	"I like to be able to show it to patients. So that part of it I really - I like to have that support, and that extra backup for the decision that I want to make."	Recommendation: CDS tools should be designed to be viewed by patient and provider simultaneously.
Provider - Computer - Patient Interaction	Patient: "my brother's living with me, he's a vet..." <i>Provider enters data from chart review in to progress note while patient talking about something unrelated.</i>	In every testing session the providers toggled between addressing either the computer or the patient during the visit.
	Provider: "So basically to summarize: about nine days ago is when you first got sick..." <i>Physician stops interacting with computer to recap history.</i>	
	[silence while Physician types]	
	<i>Providers spent between 0 - 3% of the visit listening to the patient without simultaneously engaging with the computer.</i>	Recommendation: Providers may find CDS tools easier to complete if they engage patients.
Ease of Use	Provider: "Hold on, I just need the lab to actually put in the results... my thing isn't popping up for me to prescribe the antibiotics quite yet."	Providers were able to complete the tool quickly, however, during half of the sessions hard stops and fixed elements in the tool created barriers to usability.
	"the patient instructions have some hard stop, so I got frustrated with that, and then eventually deleted and typed my own patient instructions in."	
	"Cause it's short. If it were any longer, I'd probably get frustrated with it."	
	<i>Providers spent about 1 minute of the visit time completing the CDS tool.</i>	Recommendation: Tools that are short, customizable and flexible to different workflows will have improved usability.
Missed Opportunities	<i>Provider enters shortcut ".cvui" to generate upper respiratory infection note template at start of visit.</i>	In every session providers did not use either the automatic order set or automatic documentation.
	Provider: "So the antibiotic that I would pick for you is one called Azithromycin."	
	<i>Provider orders antibiotics a la carte without re-entering tool after chest x-ray is</i>	
	"it's easier for me to order a chest X-ray just outside of the order set... then get the results back and go on with the patient visit. And then at that point, it's like the opportunity has been lost to use the [automatic order] set."	Recommendation: Elements that are incorporated into CDS tools as incentives should save the provider time or effort when compared to their usual workflow.

Figure 1. Clinical Decision Support Tool Calculator

The screenshot shows a web-based calculator for Strep Pharyngitis Risk Scoring. At the top, it says "Strep Pharyngitis Risk Scoring Tool - Pharyngitis". Below this, there are input fields for "Time taken:" (2327) and a date field (5/18/2016). A "Values By" dropdown menu is set to "Create Note". A blue header bar reads "Strep Pharyngitis Risk Scoring Tool - Click Close to continue to SmartSet". The main section contains four questions, each with a "1=Yes" and "0=No" button: "History of Fever?", "Cough?", "Tonsillar Exudates?", and "Tender anterior cervical nodes?". Below these, the "Strep Pharyngitis Risk Score (out of 4)" is displayed as 3. The "Approx Risk of Strep" is shown as "Intermediate (10-19%)". At the bottom, there are buttons for "Restore", "Close" (with a green checkmark), and "Cancel" (with a red X). A large, diagonal watermark reading "Preprint JMIR Publications" is overlaid on the image.

Question	1=Yes	0=No
History of Fever?	<input checked="" type="button"/>	<input type="button"/>
Cough?	<input type="button"/>	<input checked="" type="button"/>
Tonsillar Exudates?	<input checked="" type="button"/>	<input type="button"/>
Tender anterior cervical nodes?	<input checked="" type="button"/>	<input type="button"/>

Strep Pharyngitis Risk Score (out of 4): 3

Approx Risk of Strep: Intermediate (10-19%)

Buttons: Restore, Close, Cancel

Figure 2. Clinical Decision Support Tool Automatic Order Set

Associate Providers

Pharmacy No Selected Pharmacy

▼ Sore Throat Decision Support Last Reviewed Date: 12/2/2016 3:15 PM

✓ From BestPractice

Decision Support
Sore Throat Decision Support

Strep Pharyngitis Risk Score (out of 4): 4
Risk scores of 4 are very suggestive of strep pharyngitis or another bacterial cause of pharyngitis. Consider treating for strep pharyngitis without further testing.

Action Steps
1. Click "Accept" to open the SmartSet linked below for treatment options and patient education materials.
2. Click "Cancel" to close the window. You may revisit this alert later in the Best Practice section of the navigator.

Information

▼ SmartSet Information

Risk scores of 4 are very suggestive of strep pharyngitis or another bacterial cause of pharyngitis. Consider treating for strep pharyngitis without further testing.

Documentation

▼ Strep Pharyngitis Risk Score 4+

☐ Strep Pharyngitis Risk Score 4+ Edit

☐ Full Progress Note Edit

Prescriptions

▼ Penicillins - First-Line Therapy (Adult)

Penicillin remains the treatment of choice because of its proven efficacy and safety, narrow spectrum and low cost

☐ amoxicillin (AMOXIL) 500 MG cap - 1000 mg 1x/d-10d
1,000 mg, Disp-20 cap, R-0, First occurrence now until 12/25/16

☐ penicillin V potassium (VEETID) 500 MG tab - 2x/d-10d
500 mg, Disp-20 tab, R-0, First occurrence now until 12/25/16

> Antibiotics - Penicillin Intolerant withOUT Anaphylaxis (Adult)

> Antibiotics - Patients with Immediate/Severe Reactions to Penicillin or Known Cephalosporin Allergies

Diagnosis

▼ Diagnosis

☒ Streptococcus pharyngitis [J02.0] Details

☐ Pharyngitis [J02.9] Details

Patient Instructions

▼ Brief Patient Instructions

☐ Brief Patient Instructions Edit

▼ Healthwise General Instructions

☐ STREP THROAT (ENGLISH) Edit

Follow-up

▼ Pharyngitis Follow-up

☐ Patient to follow up in 7 days if symptoms do not improve Details

Level of Service

▼ Office Visit - Established Patient

☐ 99211, Level 1 (5 min) Details

☐ 99212, Level 2 (10 min) Details

☐ 99213, Level 3 (15 min) Details

☐ 99214, Level 4 (25 min) Details

☐ 99215, Level 5 (40 min) Details

> Office Visit - Established Patient, Resident with Faculty

> Office Visit - New Patient

> Office Visit - New Patient, Resident with Faculty

XX

> END OF SMARTSET

Figure 3. Clinical Decision Support System (CDSS) Proposed Workflow

