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Optimizing the Electronic Health Record for Cardiac Care

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Final Progress Report

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Structured Abstract (Maximum of 250 words to include the following elements)

- Purpose: The Electronic Health Record (EHR) is now recognized as a significant contributor to clinician burn-out. We undertook a multi-center, multi-vendor study to understand the wants, needs and barriers of the EHR to clinicians and to create a framework to optimize the usefulness and usability of the EHR.
- Scope: Cardiovascular clinicians and patients practicing at 4 academic and 4 private healthcare systems.
- Methods: Convergent parallel mixed methods using a simulated patients to provide consistency across the sites and avoid privacy and security concerns. Establish baseline views from 53 clinicians at 8 sites. Analyze the data and build a functional prototype using agile techniques, validated with external experts, finally, retest clinicians (n=25) in head-to-head measures between prototype and installed EHR using the system usability scale (SUS).
- Results: Baseline results: Across 8 sites and 6 different installed EHRs SUS averaged 47.1 (less than 68 indicates poor usability, 82 excellent usability). Clinicians complained about unnecessary clicks and documentation of impertinent negatives. What they desired was an EHR that supported continuity over episodic care, active involvement of patients in data collection, appropriate data pushed to them, fulfilling billing requirements without bloating the note, and support for structured data and patient narrative. Follow-up testing of our prototype versus installed EHR with 25 clinicians across our test sites demonstrated a significant improvement in SUS scores (78.1 versus 48.2, $p < .0001$).
- In conclusion, clinician-centered design can result in substantial improvements in EHR usability independent of academic versus private practice. This prototype can inform EHR vendors of desired functionality
- Key Words
 - Electronic Health Record
 - Usability
 - User-Centered Design

Purpose (Objective of Study)

Widespread adoption of the electronic health record (EHR) was touted by many as the panacea to fix healthcare. The passage of the Health Information Technology for Economic and Clinical Health (HITECH) promoted the widespread adoption of the EHR and established to promote the “meaningful use” of the EHR. EHRs are now used in over 96% of practices in the US. We are now facing what Robert Merton coined as the unintended consequences of these actions.

The current electronic health record evolved as a product of traditional paper-based records and the need to provide documentation to support billing. However, the expansion occurred with minimal involvement of clinicians. Our earlier studies indicated that clinicians believed that the EHR had a negative impact on patient care. Those concerns have been borne out in multiple subsequent studies; clinicians spend more time with their computers than with their patients and that the EHR is a major source of clinician burn-out.

The purpose of this study was understand the desiderata and perceived issues regarding the EHR, and use the best practices in user-centered design and action research methodologies to create framework based on clinician-centered design and validate that framework with a fully functional EHR prototype.

Scope

- Background

The electronic health record (EHR) was expected to transform the delivery of health care services in the United States; reducing costs and improving health outcomes through standardizing practice and reducing medical errors. The reality, however, was that EHR adoption did not substantially lower costs nor improve patient care ultimately leading to clinician burnout. This outcome should have been anticipated. Our previous work and the work of others suggested that physician resistance to adoption of the EHR, even among tech-savvy super-users, was based on the perceived negative impact on clinician workflow, communication, and insufficient functionality to assure safe management of their patients.

The inability of EHRs to fulfill these goals stimulated investigation by the American Medical Informatics Association’s Task Force on Usability, which recommended human factors research to improve EHR usability. Attention to usability for EHR system designs that support the cognitive work of clinical users is also recognized as a requirement by the Healthcare Information and Management Systems Society.

There are two definitions of usability. Usability is defined by the International Standards Organization (ISO) as the “effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment”. Zhang and Walji in their task, user, representation, and function (TURF) model define usability model of usable, useful and satisfying. An excellent discussion of usability is presented in Linda Harrington's recently published book on usability.

While the benefits of a usability-based approach to EHR requirements are well documented, the practical application of usability assessment into EHR software design and development is

limited. Recommendations by industry and government experts point to an insufficient focus on usability as an ongoing problem.

- Context

Our research focused on cardiovascular clinical scenarios. Cardiovascular disease is the leading cause of death in the US, with nearly 600,000 deaths per year. Death rates for cardiovascular disease have declined substantially since 1999, 44% due to lifestyle and environmental changes, and 47% due to increased use of evidence-based medical therapy. Yet nearly 40% of US citizens are projected to have some form of cardiovascular disease by 2030, and estimated costs for treatment are projected to grow to nearly \$1.5 trillion. The management of cardiovascular disease; is by its nature, multi-dimensional (acute and chronic, inpatient and outpatient, primary and secondary prevention) and multidisciplinary (cardiologists, primary care providers, emergency room physicians, CCU nurses, catheterization lab nurses and technicians, and outpatient nurses and technicians), and thus it is ideal to test the full functionality of the EHR. Finally our access to cardiovascular content experts through our association with the American College of Cardiology (ACC) and, in particular the ACC Informatics and Health Information Taskforce was critical to our grants success.

- Settings

This was multisite, multivendor evaluation of the EHR. Four academic and four private practice settings were included. The academic settings included the University of Nebraska Medical Center, Indiana University, Duke University and the Veterans Administration Medical Center in Omaha, affiliated with Creighton University. The four private settings were Swedish Medical Center in Seattle Washington, St. Vincent Health System in Indianapolis, Indiana, Parkview Health in Fort Wayne, Indiana, and Faith Regional Health in Norfolk, Nebraska. Simulations of the clinical encounters were performed in clinic rooms or meeting rooms adjacent to clinical rooms.

Early in this project we identified that any solution to optimizing the EHR needed to include the patient on the healthcare team. Therefore we added patients into our model of the healthcare team and created a personal health record prototype. The prototyping of desired personal health record (PHR) functionality was performed only at the University of Nebraska Medical Center's clinical partner Nebraska Medicine.

- Participants:

- In the initial phase we recruited 53 clinicians (physicians or advanced practice providers) were recruited from the eight clinical sites mentioned above. A minimum of 5 clinicians from each site were recruited. This was a convenience sample based on clinician availability but reflected the demographics of that site. Further, we were not involved in the selection process of clinicians sampled.
- In the final phase of the project (validation of our clinician-centered framework) involved 25 clinicians at 7 sites. We excluded UNMC from the final site to reduce the potential for bias.
- 105 patients were recruited for the design and development of the personal health record. Patients were recruited at the time of their regular clinic visit and recruited to be fully representative of normal patient population based on age, gender, race or ethnicity, and zip code.

Methods

- Study Design

1) Understanding the wants, needs, and barriers of clinicians:

To understand the wants and needs of clinicians and the barriers imposed by the EHR we applied a convergent, parallel mixed methods (CPMM) approach. We developed complex clinical scenarios and used a simulated patient (actor) to present the case to clinicians.

The moderator introduced the subject to the system, presented an overview of the session, and described the think aloud protocol. The subject was introduced to the trained simulated patient, and received a written copy of the clinical scenario. The investigators digitally recorded the sessions, observing user's system interactions as they completed the tasks defined within the scenario, and completed field notes which included observations, participants' comments while using the system, where and when system problems occurred, along with nonverbal user feedback. A second, independent observer was present to ensure digital recording of video and audio, record comments and non-verbal responses and track completion times.

The research design consisted of two components, quantitative and qualitative data collection. Baseline demographics were collected as well as the system usability scale as well as Likert ratings of the realism of the simulation and the ability for the clinician to fully express their wants and needs.

Survey responses were loaded into Excel. Participant's scores were summarized and multiplied by 2.5 to convert the original scores of 0-40 to a standardized score of 0-100. Using Brooke's analysis strategy, respondents who score above 68 were classified as satisfied users. Respondents who score below 68 were classified as dissatisfied users.

A post-walkthrough interview followed, where participants answered open-ended questions and discussed perceptions of usability and satisfaction. After the user session, task measurements specified by the case scenario were recorded, user screen manipulations and audio files were stored, and field notes were completed.

Data was collected and analyzed in an iterative manner. Quantitative data included successful task completions as a measure of effectiveness, time to complete tasks and associated number of mouse clicks as measures of efficiency; and task difficulty and task satisfaction ratings as measures of satisfaction. Results were examined using descriptive statistics to measure central tendency and variability.

Qualitative data including the digital recordings and field notes were reviewed by the investigators. All documents were imported into NVivo 9.0, and identified by session date and time. The investigators independently reviewed each session's recording to identify patterns within the participants' responses, annotating the recording with relevant concepts through NVivo. Using the method of grounded theory and constant comparison, the investigators met weekly to compare concepts, resolve discrepancies in interpretation, explore the various meanings of words, discuss emergent themes, and resolve ambiguities, until consensus was achieved and potential biases in interpretation were reconciled. Important user themes were built using this iterative process of reviewing and grouping concepts during the review sessions. The relevance and importance of themes was assessed by the investigators using a rating scheme of frequency, convergence and intensity. Frequency represents the number of times

that the topic appeared in the users' discussion, and was documented using NVivo's frequency reporting feature. Convergence, the relative occurrence of the topic across the groups of satisfied and dissatisfied users, was assessed by each investigator as high, medium, or low. Intensity was defined as the emotion and importance of the topic to the user, using a scale of high, medium or low based on a subjective analysis of the digital recording for vocal tone, pace and volume. According to grounded theory, we continued the iterative process of review and data collection until no new concepts were discovered and content saturation was reached. A summary of relevant themes was compiled.

Resulting themes from the quantitative and qualitative analyses were reviewed. Using the CPMM framework, results from the two approaches were merged to identify and resolve differences between the sets of results, and to clarify findings through triangulation, providing a more comprehensive interpretation of EHR usability requirements for the cardiac care team, and a broader understanding of the implications of EHR design.

Personal Health Record

To understand the wants, needs and barriers imposed by the PHR on patients we used similar methods with the following exceptions. To reduce the barrier to recruitment especially around venerable patients the testing sessions were scheduled in conjunction to their routine clinic visit. Rather than a simulated patient we had the research subjects (patients) use their own data. To assure a diverse sample we used age, gender, race/ethnicity and zip code. Baseline demographics were recorded as well as patient activation measures, health and computer literacy scales. Similarly, CPMM framework was applied.

2) Agile Development of Desired Functionality

In parallel with understanding the wants and needs of clinicians we conducted a heuristic evaluation of the current EHR to assess usability using the clinical scenarios. Heuristic evaluation is a commonly used expert method where Human-Computer Interaction (HCI) specialists study the interface in depth and look for properties that they know, from experience, will lead them to identify potential problems. The University of Nebraska Research team - consisting of HCI experts from the UNO College of Information Science and Technology and UNMC performed the heuristic evaluation process. ACC clinical and informatics domain experts also participated in the evaluation based on Nielsen's 10 heuristics, plus an additional 3 identified by Denise Pierotti, Xerox Corporation. The list includes criteria to evaluate productivity and efficiency, error prevention, user control, ease of learning, flexibility of use, and user satisfaction. The expert team met in group sessions (in person and via webinar) to review the meaning of each heuristic and discuss its relevance to EHR user interface design and to assess how well the EHR adhered to the heuristic on a scale of 1 to 5. Also, comments were captured on how the EHR could be modified. Heuristics were prioritized according to Impact – number of users it affected, severity, the consequence if the heuristic was not followed (patient safety in particular), and the frequency – how often a user would encounter the event where the heuristic was not followed. The results of the heuristic evaluation provided us with a prioritized list of actions that need to be taken to improve the user interface. In essence we developed a robust action plan for enhancements and features in the prototype.

In the assessment, each evaluator entered a rating on how well the current-state EHR enforces the heuristic. During this process we captured comments from each evaluator indicating where the current-state EHR violated the heuristic and where it could be improved. Examples of

success or failure was discussed and the team decided which heuristics were applicable. Each evaluator entered his or her rating independently and also add comments to explain the rating, especially if the system did not comply with the heuristic. The current-state EHR was projected for all to view during these discussion sessions. After all the ratings were completed, we analyzed for inconsistencies in our evaluations (standard deviations) and then prioritize the results based on the ratings. We also captured other enhancement ideas that were generated from our analysis and discussion. We created a report on the general and specific findings to be included in the design requirements for an optimized EHR prototype.

3) Electronic and Personal Health Record Prototyping

The grant originally was going to develop wireframe prototypes to test desired functionality. Initial testing indicated that wireframes, even complex wireframes did not create the veracity necessary for clinicians to concentrate on the clinical encounter. Therefore, we built a fully functioning web-enabled prototype using Microsoft SQL to support the database needs of the prototype, thus supporting documents, lab values and images. The front end used Bootstrap (Bootstrap.com) and Angular (Angular.IO)

In developing these models, we employed two highly respected information system development methodologies: Value-Based Software Engineering principles and Agile Development methods. In addition, we followed the Action Research methodology approach as we prepare for each iteration. Action research has the dual intention of improving practice and contributing to theory and knowledge (Argyris et al. 1982; Checkland 1981).

In our project we employed all four activities of action research: Plan, Act, Observe, and Reflect. 'Plan' concerns exploration of the research environment and the preparation of the intervention (create the wireframe model). 'Act' refers to the actual intervention made by the investigator (Intervention is the implementation the new design changes to wireframe model and thee user evaluation of the new design). 'Observe' concerns the collection of data during and after the actual intervention to enable evaluation (collect data from the users' feedback). Finally, the 'Reflect' activity analyses the collected data and infers conclusions (Analyze the feedback from the user and identify the next intervention – user interface design changes) that may feed into the 'Plan' activity of a new iteration.

This approach allowed us to quickly design and build what the end-users (the cardiac care team) want and convert those results into a set of requirements that directly impacted the workflow, information flow and decision support needs of the cardiac care team. By partnering with the ACC we be able to work with the EHR's success-critical stakeholders (SCS) eliciting their value propositions with respect to the system; and reconciling these value propositions into a mutually satisfactory user interface.

Value Based Software Engineering Philosophy

Value Based Software Engineering (VBSE) theory states stakeholders beyond users were critical to the success of the software development project and must be considered. VBSE asserts that traditional software engineering practice and research is value-neutral where each deliverable is given equal importance across the board i.e. no prioritization is done and no cut-offs were set when unit costs exceed derived unit benefit. VBSE represents a paradigm shift from value-neutral to value-based thinking.

Value Based Software Engineering principles are explicitly concerned with stakeholders' value concerns in the application of science and mathematics by which the properties of computer software are made useful to people ⁶⁵. In other words, what do critical-success stakeholders value as important requirements of an information system, and how these competing requirements could be integrated to create a WIN-WIN scenario for all stakeholders. The objective of Value Based Software Engineering principles are to integrate value considerations into the full range of existing and emerging software engineering principles and practices, and develop an overall framework in which they compatibly reinforce each other.

At the core of Value Based Software Engineering is Theory W. Theory W is defined as determining what is important to each of the success-critical stakeholders (SCS) and defining how success is assured for all SCSs. The desired end state for requirements then is a negotiated win-win state in which the system stakeholders agree to an option from which all can derive benefit. We operated in a value-based setting rather than a value-neutral setting. A value-neutral setting is where every objective, requirement use-case defect are treated equally important. In the past, this approach has been acceptable; however, today there are many competing values. Different stakeholders have different value propositions. In order to optimize the EHR as many as possible value propositions need to be addressed.

4) Testing the Prototype EHR

A new simulated complex patient was developed for the final testing of the prototype versus the installed EHR. Twenty five clinicians were recruited from the eight clinical sites. The clinician recorded SUS scores for their installed EHR. Orientation to the prototype EHR was then performed prior to formal testing with the simulated patients. This orientation took between 15 and 25 minutes. The simulated patient had recently been discharged from the hospital and was establishing care as a new patient with the clinician. This allowed us to fully test the review, interview, and document process. Debriefing and SUS scores were collected after the simulation.

5) Evaluation and Testing of the Prototype PHR

The methods described above (1-4) were used with patients to create a functional PHR prototype with some modifications. Initially we tried using simulation with patients but quickly discovered that was too complex and let them use their own situation and problems. The use of the EHR is a mandate not a choice, not so with patients. We, therefore, looked into barriers of adoption from a socio-technical framework. Near the end of the grant we received funding to add eye-tracking. We then added measures of cognitive load through the NASA taskload index and eye tracking.

- Data Sources/Collection: See above
- Interventions: Development and testing of the prototype personal health and electronic health record
- Measures: Convergent parallel mixed methods (quantitative and qualitative data collection and analysis of clinicians and patients, and expert consensus building).

- Limitations: Although we believe the results are generalizable, the prototype is specifically tailored to the patient with cardiovascular disease in the outpatient clinical environment. Further, we did not specifically measure efficiency, relying on clinician comments for validation. Our prototype achieved 100% effectiveness, but the system was optimized for quality documentation in the workflow and these results need to be independently validated. Industry's self-reported measures of SUS are substantially higher than our subjects reported, possibly reflecting recruitment of subjects by EHR vendors in industry reports. We did attempt to limit bias by excluding clinicians from UNMC and those associated with our design from the quantitative analysis. Finally, while we did achieve levels of satisfaction bordering on excellent with minimal training, we did not specifically measure cognitive load.

Results

- Principal Findings

Between 2015 and 2017 we surveyed 53 clinicians (19 female, 34 male) at the 8 sites. Participants included 28 practicing cardiologists, 12 fellows in training, and 13 APPs. Fourteen reported EHR use between 10-25 hours per week and 39 reported >20 hours per week. Forty reported extensive experience with Epic, 13 CPRS, 9 Cerner, 4 Allscripts, 4 NextGen, and 4 Athenahealth EHR systems. Three sites (UNMC, Duke, and Parkview Health) also had experience with homegrown electronic medical record systems prior to the EHR Incentive Program of the HITECH Act. To reduce potential bias, we excluded SUS scores from clinicians at UNMC or who served on our expert panel (n=14). Thus, 39 clinicians participated in the quantitative data collection.

EHR Wants, Needs, and Barriers

The first step was to understand the desiderata and barriers regarding EHR use by clinicians. Key findings include the following. The general perception is that the EHR impedes clinician workflow, inhibits communication, and adversely affects decision-making. Despite training, EHR design is not intuitive, and there are endless clicks. Reviewing patient records and documenting patient encounters is highly burdensome, especially documentation of "impertinent negatives". A common comment is that the EHR adds 90 minutes to the workday. Copying and pasting is frequently mentioned as the method to efficiently bring forward information from previous encounters. Most clinicians did not use the problem list because it is "bloated", hard to manage, and not useful.

Clinicians stated they want high quality, context-specific, verified data pre-compiled and pushed to them, along with easy access to good patient narratives. They want intuitive support for documentation and ordering. They also want to eliminate "impertinent negatives" and note bloat.

This study did not intend, nor was it powered, to compare installed EHRs. However, we did not detect substantive differences favoring one EHR system over another. Of critical importance, while clinical tasks were assigned and managed differently at different sites, we noted that clinical care is practiced the same across the country and independent of installed EHR. This should allow generalizable best practices in EHR implementation at scale.

Quantitative Results:

The design and usability of the EHR to manage the complex clinical scenario and simulated patient was assessed post-evaluation using the System Usability Scale. During the initial testing clinicians rated their installed EHR design as poor 47.1 +/- 16.8 (range 20-82.5) and their overall satisfaction with the EHR as neutral (3.1 +/- 1.0).

Effectiveness was measured using quality metrics from the PINNACLE Registry (Table 1). The average score was 15.4 (range 8-21). This project specifically did not rate the effectiveness of the individual clinician but instead attempted to identify consistent gaps across clinicians in terms of the quality of documentation. The most commonly missed measures were the Canadian Angina Classification, New York Heart Association Heart Failure Classification, and CHA2DS2-Vasc score. We also identified the prescription of exercise and treating hypertension to goal as common issues not addressed in this simulation.

All 39 clinicians completed a two-question post-protocol survey to validate our methodology. The simulated patient and the complex clinical scenario did accurately reflect their clinical practice (4.6 +/- 0.4) and allowed them to fully express their wants, needs, and barriers to effectively using an EHR (4.8 +/- 0.2).

Deconstructing the Clinical Encounter

The poor usability scores and consistent complaints about the EHR convinced us that we needed to start with a clean slate. We started with task analysis of workflow (presented in Table 2). Across different organizations, we noted different roles and responsibilities assigned to physicians, APPs, the clinical team, the primary care provider, and even patients. Critically, we identified no differences among sites in the tasks that needed to be performed to complete the clinical encounter.

We observed that direct patient care for the clinician breaks down into three phases: review, interview, and documentation (including ordering). The review process includes historical and diagnostic data obtained from the medical record and the patient. The clinician uses the review process to begin creating a mental model of the patient's problems. The clinician uses the interview to complete their model and then document the encounter.

We observed that clinicians struggle with navigating the EHR to find needed information. This was one of several expressions of cognitive load, or the relative burden of performing tasks. Another was the high knowledge base required simply to accomplish EHR functions such as authoring of encounter notes.

Prototype Construction and Validation

Working with clinicians and informatics experts we developed a clinician-centered clinical encounter framework based on the flow of data (Figure 1), identifying key design characteristics and first principles (Figure 2). Core to our design principles is transitioning from a document to a data focus. Data can be aggregated and viewed as needed. We used the problem list and problem-based connectors as advanced by Lawrence Weed. We associate candidate diagnostic, therapeutic (including medications), and quality metrics for each clinical problem.

These connectors support both documentation and ordering. Further, previous work informed us that different clinicians wanted and used different data.

Gains in efficiency must come by reducing the time needed to review and document the clinical encounter, increasing patient-clinician contact time. To organize clinical content, we created the metaphor of the patient's medical record as a library; different clinicians want different "books" from the patient library. The clinician can take a book off the shelf, view it, use it, or reshelv it. This metaphor reduces note bloat while supporting information synthesis and documentation for billing. Embedded reminders and context-specific decision support was well received.

The heuristics of good design to reduce cognitive load are well-established. While humans have a limited ability to hold multiple independent data elements in short term memory, studies of experts recognize their ability to process chunks of data and place them in established schema to provide greater granularity of data. Further, we found that standardized actions portrayed across a large physical display with no hidden data optimized data representation. While administrative requirements are often cited as a major factor in burn out, we specifically incorporated all known administrative tasks within the fabric of our prototype design.

Prototype Evaluation

Between May-November, 2019, 25 clinicians from the 7 sites participated in validation of the prototype (UNMC was excluded to reduce bias). None of the clinicians were involved in the action research although a few participated in the initial study. We tested 15 practicing cardiologists, 3 fellows, and 7 APPs. The installed EHR at all sites had not changed from the initial visit.

The EHR prototype required two high-resolution monitor screens to achieve the desired functionality. Reviewing and validating data was predominately a function of the left monitor screen. By keeping key data and narrative persistent on the left screen, information synthesis is facilitated. The library metaphor is used to review clinical data and the building of different views of the data on the right screen. Persistence of key data, the ability to review raw data and images, and facilitation of processes to validate patient and nursing entered data was viewed by clinicians as major efficiency gains. Although concerns about the utility and curation of the problem list were voiced, clinicians understood and appreciated having the EHR compile and aggregate data while anticipating diagnostic testing and therapeutic intervention recommendations. (A display of the design and functionality can be found in the attached PowerPoint presentation).

As shown in Figure 3, the SUS scores of the installed EHRs remained poor at follow-up at 48.1 +/- 16.7 (range 27.5-92.5), which was essentially unchanged from the baseline obtained several years earlier (2015-2017). By contrast, our prototype scored 77.8 +/- 12.4, (range 52.5-92.5, $p < 0.001$), a value at the upper range of good, bordering on excellent. Single value satisfaction scores also reflect this difference. The follow-up installed EHR score was 3.2 +/- 0.9 versus the prototype score of 4.4 +/- 0.6, ($p < 0.001$). Because of our linkage of problems and quality metrics, all quality metrics were completed (21 of 21 metrics). Further, at no point in the final usability evaluations did a clinician ask for data that was not in the system.

Coronary Artery Disease	Heart Failure	Atrial Fibrillation	Hypertension
History of Myocardial Infarction	NYHA Class	CHA2DS2-VASc Calculated	Hypertension Medications Prescribed
Presence of Coronary Stent	Ejection Fraction	Antithrombotic Therapy	BP at Target
Antiplatelet Therapy	Heart Failure Symptoms	Symptom Assessment	
Statin Therapy	Heart Failure Education		
Beta Blocker	ACE/ARB		
Angina Class (CAA)	Beta Blocker		
Smoking Status	ICD Counseling		
Exercise Prescription			
Lipid Profile			

Table 1: Quality metrics from the American College of Cardiology's PINNACLE Registry were used to measure effectiveness. These 21 elements represent the metrics for the four primary problems to be addressed in the clinical encounter.

Administrative Data Collection	Direct Patient Care	Medical Decision-Making	Communication
Demographics	Chart Review	Problem List Reconciliation	Self and Partners
Quality Metrics and Registries	History Taking	Medication Reconciliation	Clinical Team
Research	Patient Education	Decision Support Tools	Primary Care Provider
Billing	Patient Engagement	External References	Patient
	Information Synthesis	Ordering	Payers
	Clinical Documentation		

Table 2: Deconstruction of the clinical encounter resulted in the identification of four participants in the clinical encounter workflow: the clinician, the clinical team, the primary care provider, and the patient. Tasks identified as part of the clinical encounter occurred under four major headings: Administrative Data Collection, Direct Patient Care, Medical Decision-Making and Communication. Optimizing workflow requires an understanding of what different participants can and should do.

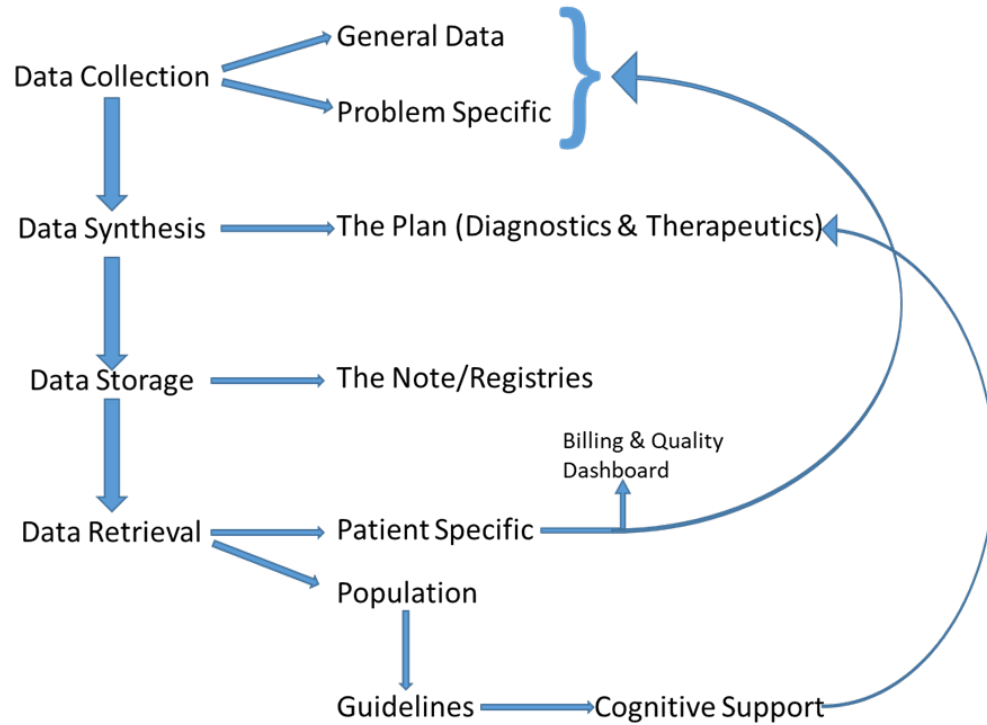


Figure 1: The framework based on clinician-centered design. Clinical encounter dataflow deconstructed into components of data collection, data synthesis, data storage, and data retrieval. This figure illustrates how data can be mapped to workflow and tasks.

Observations and Design Assumptions

- Clinical care is continuous, an encounter simply represents a snapshot of their care
- Clinical problems (symptoms, diagnoses, and therapeutics) and associated connectors can efficiently drive workflow and dataflow but must be well-curated
- Data needs for a clinical encounter are typically constrained and independent of clinical location or installed EHR
- While workflow varies by clinician and installed EHR, the core tasks of clinical care are present across all systems; best practices can therefore be established
- Domain knowledge and clinical expertise drive the information/data needs of the clinicians
- Clinicians, especially experienced clinicians, are capable of assimilating and synthesizing vast amounts of data and want access to data throughout the clinical encounter
- Data can be entered by the patient, clinical team, or the clinician but must be verified by the clinician (physician or APP)
- Clinicians want appropriate data pushed to them, including images
- Data persistence reduces administrative burden and note bloat
- Moving away from primarily analog text in documents for documentation is essential
- Robust structured data plus a concise clinical narrative accurately and efficiently conveys the patient's problems and story

Figure 2: Series of clinician-centered design assumptions generated by the action research methodology.

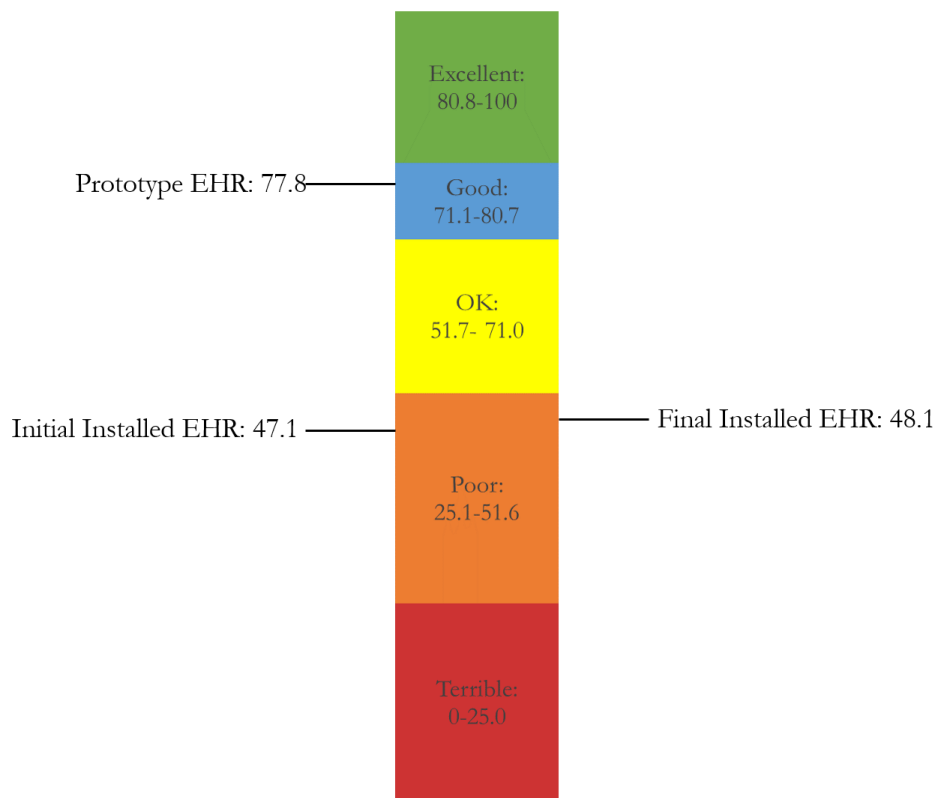


Figure 3: System usability scale (SUS) scores for the installed and prototype EHR. The scores from our initial testing of the installed EHR (n=39) was 47.1. SUS scores for the installed EHR did not significantly improve over the ensuing 3 years with a follow-up SUS scores of 48.1 (n=25). The prototype EHR demonstrated a substantial improvement in SUS score compared with the installed EHR used by the clinician (77.8, $p < 0.001$)

PHR Evaluation and Prototyping:

- Impact of Age on Desired PHR functionality.

We evaluated the impact of three age ranges on desired PHR functionality, less than 40, 40-64, and 65 and older. Younger patients had no fear of technology, they in fact, preferred electronic documents to paper and mobile devices. The older patients gave mixed results, there was substantially greater fear of technology including security and privacy, preference of monitor to mobile devices.

- Impact of Demographics and Social Determinants of Health on PHR adoption.

We next sought to study the adoption of the PHR based on the demographic and social determinants of health. In this study using group of patients with diverse demographics (race and ethnicity, urban, suburban and rural based on zip codes) and using measurements of health literacy, medication adherence measures, patient activation and computer self-efficacy, only computer self-efficacy was significant. All other demographic and social measures were not significant. While this study was relatively small (75 patients) it suggests that individual measures (personalization) rather than demographic grouping maybe be necessary to demonstrate improvements in care.

- The PHR Prototype and Cognitive Load

To potentially move the needle on patients limitations due to computer self-efficacy we introduced eye-tracking and the NASA task index to measure cognitive load. Cognitive load has three components: intrinsic, extrinsic and germane cognitive load. Better design affects extrinsic cognitive load. By altering our design we have been able to minimize extrinsic cognitive load.

- **Outcomes:** Measuring outcomes was out of scope of this grant.
- **Discussion:**

The intent of the HITECH Act was to maximize the “meaningful use” of health information technology, specifically the EHR. A decade later that goal is still unrealized; the EHR is still viewed as a barrier to good patient care and a source of clinician burn-out. Unfortunately, our analysis confirms these concerns. In the 2 to 4 years between the measurement of SUS scores of installed EHR systems there was no significant improvement in their “poor” usability ranking. Yet our prototype scored 30 points higher (very good). The salient question is why?

The key to us is two-fold: first was to start with a clean slate, and second was to align design with a deep understanding of how clinical care is actually delivered through the use of a realistic clinical simulation. This “tabula rosa” approach allowed our clinical and informatics experts the freedom to validate our ideas through a fully functional prototype not constrained by legacy design or constructs. Early in this project we realized that usability as defined as useful, usable, and satisfying or efficient effective and satisfying was not easily operationalized. The big leap occurred when we utilized an actionable definition of usability as optimizing workflow and dataflow while reducing cognitive load imposed by the EHR.

Little of the individual elements described in this project is completely novel. Position papers of the Office of the National Coordinator for Health Information Technology (ONC, American College of Physicians (ACP) and the American Medical Informatics Association (AMIA) as well as the writings of Carter and Sinsky provide excellent insight into the perceived problems. What we do believe is the primary contribution is the synthesis and validation of a robust framework for understanding usability through an EHR prototype that is independent of legacy system design.

We have developed and validated a functional EHR prototype that satisfies the objectives laid out by the ACP, AMIA, and HL7's Reducing Clinician Burden Project. Understanding that workflow and dataflow needs were universal across sites allowed us to develop a framework to improve usability through the application of robust heuristics of good design. Specifically, promoting data and data persistence, and bringing the patient actively onto the health care team improved dataflow and workflow. Understanding how expert clinicians collect and synthesize data allows us to push relevant domain specific content (including images) to the clinician. The use of two high-resolution screens and standardized functionality allows the clinicians to review, synthesize, and document with minimal need to open and close applications thus reducing cognitive load (and physical action) imposed by the EHR. Implementation of a bookshelf metaphor allowed the clinician to separate the viewing of data from the necessity of including same in the clinical note. The linking of problems with problem-based connectors for diagnostic, therapeutic and quality purposes improved clinician efficiency and effectiveness, and the ability to create custom views of the data for communication reduced note bloat

- **Conclusions:**

Clinicians want a well-designed EHR that improves their efficiency and effectiveness. Our framework and functional prototype substantially achieved that goal. Our intent is not to create another EHR but to demonstrate a framework that can improve the usefulness and usability of the EHR. We hope these findings will create a dialog between clinicians, informaticians, and EHR vendors and ultimately reduce clinician burnout.

- **Significance:**

More work needs to be done to confirm and validate these findings. However, this clinician framework holds the promise of making clinicians more efficient, effective and satisfied with their EHR.

- **Implications:**

AHRQ and the Office of the National Coordinator for Health Information Technology should support more research and development of non-incremental solutions to reduce clinician burden.

List of Publications and Products

Journal Articles

Tarrell A, Grabenbauer L, McClay J, **Windle J**, Fruhling AL. Toward improved heuristic evaluation of EHRs. Health Systems (2014) 1-13.

Clarke, M., Schuetzler, R., Pachunka, E., **Windle, J.**, Fruhling, A. (2019) "Usability and Cognitive Load in the Design of a Personal Health Record", *Health Policy and Technology*, Volume 9, Issue 2, June 2020, Pages 218-224.

Tcheng JE, Drozda JP, Gabriel, D, Wilgus RW, Williams M, Windle TA, **Windle JR.** (2018). Improving Healthcare Interoperability – Project Report. *Pew Charitable Trusts and Duke Clinical Research Institute*, 1-42. Retrieved from <https://dcric.org/registry-data-standards/>

Clarke MA, Sitorius M, Windle T, Fruhling AL, Bernard TL, **Windle JR.** "Impact of Age on User-Desired Preferences for the Personal Health Record: A Qualitative Study" *Journal of Medical Internet Research (JMIR)*. In Review

Clarke MA, Fruhling AL, Sitorius M, Windle TA, Bernard TL, **Windle JR.** (2020) Impact of Age on Patients' Communication and Technology Preferences in the Era of Meaningful Use: Mixed Methods Study *JMIR* 2020;22(6):e13470

Windle, TA, Tcheng JE, Drozda JP, Wilgus, RW, Gabriel, D, Windle, JR. (2019) Conformance to Interoperability Data Standards for Medications. *JAMA*. In Review.

Tcheng JE, Drozda JP, Gabriel, D, Wilgus RW, Williams M, Windle TA, Windle JR. (2019) Achieving Data Liquidity: Lessons Learned from Analysis of 38 Clinical Registries. *Annals* In Review.

Abstracts

Windle, TA. (2019, March 26). Adherence to Interoperability Data Standards for Medications. Data Exchange and Patient Management, AMIA 2019 Informatics Summit, Parc 55 Hotel, San Francisco, CA.

Windle, TA, Grabenbauer LA, Fruhling, AL, Tcheng, JE, Windle, JR. (2017, June 26). Multicenter Evaluation of the Electronic Health Record Using a Simulated Patient. Academy Health Annual Research Meeting, Hyatt Regency, New Orleans, LA.

Clarke MA, Sitorius M, Windle TA, Fruhling AL, Bernard TL, Windle JR. A Qualitative Study of User-desired Personal Health Record Functionality: Impact of Age on desired PHR functionality. In 2016 American Medical Informatics Association, Chicago, IL. Podium Presentation.

Clarke MA, Sitorius M, Windle T, Fruhling AL, Bernard TL, Windle JR. A Qualitative Study of User-desired Personal Health Record Functionality: Impact of Age on desired PHR functionality. 2016 Cardiology Grand Rounds, Omaha, NE. Podium Presentation.

Tarrell A, Clarke MA, Windle TA, Windle JR "Computer Skills Drive User Decision for Personal Health Record." Academy Health Annual Research Meeting 2017, New Orleans, LA. Poster Presentation.

Fruhling, A., Ramachandran, D., Bernard, T., Schuetzler, R., Windle J.R., (2018). Patient Preferences for Authentication and Security: A Comparison Study of Younger and Older Patients. Proceedings in the ACM Computers and People Research Conference, Buffalo, NY, June, 2018.

Fruhling, A. (2018). Multidisciplinary Team Collaboration Builds Creativity and Synergy among HCI Researchers, CHI 2018 Workshop Bridging a Bridge: Bringing Two HCI Communities Together, Montreal, Quebec, Canada. April, 2018.

Rose, J., Windle, J., Schuetzler, R., Fruhling, A. (2018). Evaluation of Voice Authentication for Patient Health Record Access. Presentation at the Twenty-fourth Americas Conference on Information Systems, New Orleans, LA. August, 16, 2018.

<https://aisel.aisnet.org/cgi/viewcontent.cgi?article=1174&context=amcis2018>.

Fruhling, A., Ramachandran, D., Bernard, T., Schuetzler, R., Windle J.R., (2018). Patient Preferences for Authentication and Security: A Comparison Study of Younger and Older Patients. Proceedings in the ACM Computers and People Research Conference, Buffalo, NY, June, 2018.

Schuetzler, R., Windle, J., Clarke, M., Pachunka, E., Fruhling, A., (2019). "Understanding System-induced Cognitive Load with Eye Tracking", Proceedings of the Americas Conference on Information Systems, Cancun, Mexico.

Pachunka, E., Windle, J., Schuetzler, R., Fruhling, A., (2019). Natural-Setting PHR Usability Evaluation using the NASA TLX to Measure Cognitive Load of Patients. Proceedings of 52nd Hawaii International Conference for System Sciences, Grand Wailea, Maui, January 8-11, 2019.

Presentations

Clarke, MA (2019 Apr) 4th Annual Midwest Bioinformatics "Increasing the Use of Personal Health Records through User-Centered Design"

Clarke MA (2019 Mar) University of Missouri Colwill Seminar: "Optimizing the Personal Health Record for Cardiac Patients."

Windle, TA. (2018, September 24). Improving Healthcare Data Interoperability. PEW/DCRI, Stakeholders Meeting, Duke University, Durham, NC (Remote).

Windle, TA. (2018, July 12). Interoperability Usability for Specialty Registries. PEW/DCRI, Stakeholders Meeting, Duke University, Durham, NC (Remote).

Windle, TA. (2018, January 8). Personal Health Record Usability. American College of Cardiology Informatics Committee, Cardiology Specialty Steering Board, Epic Campus, Verona, WI.

Windle, TA. (2017, July 15). EHR Usability Demonstration. Beyond Boundaries: ONC's 2017 Technical Interoperability Conference, Washington Plaza Hotel, Washington, DC.

Tcheng JE. (2019, March 22) Envisioning Data Liquidity: The DCRI-Pew Data Interoperability Project. NIH Collaboration Grand Rounds

Windle, JR. (2019, September 13) Deconstructing the Clinical Encounters. Cardiovascular Medicine Grand Rounds, UNMC

Windle, JR. (2019, October 23) Human and Computer Collaboration in Medicine. Great Plains IDeA Clinical Translation Research Meeting