Usability and Workflow Evaluation of "RhEumAtic Disease activitY" (READY)

A Mobile Application for Rheumatology Patients and Providers

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Keywords

Rheumatoid arthritis, mobile health, disease activity, time motion study, mobile application, mHealth, workflows and human interactions, mobile computing and communication, usability

Summary

Background: RhEumAtic Disease activitY (READY) is a mobile health (mHealth) application that aims to create a shared platform integrating data from both patients and physicians, with a particular emphasis on arthritis disease activity.

Methods: We made READY available on an iPad and pilot implemented it at a rheumatology outpatient clinic. We conducted 1) a usability evaluation study to explore patients' and physicians' interactions with READY, and 2) a time motion study (TMS) to observe the clinical workflow before and after the implementation.

Results: A total of 33 patients and 15 physicians participated in the usability evaluation. We found usability problems in navigation, data entry, pain assessment, documentation, and instructions along with error messages. Despite these issues, 25 (75,76%) patients reported they liked READY. Physicians provided mixed feedback because they were concerned about the impact of READY on clinical workflow. Six physicians participated in the TMS. We observed 47 patient visits (44.72 hours) in the pre-implementation phase, and 42 patient visits (37.82 hours) in the post-implementation phase. We found that patients spent more time on READY than paper (4.39mins vs. 2.26mins), but overall, READY did not delay the workflow (pre = 52.08 mins vs. post = 45.46 mins). This time difference may be compensated with READY eliminating a workflow step for the staff.

Conclusion: Patients preferred READY to paper documents. Many found it easier to input information because of the larger font size and the ease of 'tapping' rather than writing-out or circling answers. Even though patients spent more time on READY than using paper documents, the longer usage of READY was mainly due to when troubleshooting was needed. Most patients did not have problems after receiving initial support from the staff. This study not only enabled improvements to the software but also serves as good reference for other researchers or institutional decision makers who are interested in implementing such a technology.

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1. Introduction

The increasing adoption of Health Information Technology (HIT), Electronic Health Records (EHRs), and the consequent increase in electronic clinical data collection present enormous opportunities for advancing the science and practice of medicine. Clinical research and comparative effectiveness research (CER) which employs secondary use of existing data collected for clinical care are some examples. While HIT and EHRs primarily facilitate data capture by providers at the point of care, critical steps in the advancement of patient-centered comparative effectiveness and outcome research include the efficient capture of patient-reported data and integration with existing EHR data [1, 2].

International and U.S. rheumatoid arthritis (RA) initiatives, such as treat to target (T2T), encourage the incorporation of RA activity assessments through validated instruments and shared decision making as part of their overarching principles to achieve quality care and improve patient outcomes [3]. Data collected both at physician office visits and at patients' homes between visits enriches the information available to reach this goal. A variety of tools exist to capture disease activity measures, with many of them based upon paper questionnaires or manual calculations [4–6].

Mobile health (mHealth) applications have been used for health promotion and disease self-management with a growing number of specialized tools and resources [7–10]. Mobile devices such as smartphones and tablets offer the opportunity for more efficient data capture and subsequent shared decision making between patients and their providers [7].

Seeking to effect tangible improvement in RA patients' outcomes and better quality of care, we built on existing relationships and ongoing collaborations at University of Alabama at Birmingham and The Ohio State University to bring together researchers with expertise in rheumatology, epidemiology, informatics, statistics, risk communication and medical decision-making. The innovative technology, The RhEumAtic Disease activitY (READY) [11, 12], is a mobile application that aims to create a shared platform integrating electronic data from both patients and physicians, with a particular emphasis on arthritis disease activity, especially RA.

1.1 Electronic patient-reported outcomes (ePRO) on mobile devices

Mobile devices are increasingly being used for real-time data collection. Electronic patient-reported outcomes (ePRO) can be collected both at physician office visits and at patients' homes between visits, which enriches the information available for care planning [13]. READY is an example of ePRO on a mobile device that includes the capacity to select site-specific customizable questionnaires (instruments) from a 'library' of available instruments for patients with arthritis or other musculoskeletal and rheumatic diseases, along with the ability to select streamlined system flows, flexible collection locations, and real-time data reports [14]. Although ePRO on mobile devices has many benefits, it also poses new challenges including logistics of technology, security, institutional and financial support, and electronic design [15].

As READY is designed to be used by both patients and physicians, we were interested in understanding RA patients' ability and perceptions of using such a mobile application and physicians' interactions and feedback about READY to improve clinical practice and documentation. In addition, clinical workflow describes a process that comprises a wide range of steps or activities that health personnel execute to accomplish an activity in patient care [16]. Understanding clinical workflow has progressively been recognized as an essential component to consider to successfully implement and adopt HIT in health care settings [17–20]. In this study, we were interested in understanding the usability and the impact of READY on clinical workflow. We had two specific aims:

1. Conduct an end-user "think-aloud" protocol with patients and physicians to evaluate the usability of READY for future enhancement as well as understand the value of such a mobile device solution for patients with musculoskeletal conditions.
2. Conduct a workflow evaluation using a time motion study (TMS) to observe the clinical workflow before and after the pilot implementation of READY.

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2. Methods

READY is an ePRO application using multiple validated PRO questionnaires that reflects RA symptoms and quality of life, as well as optionally collecting data from physicians with a particular emphasis on arthritis disease activity. Data captured in READY is customizable and can include the Multi-dimensional Health Assessment Questionnaire (MDHAQ), Pain Visual Analog Scale (VAS), Fatigue VAS, Patient Global VAS, SF-12 (Short-Form 12, quality of life), EQ5D (health utility), RA Disease Activity Index (RADAI), Patient Acceptable Symptom State (PASS), Tender joint count (0–28), swollen joint count (0–28), Physician Global VAS, and disease characteristics. These satisfy Centers for Medicare & Medicaid Services (CMS) Physician Quality Reporting System (PQRS) and other quality measures, and can automatically calculate and trend composite disease activity metrics, such as RAPID3, DAS28 and CDAI [4–6].

READY enables the data capture process to occur at physician offices using a tablet PC (Apple iPad®) and the data is available and graphed longitudinally in real-time. This may provide benefits and opportunities for patient and physician shared decision-making, real-time decision support to facilitate 'tight control' and T2T treatment strategies, clinical and research-related data collection in a time and cost-effective manner, and documentation to justify reimbursement for costly arthritis medications. READY also incorporates visual representations to provide user friendly interfaces, such as a graphic representation of joint pain and a risk-benefit decision aid to support discussions of biological therapies and newer RA therapies to assist patients in choosing their arthritis treatments.

To evaluate the usability of READY and its impact on clinical workflow once implemented, we conducted a cross-sectional study from 2013 to 2015. We loaded PRO measures in READY to be exactly the same as the PRO paper questionnaires. Before READY was pilot implemented, patients completed PRO paper questionnaires. Clinicians were required to calculate the disease activity metrics scores, such as RAPID3, DAS28 and CDAI, and charted the information into EHR. In this study, READY was not linked to the EHR yet. Therefore, we anticipated that clinicians continued to chart the composite disease activity scores in EHR as before. However, READY automatically calculated the disease activity metrics scores, which eliminated a step for clinicians compared to using PRO paper questionnaires.

2.1 Study Design

Usability evaluation: Think-aloud protocol was used to facilitate the data collection process by observing patients and physicians' interactions with READY. Think aloud protocol was developed by Lewis in 1982 to understand human cognitive process [21]. Think-aloud protocol encourages users to express out loud what they are looking at, thinking, doing, and feeling, as they perform tasks [21]. This allows observers to see and understand the cognitive processes associated with task completion. Using actual users or intended users as the participants in the think-aloud protocol provides a closer view of how users use the system and reveals practical usability problems related to task performance [22]. It has been demonstrated to be effective and is widely used to evaluate health information technology [23–27].

Time motion studies (TMS): TMS have been successfully adopted as a working method to describe and assess workflow in clinical environments [28]. It is defined in the National Library of Medicine's controlled vocabulary thesaurus as "the observation and analysis of movements in a task with an emphasis on the amount of time required to perform the task" [29]. TMS consists of two major components: time and motion analysis. Motion analysis represents workflow, which is a sequence of all of the "steps" or "tasks" for a process or an event, such as a patient encounter visit or medication administration; Time analysis focuses on the time duration of the tasks or the entire process. In this study, we were interested in describing a typical process for a patient visit (the event). We looked at a sequence of tasks such as checking in at registration, waiting in the waiting room, filling out paperwork, using READY, physician encounters, patient assessment, charting, reviewing READY, patient and physician communication, etc.

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2.2 Setting and Sample

Usability evaluation: The usability study was conducted at two outpatient clinics of The Ohio State University Wexner Medical Center (OSUWMC) and University of Alabama at Birmingham (UAB). It involved the participation of physicians and RA patients, who are the potential users of READY in these sites. Physicians caring for RA patients age 18 or older that demonstrated interest in the study were identified by nurses or clinic staff and approached for participation. We facilitated the think aloud protocol in a private and quiet meeting room where participants were able to interact with READY without any interruptions and were free to provide feedback.

Time motion study (TMS): TMS was conducted in an OSUWMC Rheumatology outpatient clinic. It involved the participation of physicians, nurses, and RA patients who are the potential users of READY. Physicians were invited to participate at the time of site recruitment. Physicians that agreed to participate were asked to refer patients that met the inclusion criteria of the research. Patients age 18 or older that demonstrated interest in the study were identified by nurses or clinic staff and approached for participation. Patients were invited to participate while they checked-in for their appointment (the same day of referral). Informed consent was obtained for this evaluation study at the time of recruitment. Both nurses and physicians received one hour of training on how to use READY as well as written instructions before the observation. The one hour training included an introduction to READY, step-by-step usage of READY, specific features, and Q&A. Patients were only given one-page of written instructions when READY was provided.

2.3 Data collection

Usability evaluation: Participants were asked to think aloud as they completed associated tasks in READY, such as completing symptom and quality of life questionnaires, navigating the system, patient and physician assessment of pain, documenting medications, and interpreting results. Also, they were probed for additional information regarding functionality, features, processes, user interfaces, and user-system interactions. Their utterances and interactions with READY were recorded using a digital camera. Data were managed and coded using Morae™ software. Each usability evaluation session took approximately 20–30 minutes.

Time motion study (TMS): To observe clinical workflow, we trained observers to use TimeCaT [30], a comprehensive electronic time capture tool specifically developed to support data capture for time-motion studies. TimeCaT can be used on any internet capable device, and has been optimized to support data capture using touch enabled devices, which is suitable for our study. We loaded the selected tasks on TimeCaT, trained our observers, and validated the data capture process using the inter-observer reliability module included in the system. The visualizations included in the system allowed us to provide immediate feedback to our observers after the training sessions. Data could later be downloaded to a desktop computer via the web portal and analyzed using standard statistical packages.

We had four observers responsible for the data collection. A post-doctoral fellow, who holds a medical degree and a master of science in public health, served as the gold standard of our observational data. This approach was essential to ensure the consistency of our data. The post-doctoral fellow trained the other three observers who were junior level nursing students with clinical experience. Each observer had to go through a series of training and validation processes before they could begin the study-related data collection. Besides basic introduction to the study and the TMS method, our observers needed to be familiar with a pre-defined activity list and be able to use TimeCaT to collect data. They were also required to pass the inter-observer reliability assessment (IORA). We used the IORA provided in TimeCaT [30], which is a robust, comprehensive method for inter-observer reliability assessment [2]. It considers four types of agreements on workflow observation: 1) proportion-kappa (proportion-K): agreement on the proportion of time on a task overall; 2) naming-kappa (naming-K): agreement on naming a task; 3) duration-concordance correlation coefficient (duration-ccc): agreement on the duration of a task, 4) and sequence-Needleman-Wunsch (sequence-NW): agreement of the sequence of tasks. Figure 1 shows an example IORA on physician tasks comparing a student observer against a gold standard. Our IORA scores ranged between 85% – 98% kappa from all observers (▶Fig. 1).

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Following informed consent, the observation started from the moment the patient checked-in at the clinic front desk and continued through the completion of the patient visit. During the observation, observers were not allowed to interact with patients, nurses, or physicians. The data collection phases included

1. pre-implementation (baseline) observation: this phase established baseline data before READY implementation. The phase lasted until the information was fulfilled to establish the baseline data; and
2. post-implementation observation: this phase focused on identifying workflow changes after READY implementation.

►Figure 2 shows an example of workflow visualization created by TimeCaT. We observed three major types of players or "characters" involved in the observed interactions: patients, physicians, and nurses. Among the three characters, there are three independent actions and two shared actions. Independent actions were actions not shared with other characters, and such were labeled as patient-task, physician-task, and nurse-task. Shared actions were actions shared with another character and were named as physician-communication and nurse-communication when physicians and nurses interacted with patients. The colored rectangles represent activities performed in each action, such as checking-in, waiting, filling out paperwork, using READY, chart review, chart entry, etc. Because of the design of the workflow visualization, some texts were truncated because of the smaller size of some colored rectangles. We used the workflow visualization to detect task changes, multi-tasking, and patients' interactions with nurses or physicians. For example, in Figure 2, the physician discussed the patients' history of present illness (HPI), while reviewing information on READY at the same time.

Besides the time and motion data, observers were also asked to document unusual events and their reflections about the patient visit. For example, the patients that had trouble using READY were helped by a staff nurse.

2.4 Data analysis

Usability study: videos generated from think aloud protocol observations were analyzed. We also collected participants' feedback on READY and their recommendations for future improvements.

Time motion study (TMS): We created a general workflow based on the observations obtained, and compared the time patients spent using READY against the time spent using paper for data capture. Because no patients were repeated during the study, independent sample t-tests were used to compare time spent before and after READY implementation. We also provided the field notes documented by the observers that were helpful to explain our findings.

3. Results

3.1 Usability Evaluation

A total of 33 patients (19 from OSUWMC; 14 from UAB) and 15 physicians (6 from OSUWMC; 9 from UAB) participated in the usability evaluation. Below we summarized our findings. For patients' data, we found usability issues in the following three categories: system navigation, general data entry, and pain assessments using a homunculus manikin; for physicians' data, we found usability problems in the following five categories: system navigation, general data entry, pain assessment, documenting diagnoses and medical treatment, and prompted instructions along with error messages.

3.2 System navigation

Patients did not find any navigation issues as they were able to easily move forward and back on the iPad while answering questions in the PRO questionnaires. Because the large size of the buttons made it easy to navigate, patients were satisfied using READY. However, for physicians, system navi-

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gation was somewhat challenging. There were several modules/functions (symptom trend, pain assessment, lab report, medication documentation, shared discussion on side effect, etc.) available for physicians. Some physicians took more time to document than others, and some requested additional information to be available for their documentation. Because READY allowed flexible navigation, moving to a different module was confusing for some physicians. These issues underscored the expected tradeoffs between simplicity with a less customizable user experience versus more complexity with a more complicated setup and navigation.

3.3 General data entry

During the think aloud protocol, patients were free to use a stylus or their hand to navigate the touch screen. In our study, all patients chose to use their own hands. Patients were fond of the larger font size and the ease of 'tapping' (answering) the questionnaire on READY. It was easier for them compared to writing-out or circling answers using conventional pens on paper. One patient commented that compared to conventional pen and paper, because of the large size of the buttons on the screen, "changing answers seems to be easy". The main data entry issue was the touch screen sensitivity issue. About 37% of patients found touch screen sensitivity to be an issue- the application was not sensitive enough when a patient attempted to complete an action. Patients had to occasionally tap multiple times on the touchscreen. Sometimes READY may fail to respond quickly enough to an action. Often during these occurrences, patients felt the need to press the button again and that led to another system error message. For example, while navigating in the system, if a patient pressed the "next" button twice because of the slow system response, an error message appeared because the system detected that a page was skipped. As the results demonstrate, patients had to spend time detecting whether the system had responded and thus correct errors more carefully. This decreased efficiency and caused some confusion for patients.

Physicians faced similar issues when it came to selecting the physician global assessment, which was a 20-point ordinal scale on a horizontal display. The size of the selection boxes for the global assessment was suggested to be larger to allow easier data entry. Also, the sensitivity problems occurred when physicians were tapping on the screen and the system was either too slow or did not respond. Except for these data entry problems, physicians in general had no problem using the virtual keyboard.

3.4 Pain assessment

READY provided a homunculus manikin (▶Figure 3) as a visual cue for patients to indicate their pain location and level. Surprisingly, a significant majority (95%) of patients struggled in using this homunculus. The image provided was a mirrored image for ease of understanding. However, patients were confused if they correctly perceived it as a mirrored position. Some were not able to correctly identify which side of the homunculus represented the left and ride sides of their own body, despite text labels specifying laterality ('left' and 'right'). This could be an issue for physicians when treating pain indicated by the patient on the incorrect joint. Improvements should be made to provide clearer instructions or illustrations to help patients correctly report their joint pain.

Another issue patients struggled with was changing the color of the joint on the homunculus manikin to indicate the level of pain they experienced. The system was designed that in order to change the color of the joint, patients should click on the desired joint multiple times to change its color. However, the design was not intuitive. Patients attempted to drag and drop a selected color onto the joint, or to click a color from the key before clicking on the joint. It would be ideal to provide more flexible approaches. While touchscreen mobile applications are widely available, using drag and drop for the color palette seems to be more intuitive for most users.

A different visual representation was designed for physicians, with a supine position, that is commonly used for medical education. However, because during the think aloud protocol, there were no real patients for physician participants to assess, they were asked to document joint severity on the right side of the homunculus man though some physicians incorrectly documented it on the left side. Another problem that arose was the color for the joint condition being tender, swollen or both. One of the physicians was color-blind so he had difficulty completing the tasks. This was a good les-

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son for our future enhancement of READY to consider using patterns or different color saturations for the joint statuses. We also considered implementing a data validation process to compare the data input from both patients and physicians. For example, on the physician's data entry screens, the results from patients' pain assessments could be presented in the supine position as a reference. Physicians therefore could verify patient-reported pain while assessing patients' joints.

3.5 Documenting diagnoses and medical treatment

In READY, physicians were able to document a patient's diagnosis and medical treatment. In our study, physicians had no problem documenting the diagnosis, but they usually missed a step during the task process of changing patients' medication. In order for the amount of medication to be updated or changed, the physician must use an "Update" button after entering a new value. However, after entering the new value, physicians often tapped away from the window without saving the updates. While interface design is recommended to match the real world experience, a potential solution would be to replace the 'update' button with a 'save' button and do not allow exiting the window without saving or canceling the action.

One physician recommended the need of an open text field for commenting on the medication change, "It's more than just switching (medication) there's another part of why…it's more of a thought process and that is what the notes are there for and it can't replace the note". While the reasons for treatment changes vary, specifying the purpose of the change and noting the amount or the type of medication was felt to be important to be included in patients' health record. For example, the patient could be allergic to a medication or not responsive to it. This is important to note for future reference. In addition, one physician recommended to have a warning message when a wrong dosage was entered or critical information was missing. These findings presented excellent opportunities for us to enhance the usability of READY.

3.6 Prompted instructions along with error messages

Prompted instructions and error messages are essential for users to efficiently navigate and correct errors. READY could improve the design of prompted instructions and error messages. For example, an instruction was provided for physicians to locate a graph indicating patient symptom scores over time. The task was done through swiping up from the bottom of the screen to show the graph. Errors occurred due to the instruction being too small and located at the bottom of the screen. An error message example from patients was that an error message, "please answer all questions on the page", appeared to remind patients to complete a required answer. Patients should press the "OK" button to close the message, but some patients attempted to skip the reminder, and answer the question on the page without pressing "OK". This problem can be solved by simply displaying the warning message on the page instead of having a dialog window.

Another example from physicians was to input C-reactive protein (CPR) and erythrocyte sedimentation rate (ESR) lab values in READY. An issue came out because the value units need to be manually selected. Because there was no default unit, or automatic data validation built in, all physicians were alerted to select units while attempting to proceed to the next page. The extra step of selecting units could be improved by providing default units with data validation.

In summary, usability issues were found in READY including touchscreen sensitivity, interface design (e.g. layout and font size), interactive features, and instruction and error messages. Despite these issues, patients generally preferred READY to traditional pen and paper documents. Twenty five (75.76%) patients reported they liked READY. Many found it to be easier to input information and less tedious. Patients who were previously unable to write their own information and required help from a spouse or family member, enjoyed the freedom and ability to fill out questionnaires without help. Patients also preferred the large text and visually appealing screen images. Although there is room for improvement in READY, we found that READY could be beneficial to many patients.

On the other hand, physicians had mixed feedback on READY. However, their concerns were mainly questioning the implementation of such a mobile application into the clinical workflow and how it may impact patient care.

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3.7 Time motion study (TMS)

We had a total of 6 physicians participating in the study. On average, each of them was observed 7 times before and after the implementation. We did not document the number of staff or nurses using READY as they were not the primary users of READY. Their role was mainly providing READY along with other paperwork, troubleshooting when needed, and entering disease activity scores in EHR. We observed a total of 86 patient visits, including 45 patient visits (44.72 hours) in the pre-implementation phase (October 2013 – Feb 2014), and 41 patient visits (37.82 hours) in the post-implementation phase (Feb 2014 – October 2014). From all observations, the duration of each patient visit ranged from 0.29 hour to 1.84 hour. We created Figure 4 to visualize a general "story" of clinical workflow with information on characters, activities, and locations, noting that interaction with READY was an activity only performed in the post-implementation phase. An RA patient visit can be described to include the following steps: patients started with check-in at the registration counter, and waited in the first waiting area (Figure 4, waiting room 1), and then were moved to another waiting room (Figure 4, waiting room 2) to fill out paper work; for post-implementation, patients used READY in the waiting rooms. Nurses then took patients to another room to take vital signs, weight, and height, and then to the exam room. Nurses' interactions with patients mainly consisted of querying patients' present health information. Nurses charted and reviewed on EHR and entered patient information in READY. After nurses left, patients waited in the exam room until physicians came (In Figure 2 and all cases, we noticed that patients spent most of their time waiting for physicians in the exam room). After physicians arrived, their interaction with patients included querying present health information, a physical exam, treatment if needed, answering patients' questions, and summarizing a care plan before discharge. Some physicians shared information with patients using READY during this conversation. Physicians reviewed and documented in between interacting with patients and charted on READY at the end of the visit (►Fig. 4).

We compared the time patients spent using READY against the time spent using paper for data capture. We found that patients spent more time on READY than paper (mean=4.39 mins, SD=2.29 vs. mean=2.26 mins, SD=1.36, p=0.002). However, based on our observational field notes, READY usage was longer mainly due to time for troubleshooting when needed. In our observation, most RA patients were elderly and did not have experience using computers nor touch screens. After providing a one-page written instruction, some patients did require additional explanation and support from nurses. But most did not have problems using READY after receiving support from nurses or clinical staff. Some patients encountered issues during usage, but most were minor technical issues, such as insensitive or delayed system responses that were subsequently refined.

We investigated the pre- and post- time spent on physicians' activities (►Fig. 5). We observed that physicians were comfortable using READY. Some even used READY as a substitute for the previously-implemented paper documents to communicate and discuss PRO information with their patients.

We also compared the time spent for a complete patient visit before and after READY implementation. Surprisingly, the result found the duration of patient visits decreased after READY was implemented (mean=52.08mins, SD=24.17mins vs. mean=45.46mins, SD=17.64mins). We do not consider this as evidence of READY improving the workflow efficiency because of other confounding factors, such as the variable patient wait times. For example, on average, the total wait time for each patient ranged from 0 to 0.8 hour. The wait time contributed significantly to the length of a patient visit. However, in our study, we did not find READY to increase the total time of patient visits.

3.8 Lessons learned

The observers took field notes during and after the observations to report problems or issues that occurred in the clinic. We summarized the lessons learned from the observations.

3.8.1 Tablet management in the clinic

In our study, READY was a new technology that was implemented in a pilot outpatient clinic. Even though the ideal workflow had been discussed prior to the implementation, discussion and confirmation of the device management plan was needed. For example, storage, workflow, and responsible

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personnel of device tracking and charging batteries needed to be deliberated. In addition, it was difficult to predict how many devices were needed for a clinic. Based on our study, we estimated that approximately 1–2 devices per physician will be needed, accounting for some patients who continued using READY in the exam room for data capture that was not completed in the waiting rooms. Outside of this study, READY was implemented in a UAB outpatient clinic. In the UAB outpatient clinic, the most efficient method for the clinical workflow was to allow the data capture to be done in the exam room rather than the waiting room. In that case, one device per exam room was sufficient. Nevertheless, tablet management could be different from one clinic to another. Staff meetings before, during, and after any new technology implementation are essential for successful adoption.

3.8.2 Workflow and activities restructuring

Like all other new technologies implemented in health care environments, staff training was provided before READY implementation, especially for the different activities needed on READY, such as entering patient information and charting data in EHR. In our study, we found that most problems arose because of the differences between the actions needed with paperwork versus with READY. Therefore, while implementing new technologies, training could emphasize and focus on the differences in activities compared to the existing workflow.

3.8.3 Physician and patient interaction

In this study, we noticed that even with READY, physicians did not change or decrease their interactions with patients (pre- 0.31 hour; post- 0.32 hour). They had direct interactions with patients as usual and then documented at the end of the patient visit. READY sometimes served as a tool to share information between physicians and patients, for example, trending of arthritis patient disease activity and symptoms. These findings encourage us to focus on advanced features that could aid in shared decision making with data visualization.

4. Discussion

This study evaluated the usability of READY using think aloud protocol with end-users. The approach was found to be efficient and effective in our study because we were able to identify usability problems from different perspectives. Also, because of the direct observation of the interactions, we were able to identify natural behavior from participants on the touch screen. Although system developers may have innovative ideas on designing an application, their mental model could be different from end-users' models. End-user usability evaluation is essential to fill the gaps [31]. This usability evaluation study helped us identify usability problems. These findings and suggested solutions are currently being incorporated into a revised version of READY.

In the TMS, we found that READY changed the clinical workflow. For example, staff needed to provide both a tablet (READY) and paper documents for patients along with technical support when needed. The time delay may be compensated with READY automatically calculating the disease activity metrics scores, which eliminated a step for the staff. Our findings showed that the impact on workflow was minimal and could be overcome as the clinic adapted to READY over time. Given the potentially worrisome problem that the introduction of new technologies can increase time to complete clinical tasks, it is notable that we did not find READY to delay the clinical workflow or patient-physician interactions.

4.1 Shared decision making using a mobile app in outpatient settings

Shared decision making for care planning has demonstrated that it improves risk management and patient satisfaction in outpatient settings [32–34]. As READY creates a shared platform by integrating data from both patients and physicians, the influence of technology on physician and patient interactions may become either an obstacle or the enabler of physicians' use of technology [35]. One study reported that patients and physicians were highly amenable to integrating mobile devices into clinical settings, as they are useful in collecting patient-reported outcome measures and improving patient-provider communication [36]. Another study reported that some physicians shared com-

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puter screens to build trust with patients; On the other hand, several physicians also reported that it was time consuming and caused distractions [37]. These mixed results using mobile devices for shared decision making require more research studies to understand how these factors could facilitate and enhance the redesign of READY as well as using it to improve physician-patient communication. This will allow use of READY for patients with any rheumatic disease, not just RA.

4.2 Implications of using TMS to understand clinical workflow

Using a TMS in our study effectively helped us understand the changes in clinical workflow. Another interesting finding was that in any patient visit, patients spent most of their time waiting for physicians in the exam room. Even though real-time location systems (RTLS) has been widely used to track patients' locations in order to provide efficient flow [38], it does not necessary reflect the real activities. For example, in our study, patients did not wait only in the waiting room, but the longest wait time occurred in the exam room. This observation has implications as to where the system is most efficiently deployed; it is optimal to provide the system to patients where they will spend the most time waiting, or allow the tablet to travel with them from the waiting room to the exam room, before seeing the physician. We synthesized various workflows and created a general workflow view (Figure 4) on characters, independent and shared activities, and locations. Our study approach is helpful in describing what happens during a patient visit, and a patient's interaction with health care providers.

4.3 Study limitations

The usability evaluation study observed 15 physicians (6 from OSUWMC; 9 from UAB) and 33 patients (19 from OSUWMC; 14 from UAB) interacting with READY. Although our sample size is larger than most studies that conducted think aloud protocols, we did not have a sufficient sample size to examine statistical significance. However, our findings and feedback reached the information saturation that is recommended for qualitative research.

Our TMS was conducted only in one OSUWMC outpatient clinic. The implementation experience may be different in other health care organizations. In addition, conducting a TMS is time consuming and labor intensive, although we had a total of 89 observations, the sample size was insufficient to perform advanced statistical analysis to account for other potential confounding factors including individual variance, such as clinician or staff experience, age, education, disease progress, symptom severity, and technology competency. However, our observational field notes and constant team meetings served as an additional data source to triangulate our findings and would be useful as READY is broadly deployed.

4.4 Future direction

Although usability problems were found, patients provided positive feedback on the potential of READY being used to assist RA patients in reporting their symptoms, collecting patient-reported outcome data, and improving patient satisfaction and clinical care. We also explored the impact of READY on the existing clinical workflow. It was suggested that HIT adoption should be evaluated longitudinally from both individual and organizational levels and with multi-dimensional measures of adaptation to any new technology, such as cultural conflict, team dynamic, physician champion, work productivity, cost, and quality [39–41]. As this is a pilot implementation, we also plan on studying the long term usage of READY to measure the "adoption" of READY, as well as the impact on patient outcomes.

READY is undergoing substantial improvements to both its user interface and underlying architecture. The next version of READY will enable its implementation across multiple sites. In addition, READY is being revised to store and retrieve patients' past visit occurrences, visually plot PRO data trends, and reconcile unique patients across sites using established algorithms, all via a secure cloud-based architecture [11]. It is also underway to work to enable interaction with common EHR systems and patient registries as well as incorporation of generic (e.g. NIH PROMIS [42]) and disease specific instruments for a variety of musculoskeletal conditions other than RA.

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5. Conclusion

Our study demonstrated that a majority of RA patients found READY easier to use than the current PRO paper questionnaire. This was due mostly to the larger font size and the relative ease of 'tapping' rather than writing-out or circling answers. Our TMS evaluated the impact of READY on clinical workflow. The study findings were encouraging in this pilot implementation because although clinical workflow was changed, which was predictable, there was no time delay in the patient visits. As READY evolves to enabling patient record linkages, we foresee its generalizability through centralizing patient data in the cloud space and an improved quality of care and patient satisfaction through the support of real-time trending of patient disease activity and symptoms, visual aids, risk-benefit discussions, and shared decision making.

6. Clinical Relevance Statement

We used two evaluation methods to help understand usability and workflow impact for clinicians. READY has shown to be a useful and usable ePRO system without negative impact on clinical workflow. Our study provides lessons learned and is a good reference for other researchers or institutional decision makers who are interested in implementing such a technology into other clinical environments.

Conflicts of interest statement

Dr. Curtis was the inventor and has an ownership interest in the READY software.

Protection of Human Subjects

The study was reviewed and approved by the Institutional Review Board at The Ohio State University and University of Alabama at Birmingham.

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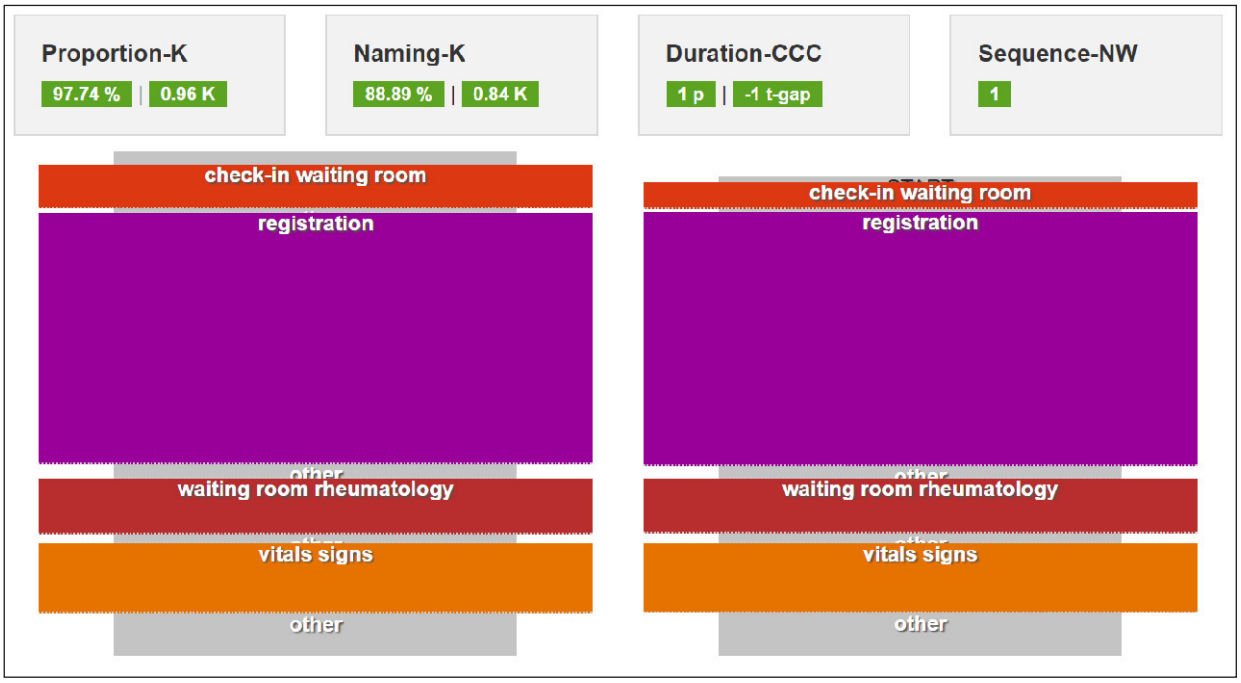

Fig. 1 Inter-observer reliability assessment

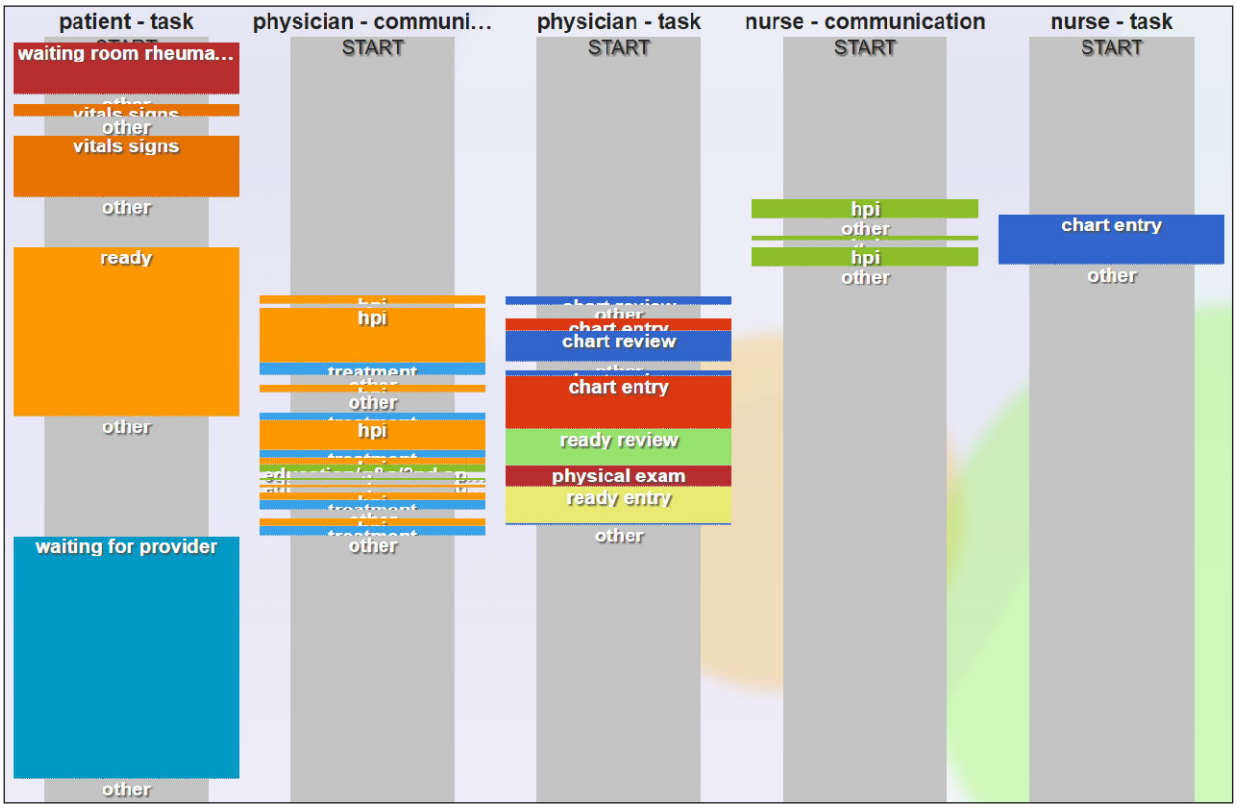

Fig. 2 Workflow visualization created from TimeCaT
(hpi = History of Present Illness)

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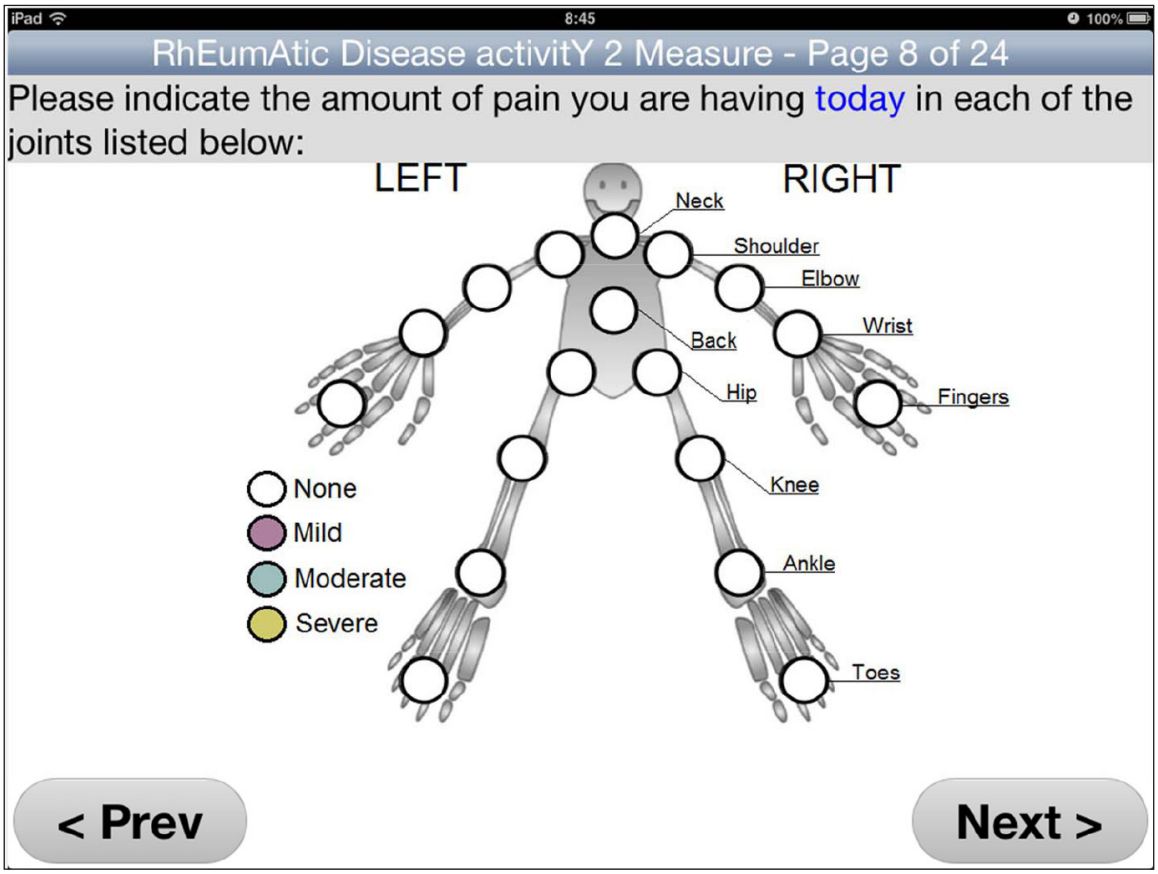

Fig. 3 Homunculus manikin

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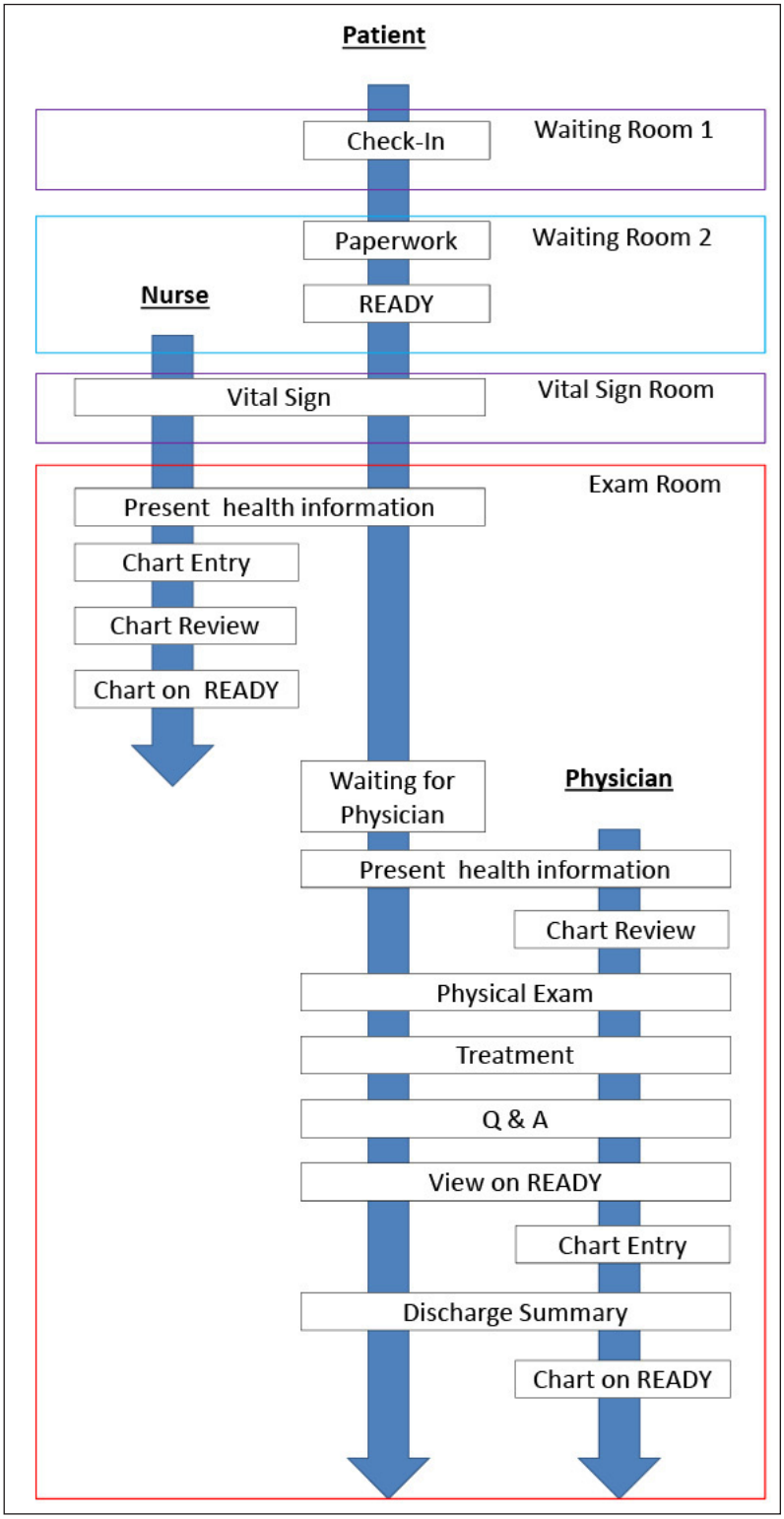

Fig. 4 Workflow visualization on characters, independent and shared activities, and locations

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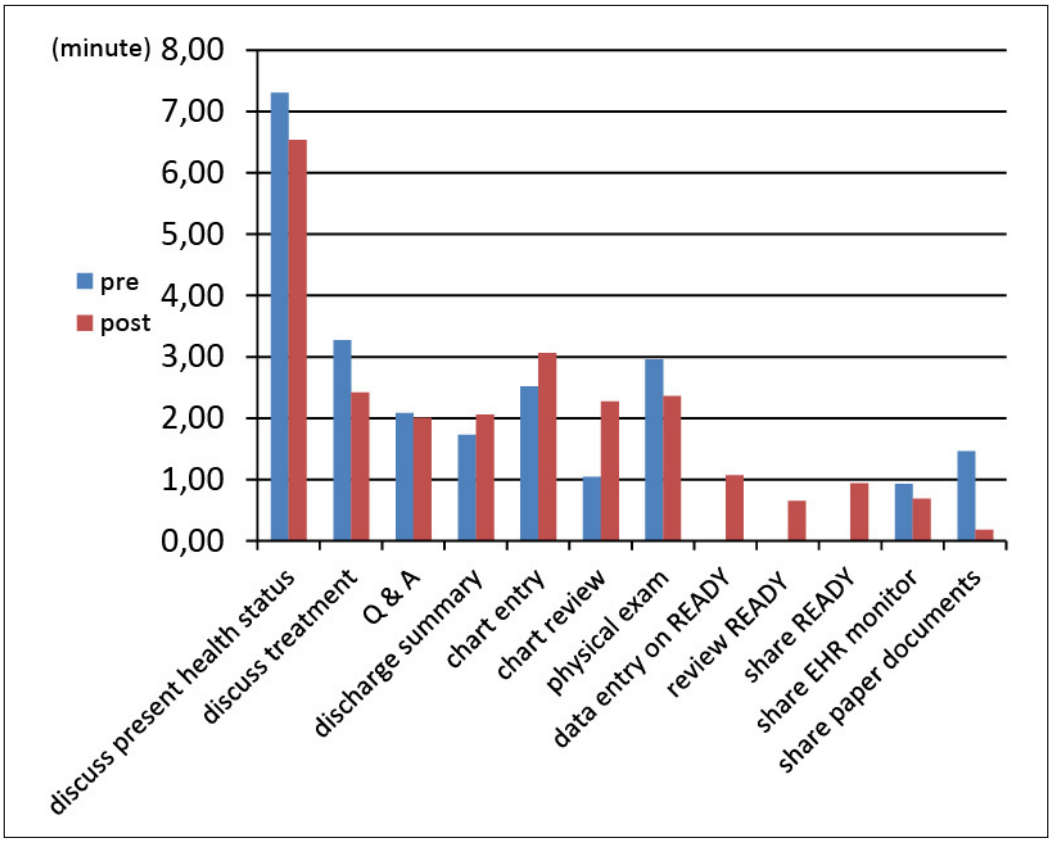

Fig. 5 Pre- and post- time spent of physicians' activities

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