

AHRQ Final Progress Report

Project Title: Registry-Assisted Dissemination of Mobile Pain Management for Youth with Arthritis

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1. Structured Abstract

Purpose: To develop a feasible method for supporting broad dissemination of effective pain self-management strategies to youth with a painful chronic health condition.

Scope: Gaps remain in the integration into clinical practice of pain management strategies shown to be effective through patient-centered outcomes research for pediatric chronic health conditions. Frequent pain remains identified as a primary concern in particular of many youth with Juvenile Idiopathic Arthritis (JIA), a chronic inflammatory disease, and is highly associated with reduced quality of life. Methods to better enable large-scale dissemination of effective nonpharmacological pain management strategies to these youth in a way that overcomes common access barriers would represent a high impact advance to quality care.

Methods: A mobile health application containing individualized information on effective pain management strategies iteratively was developed with end user input. The application was designed with features to facilitate point of care deployment to eligible patients via a network of clinical sites that participate in a large national clinical registry of youth with Juvenile Idiopathic Arthritis. Additionally, using Fast Healthcare Interoperability Resources (FHIR) data format standards, an informatics solution was built to enable transmitting prospective pain data recorded on the mobile app to the registry data warehouse for long-term monitoring of patient clinical outcomes.

Results: Work completed during this project established both the opportunities and feasibility challenges of integrating the deployment of a mHealth application with the infrastructure of a pediatric patient registry. Further work is required to evaluate patient impact of the dissemination method designed during this project.

Key Words: children; pain; mHealth; dissemination; arthritis

2. Purpose

The primary objective of this project was to develop, and evaluate the feasibility of, a method for broad dissemination of evidence-based pain management strategies to youth with a chronic painful health condition (Juvenile Idiopathic Arthritis/JIA). The proposed means of achieving this objective involved distributing a mobile health (mHealth) pain management app to youth with JIA at the time of visits to clinical sites that participate in a large clinical registry (the Childhood Arthritis and Rheumatology Research Alliance/CARRA registry). This planned approach was thought to allow for using existing clinical data on youth with JIA to identify and enroll, at point of care, those patients that may most benefit from the mHealth pain management support app. Further, this planned approach was thought to enable achieving a secondary aim for this project: to integrate a child's prospective pain self-report data into the patient registry to facilitate future secondary data analyses on long-term health outcomes. Achieving these objects was expected to produce a generalizable template for the

widespread dissemination and integration of evidence-based mobile patient support systems in pediatric rheumatology and potentially for other pediatric chronic health conditions.

3. Scope

3.1 Background and context for the project aims

3.1.1 Rationale for prioritizing dissemination of evidence-based pain management in JIA.

Juvenile Idiopathic Arthritis is an incurable chronic inflammatory disease and is among the top 5 most common chronic diseases of childhood, affecting hundreds of thousands of children and adolescents in the US. Pain consistently has been found to be one of the leading predictors of impairments in functioning and health-related quality of life in JIA worldwide. Most youth with JIA have pain on more days than not, and even mild levels of frequent pain experienced by this population can contribute to worsening pain problems and disability in the future. By extension, pain is a leading predictor of the considerable long-term burden and costs associated with juvenile arthritis, including future lost wages and unemployment. Although most children with JIA already are receiving evidence-based medical treatment of the disease, most are not receiving or ever informed specifically of evidence-based treatment for pain. To best optimize patient-centered outcomes through disseminating evidence-based care in JIA, therefore, pain is a logical and necessary focus.

3.1.2 Rationale for using mobile technology to disseminate evidence-based pain management.

Use of mobile health applications available for smartphones as a dissemination vehicle for treatment has particular appeal for the pediatric population given that most children across the pediatric age range either own or have immediate access to a smartphone that they use regularly throughout the day. The unique advantages of smartphone apps for distributing disease self-management strategies include the ability to (a) readily self-monitor symptoms, activities of daily living, and treatment use in everyday environments (e.g., home and school) and identify patterns from reports; (b) improve communication with healthcare providers by facilitating a discussion of summary results from mobile self-monitoring of symptoms; (c) promote optimal acquisition of evidence-based self-management skills through facilitating learning these skills when and where an individual most needs the information; (d) customize self-management content to the individual user; and (e) allow for regular updates as new evidence-based information becomes available from patient-centered outcomes research. Thus, use of mobile health applications are a fitting vehicle for informing and coaching youth with chronic health conditions on pain management strategies shown to be effective from patient-centered outcomes research.

3.1.3 Rationale for using a registry as a vehicle for disseminating a pain management app.

Patient registries increasingly have become common for tracking clinical and safety outcomes and identifying predictors of these outcomes. By virtue of capturing data on different patient profiles soon after diagnosis, registries are ideally suited to identify subgroups of patients that may most benefit from treatments identified as efficacious through comparative trials. As such, patient registries are a fitting vehicle for large-scale dissemination of information on evidence-based treatment, particularly treatments thought to have the capacity to prevent symptom progression and functional impairment if accessed by patients soon after diagnosis. Further, registries enable advances in knowledge and optimizing of care through providing a mechanism of prospectively storing, updating, and evaluating patient data. Patient registries therefore implicitly facilitate comparative effectiveness research and ongoing “surveillance” of important patient outcomes without the cost and time requirements of additional clinical trials. For youth with JIA, the Childhood Arthritis and Rheumatology Research Alliance (CARRA) has designed a registry for tracking clinical and safety outcomes from patients all over the US from the point of JIA diagnosis through the point of transition to adult care. Thus, the CARRA registry is

optimally suited for disseminating and monitoring evidence-based treatment that can potentially change the trajectory of pain when accessed by patients early on.

3.2 Context, Settings, and Participants.

Work to achieve the aims of this project involved collaboration across multiple stakeholders. Development of the pain management app (“iCanCope” app) was a process involving (a) development and refining of content by an interdisciplinary team of experts in pediatric pain, rheumatology, and child development at several sites in the US and Canada; (b) technical development of the app by experts in health technology development at eHealth Innovation at University Health Network (Toronto, ON); and (c) refinement of app features and design elements and acceptability testing through a series of focus groups and “end user” testing with samples ($n = 13$ and $n = 28$) of representative adolescents diagnosed with Juvenile Idiopathic Arthritis.

Development of the technical infrastructure to support deployment of the iCanCope app via the CARRA JIA registry and to integrate data from a patient’s use of the app to other patient data in the registry involved teams working at Boston Children’s Hospital (who oversee informatics for the CARRA registry), Duke Clinical Research Institute (who oversee data management and contracts for the CARRA registry), Medidata (a medical software company that built the software to support the CARRA registry), and healthcare professionals, parents, and patients participating in the CARRA organization.

Over the course of the project, the CARRA registry that was planned to be used to facilitate widescale dissemination of the iCanCope pain management app was started and enrolled over 5000 patients at over 60 pediatric rheumatology sites across the US (72% female participants, average age at enrollment of 12 years, 65% of those enrolled with over 5 joints affected by arthritis).

4. Methods

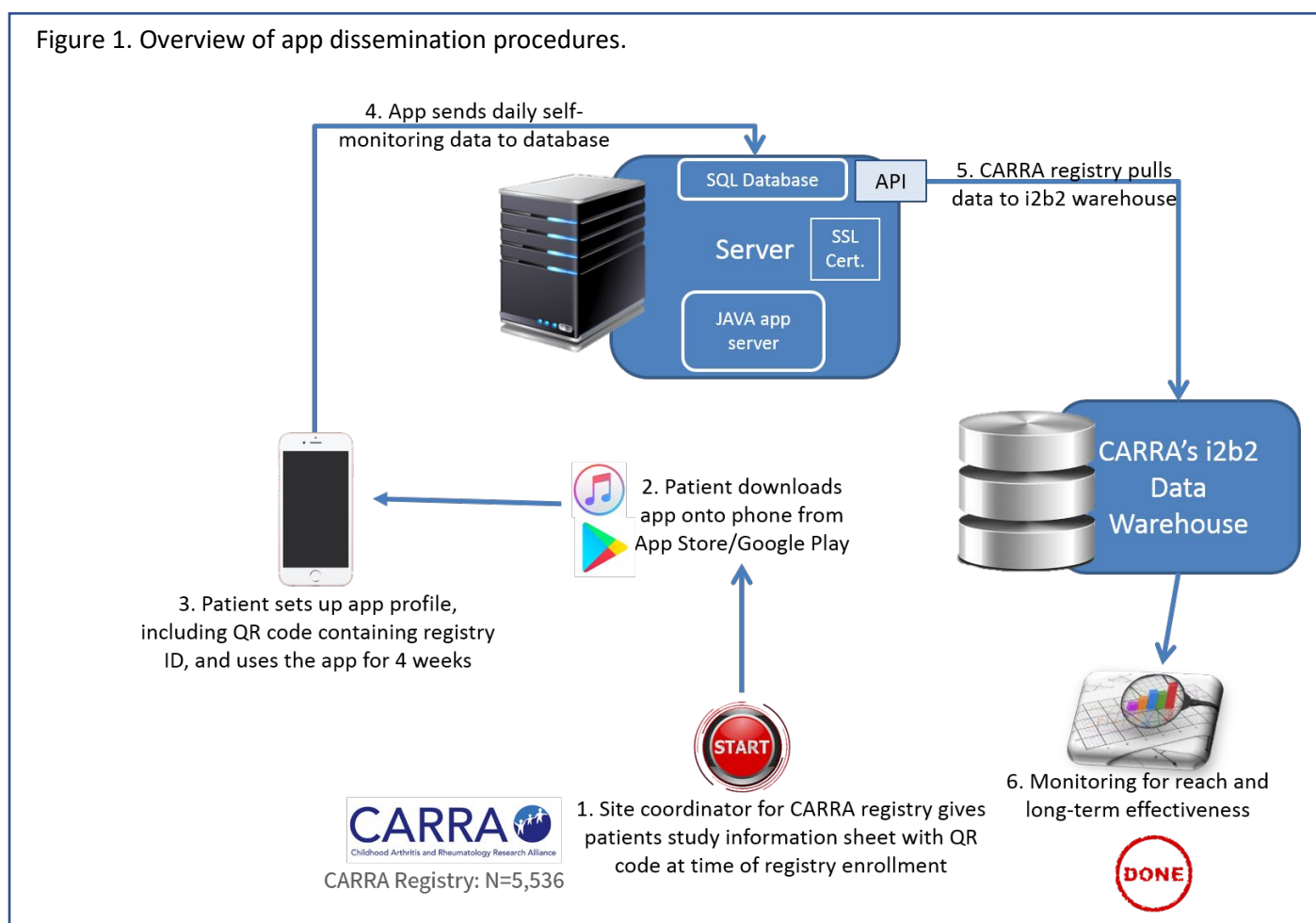
4.1 Study Design and Procedures. Figure 1 shown below provides a high level overview of the elements of the procedures designed to achieve the objectives of this project following completion of the mobile pain management app. To support broad, efficient, and secure dissemination of the completed pain management mobile app to a community of patients, we required a process that: (a) was implementable across multiple clinical sites; (b) was centralized so that personnel at the multiple sites did not have to become engaged in research; (c) was capable of relatively automatically identifying to site personnel what patients would be best suited to using the mobile app (based on diagnosis, age, and clinical data); (d) could authenticate patients to ensure privacy safeguards and to enable correct and secure storage of patient data entered in the app. For requirement “a,” we partnered with the CARRA network of registry sites to facilitate access to patients across most pediatric rheumatology centers in the US (and some in Canada). The informatics solution developed and validated (with synthetic data) during this project to meet requirements “b” through “d” involved programming of a “custom” function in the software supporting the CARRA registry (Medidata) that would enable the following:

- Coordinators working at the CARRA network sites to be automatically informed (via a clickable link in the patient’s registry record that is viewed by coordinators at clinic visits) of what patients would be eligible to be enrolled to use the pain management app
- Generation of a printable handout for site coordinators to give eligible patients that contained information about the current project and a QR code that contained an encrypted patient ID
- Ability of the mobile pain management app downloaded by patients to their smartphone to decrypt the QR code for authentication when first setting up the app,

and to then correctly identify patient data entered into the app when ingesting those data with the patient's other clinical data stored in the CARRA registry

When first setting up the mobile app, patients agreeing to use it would be guided through an initial profile setup and given instructions for use within the app. Instructions included completing the self-monitoring portion of the app (twice daily reports on pain and related variables that were used to subsequently trigger tailored pain management recommendations), implementing the pain management recommendations provided by the app, and entering ratings of perceived utility of recommendations provided so that the app would begin to increasingly tailor content to patient preference; additional information on the features of the mobile app is provided in a subsequent section (4.3). The app was programmed to transmit daily/weekly data entered by the patient to the CARRA registry data warehouse, which contains other clinical data on the patient and has extensive security safeguards in place.

Figure 1. Overview of app dissemination procedures.



4.2 Data Sources and Measures.

4.2.1 *Feasibility outcome measures.* Evaluation of the feasibility of the approach designed in this project to disseminate evidence-based pain management to youth with JIA was intended to be evaluated using RE-AIM criteria, which involves assessing key elements necessary for effective translation of evidence-based interventions into practice based on Reach

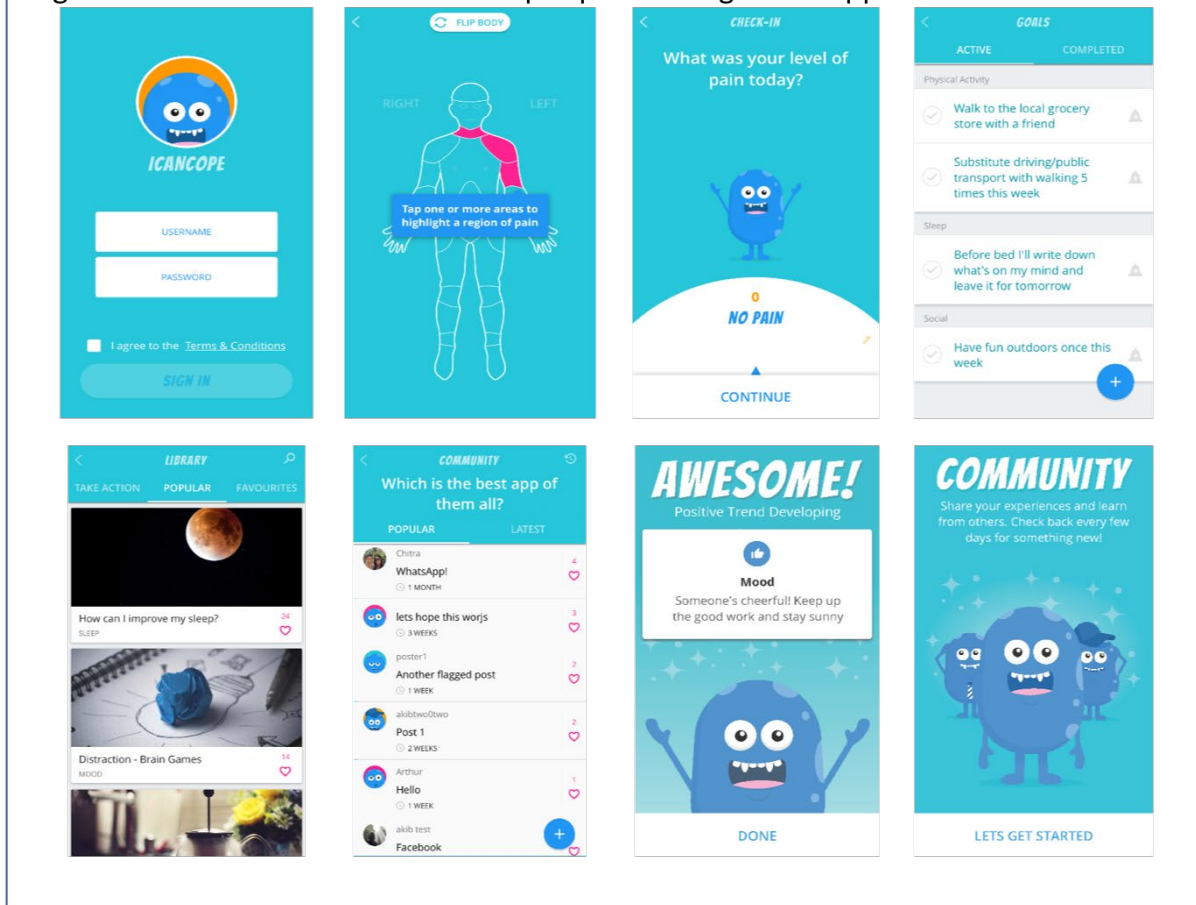
(proportion and representativeness of patients willing to use the mobile pain management app), Effectiveness (benefit to the individual of using the app), Adoption (proportion and representativeness of settings willing to participate in dissemination efforts), Implementation (ability to distribute and for patients to use the app as intended), and Maintenance (long-term usage and benefit of the app and its deployment method). As discussed in a subsequent section, however, delays in the project resulted in not being able to fully evaluate these criteria.

4.2.2 *Mobile pain data.* Patient data collected by the completed mobile pain management app includes pain characteristics (current pain intensity, best/worst pain intensity over past 12 hours, pain location using a body diagram), pain interference (extent to which pain interferes with sleep, mood, and physical, social, and school-related activities), medication use taken for pain and perceived efficacy, and pain coping strategy use and perceived efficacy.

4.2.3 *Registry data.* Patient health outcomes already being collected from patients during clinic visits as part of their participation in the CARRA JIA registry were planned to be used for evaluating long-term patient outcomes and impact of using the pain management app. These outcome measures included the following: complete joint count (an indicator of disease activity measured by counting the number of joints that are swollen, tender, or limited in range of motion), severity of physical limitations as measured by the Child Health Assessment Questionnaire, patient/parent ratings of health-related quality of life and well-being, child/parent and physician global rating of disease severity, prescription medication use, and hospitalizations.

4.3 *mHealth Pain Management App.* The mHealth pain management tool built over the course of this project, called the “iCanCope app,” was largely based on the theoretical foundation and established comparative efficacy of cognitive-behavioral therapy in improving pain and health-related quality of life outcomes for youth with musculoskeletal pain. The app was developed as a native app for both iPhone and Android phones. With the app, patients self-monitor symptoms by responding twice daily (morning and evening) to a brief set of questions about pain, the impact of pain on activities, medication use, and other coping strategy use and receive real-time customizable reports to help understand patterns of pain. Reminder notifications (a sound and text popup) are used to remind patients to complete the self-monitoring items. Goal-setting related to improving pain and its impact on sleep, mood, and activities is included to help set patient priorities so that progress can be continuously monitored. Psychological and behavioral/physical strategies known to be effective for managing pain and its impact based on prior patient-centered outcomes research are then provided to the patient “just in time” – at moments they are most likely to be helpful – based on an algorithm vetted during preliminary work. For example, if a patient reports that pain is interfering with sleep, brief relaxation exercises (breathing and guided imagery) are provided along with sleep hygiene recommendations. Patients then are asked to complete a brief reassessment of pain and pain interference after being provided with pain management recommendations and to answer questions on what strategy(ies) were used and the likeability of the strategy; these data are used to rank order future recommendations, such that the app is “teachable” and becomes increasingly tailored to the individual patient. Some example screenshots from the “iCanCope” app are provided below.

Figure 2. Screenshots of the “iCanCope” pain management app.



4.4 Limitations. The pain management dissemination framework built during this project required vested effort and coordination across multiple sites, agencies, personnel, and disciplines. Although this was largely known at the start of the project, needs for additional information technology expertise were identified over the course of the study which added even further complexity for coordination of teams and maintaining the originally proposed timeline. Thus, a discovered major limitation of the selected approach to broad dissemination of pain management support to patients was the complex and sometimes fragmented coordination of information technology resources required to support project aims. Ultimately this complexity and new challenges encountered at each technical development step for this project resulted in significant delays and an inability to fully complete the project within the originally proposed timeline. Alternatives to the designed model of disseminating a mobile evidence-based pain self-management tool for youth with JIA could have included just notifying patients about the tool using public websites (e.g., Arthritis Foundation), arthritis camps, distribution lists, and social networking groups. However, we deemed such methods as unlikely to have comparable scalability, reach, impact, and security of using the existing CARRA registry infrastructure for dissemination, for which a large group of youth with JIA and their families already are invested. Also, unlike these alternative methods of reaching patients with the mHealth pain management app, use of the CARRA registry ensured an alignment and partnership of the dissemination

method with rheumatology clinics and providers, which we thought would be necessary for sustainability of the proposed dissemination framework over time.

5. Results

5.1 Findings and Outcomes. The primary achievements occurring from this project included the following: (a) completion of an individually tailored mobile pain management app for youth with Juvenile Idiopathic Arthritis that was built on a foundation of efficacy evidence from past patient-centered outcomes research and vetted for acceptability by a representative group of patient stakeholders; (b) completion of the technical infrastructure and related quality assurance necessary to facilitate large-scale deployment of an mHealth pain management application (or future mHealth patient support applications) to patients identified by automatic data query at points of care as fitting users for the app; and (c) completion of a generalizable technical infrastructure (using Fast Health Interoperability Resources/FHIR standards) that permits secure transfer of prospective data elements recorded on the mHealth pain management app to an existing patient registry clinical data warehouse, which in turn provides a centralized and efficient method for long-term efficacy monitoring of using an mHealth support tool.

Where this project fell short, however, is comprehensively testing the feasibility of the intended mHealth app dissemination plan across sites that are enrolling patients into the CARRA JIA patient registry. In particular, we were unable to fully assess the intended “RE-AIM” feasibility metric (Reach, Effectiveness, Adoption, Implementation, and Maintenance) of the dissemination framework we designed. Ultimately the challenges encountered with technical development and methods for ensuring optimal safeguarding of data security resulted in sufficiently long delays that we could not begin implementation of enrolling patients to use the iCanCope throughout CARRA registry sites as originally intended. These challenges themselves have informed feasibility of the methods we designed to achieve project aims. In particular, it is now evident that our developed method for broad dissemination of evidence-based pain management strategies to children with a chronic health condition was *not* feasible to complete within what we initially thought was an adequate timeframe and with what we initially thought were sufficient resources to complete the project. With the technical infrastructure completed within the timeframe of this project, however, we are now positioned for future projects to broadly disseminate effective pain management strategies via a mobile app to youth with a chronic health condition and evaluate the impact of doing so.

5.2 Discussion and Conclusions. Through work on this project, we have helped establish both the relevant challenges and opportunities of integrating the deployment of mobile health self-management applications with the infrastructure of a pediatric patient registry. Informatics solutions to the challenges worked out over the course of this project have resulted in a scalable design for mobile app dissemination and data integration that will enable efficiency of future projects in this area, but that resulted in the inability to achieve the originally envisioned outcomes of the current project.

6. List of Publications and Products

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