Title:

Feasibility Study of a Mobile Digital Personal Health Record for Family- Centered Care Coordination for Children and Youth with Special Healthcare Needs

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STRUCTURED ABSTRACT

Purpose: To evaluate feasibility of a Fast Healthcare Interoperability Resources (FHIR)-enabled mobile application to coordinate care for children and youth with special health care needs (CYSHCN); characterize implementation determinants; and explore associations between adoption and patient/family-reported outcomes.

Scope: FHIR-enabled mobile apps might improve care coordination by integrating care plans with electronic health records (EHR). However, FHIR-enabled mobile apps to support CYSHCN have not been tested.

Methods: This study tested a FHIR-enabled mobile app for care coordination by families of CYSHCN. Key app features included FHIR-enabled EHR data integration, longitudinal care goal tracking, and clinician dashboard. We applied an intervention mixed methods study design to characterize implementation determinants.

Results: We enrolled twelve parents of CYSHCN and nine primary care providers (PCPs). 67% of parents engaged with study materials sent via EHR portal. Technical feasibility was supported by a median 13.6 FHIR-enabled data transfers completed per month. Implementation feasibility – based on the Feasibility of Intervention Measure – was mixed for parents (mean 3.5; SD 0.6) and PCPs (mean 3.6; SD 0.8). 92% of participants were early app adopters; 33.3% were sustained adopters. Technical issues highlighted in mixed method analyses were major barriers to adoption and sustainment. A FHIR-enabled mobile app to coordinate care for CYSHCN was feasible. However, implementation measures and user feedback were mixed. Enhanced technical support is essential to optimize user experience and app engagement.

Key Words

Care coordination; Children and youth with special health care needs (CYSHCN); Fast Healthcare Interoperability Resources (FHIR); Mobile app

PURPOSE

The objectives of this study were to: (1) evaluate the feasibility of a digital personal health record mobile application with FHIR-enabled EHR integration to coordinate care for CYSHCN; (2) characterize barriers and facilitators (determinants) of mobile app implementation; and (3) explore associations between mobile app adoption and patient/family-reported outcomes.

SCOPE

Background: Nearly one in five children in the United States have special health care needs that stem from chronic conditions and require support from services beyond that required by other children.(1) Care coordination relied upon by CYSHCN and their families is best accomplished within a medical home. However, only 43% of CYSHCN have access to a medical home,(2) nearly one-third of families of CYSHCN report not receiving care coordination,(3) and care coordination is often inadequate.(4) As a result, over 85% of CYSHCN – over 12 million children and families – report not having access to a well-organized system of care.(1, 5)

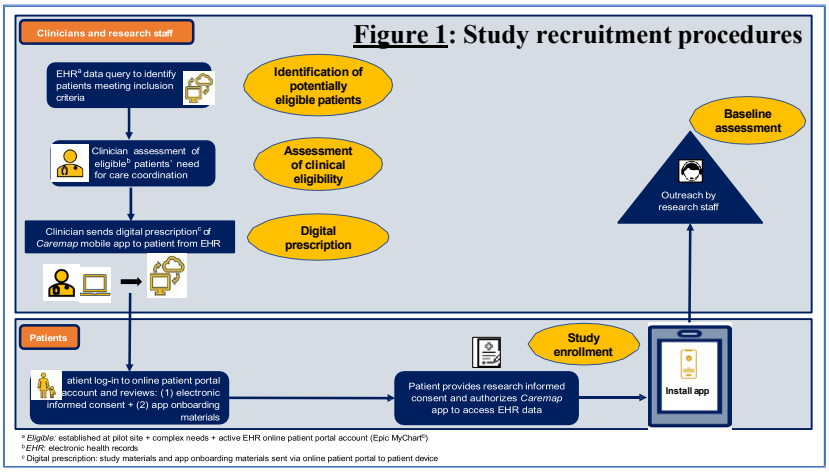
Care plans are an evidence-based tool(6) recommended to assist parents/caregivers of CYSHCN with care coordination. A care plan is a portable, comprehensive personal health record that should be regularly updated, accessible to providers and caregivers, created in partnership with patients and families, and integrated with the EHR.(7-9) Despite their potential as a tool for CYSHCN, there has been limited experience with care plans that are well-integrated in the system of care and family-centered. As a result, many families of CYSHCN maintain care plans in manually curated paper binders.(10, 11) Although comprehensive and patient-centered, a paper-based care plan is difficult to maintain and share, and it is disconnected from the EHR.

EHR integratin has been highlighted as essential to increase usability and acceptability of care plans.(9) Integration of structured EHR data into care plans is possible with mobile applications (‘apps’) that leverage Fast Healthcare Interoperability Resources (FHIR).(12, 13) Our team developed and established proof-of-concept for a FHIR-enabled digital PHR mobile app (Caremap)(14) to support care coordination for CYSHCN. The Caremap mobile app has three core components: (1) FHIR-enabled EHR integration; (2) storage and organization of longitudinal health information on a parent/caregiver’s personal device; and (3) ability to tailor information to family needs and preferences (e.g., tracking patient-specific symptoms and outcomes over time

within the app).(15) However, a FHIR-enabled mobile app that serves as a care coordination solution for CYSHCN has not been tested in real-world environments.

The primary purpose of this study was to conduct a mixed methods evaluation of the feasibility, acceptability, and implementation of the Caremap mobile app for families of CYSHCN. The specific aims of this study were to: (1) evaluate the feasibility of a FHIR-enabled digital personal health record mobile application to coordinate care for CYSHCN; (2) characterize implementation barriers and facilitators (determinants); and (3) explore associations between app adoption and patient/family-reported outcomes.

Participants and Setting: Participants were recruited from three Duke Children's Primary Care Pediatric practices affiliated with Duke Children's Hospital, a large tertiary care children's hospital in North Carolina. Child and adult parent/guardian participant eligibility criteria included: (1) child age 0-16 years; (2) presence of special health care needs; (3) primary care attribution to a participating site; (4) English-speaking; (5) child's online EHR (Epic©; Verona, WI) patient portal account is active with full parent/guardian proxy access; and (6) family has technology at home to use the app (internet access, Apple iOS© mobile device). An Apple iOS mobile device was required because Caremap was developed using Apple CareKit© and has not yet been adapted to other platforms. CYSHCN status was determined by a combination of being at high-risk for hospitalization in the next six months using an EHR-based clinical predictive model(16) and their primary care provider's (PCP) clinical determination that the child has complex needs that can benefit from care coordination support. PCPs were also recruited for participation. Eligible PCPs were clinicians practicing in one of the three primary care study sites and were not required to have an enrolled patient to participate themselves.



Context: Participant recruitment and enrollment followed a three-step process (Figure 1).(15) First, potentially eligible patients were identified using an EHR data query (child age 0-16 years, primary care attribution to a study site, active online portal account with full proxy access, English preferred

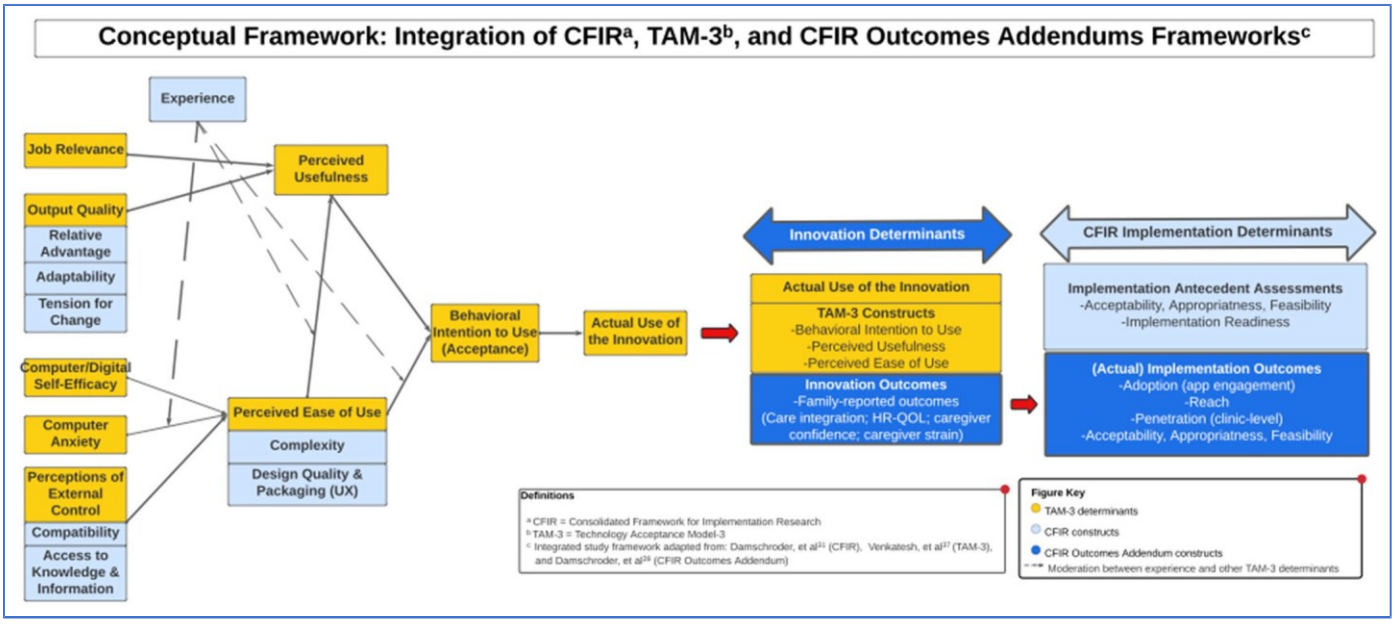
language). To this list, we applied a predictive data model(17) with a threshold of 3% or higher risk for future hospitalization as a proxy for CYSHCN status. Next, we complemented EHR data with PCP assessment of each child's care needs to confirm CYSHCN status and eligibility. Finally, study materials were sent directly via the EHR online patient portal to eligible patients as a 'digital prescription.' Digital prescription transmission was facilitated by a third-party platform (Xealth©; Seattle, WA) with established partnerships with Duke Health.

METHODS

Study design: This was a non-randomized, single site, prospective feasibility trial of the FHIR-enabled mobile app Caremap as a care coordination tool for families of CYSHCN in primary care settings. Within this trial, we conducted an intervention mixed methods study design(18) to link quantitative and qualitative data for characterizing implementation determinants. The study was conducted from September 2021 – September 2024. Recruitment, intervention, and data collection occurred from October 2022 –September 2024. Parent/caregiver (referred to as 'parents') participants were compensated $50 for survey completion; interview participants received an additional $50. The study was reviewed and approved by the Duke Health IRB.

Data Sources/Collection and Measures: As described in the protocol,(15) a combination of established care coordination(19, 20) and evaluation theoretical frameworks(21-24) were integrated to construct the study's guiding conceptual framework (Figure 2).

Figure 2: Study Framework: Integration of CFIR, TAM-3, and CFIR Outcomes Addendum



CFIR:(25) Consolidated Framework for Implementation Research. TAM-3:(26) Technology Acceptance Model (v3).

Quantitative measure aligned with our study framework included data from multiple parent- and provider-reported surveys, the mobile app, and EHR (Table 1).(15) The primary outcome – feasibility – was evaluated as technical and implementation feasibility. Technical feasibility was measured as number of completed FHIR-enabled data transfers between the app and EHR per participant, per month and per six-month study period. Implementation feasibility was evaluated by parent and provider response to the Feasibility of Intervention Measure (FIM) that assesses whether an intervention can be successfully used in a specific setting [5-point Likert scale = 1 (completely disagree) to 5 (completely agree); higher score indicates greater feasibility].(27).

Secondary outcomes included adoption (number of logins), acceptability and appropriateness (using the Acceptability of Intervention Measure (AIM), and Intervention Appropriateness Measure (IAM) [same 5-point Likert scale as FIM],(27) usability (System Usability Scale),(28, 29) and parent-reported outcomes (care integration; quality of life; caregiver strain).(30-32) Surveys were collected at baseline and at 6 months.

Table 1: Summary of quantitative measures

Measure Name	Definition/Approach	Time Point	Source
Primary Outcomes			
Technical Feasibility	Number (count) of FHIR-enabled data transfers[a] completed per patient family during the 6-month study period and per month	Monthly	Mobile app EHR
Implementation Feasibility	Parent and provider report of app feasibility based on 4-item Feasibility of Intervention Measure (FIM)[b]	6 months	Parent + provider surveys
Secondary Outcomes			
Adoption	Measurement of: • App engagement (number of logins) • Clinician engagement • Number of times mobile app digitally prescribed to families by clinicians	Weekly (parents) Monthly (clinician)	Mobile app EHR
Care integration	Parent report of degree of care integration using 19-item Pediatric Integrated Care Survey (PICS)(30)	Baseline 6 months	Parent survey
Health-related quality of life (HR-QOL)	Parent report of HR-QOL for child using 9-item PROMIS global HR-QOL survey (parent-proxy)(31)	Baseline 3 months 6 months	Parent survey
App usability	Parent and clinician report of app usability based on 10-item System Usability Scale (SUS)(28, 29)	Baseline 6 months	Parent + provider survey
Caregiver strain	Parent report of degree of strain experienced by providing care for their child's health conditions using the 7-item Caregiver Strain Questionnaire-Short Form 7 (CGSQ-SF7)(32)	Baseline 3 months 6 months	Parent survey
Parent confidence	Parent report of level of confidence in avoiding hospitalization using single item(33)	Baseline 3 months 6 months	Parent survey

Measure Name	Definition/Approach	Time Point	Source
Net promoter score	Parent report of likelihood of recommending the (Caremap) app to others using single item	End of study (6 months	Parent survey
Implementation outcomes	Parent and clinician report of mobile app acceptability and appropriateness of based on 4-item Acceptability of Intervention Measure (AIM) and 4-item Intervention Appropriateness Measure (IAM)[b]	6 months	Parent + provider surveys

[a]*FHIR-enabled data transfers calculated as sum of FHIR EHR data transfers and FHIR-enabled non-EHR data transfers*
[b]*Five-point Likert scale from 1 (completely disagree) to 5 (completely agree).*

The primary objective for qualitative data collection was to assess implementation determinants (study aim 2). One qualitative data source was input from parents of CYSHCN who participated in a pre-trial family engagement panel modeled after Community Engagement Panels.(34) The pre-trial family engagement panel was conducted in fall 2021 and gathered formative pre-trial feedback that informed study procedures and improved patient/family-centeredness of workflows (e.g., study recruitment methods).(15) The second source of qualitative data was semi-structured interviews with a sample of parents who participated in the study. Each interview was conducted at the end of the six-month study period. All interviews were conducted by a trained interviewer via video call (Zoom©), recorded, and analyzed using rapid qualitative descriptive methods.(35) The interview guide and rapid analyses were mapped to our study conceptual framework and core domains from two foundational theoretical frameworks (Technology Acceptance Model, TAM;(21, 26) Consolidated Framework for Implementation Research, CFIR).(25)

Within the intervention mixed method study design, data integration via embedding linked quantitative and qualitative data before and at the end of the trial.(18) Pre-trial, data integration via building linked parent qualitative data from the family engagement panel with preliminary counts of eligible participants to shape study procedures.(15) At end of the trial, data integration via merging linked parent interview data and multiple sources of quantitative data (technical feasibility, parent-reported surveys, EHR data). Summative findings from end-of-trial data were organized using a joint display.(36) Within the joint display, we mapped quantitative and qualitative findings to feasibility outcomes (study aim one). Next, we mapped quantitative and qualitative findings to the outcomes (acceptability, appropriateness, usability) best aligned characterizing implementation determinants (study aim 2). The joint display included meta-inferences built from integrated data analyses.

Interventions: The primary intervention was use of the Caremap mobile app by adult parents/guardians of

CYSHCN for a 6-month period to facilitate care coordination. Participants were free to use the app as much as they felt was needed (i.e., no minimum use was required).

RESULTS

Study recruitment: Ninety eligible participants were identified and 62 actively recruited to the study. Among 62 recruited participants, 12 parent-child dyads enrolled in the study (overall recruitment rate of 19%). Recruitment methods included: digital prescription (structured message with key study materials directly sent to parents via the EHR online patient portal); recruitment letter from patient's PCP); and in-person recruitment during clinic visits. The recruitment letter was most successful (40% enrollment versus 9-19% study enrollment with other methods). Full details of recruitment are summarized in the study flow diagram (Figure 3).

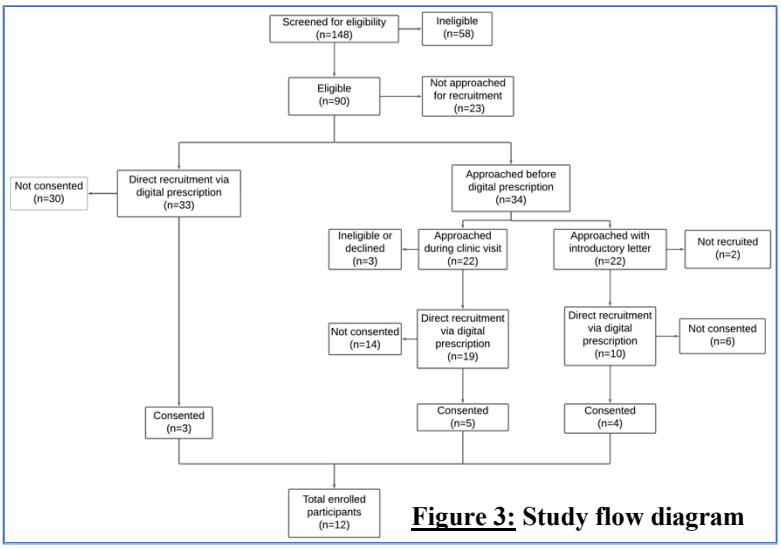


Figure 3: Study flow diagram

Regardless of recruitment method, all participants received a digital prescription. In addition to study materials, the digital prescription included a bundle of three orientation videos: high-level overview of the app; what participants should expect during the study (e.g., study participation length, surveys, etc.); and a detailed user tutorial. Engagement with digital prescriptions was high: 67% of participants engaged with at least one component of the digital prescription, and 50% watched at least one of the three orientation videos (Table 2).

Table 2: Engagement with Caremap bundle

Engagement measure	Enrolled in study
Opened email about Caremap	8 (66.7%)
Engaged with at least one component of the digital prescription	8 (66.7%)
Watched at least one video	6 (50.0%)
Caremap high-level overview video	4 (33.3%)
Caremap study video (what study participants should expect)	5 (41.7%)
Caremap user tutorial video	1 (8.3%)

N=12 participants

***Participant characteristics*:** Parent demographics of the enrolled child-parent dyads who completed the baseline intake survey are summarized in Table 3. Most parents were mothers, married, employed, and white race. Most parents reported high baseline health literacy and mobile device.(37) All children met CYSHCN criteria based on parent responses to the 5-item CYSHCN Screener.(38, 39) The mean number of 'yes' responses on the CYSHCN Screener was 3.2; the three most common categories of special needs were special therapies (e.g., physical or occupational therapy), medical care/mental health/educational services, and prescription medications. At baseline, the study sample of CYSHCN experienced high medical complexity and health service use. Chronic conditions affected a median of four organ systems per child. In the 12 months before the study, children had a median (Q1, Q3) of 11 (6.5, 22.5) outpatient visits; and 16% and 25% were hospitalized or went to the emergency department, respectively.

Table 3: Sociodemographic characteristics of parents/caregivers

Variable	Overall[a]
Age (years), Mean (SD)	37.9 (5.4)
Female gender, n (%)	8 (80)
Race, n (%)	
Black or African American	2 (20)
White	6 (60)
Other or unreported	2 (20)
Highest education level: Four year or graduate/professional degree, n (%)	7 (70)
Employment status: Employed full-time, n (%)	6 (60)
Marital status: Married or partnered, n (%)	8 (80)
Relationship to patient: mother or stepmother, n (%)	8 (80)
Health literacy level: Extremely high, n (%)	8 (80)
Mobile Device Proficiency Questionnaire score[b], Mean (SD)	37.9 (2.4)
Access to technology, n (%)	
Owns a smartphone	10 (100)
Broadband (high speed) internet service	9 (90)

[a]*N=10 participants (out of 12 total enrolled participants) who completed the baseline survey.*
[b]*MDPQ total score ranges from 8 to 40, with a higher score indicating greater proficiency.*

Nine primary care providers were enrolled into the study from the three sites. The majority were physicians (89%) and at baseline, most had limited personal (78% never/occasionally/rarely used) or professional experience (78% never recommended) with mobile health apps.

Principal Findings and Outcomes:

Feasibility and adoption: Among 12 study participants, a median (Q1, Q3) of 13.6 (8.8, 25.6) FHIR-enabled data transfers were completed per month and a median (Q1, Q3) of 81.5 (52.5, 153.5) data transfers were completed over the six-month study period. Parent responses (n=9 respondents) to the Feasibility of Intervention Measure (FIM) demonstrated a mean (SD) of 3.7 (0.7). PCP responses (n=5) to the FIM were similar with a mean (SD) of 3.6 (0.8). 92% of study participants adopted the app during the study period. All adopters used the app early (within the first 30 days of the study period). However, only 33% of adopters demonstrated sustained adoption, defined as any use in the first 30 and last 30 days of the study period. The median (Q1, Q3) number of days that the app was used by participants was 7 (4, 9).

Parent- and provider-reported survey responses: Minimal change was observed between baseline and 6-month follow-up parent report of their child's health-related quality of life and their own caregiver strain (Table 4). Most respondents reported high confidence at baseline (91%) and 6-month follow-up (100%) that their child could avoid unplanned hospitalization. Parent report of experiences with care integration on the Pediatric Integrated Care Survey(30) increased (mean 8; SD 13.7) from baseline to 6-month follow-up. Associations between parent-reported surveys and app adoption (study aim 3) were not calculated due to small sample size.

Parent responses to the Acceptability of Intervention Measure (AIM) demonstrated a mean (SD) of 3.8 (1.0) and the Intervention Appropriateness Measure (IAM) demonstrated a mean (SD) of 3.4 (0.9). Provider responses to these measures were similar: AIM mean (SD) = 3.7 (0.8); IAM mean (SD = 3.4 (0.9). Parent report of app usability was similar after a 6-month period of use (mean System Usability Scale, SUS, score = 64.4; SD 18.1). This level of reported usability was consistent with below average ratings compared to prior studies of the SUS.(28, 29) An overall parent-reported Net Promoter Score(40) of -22.2 represented more detractors than promoters among parents at the conclusion of their six-month experience of app use.

Table 4: Parent/caregiver-reported measures

Variable	Parent/caregiver, mean (SD)		
	Baseline	6-month follow-up	Change baseline to follow-up[a]
N	10	9	
Experiences with care integration (PICS)	51.5 (24.0)	60.9 (25.6)	8.0 (13.7)
PROMIS health-related quality of life	44.7 (12.6)	46.4 (14.1)	0.8 (9.3)
My child got tired easily	55.1 (6.5)	54.1 (7.6)	-0.2 (11.3)
My child had trouble sleeping when he/she had pain	54.8 (7.6)	53.4 (10.8)	-1.0 (13.5)
Caregiver Strain Questionnaire	4.8 (1.6)	4.9 (2.4)	0.4 (3.3)
Confident that their child can avoid an unplanned hospitalization in the next month	9 (90.0%)	9 (100.0%)	
App usability (System Usability Scale)	61.5 (18.5)	64.4 (18.1)	2.2 (27.4)
Net promoter score		-22.2	
Promoters		2 (22.2%)	
Passives		3 (33.3%)	
Detractors		4 (44.4%)	
Acceptability of Intervention Measure (AIM)		3.8 (1.0)	
Intervention Appropriateness Measure (IAM)		3.4 (0.9)	

[a]*Among n=9 respondents with measurements at both time points*

Qualitative parent interviews: Five semi-structured interviews were completed with parents following their six-month app use period. Interview questions addressed three domains: experience with using the Caremap app, how to improve app user experience, and how to make the app available and accessible to any user. The overall experience of using Caremap was mixed. Positive feedback about the ease of using core features of the app, relative advantage of the app for organizing information compared to alternative systems (e.g., EHR online patient portal, manual/paper), and good fit of the app with parent/caregiver daily routines were tempered by difficulties created by frequently encountered technical issues (e.g., log-in issues; difficulty making initial connections between app and EHR). Resolution of these technical issues, app enhancements via the addition of features recommended by parents (e.g., personalized reminders; tailored data visualizations; easier data sharing with other members of care team), and better technical support were highlighted as important for improving the app and enhancing accessibility of the app to more users.

Mixed method data integration: Based on end-of-study mixed method analyses that merged quantitative and qualitative findings, we identified two key conclusions. First, despite evidence of overall technical feasibility

supported by high FHIR-enabled data transfer and app adoption rates, frequent technical issues and challenges with basic app functions (e.g., log-in process) were key implementation barriers that manifest in average parent-reported implementation feasibility ratings and low sustained app use. Second, parental reports that Caremap was better than alternative systems for organizing their child's health information (e.g., EHR online patient portal) contrasted with low parent ratings of app acceptability, usability, and appropriateness. This discordance was driven by a combination of frustration with technical issues, limited capacity of current app features to meet parents' care coordination needs, and high volume of caregiving responsibilities and stressors routinely faced by parents of CYSHCN. A joint display summarizing full details of integrated data analyses is provided in Table 5.

Table 5: Mixed method analysis – joint display of merged quantitative and qualitative findings

Study aim	Outcome	Quantitative findings	Qualitative findings	Mixed method meta-inference
Aim 1: Feasibility of mobile app	Technical feasibility	**Overall number of FHIR-enabled data transfers (6-month study period)*** Median (IQR) = 81.5 (52.5, 153.5) **Monthly FHIR-enabled data transfers*** Median (IQR) = 13.6 (8.8, 25.6)	**Users encountered technical issues with basic app functions:** - Technical errors during app log-in process - Challenging to make initial connection for data transfer between app and EHR online patient portal - Incomplete data transfer to app **App use facilitated by helpful core app features:** - Centralized organization of health information - Patient-specific information reference and tracking tool - Easy navigation, responsive app	Successful FHIR-enabled data transfers and high levels of adoption supported overall feasibility. However, lower feasibility scale ratings and limited sustained app use might have been due in part to frequently encountered technical issues with basic app functions (e.g., log-in; data transfer).
	Implementation feasibility	**Feasibility of Implementation Measure, FIM** [b] Mean (SD) = 3.7 (0.7) **Mobile app adoption, n (%)*** Any app use = 11 (92) Early initiation in month 1 = 11 (92) Sustained app use in month 6 = 4 (33) Number of app use days, median (IQR) = 7 (4, 9)	**Good fit of the app into life routines and daily practices** due to: - Centralized, straightforward information access - Ability to track information and reference core health details	
Aim 2: Implementation determinants	Acceptability	**Acceptability of Implementation Measure (AIM)** [b] Mean (SD) = 3.8 (1.0) **Net Promoter Score (NPS) = -22.2^** Promoters = 2 (22.2%) Passives = 3 (33.3%) Detractors = 4 (44.4%)	Centralized, easily accessible information made **Caremap more advantageous for organizing information than alternative systems** (e.g., paper, online portal) **Relative advantages of the app overshadowed by parent stressors** (e.g., concurrently managing numerous caregiving responsibilities)	Satisfying features of the app that made it advantageous in comparison to alternative systems did not translate into higher acceptability ratings or likelihood of recommending Caremap to others. This discordance might be due in part to the significant responsibilities and stressors that are routinely faced by parents of CYSHCN.

Study aim	Outcome	Quantitative findings	Qualitative findings	Mixed method meta-inference
	Appropriateness	**Implementation Appropriateness Measure (IAM)** [b] Mean (SD) = 3.4 (0.9)	**App more useful for more complex patients and time periods** (e.g., children with higher complexity needs; less clinically stable times) **App improvements needed to promote more routine use** (e.g., automated task reminders), particularly in times when child is ill	Limited implementation appropriateness scale ratings potentially reflected lack of user-preferred features in the app and mismatch between the app and ideal user (i.e., most compatible during times of illness and/or for patients with higher complexity needs)
	Usability	**System usability scale (SUS)**[b] Baseline: mean (SD) = 61.5 (18.5) 6-month follow-up: mean (SD) = 64.4 (18.2) Change (baseline to 6-month follow-up) = 2.2 (27.4) *[Benchmark SUS scores: average usability = 68; good usability >80]*	**High usability for some users - intuitive, easy to use and find information** **Technical improvements needed** (e.g., smoother log-in process) **More app features desired:** - Personalized, automated reminder to complete tasks - Better ability to visualize and share tracked data Improved guidance on app use	Below average usability ratings might reflect that beneficial aspects of the app were insufficient to overcome frequently encountered technical issues (log-in errors) and limited ability of existing app features to meet user needs

[a] *n=12 study participants*
[b] *Among 9 participants with responses at baseline and six months*

App updates during the study period: In response to user feedback, we made nine major and four minor app updates (Table 6). Each major update required approximately 30-40 hours of development and testing time by our app developers to implement. Each minor update required approximately 4-8 hours to implement. A conservative estimate of total time spent to implement these 13 technical updates was approximately 300 hours.

Table 6: Technical updates completed (October 2022 – March 2024)

Version	Date	Update details	Scope
v1.3	Oct 2022	• Upgraded to latest Apple CareKit and Research Kit versions • Activated ability to link with EHR using FHIR • Enhanced care goal tracking and visualization	Major
v1.3.2	Nov 2022	• Updated research study informed consent documents	Minor
v1.3.3	Dec 2022	• Minor app improvements and bug fixes	Minor
v1.3.4	Dec 2022	• Updated research study information • Bug fixes to address app functionality during log-in process	Minor
v1.3.5	Jan 2023	• Improvements to Insight graphs o Show monthly insights for items tracked weekly o Improved display of yes / no type care items o Added some missing care item values being tracked • Ability to login directly if participant already signed up	Major
v1.3.6	Feb 2023	• Improvements to care goal tracking o Ability to add or edit tracking of care Items in the past o Global Health Index available for daily tracking o Weight tracking supports decimal values • Added ability to automatically notify users when new app update is available	Major
v1.3.7	Apr 2023	• Made improvements to the app log-in process • Fixed glitches and crashes during log-in and enrollment processes • Added 'eye' icon so user can see characters when entering password	Major
v1.3.8	Jun 2023	• Added ability to track customized care goals • Fixed issues with EHR connectivity for new users • Streamlined passcode and username/password entry when returning to app o If <30 days since last login, re-enter by typing in passcode only o If >30 days, enter passcode then username/email + password + passcode	Major
v1.3.9	Jul 2023	• Fixed issue with app EHR data sync when patient profile details exist before EHR connection is linked	Major
v1.3.10	Oct 2023	• Fixed issue with syncing across multiple devices • Updated consent forms for DIHI study (new IRB stamp)	Major
v1.3.11	Nov 2023	• Minor update to IRB consent details	Minor
v1.3.12	Mar 2024	• Switched to using FHIR R4 version • Support passcode reset if the app is reinstalled	Major
v1.3.13	Mar 2024	• Fix pulling medications using FHIR R4 • Fix pulling "official" name of the patient from the FHIR API call	Major

Discussion: This study demonstrated that a FHIR-enabled mobile app (Caremap) was feasible for care coordination by parents of CYSHCN recruited from a pediatric primary care setting. Parents were able to navigate the app, and core app features were well-received. Parents also reported that Caremap offered a better

way to access and organize health information than alternative systems (e.g., EHR online portal, paper). These promising findings were tempered by average to below average parent-reported ratings of implementation feasibility and other implementation outcomes (e.g., acceptability, appropriateness, usability).(41) Integrated quantitative and qualitative data analyses revealed that technical issues and lack of customization to tailor the app to meet individual user needs were prominent barriers to full implementation success.

In a prior study by Desai, et al that examined the role of cloud-based care plans for children with medical complexity,(9) lack of EHR integration was a key barrier to users acceptability of care plans. National organizations also recommend leveraging the EHR to enhance care coordination and communication.(42) Although Caremap's FHIR-enabled core feature addressed the issue of EHR integration, it was insufficient to satisfy user frustrations with common technical challenges (e.g., log-in and EHR connection difficulties; outdated iOS version; device setting errors; etc). Although we attempted to quickly respond, our capacity to provide individualized, real-time technical support was limited. This support need highlighted the essential role that technical challenges play in implementation success. Like other digital health studies,(43) we observed how technical challenges can negate advantages of user engagement, organizational commitment (multi-site collaboration in our study), and strong technical foundations provided by the pre-existing Caremap mobile app.

An essential challenge for studies of mobile medical apps is resourcing to implement and monitor technical issues throughout the study and follow-up period.(44) This is particularly challenging for researchers because app development and maintenance costs are high, and grant-funded budgets – particularly projects in academic medical centers – are often insufficient.(44) Responsiveness to unexpected technical issues is not the only development need. Enhancing the app (i.e., improve features and functionality), creating infrastructure to continuously gather user feedback, and providing individualized technical support are also required. We hypothesize that our study participants' expectation of a seamless user experience with minimal technical errors and an app tailored to meet their individual needs is the norm. Although our sample of parents with high education, health literacy, and mobile device proficiency represented a well-resourced user group, the vast majority of adults in the United States own smartphones and 40% report being online almost constantly.(45) As such, it was not surprising that parents in our study might have held Caremap – even in this early stage testing –

to the same high performance and usability standards expected of any modern app. Digital health researchers must recognize that user expectations are high, and better funded study teams (e.g., public-private partnerships; more funds for app development) may be better positioned to meet these high user expectations.

Strengths: First, the use of digital prescriptions to deliver study materials and recruit participants was feasible. Engagement with study materials sent via digital prescriptions was high; this approach offers a promising, scalable recruitment strategy for future studies. Second, parents reported that Caremap's core features offered organizational advantages, particularly during times when their child's health needs might be more complicated and acute. This suggested that CYSHCN with higher medical complexity or experiencing health crises might benefit most from Caremap, but more research is needed to improve understanding of who benefits most and why. Finally, use of a rigorous mixed methods design combined with established implementation research frameworks facilitated maximal learning from the combined quantitative and qualitative data sources.

Limitations: This study's single center design, small size, and lack of randomization limited generalizability. In part the small sample size reflected challenges in subject recruitment. Despite adopting multiple recruitment strategies (e.g., digital recruitment, mailed letter, direct study introduction by patient's PCP) and significant efforts by research staff to answer eligible participants' questions about the study, we did not achieve our original enrollment target. Exclusion of non-English speaking participants, those without an iOS© device, and those without home internet were additional key barriers to recruitment and participation.

Technical challenges and unanticipated expenses presented important limitations. Our study launch was delayed by more than six months due to new institutional requirements for mobile apps to undergo external penetration testing to meet modern data security standards. Identification of a vendor, execution of requisite vendor contracts, and payment for these unanticipated costs added significant expenses and delays to the study. In our experience, penetration testing may add $50,000 to $100,000 in costs to already limited budgets.

Another major technical issue was testing and building the EHR-integrated clinician dashboard. The clinician dashboard was intended to be a visual summary of information recorded by families on Caremap in their personal device and synchronized with the EHR, thus providing PCPs with view-only, point-of-care EHR access to family-reported health information (e.g., tracked symptoms in the app). This was intended to be the

main way PCPs could engage with users' information tracked in Caremap. Although the dashboard was built, we were unable to fully implement and test with parents and PCPs. As such, PCP engagement with Caremap during the study was sharply limited and the main users were parents/caregivers of CYSHCN.

Conclusion: This study demonstrated technical feasibility and support from parents/caregivers of integrating a FHIR-enabled digital personal health record mobile app to coordinate care for CYSHCN. Full implementation success was hampered by technical challenges and limited app features to address individual user needs.

Significance, Implications, and Future Directions: User-identified technical challenges and desire for more customization could be addressed with more app development resources. Targeted resources to enhance the app, overcome common issues, and ensure equitable app access (e.g., adapt to Android©; dual language use) could address key user concerns. Newer advancements (e.g., artificial intelligence) have potential to further enhance the app; however, ensuring the app sustainably delivers an outstanding user experience is the next top priority.

Implementation of technical enhancements to buttress core features that users in our study found to be advantageous may position Caremap or similar FHIR-enabled apps to support the complex care coordination needs for CYSHCN. Although Caremap was focused on CYSHCN, many challenges faced by patients with complex health needs and their caregivers are similar across the life course.(46) As such, an important future direction is to extend app use to adult populations across the age spectrum who have special health care needs.

LIST OF ASSOCIATED PUBLICATIONS AND PRODUCTS

1) Wong W, Ming D, Pateras S, Fee CH, Coleman C, Docktor M, Shah N, Antonelli R. "Outcomes of End-User Testing with Families of CYSHCN on a Care Coordination Mobile App: A Simulation Study," *JMIR Formative Research*, 2023 Aug 28. doi: 10.2196/43993. [PMID 37639303]

2) Ming DY, Wong W, Jones KA, Antonelli RC, Gujral N, Gonzales S, Rogers U, Ratliff W, Shah N, King HA. "Feasibility of Implementation of a Mobile Digital Personal Health Record to Coordinate Care for Children and Youth with Special Healthcare Needs in Primary Care: A Mixed Methods Study Protocol," *JMIR Res Protoc,* 2023 Sept 20:12:e46847. doi: 10.2196/46847. [PMID 37728977

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