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

E-Consent for Parents/Caregivers of Children with Complex Care Needs

Purpose

You and your child are being asked to take part in a research study because your child has complex chronic conditions and their usual Duke provider reports that they may benefit from additional care coordination support and resources. This study will implement a new mobile application (‘app’) called Caremap to improve care coordination for patients with complex health needs. The goal is to pilot test the mobile app with patients/families and clinic doctors to gather input on how well the app works and how to make it better. We plan to enroll up to 40 parent or caregiver/children or youth dyad participants from Duke University for this study. The study is sponsored by the Agency for Healthcare Research and Quality (AHRQ).

Study Activities

If you agree to participate, your child’s medical records will be used. You will need access to a personal mobile device in the form of an Apple iPhone, iPod touch, or iPad on which you can use the Caremap app to coordinate care and transfer information with the electronic health record system at Duke (Epic). You will also need to have an active My Chart account. As a parent or caregiver, you will need to have full proxy access to your child’s medical chart in Duke MyChart. The mobile app will use your existing MyChart account details to link with your child’s medical record. After completion of this consent form, you will install the Caremap app on your device. You will login using the same credentials that you usually use for accessing Duke MyChart. A study coordinator will be available to assist with device management, questions, and other support remotely (via Facetime, Zoom, phone call, etc.) or in-person if needed.

During the study period, you will be asked to use the mobile app for up to 6 months to organize detailed care information, establish and track progress towards care goals, and share key insights into health status and progress towards care goals with your usual clinical provider at Duke. A summary of these care coordination and health status details will be visible to your provider in the electronic health record. The recommended time point at which to review this information with your provider is during a scheduled outpatient clinic visit. During those routine visits, the information you have tracked and summarized for your provider will give him/her valuable insight into how your or your family member’s health has progressed over time. These family-reported insights from the home setting are typically very challenging for providers to fully assess between routine clinical visits. Thus, your use of the Caremap mobile app will not only assist with care coordination for your child’s care, but it could also be a valuable tool for communication with their provider.

The Caremap app is not intended to replace your regular use of MyChart for communication with your child’s provider(s). You will not be able to send a message to or communicate directly with your child’s provider in real-time. In the event of a medical emergency, please call 911; if you have any urgent medical need, please contact your child’s provider directly.

Periodically during the study, you will be asked to complete online surveys, which include questions about how easy it was to use the app and how the app has impacted, if at all, the care experience and health outcomes for your child. You will be asked to complete surveys at baseline/time of study enrollment, and then 3 months and 6 months after enrollment. We will obtain and review information about technical aspects of the app (e.g., number of log-ins, successful transfer of medical record information to the app, successful transfer of family-reported information from the app to the provider dashboard, and provider use of the dashboard).

At the end of the study period (6 months after enrollment), we will invite you to participate in a one-on-one interview with our study team so that we can learn more from your experiences about how the app can be further improved to support the care coordination and communication needs of patients and families.

Your child will not be asked to interact with the app or to personally participate in interviews or surveys.

Caremap App Data Collection

As part of this study, data collected from your electronic health record at Duke into the Caremap app includes the following:

- **Medical Condition and History and Other Related Information**, pulled from your child's electronic health record – for example, allergies, conditions, medications, past admissions, provider encounter notes, care goals
- **Survey Data**, such as information you provide in the Caremap app. For example, medical history, medications, health behaviors, functional capacity, fall risk, mental health, and major life events.
- **Research App Usage Related Information**, such as information about your usage of and interaction with the Research app and this study (for example, if study-related notifications were received and actions taken, number of study-related tasks started and completed, how often Study Data is sent and the size of the data, how the app is launched, when you enrolled in the study, and information about the app's functioning).

Research App Usage Related Information, such as information about your usage of and interaction with the Research app and this study (for example, if study-related notifications were received and actions taken, number of study-related tasks started and completed, how often Study Data is sent and the size of the data, how the app is launched, when you enrolled in the study, and information about the app's functioning).

<u>Doctor on Study</u>

If you decide to participate, Dr. David Ming will be your child's study doctor for this project and will be in contact with your child's regular health care provider throughout the time that you are in the study and afterwards, if needed.

<u>Compensation/Cost</u>

There are no costs to you for taking part in this study. You will be paid $50 total for completing the surveys - $25 at baseline and $25 at 6 months. If you are asked to participate in the optional feedback interview, you will receive an additional $50 for completing the interview. All payments will be provided by ClinCard.

Risks and Benefits

There are no physical risks from involvement in this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your/your child's information confidential; however, this cannot be guaranteed.

Risks specific to mobile apps:

Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully and discuss with the study team if you have any questions. Many mobile apps that are developed are intended to be very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks. We have self-developed the mobile app for the current study and have made efforts to limit potential security risks associated with mobile applications; however, Duke cannot guarantee that the mobile app is free of risk. Other applications on your device will not have access to data entered into the study app. Information that you enter into the mobile app that is stored outside of Duke is stored on a server, with authorized access by only the study team. Caremap may store or use data stored on cloud servers managed or hosted by Microsoft, Google and its affiliates, Apple, AWS, and/or Sharefile as appropriate. You will be asked to use an email address to set up your account within the mobile app; if preferred, the study team will provide an email for the purpose of the study. You will also be asked to use your Duke MyChart account log-in to link the app with your existing Duke Epic electronic health chart. Other identifying information entered into the app will be stored confidentially as described below.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. The application may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (for example, battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile app from your device. While this app is intended to help coordinate care, track health information and progress towards patient/family-centered goals, and communicate with providers, the app is not intended to supplant health care decisions directly discussed with the subject's health care provider. The app is also not intended for use as a real-time communication tool with providers nor is it intended to supplant usual, existing patient/family-provider communication channels (e.g., My Chart).

Regarding benefits, you/your child may experience better coordinated care and communication with your child's provider, which may improve overall care. However, there may not be a direct medical benefit to you or family member. Regardless of level of direct medical benefit received, we hope that the information learned from this study will benefit other people in the future.

Confidentiality Process

This is voluntary, and you do not have to participate. If you do not agree to participate, your child's medical care or yours, if you are a Duke patient will not be impacted. If you do want to participate, you can choose to not answer questions that are part of the surveys or interview.

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your [and your child's] personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your/your child's personal information may also be given out if required by law. Study records that identify you/your child will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Identifiable and anonymized data will be accessed and shared with collaborating study personnel at Boston Children's Hospital for the purpose of data analysis and app support. In addition, your/your child's records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of Duke University Health System Institutional Review Board. Reviewers here at Duke may also include the OARC (Office of Audit, Risk and Compliance). If any of these groups review your research record, they may also need to review your entire medical record. Caremap will store your/your child's information to allow two-way communication between you and the study staff. All information entered through the app will be accessible by Caremap staff and if further disclosed by them, or their cloud storage site, is no longer covered by the Duke privacy protections. Some information collected about you/your child only for this research study may be kept in a research study record separate from your medical record, and some research information may also be part of your child's medical record. You will not have access to this research information until the end of the study. However, it will be available to your physicians if needed for your child's care. Your/your child's name will not appear in any research report or publication. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your/your child's identity will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The study results will be retained in your research record for six years after the study is completed or until your child reaches the age of 21, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from the study results at DUHS. Any research information in your child's medical record will be kept indefinitely. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Conflict of Interest Statement

Drs. Ming, Antonelli and Nitin Gujral have developed the technology that is being used in the study and are a part of the study team. If the technology is commercially successful in the future, the developers and Boston Children's Hospital may benefit financially.

Withdrawal

You may choose not to be in the study, or, if you agree to be in the study, you and your child may withdraw from the study at any time. If you withdraw from the study, no new data about you or your child will be collected for study purposes other than data needed to keep track of your withdrawal. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you or your child are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact the study coordinator at 919-668-1226 let them know that you are withdrawing from the study.

Contact Information

If you have any questions about the study, please contact Dr. David Ming (David.ming@duke.edu) by telephone at 409.539.0411, or by pager at 919.970.7637. For questions about your rights as a research participant, or to discuss problems about the research, contact the Duke Health Institutional Review Board (IRB) Office at (919) 668-5111.

Statement of informed consent

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions. My questions have been answered to my satisfaction. I have been told whom to contact if I have questions or problems about the research. I have read this consent form and agree to be in the study. I understand that I can withdraw at any time. I have been told that I will be given a signed and dated copy of this form."

☐ Yes, I have read the consent form and I wish to participate in the study

☐ I DO NOT wish to participate in the study

Date ___________