Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Rationale and design of the TAILOR-PCI digital study: Transitioning a randomized controlled trial to a digital registry

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Background Tailored Antiplatelet Initiation to Lessen Outcomes Due to Decreased Clopidogrel Response after Percutaneous Coronary Intervention (TAILOR-PCI) is the largest cardiovascular genotype-based randomized pragmatic trial (NCT#01742117) to evaluate the role of genotype-guided selection of oral $P2Y_{12}$ inhibitor therapy in improving ischemic outcomes after PCI. The trial has been extended from the original 12- to 24-month follow-up, using study coordinator-initiated telephone visits. TAILOR-PCI Digital Study tests the feasibility of extending the trial follow-up in a subset of patients for up to 24 months using state-of-the-art digital solutions. The rationale, design, and approach of extended digital study of patients recruited into a large, international, multi-center clinical trial has not been previously described.

Methods A total of 930 patients from U.S. and Canadian sites previously enrolled in the 5,302 patient TAILOR-PCI trial within 23 months of randomization are invited by mail to the Digital Study website (http://tailorpci.eurekaplatform.org) and by up to 2 recruiting telephone calls. Eureka, a direct-to-participant digital research platform, is used to consent and collect prospective data on patients for the digital study. Patients are asked to answer health-related surveys at fixed intervals using the Eureka mobile app and or desktop platform. The likelihood of patients enrolled in a randomized clinical trial transitioning to a registry using digital technology, the reasons for nonparticipation and engagement rates are evaluated. To capture hospitalizations, patients may optionally enable geofencing, a process that allows background location tracking and triggering of surveys if a hospital visit greater than 4 hours is detected. In addition, patients answer digital hospitalization surveys every month. Hospitalization data received from the Digital Study will be compared to data collected from study coordinator telephone visits during the same time frame.

Conclusions The TAILOR-PCI Digital Study evaluates the feasibility of transitioning a large multicenter randomized clinical trial to a digital registry. The study could provide evidence for the ability of digital technology to follow clinical trial patients and to ascertain trial-related events thus also building the foundation for conducting digital clinical trials. Such a digital approach may be especially pertinent in the era of COVID-19. (Am Heart J 2021;232:84–93.)

Clopidogrel is the most widely prescribed anti-platelet drug in the United States and Canada, along with aspirin, after percutaneous coronary intervention (PCI).[1–3] However, clopidogrel is a prodrug that requires hepatic cytochrome P450 enzyme CYP2C19 metabolism in order to be bio-transformed to an active metabolite that limits the platelet aggregation that commonly occurs during PCI. The Tailored Antiplatelet Initiation to Lessen Outcomes Due to Decreased Clopidogrel Response after PCI (TAILOR-PCI; NCT#01742117) study was a large, multicenter, international, randomized

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Abbreviation List

COVID-19	Coronavirus Disease 2019
DAPT	Dual antiplatelet therapy
IRB	Institutional Review Board
MACE	Major adverse cardiovascular events
TAILOR-PCI	Tailored Antiplatelet Initiation to Lessen Outcomes Due to Decreased Clopidogrel Response after Percutaneous Coronary Intervention.
SMS	Short message service
UPC	Unique Participant Code

clinical trial comparing point-of-care genotype-guided antiplatelet therapy with routine care to determine whether identifying *CYP2C19* loss-of-function allele patients prospectively and prescribing alternative antiplatelet therapy was beneficial (Supplemental Figure 1).[3,4] The TAILOR-PCI trial initial 1-year follow-up was extended to 2 years with study coordinator initiated telephone visits, in the "Extended Follow-Up Study." The purpose was to determine the role of *CYP2C19* genotyping in long-term antiplatelet drug use.[3,4] However the significant costs and inconvenience associated with conventional assessment of patients in a large, multi-center randomized clinical trial like the TAILOR-PCI study complicates extended follow-up initiatives. In the context of increasing costs of performing cardiovascular clinical trials,[5] there is a need to conduct more streamlined, efficient, low-cost technology-driven studies to generate real-world evidence and inform clinical practice.[6,7] Digital-based studies are poised to play an important role, not only in their potential ability to increase recruitment of patients by enabling easier remote follow-up, but also may be useful in the pandemic era of COVID-19, where in-person study-related visits may be limited or restricted.

The TAILOR-PCI Digital Study is performed using Eureka,[8] a National Institute of Health (NIH)-funded, direct-to-participant digital research platform, designed by researchers at the University of California, San Francisco. The platform is used to consent and collect data from participants so that study follow-up could be entirely remote. Hospitalization data from the digital study are compared with data from the conventional extended follow-up that is obtained via study coordinator-initiated telephone visits. TAILOR-PCI extended follow-up can be considered as a hybrid study involving participating site-based study coordinator telephone visits and a centralized patient enabled digital registry. This endeavor might provide evidence needed to extend follow-up of clinical trials using digital technology and to conduct a pragmatic clinical trial with digital approaches. The rationale, design, approach, objectives and challenges of the TAILOR-PCI Digital Study are described.

Methods

Study aims and outcomes

The follow-up of the TAILOR-PCI trial was extended beyond 1 year with conventional telephone visits, for a total of 2 years after randomization. The TAILOR-PCI Digital Study complements the TAILOR-PCI Extended Follow-Up Study by comparing digital to conventional approaches. National Institute of Health funding was used to support the research presented in this manuscript.

There are 2 primary aims of this study:

Aim 1. To determine the feasibility of transitioning a clinical trial to a digital platform.

Aim 2. To compare the ability of digital technology to detect cardiovascular hospitalizations with conventional clinical trial follow-up.

The third exploratory aim will be to assess the association of digital biomarkers derived from smartphone-based data such as heart rate and activity levels with ischemic and major bleeding events.

The primary outcomes of the study for Aim 1 that will be measured are the percentage of eligible clinical trial subjects that will consent to the digital study and participate in at least 80% of eligible eVisits. Secondary outcomes that will be measured are the individual components of the primary outcome and will also include the geofencing consent rate, the proportion of consented patients who downloaded the Eureka app, the average time until study drop off (described as skipped $\geq$1 month of survey activities and not re-engaging with the Eureka app despite Mayo Coordinator phone calls), eVisit participation rate (number of monthly eVisits completed over the number of eVisits available), and individual survey completion rate (number of surveys completed over the number of surveys available, the relative completion rates for weekly, monthly, and less frequent activities). The primary outcome of the study that will be measured for Aim 2 is the percentage of cardiovascular hospitalizations ascertained by digital technology (geofencing $\pm$ monthly digital surveys) as compared to cardiovascular hospitalizations assessed by study coordinators with telephone visits and health record review. The secondary outcomes measured will include cardiovascular hospitalizations ascertained by geofencing, by monthly digital surveys, conventional phone survey/medical records review, and hospitalizations ascertained by all 3 methods.

The digital study is an unprecedented effort to enroll patients who have previously consented to a clinical trial to digital activities and therefore determining a metric of success for this effort is difficult. Ideally, if digital activities were to substitute traditional clinical trial follow-up we would like to enroll and maintain engagement of at least 80% or more trial participants in the digital study. However, given the recent introduction of digital technology in clinical trials success of this digital study can

also be determined by comparing enrollment and engagement rates to that of other digital studies.

All participants are followed up by telephone visit during the extended follow-up of the main trial, at 18 months and 24 months. This allows direct comparison between the telephone visits used in the extended follow-up to ascertainment of outcomes by digital study.

Statistical considerations

Continuous variables will be summarized as mean (standard deviation) if approximately symmetrically distributed and with median (first and third quartile) otherwise. Discrete variables will be summarized with frequency (percentage). Outcomes which are summarized with percentages (such as the number of subjects consenting and participating in the digital registry and the number downloading the Eureka app) will be accompanied with 95% confidence intervals for the percentage, using the Agresti-Coull method for interval estimation.[9] The eVisit participation rate and the survey completion rates will be calculated within subjects to estimate a percentage, and then summarized across individuals as continuous measures. Confidence intervals for continuous variables will be estimated using normal approximations for the mean, using transformations as needed. To compare hospitalization ascertainment between digital registry follow-up and extended telephone follow-up, hospitalizations identified by either of the 2 follow-up processes will be classified into 1 of 3 groups: (1) ascertained by digital/geofencing process only, (2) ascertained by phone survey/medical records only, and (3) ascertained by both. We refer to the proportions of events in these 3 classes as $p1$, $p2$, and $p3$. Because of the possibility for multiple events occurring on the same subject, and the resulting correlation in events ascertainment, we will use subject-level bootstrapping to estimate 95% confidence interval for the difference in $p1$ and $p2$. As a sensitivity analysis, we will also use classical estimates of the covariance matrix for the multinomial distribution to estimate the standard error and confidence interval for $p1$ to $p2$. We will also compare baseline characteristics between those who do and do not consent for the digital study, and we will also use multiple logistic regression to model the effects of baseline characteristics (age, sex, etc.), on the propensity to consent digitally.

Patient eligibility

TAILOR-PCI patients based in the U.S. and Canada, who were within 24 months of randomization and who had an Apple or Android smartphone were eligible to participate (Figure 1). Patients from 24 of the 40 TAILOR-PCI trial participating sites were eligible to enroll for the Digital Study. Patients from 4 Korean and 2 Mexican sites and those from the 7 sites that had recruited patients who had already completed 2-year follow-up were not eligible to participate. There were 3 sites that declined participation, resulting in 930 patients alive and available for further follow-up.

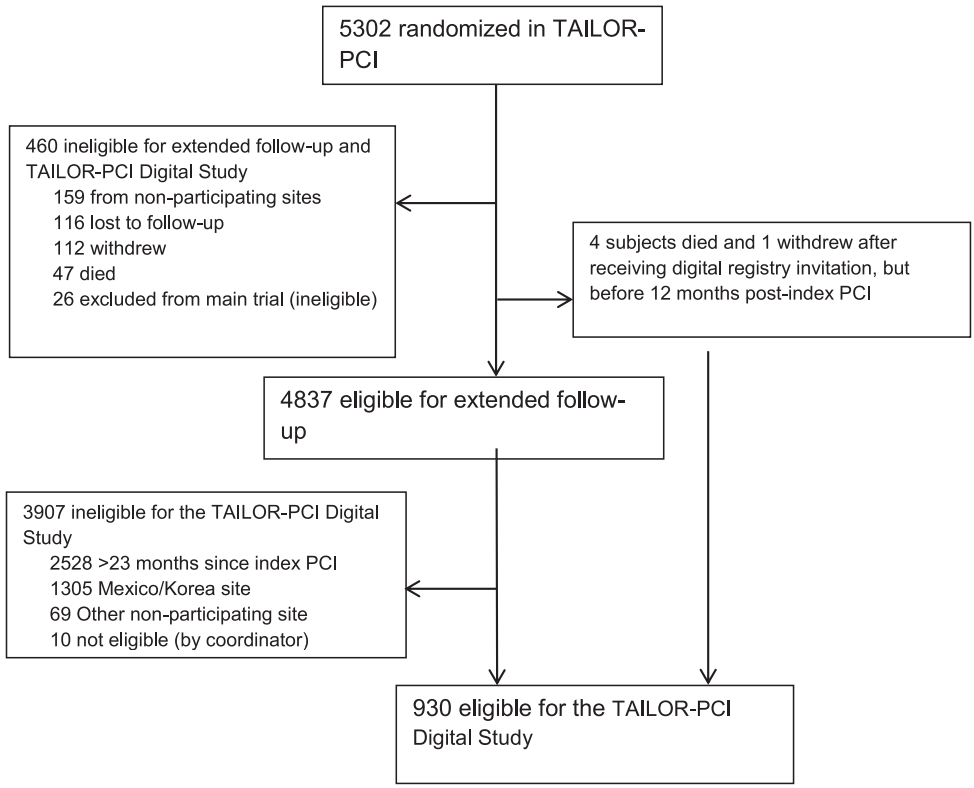
Trial oversight

Efficiently transitioning a multicenter clinical trial to a digital registry is a complex process requiring collaboration between different participating centers. For TAILOR-PCI, Mayo Clinic acted as the clinical coordinating center and the University of California San Francisco (UCSF) acted as the digital technology center. UCSF developed the digital study on the Eureka platform and provided technical support for the study. Mayo Clinic received Institutional Review Board (IRB) approval for the TAILOR-PCI Digital Study, while UCSF had received IRB approval for using the Eureka Research Platform (described below). Each participating site obtained approval from their respective IRBs for distributing study recruitment letters referring patients to the Digital Study and for contacting them if they had not enrolled. Participating sites were not responsible for consenting participants for the digital study. This process simplified the trial oversight and day-to-day operations by centralizing patients' digital research activities under a single clinical coordinating center and IRB (Mayo Clinic). Once it was determined that patients were eligible and consented for the digital study, Mayo Clinic (but not UCSF) was allowed to and responsible for engaging with patients enrolled for the study. Individual participating study sites continued telephone follow-up in the conventional (nondigital) TAILOR-PCI Extended Follow-Up Study.

Recruitment

TAILOR-PCI patients received a letter inviting them to join the Digital Study (Figure 2). In order to ensure a one-to-one linkage between the data collected in Eureka (for the digital study) with the TAILOR-PCI data, an innovative approach built into Eureka allowed for automatic de-identified cross-linking; a unique participant code (UPC) generated by Eureka was assigned to each TAILOR-PCI patient and included in the invitation letter (to be entered by the patient upon signing up on the web). The UPC is used as a "one-time access code" during the Eureka account creation, to restrict enrollment only to those who have been invited and to establish the needed 1:1 link between the Eureka participant identification (ID) and the TAILOR-PCI study ID numbers. Mayo Clinic generated a spreadsheet used for mail merge that was completely de-identified (contained a list of TAILOR-PCI study IDs and Eureka UPC codes) for each participating study site. The site study coordinators extracted the addresses of the potential study patients and their contact information from the medical record by matching patients' medical record numbers with the TAILOR-PCI study ID found in the recruitment spreadsheet.

Figure 1



CONSORT diagram for TAILOR-PCI Digital Study.

All eligible patients will be contacted via telephone by participating sites' study coordinators if they had not consented for the digital study after receiving the initial study invitation letter to capture reasons for nonparticipation using a standardized telephone script.

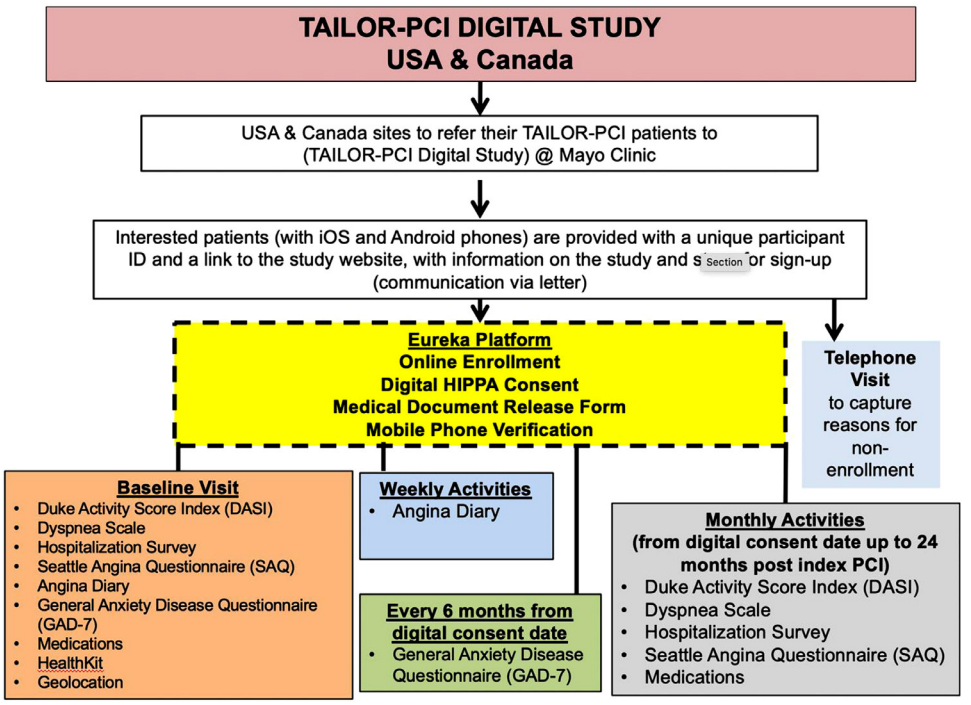
Eligible patients who were yet to consent even after receiving the initial study invitation letter will be contacted via telephone (using standardized telephone script) by study coordinators from the respective participating sites enabling to capture reasons for nonparticipation.

After verbal consent, patients were asked if they had received the letter, if they wanted additional information on the digital study, about their education level and computer literacy and if applicable, to describe a reason for not participating in the digital study. These calls were timed when possible to coincide with the main TAILOR-PCI trial follow-up telephone visits to capture medication data and trial end points. In parallel, patients in the TAILOR-PCI Extended Follow-Up will be contacted at 18- and 24-months post-PCI by site study coordinators to inquire about their health status. If during these calls, patients have questions about the Digital Study, site study coordinators will refer them to the Mayo Coordinator for further assistance. The Mayo Coordinator is solely responsible for assisting patients in completing their digital tasks.

The Eureka research platform

The TAILOR-PCI Digital Study is built on the Eureka Research Platform (info.eurekaplatform.org),[8] a disease-agnostic research platform containing multiple digital studies and designed for rapidly developing, deploying and running mobile and digitally enabled direct-to-participant clinical research studies. Eureka is a university-based, NIH-funded digital research platform developed and managed by a team of researchers, designers and programmers at the UCSF based on the technology and experience of the Health eHeart Study.[10] The platform and approach differs from many mobile research approaches in that a separate unique application is not needed for each study (Supplemental Figure 2). Eureka is developed with an architecture that can host multiple studies on a single mobile application or website, and that can dynamically deliver study content to the Eureka smartphone app or browser. Researchers can update the study activities and content without the need of study participants to update the app. Studies have their own branding, look and feel, unique workflows and

Figure 2



TAILOR-PCI digital study overview.

content that includes study onboarding (eligibility, consent, and randomization if needed), surveys (triggered by timing or other events), integration with connected devices or apps, passive collection of data from smartphones including geolocation and a robust messaging and reminder system in the form of app-based notifications ("push notifications"), short message service (SMS) messages and e-mails. The platform shares prebuilt features and has tested workflows across multiple studies leading to a more cost-effective study design. Currently, the Eureka platform hosts more than 25 studies with over 370,000 participants.

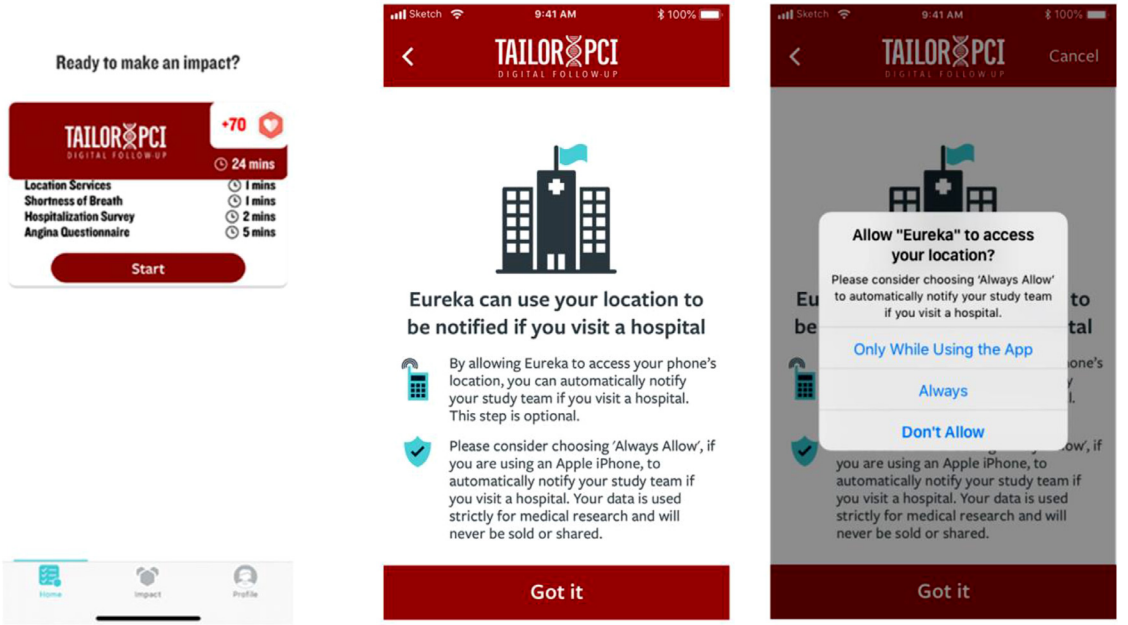
A uniquely branded study experience was built for the TAILOR-PCI Digital Study within the Eureka app and on the web (Figure 3). TAILOR-PCI patients were instructed in their invitation letter to visit the Digital Study website via the link provided in their letter. They could also text a study-specific keyword (ie, TPCI) to a cellphone number to receive the study link by SMS text on their smartphone. Once they visited the study website, patients entered their UPC, automatically linking them to their TAILOR-PCI study ID and confirming them as a TAILOR-PCI patient, in order to be able to register for the study. After answering a question about their smartphone model to determine eligibility, the patients were presented with an electronic informed consent and a separate electronic medical release form. The medical release form allows Mayo Clinic to collect medical records of consented patients who report a hospitalization to adjudicate outcomes. Once consented, patients confirmed their smartphone number in order to receive a text message containing a link to download the Eureka app. The content of the digital approaches used during registration, eligibility, consenting and data collection was developed by incorporating participant input and focus group feedback. All data collected in the app are securely transferred to the Eureka HIPAA-compliant backend.

Innovative operation approaches

Tracking of hospitalizations using geofencing

Collecting hospitalization data are essential to determine the primary outcome of TAILOR-PCI. In the Digital Study, passive detection of hospitalizations using geofencing is explored. Geofencing is the use of smartphone Global Positioning System (GPS) technology to define virtual geographic boundaries around places of interest, enabling software to trigger a response when a mobile device enters or leaves the area. This approach for the use of geofencing to detect hospitalizations has previously been published.[11] An improved algorithm was designed for the TAILOR PCI Digital Study. The algorithm

Figure 3



TAILOR-PCI digital study participant facing screens within the Eureka App.

leverages up-to-date, dynamic databases of hospitals and clinics to detect hospital visits and has a reduced impact on the smartphone battery.[11] The Eureka app separately requests consented patients to allow background location tracking. The language and content of the location request was approved by Mayo Clinic IRB (Figure 3). While this step is optional, accepting these permissions allows Eureka to use location services to determine if participants are in or near a health care facility, regardless if the Eureka app is actively running on the smartphone, throughout the study period. If a patient is at a location that is determined to have a high probability of being a hospital by the algorithm and stays in that area for 4 or more hours, upon detection of a significant change of location by the geolocation algorithm (usually, when leaving the hospital), a survey is delivered to the patient via an app-based push notification (Supplemental Figure 3). If the patient doesn't answer the survey, a push notification is sent at 48 hours and a SMS is sent at 96 hours, then the survey expires after 1 month. This survey asks the patient if they were in a hospital for their medical care and if so, they are asked to input the main reason for hospitalization, the admission and discharge date and the location of the hospital. To respect patient confidentiality, if GPS coordinates do not match to a hospital, the data are not uploaded on the Eureka backend. This approach has been successfully used in a prior validation study. [11]

Digital study activities and workflows (Table 1)

After opening the Eureka app, consented participants are asked to provide access to phone sensors (eg, activity) through HealthKit on Apple smartphones. Also, Eureka requests permission for app-based notifications ("push notifications") to enable the participants to receive phone reminders for activities, as described below, and alerts for hospitalization detection.

Once the on-boarding is complete, study activities are available within the app. At baseline, patients complete the following activities: Duke Activity Score Index,[12] Seattle Angina Questionnaire,[13] and the Modified Medical Research Council Dyspnea Scale.[14] Patients also enter their medication list. The Eureka medication entry activity allows for automatic matching of drug names and dosages using the RxNorm database,[15] which has previously been shown to reduce medication input errors.[16] These activities are repeated every month. In addition, participants are invited to complete a monthly survey asking about hospitalizations and emergency room visits and their reason for their hospitalization (eg, MI, stroke, HTN, heart failure, atrial fibrillation, hypertension, etc). Patients are asked to complete a weekly 2-question angina diary to report the presence of chest pain or shortness of breath (angina equivalent) and its frequency over the prior week. In addition, anxiety scores are collected every 6 months using the GAD-7 questionnaire[17].

Table 1. Schedule of data collection

Baseline	Baseline and weekly	Baseline and monthly	Baseline and every 6 months	Passive data collection
• Consent • HIPAA and MRF form* • Mobile Phone Verification • Geolocation permission • HealthKit	• Angina diary	• Medications • Duke Activity Status Index [12] • Shortness of Breath Questionnaire[14] • Seattle Angina Questionnaire • Hospitalization survey	• General Anxiety Disease Questionnaire[17]	• Geolocation detection of hospitalizations • Step count

HIPAA, Health Insurance Portability and Accountability Act; MRF, Medical Release Form.

Study engagement and reminders

The Eureka app and platform have built-in engagement tools to improve participation in study activities. For example, when each activity is completed, patients are rewarded with points immediately after they contribute data which allows them to monitor their own progress and encourages them to continue completing activities. Also, an automated messaging system sends reminders to the user's phone when activities are due. These reminders are initially SMS messages at the start of the monthly visit, then simultaneous push notifications and SMS messages are sent weekly if the monthly tasks are not completed. In total, for each monthly visit, a participant will get 5 SMS and 4 push notifications. For the digital study, Mayo Clinic's study coordinators email or call participants who have not completed digital study visit activities.

TAILOR-PCI digital study management portal

Eureka has an integrated study management portal that allows the coordinating center at Mayo Clinic to manage all study patients (Supplemental Figure 4). It includes an overview of patient's status (registered, eligible, consented, and withdrawn) and provides the ability to download study reports to monitor overall study progress. Mayo Clinic study coordinators can drill down to the individual patient level to troubleshoot technical issues, monitor their progress and manage their consent. The management portal provides different levels of privileged access to the features (eg, data download, consent management) allowing data to be visible to the central coordinating center, without it being visible to the digital coordinating center.

TAILOR-PCI digital study data storage

Maintaining subject privacy and data security is of utmost importance. Data from the extended follow-up study coordinator telephone visits and data retrieved from the medical records are stored using Medidata Rave (Medidata Solutions), an FDA-approved platform that is being used in the parent TAILOR-PCI trial. Patient-reported data in the TAILOR-PCI Digital Study are directly downloaded to Mayo Clinic secure servers (secured both by firewall and group access rights), then the data are imported into Mayo's statistical software.

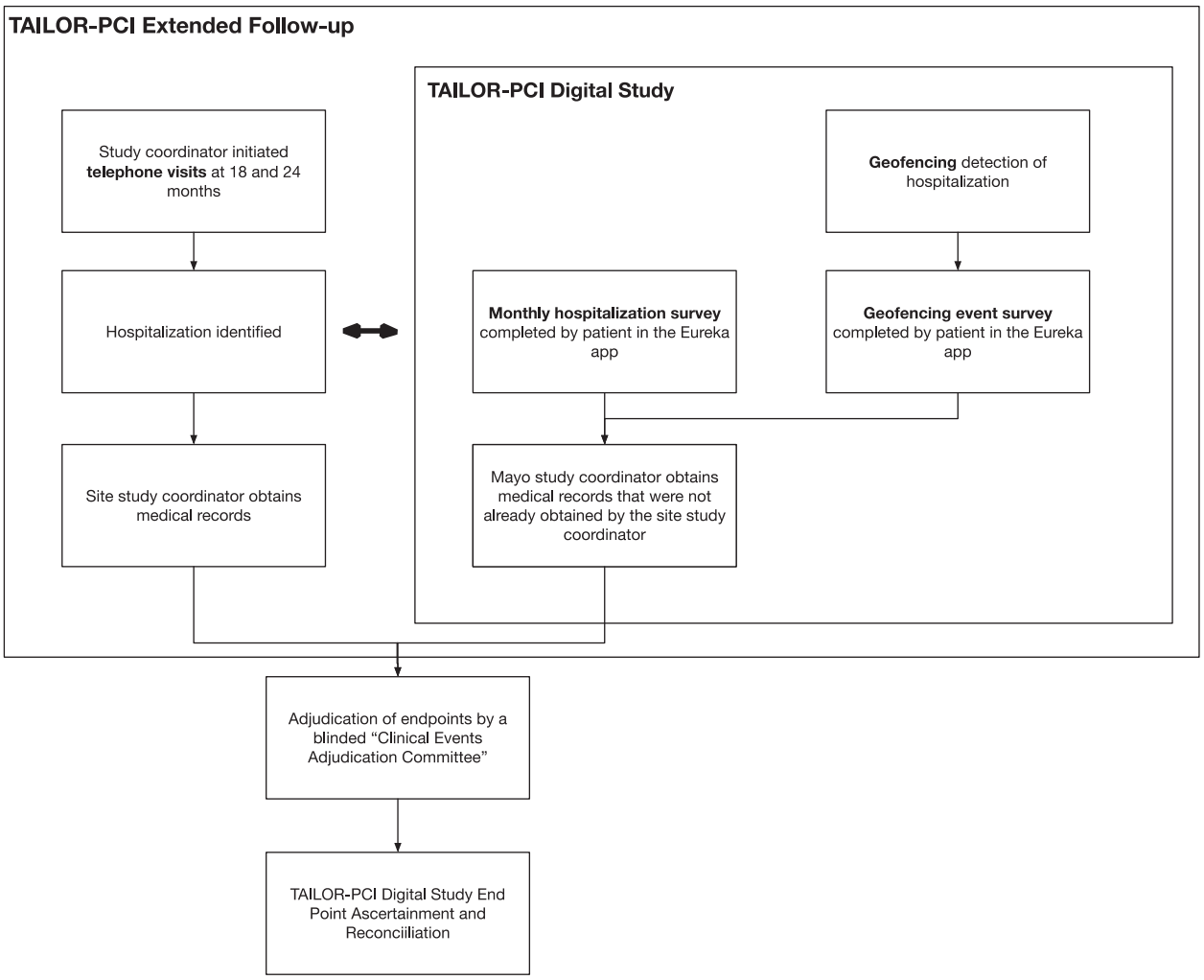
Ascertainment and confirmation of patient outcomes (Figure 4)

Patient reported outcomes in the Digital Study, obtained via the monthly hospitalization survey and the geofencing will be compared with hospitalization information obtained from the extended follow-up telephone visits. For Aim 2, site study coordinators, by means of a phone call, will obtain information regarding cardiovascular hospitalizations at 18- and 24-month post-PCI in addition to medical record review, while being blinded to the patient geofencing-reports and self-report hospitalizations. An event summary CRF will then be completed. The latter Digital Study based information is collected by the Mayo Clinic Coordinating Center which is responsible for monitoring and following up on the Digital Study hospitalization events. The Mayo Clinic CCC coordinator will be blinded to the results of the regular phone call follow-up activities. Standard definitions of the various clinical events are based on the American College of Cardiology's National Cardiovascular Data Registry.[18] All events will be adjudicated by an independent, blinded Clinical Events Adjudication Committee.[3]

Discussion

The TAILOR-PCI Digital Study is testing the feasibility of extending the follow-up of the main TAILOR-PCI trial for up to 24 months using digital technology. To the best of our knowledge, this is the first known attempt at converting an existing clinical trial into a digital registry. Using digital solutions for this purpose could allow for a relatively seamless and more cost-effective way of following up the participants after the end of the trial (with the caveat of crossovers that exist for all such observational follow ups) and for testing additional hypotheses by combining existing rich phenotypic data collected in a trial with digitally collected data. For the purposes of the main trial itself, the extended period of follow-up could result in aggregating a greater number of events

Figure 4



End Point Ascertainment and Reconciliation. TAILOR-PCI extended follow-up hospitalizations are captured by (i) telephone visits at 18 and 24 months. These will be compared with TAILOR-PCI Digital Study hospitalizations that are captured by (i) the monthly hospitalization survey and (ii) the geofencing event survey. Source documents for hospitalizations will be obtained by the site coordinators or by Mayo's study coordinators (if they weren't already obtained by the site study coordinators).

and may improve the power of the primary study in an efficient and cost-effective manner and by reducing the burden of data collection on study coordinators.

The TAILOR-PCI Digital Study will explore several challenges digital studies face and is testing several unique and innovative operational approaches that could influence the extension of clinical trials. First, the collaboration between participating sites that help recruit patients to the digital study and a central coordinating center that conducts the study by directly interacting with and obtaining data from consented patients of those participating sites. Second, geofencing has been used to detect hospitalizations[11] but has not been compared to more conventional approaches used in trials such as study coordinator telephone visits to validate the approach. Traditionally, study coordinator telephone visits (or in-person visits) are made to all participants at regular intervals to ask participants if they have had medical encounters or hospitalizations. Medical records are then retrieved and used in conjunction with the patient recall of events in order to document hospitalizations. Depending on its performance, the use of geofencing may obviate the need to call all participants, and instead focus efforts on participants that have been detected to have hospitalizations.

In addition, the geofencing algorithm is also independent of patient recall of events. Currently, digital studies suffer from low engagement and high attrition rate.[19–22] By targeting motivated participants already participating in a trial, the TAILOR-PCI Digital Study could provide initial evidence for the ability of digital technology to consent and engage patients and captures reasons for nonenrollment which will inform future digital study design.

Several challenges are anticipated with transitioning TAILOR-PCI to a digital registry. First, the Digital Study was not embedded in the parent study design from the inception; therefore, participants have to be consented-separately. Second, approval for the digital study had to be obtained from IRB's of multiple participating sites, since patients recruited to the parent trial are de-identified and cannot be contacted directly by the clinical coordinating center. Navigating the IRB process was a significant challenge in the context of a single U.S. based coordinating center, with multiple, cross-border (U.S. and Canada) recruitment sites. For example, concerns (that were ultimately resolved by the fact that the IRB of record for the Digital Study was the Mayo IRB and not the actual site IRB) were raised by Canadian IRBs regarding data ownership and privacy across international borders. Third, digital studies are relatively new and not all study sites are familiar with participating in direct-to-participant digital studies. A study operation manual written by the digital coordinating center which outlines the process of generating the invitation material and states potential issues to assist participants with troubleshooting is essential for getting a digital study up and running. Fourth, the population enrolled in TAILOR-PCI is older[23] and their familiarity with and use of digital technology was unknown at the initiation of this study. Older age might not be an issue with engagement, as it was found to be associated with an increased retention in digital health studies.[24] Currently only 67% in the U.S. $\geq$ 60 years old own a smartphone,[25] a requirement for participation in this digital study. Fifth, the TAILOR-PCI IRB approval limited contact to 3 attempts with participants. Based on experience in other digital studies using the Eureka platform, the chances of consent increase with additional contact attempts with participants. Digital studies should aim for a more permissive communication strategy for engaging participants. Sixth, collecting GPS data for geofencing pushes the boundaries of personal privacy. While trial participants have previously agreed overwhelmingly to sharing health data contained in national databases with researchers,[26] their perception toward sharing data that might be perceived as more sensitive, such as location data, might not be as favorable.[27]

Conclusions

As we enter the new frontier where vast amounts of electronic health data can be collected for research using digital solutions, collaboration between participants, clinical centers, researchers, regulators, and ethicists is paramount. Within this context, the TAILOR-PCI Digital Study will (1) provide evidence for the feasibility of transitioning a clinical trial to a digital registry; (2) describe reasons for nonenrollment; (3) describe the digital engagement rate; and (4) determine the performance of geofencing to detect hospitalizations when compared with study coordinator telephone visits and medical record review. This innovative approach to digital study is consistent with the goals of the FDA which has mandated researchers to develop technology-enabled trials, and is especially pertinent in the COVID-19 era.[28]

Disclosure

None reported.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ahj.2020.10.069.

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