Mobilizing mHealth Innovation for Real-World Evidence Generation

Duke
MARGOLIS CENTER
for Health Policy

Executive Summary

Mobile health (mHealth) has the potential to enable progress in precision medicine and better evidence in health care. "Patient/consumer-facing" apps and wearables that collect patient-generated health data can provide a low-cost mechanism for gathering real-world, high frequency, and/or longitudinal data on measurable outcomes that people care about. As mHealth technologies are increasingly adopted for clinical use and in the consumer space, the data may be reused as part of real-world evidence generation. Such data reuse could also become an additional source of revenue for mHealth companies, beyond their value to payer or provider systems, for use in predictive analytics and improving quality of care. But despite some promising examples, the impact of mHealth on research is limited today. There is not yet a clear path for how mHealth technologies can reliably and efficiently elicit, validate, and transmit relevant data, and such data are currently not being collected on a sustained and longitudinal basis. Consequently, this is a crucial time for mHealth, with growing attention to overcoming the challenges of interoperability, common data elements, and data definitions in order to allow disparate data streams to combine to create actionable insights for improving or maintaining an individual's health and treating disease.

To accelerate the use of mHealth for research on medical treatments, the Duke-Margolis Center for Health Policy convened a working group of experts from throughout the healthcare and mHealth ecosystem to form a set of recommendations that will help:

- Create collaborations between the patient, clinical, and research communities as well as mHealth companies to advance the science on collecting and using mHealth data for evidence generation;
- Enable mobile health developers and companies to build their products on a strong standardized base in the pre-competitive space; and
- Ensure that users of patient/consumer-facing technologies understand and can more efficiently consent to how their data may be used, and are kept informed of research developments resulting from their data donations.

The working group made the following broad recommendations; below each is an example of a specific action step aimed at improving the collection and use of data for high-priority research and public health activities.

1. **Establish a Learning mHealth Research Community to advance the development and use of patient/consumer-facing mHealth technologies in evidence generation.**
   Publish initial priority list of areas where mHealth could have a large impact.
2. **Help mHealth companies save development time and increase marketability with a research-capable design that returns actionable insights to patients and/or consumers to encourage long-term use.**
   Use entities such as Open mHealth, Github, ResearchKit, ResearchStack, etc. that provide open source information on technology standards.
3. **Ensure efficient access to well-characterized, standardized, and robust user-generated health data.**
   Utilize continued development of standards through trade organizations such as the Consumer Technology Association's standards for physical activity and sleep monitors.
4. **Use mHealth technologies to communicate with study participants to provide meaningful and understandable feedback of study progress and research results.**
   Academic journals should allow researchers to send study participants any resulting articles for free.
5. **Use mHealth to promote easier participation in research through the awareness and adoption of standardized approaches for informed consent and patient privacy.**
   Adopt reusable mobile-ready frameworks such as the Eureka Research Platform, Hugo, and Sage's Participant-Centered Consent toolkit for enrollment and informed consent.

More action steps are listed in the main document. Following the Action Plan, there is an extensive series of appendices which are meant to serve as a resource guide of current efforts in each space.

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About the Duke-Margolis Center for Health Policy

The Duke-Robert J. Margolis, MD, Center for Health Policy, founded with a gift from Duke University School of Medicine alumnus Robert J. Margolis and his wife Lisa, connects the intellectual resources at Duke with policymakers and policy analysts in the public and private sector. Disciplines involved in the Duke-Robert J. Margolis, MD, Center for Health Policy will include business, biomedical research, clinical care, public policy, global health, law and other areas.

The Duke-Margolis Center has staff and offices in both Durham and at Duke's center in Washington, D.C. It has participation from faculty and staff at Fuqua, Sanford School of Public Policy, School of Medicine, School of Law and other units, and collaborates with experts and health care reformers from across the country and around the world. The center's activities include serving as a hub for translational policy research and analysis — that is, for supporting the movement of promising ideas in health reform into the implementation of effective policy.

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Abbreviations

AMA	American Medical Association
API	Application Programming Interface
CTTI	Clinical Trials Transformation Initiative
EHR	Electronic Health Record
ePRO	Electronic Patient-Reported Outcome
FDA	Food and Drug Administration
FTC	Federal Trade Commission
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
MDIC	Medical Device Innovation Consortium
mHealth	Mobile Health
NEST	National Evaluation System for health Technology
NESTcc	National Evaluation System for health Technology Coordinating Center
NIH	National Institutes of Health
ONC	Office of the National Coordinator for Health Information Technology
PCORI	Patient-Centered Outcomes Research Institute
RWD	Real-World Data
RWE	Real-World Evidence
SAE	Serious Adverse Event
SaMD	Software as a Medical Device
SDK	Software Development Kit
WEDI	Workgroup for Electronic Data Interchange

Icon Glossary


Action Step


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Introduction

Contribution of mHealth Data for Novel Real-World Evidence Generation

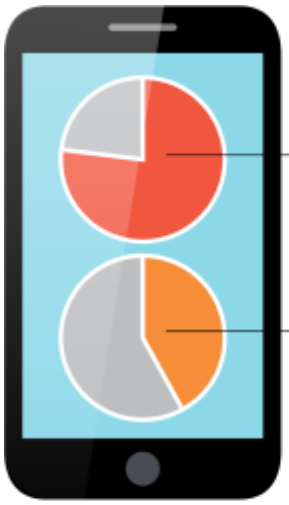
Given the current pace of technological change, there are incredible opportunities for advancements within the healthcare ecosystem. A learning healthcare system,[1] which is designed to continuously study and improve medical and patient care, requires a collaborative approach that iteratively shares data and resulting research insights across the entire healthcare ecosystem. However, real-world data (RWD)[a] are often incomplete or unavailable to clinicians, patients, and researchers, and the outcomes collected often are not those that matter most to people.

Mobile health (mHealth) apps and wearables, particularly those that collect patient- and consumer-generated health data, can fill some of these data gaps by providing real-world, more meaningful, high frequency, and/or longitudinal data. The recommendations in this Action Plan are focused on improving the ability to efficiently collect and use RWD from patient/consumer-facing mHealth apps and wearables that have been made for clinical purposes or consumer use, in order to reuse these data as part of real-world evidence (RWE[b]) generation for medical treatments and products.

[a] Real-world data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. This includes data from insurance claims, electronic health records (EHRs), registries, and patient-generated health data, as well as certain types of data collected in both interventional and observational studies.[2]

[b] Real-world evidence (RWE) is evidence derived from RWD through the application of research methods.[2]

This is a crucial time of growth for mHealth. Interoperability as well as common data elements (and tightly bound self-defining metadata) and definitions will be critical, as disparate data streams will increasingly need to be combined to create actionable insights for maintaining an individual's health and treating disease. The Duke-Margolis Center for Health Policy, under a cooperative agreement with the Center for Devices and Radiological Health at FDA, convened a working group of experts from throughout the healthcare and mHealth ecosystem. This working group has created a set of recommendations on how to promote efficient and ethical research-capable mHealth technologies, as well as support a broad range of research by connecting efforts from across research communities. Currently, many RWE efforts are hampered because most health data are collected in a healthcare setting and fail to adequately capture critical information from patients about their daily lives. Patient/consumer-facing mHealth tools create the ability to collect data before, during, and after they interact with the healthcare system. The National Evaluation System for health Technology (NEST) is an example of one such multi-stakeholder effort that could benefit from the ability to link mHealth data to other types of real-world health data in order to improve evaluations and surveillance of medical devices. As interest in using mobile phones and tools to support patients' and consumers' wellness and health grows, mHealth offers a unique opportunity to meet personal health needs while contributing to the public health.



According to the Pew Research Center:

77% of the overall population **and** **42%** of persons 65+ **in the United States owned an app-enabled mobile phone** *(2016 data)*[3]

Almost **two-thirds** of Americans **say they would use a mobile app to manage health-related issues** *(2015 data)*[4]

NEST

The National Evaluation System for health Technology (NEST) is envisioned as a voluntary network of data partners organized around a foundation of trust, transparency, and accountability. Stakeholders in the healthcare ecosystem will use data from the network to efficiently consolidate RWE to inform medical device evaluations and support regulatory decision-making for mutual benefit, by leveraging strategies such as standardized data-sharing agreements and pre-competitive frameworks for technological innovation.

The NEST Coordinating Center (NESTcc), established in September 2016, is run by the Medical Device Innovation Consortium (MDIC). The Coordinating Center is tasked with establishing organizational governance for NEST as well as developing shared resources to facilitate stakeholder alignment and collaboration.

Patient/Consumer-Facing mHealth Technologies and Data Types

The working group defined four categories of patient/consumer-facing mHealth data for this Action Plan — patient/consumer-reported data, task-based measures, active sensor data, and passive sensor data. These mHealth data types could be used individually or in combination for a broad range of research studies, each type with their own benefits and challenges. Best practice strategies for collecting and validating these four types of data are likely to be quite different, as will patient/consumer engagement techniques.

PATIENT/CONSUMER-REPORTED DATA

Data reported manually by the person themselves (or their caregiver if the person is unable to enter the data)

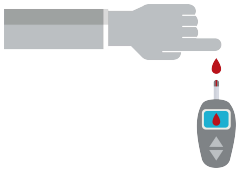
Patient/consumer-reported data may include responses to questionnaires, symptom and behavior tracking, or other means of collecting patient/consumer-reported outcomes. Historically, patient-reported data have been captured through paper-based and web-based surveys, phone calls, and so forth. However, such data can also be collected through mHealth apps/websites. These data could be used for, but are not limited to, validated outcome measures known as Patient-Reported Outcome (PRO) assessments. This could allow researchers to collect data more frequently and/or for a longer period of time. Current challenges include managing missing data and lack of formal validation of many PRO assessments for digital and/or mobile use.

TASK-BASED MEASURES

Objective measurement of a person's mental and/or physical ability to perform a test consisting of a defined task or set of tasks. Task-based measures require cooperation and motivation

Task-based measures may include physical (e.g., 6-minute walk test) or cognitive functioning (e.g., digit symbol substitution test) tests performed by the patient or consumer. Some of these measures historically are captured in a clinical setting with appropriate clinical or task procedure validation. Task-based measures can be collected through remote sensors and/or mobile apps which may utilize sensors within the smartphone. These measures require specific instructions to be given to the patient or consumer and confirmation that the task is performed as directed. Challenges include difficulty knowing if the right person took the test, if the procedure was done correctly, and accounting for differences between diverse wearables/apps/phones when analyzing the data.

ACTIVE SENSOR DATA



Measurement of a person's daily activities, mental state, or physiological status that requires an activation step (e.g., stepping on a scale, glucose self-measurement)

Active sensors require an activation step for a measurement to be taken. Active sensor data differ from task-based measures because the desired data are not related to the ability to perform the activation step. Active sensing at times will require specific metadata concerning the activation step (e.g., the start and stop time of the measurement, the precipitating event, etc.)

PASSIVE SENSOR DATA

Measurement of a person's daily activities, mental state, or physiological status that does not interrupt the person's normal activities (i.e., it measures what the person actually does in daily life)

Sensors such as wearable and remote sensors (both consumer-grade and FDA-approved/cleared), sensors on mobile devices, and tools that monitor behavior (e.g., analyses of changes in social media habits) can passively collect information about people's daily lives. This can include measures such as activity level, heart rate, and sleep patterns. Passive sensing has the benefit of being "invisible" because it does not require active interaction and therefore is less disruptive of normal routines. These data capture what the patient or consumer actually does, but may not show what they are capable of doing.

Intersection of Stakeholder Needs and Incentives

Patients and consumers using mHealth, mHealth companies, and researchers (as well as organizations sponsoring research) have intersecting and shared needs and incentives for advancing the use of patient/consumer-facing mHealth data in research (see Figure 1).

PATIENTS AND CONSUMERS

Patients and consumers want their mHealth devices to measurably improve their lives, provide something of value in return, or at least provide useful information about their health and wellness. Patients and consumers will not continue to use mHealth if the tools are cumbersome, hard to use, do not fit into their lifestyles, and/or do not give them information they need in a way that is usable to them. Patients and consumers also want to know and control with whom and for what reason their data will be shared. For many patients and consumers, they also want their doctors to be able to use their data to inform care and shared decision-making.

RESEARCHERS AND SPONSORS

Researchers and sponsors see the potential for mHealth technologies to collect data outside of the doctor's/investigator's office to improve research methods and insights. However, they face challenges finding the right platforms, technical integrations, tools, and methods to access and use mHealth tools appropriately. They need to understand how to characterize the reliability and consistency of different types of mHealth data to determine if it is fit-for-purpose (see Page 5) in research as well as ensure the data have been collected and handled ethically for research. Researchers also need to ensure that patients and consumers using mHealth tools will sustain use of the technology to ensure complete longitudinal data are collected.

mHEALTH COMPANIES

mHealth companies, and companies that have mHealth divisions, are looking for a competitive edge and economic models to engage new patients and consumers and sustain the long-term use of their products. The market is shifting from just returning data (e.g., number of steps) to transforming these data into useful information and valuable insights for both consumers and healthcare professionals (e.g., feedback in relation to health goals). In the past, companies often have not seen the value of making data from their devices available for research and had concerns about how these capabilities might affect their status in FDA regulations. However, clear incentives now exist for mHealth developers to build their devices and applications in a patient/consumer-friendly and research-capable way. They need clinical researchers to discover what actionable information their data can provide and behavioral researchers to help them understand how to build products that engage patients and consumers. There is also an emerging market for mHealth companies to work with researchers, insurance companies, and healthcare provider systems. However, the mHealth market is competitive and fast-paced. Any additions that slow time to market, increase regulatory exposure, or complicate marketability can be seen as disincentives to designing research-capable technologies.

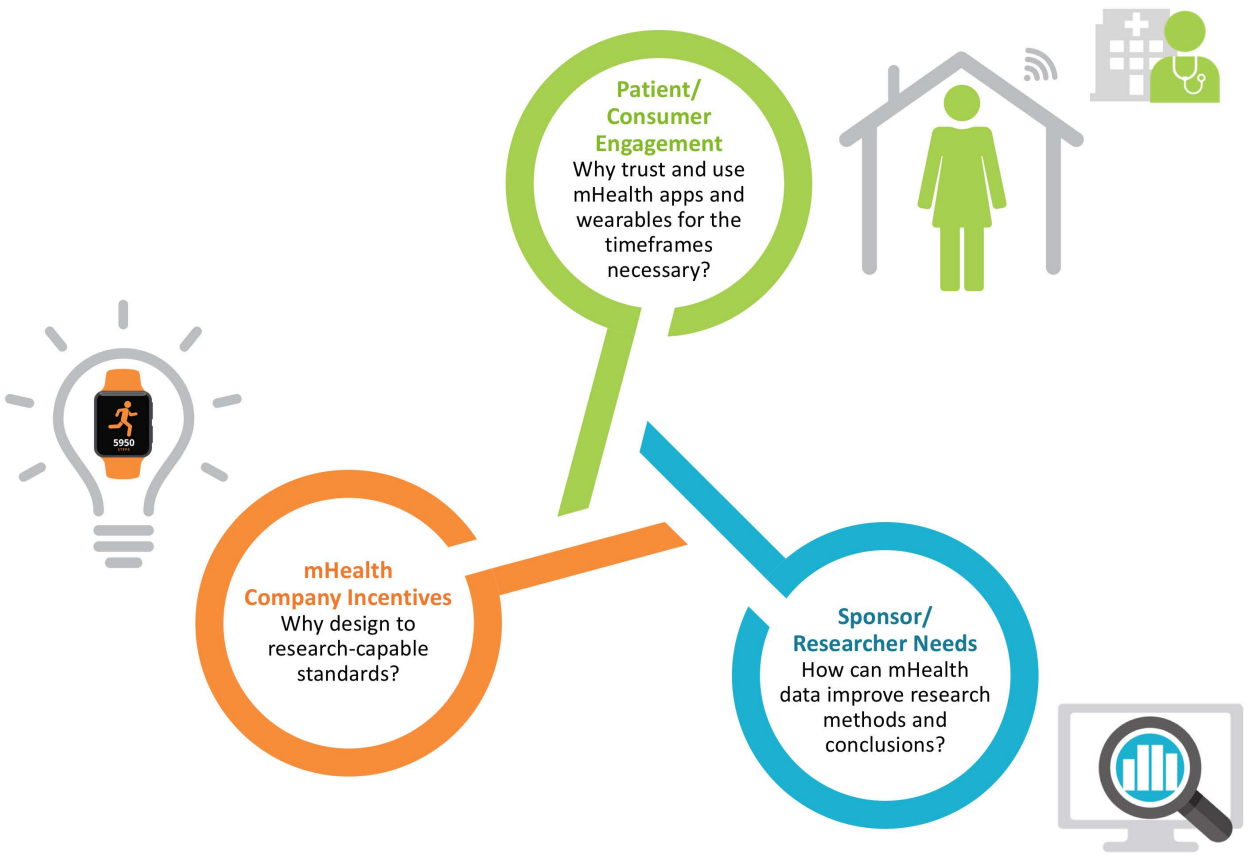
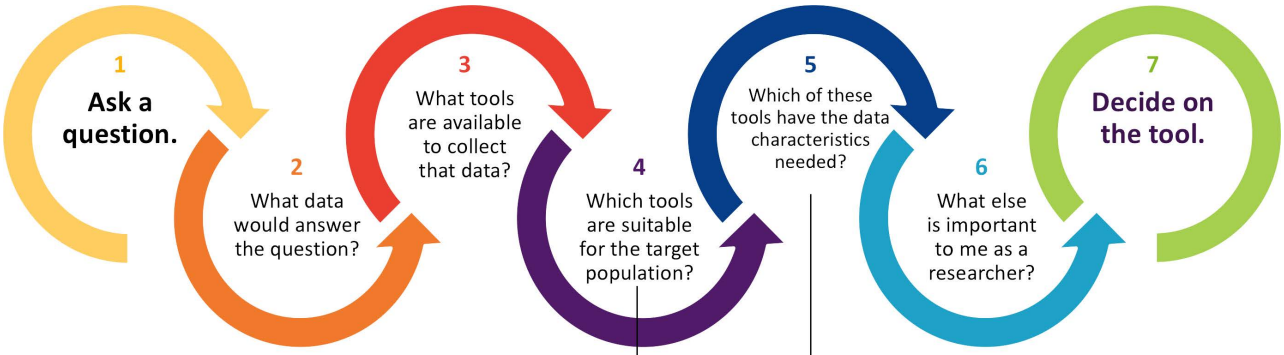


Figure 1. Intersection of Stakeholder Needs and Incentives.
Patients and consumers using mHealth, mHealth companies, and researchers have intersecting and shared needs and incentives for advancing the use of patient/consumer-facing mHealth data in research. Balancing these needs and incentives will be essential to producing mHealth data appropriate for research.

Determining Fit-for-Purpose

Determining if data from mHealth technology are "fit-for-purpose" is a critical requirement in choosing a tool to collect data. In this context, fit-for-purpose is defined as data from a specific mHealth tool that, within the stated context of use, comply with study requirements on accuracy/precision, and include the appropriate metadata needed to understand how to analyze the data.[5] It also means that the tool is suitable for use with the target population. Figure 2 shows the decision process that should be followed when choosing an mHealth tool in order to ensure the resulting measurements are fit-for-purpose.

There are a number of efforts currently underway to better characterize how mHealth data might be used in research. In some cases, mHealth data can be compared to an existing "gold standard." In other cases, the measurement may be only possible because of mHealth technology. For example, the Johns Hopkins EpiWatch ™ study has worked with THREAD to utilize apps on the iPhone and Apple Watch™ to enable patients to manage their epilepsy by tracking their medications, seizures, and possible triggers or side effects. Early results on nearly 600 participants are providing researchers with data on what was happening before a seizure struck.[6] The Clinical Trials Transformation Initiative (CTTI), a public-private partnership established by Duke University and FDA, is taking the first step towards novel endpoint optimization by developing recommendations and tools that address barriers to using such novel endpoints within clinical trials.



4. Understanding suitability for the population

Will the target population understand how to use it?

If necessary, how often will the tool need to be charged? Does the app use a lot of data and/or drain the battery?

What will the burden(s) be on the participant?

Could this approach to data collection endanger a participant's ability to get insurance?

5. Defining the characteristics of the data

Did my participant generate this data (i.e., identity management)?

Is the algorithm producing data today the same as yesterday (i.e., algorithmic stability)?

How will the data be captured, stored, and shared (e.g., reliability of data storage and transmission)?

How has the mHealth technology been tested (e.g., accuracy, precision, and calibration frequency)?

Has this technology already been validated for this purpose?

Figure 2. Fit-for-Purpose Decision Process.
This tool is a series of questions that researchers should ask as they are looking for an mHealth technology that will meet their research needs. Each step narrows the list of possibilities, so the final selection will be chosen from a set of "fit-for-purpose" options. Along the way, special attention must be paid to the appropriateness of the tool for the target population, what is known about the data quality, and how the mHealth tool collects, validates, and transmits data.

(Graphic informed by the ePRO Consortium's framework for the selection and evaluation of wearable devices)[7]

While this effort focused on mHealth specifically designed for clinical trials, many of the findings are relevant to consumer and/or clinical-use mHealth technologies. CTTI's recommendations include focusing on measures that are meaningful to patients, establishing industry-wide semantic, measurement, and interoperability standards, and encouraging sponsors to add mobile-technology-derived measures to existing studies and trials to determine overall utility.[8,9] Another important effort is the ePRO Consortium, which works to generate data and guidance focused on enhancing the quality, practicality, and acceptability of electronic capture of clinical trial endpoint data. They have produced multiple recommendations around best practices for electronic patient-reported outcomes (ePROs).[10]

As mHealth technology advances and more is learned about how to use data from these tools, researchers and mHealth companies could partner to create a "stepwise validation" process.[11] For example, a pivotal trial for a device may use mHealth data as an exploratory outcome (such as daily activity level as measured by a Fitbit Alta™). Positive correlation of the data with a widely used primary clinical outcome measure (such as the traditional six minute walk test) could support the validity of the use of the mHealth data as a secondary outcome in a subsequent pivotal trial of another device for a similar indicated population. If the positive correlation persists and it is deemed to be clinically appropriate, the mHealth data can be considered as one of the co-primary outcomes or a component of the composite primary outcome in subsequent pivotal studies for devices.

Recommendations

Recommendation 1. Establish a Learning mHealth Research Community

There are many efforts trying to understand how to effectively collect and use mHealth data, but there is still much to learn. We recommend that a collaborative group of mHealth stakeholders form a Learning mHealth Research Community[12] to advance the development and use of patient/consumer-facing mHealth technologies in evidence generation. The goal would be to create a centralized hub that collects relevant results and best practices from existing efforts, aligns behavioral science, informatics, and analytical methodologies for the continuous improvement of and innovation in mHealth research, and identifies and promotes areas where additional mHealth efforts would have the greatest impact.

POTENTIAL STAKEHOLDERS

- Advocacy and patient support communities
- Analytics tool companies
- Device, drug, and biologics industry
- Clinical societies
- mHealth companies
- Payers
- Providers and healthcare centers
- Regulators
- Researchers

ACTIVITIES

- Bring together the communities involved in mHealth and research
- Determine best practices for pre-competitive use
- Evaluate existing efforts and fill any gaps in the learning areas
- Publish lessons learned and knowledge gained
- Support learning and build community consensus
- Support demonstration projects

LEARNING AREAS

We recommend that the Learning mHealth Research Community establish four distinct learning areas (see Figure 3). These areas should rely on high-quality work produced by outside groups whenever possible — the goal is to augment and fill in gaps in existing capabilities, not duplicate them. Some groups already engaged in this work include the CTTI and ePRO Consortium work described earlier, as well as efforts like the Workgroup for Electronic Data Interchange (WEDI), which published recommendations for guidelines and compliance standards for mHealth companies developing mobile applications in 2013.[8] The recommendations covered diverse topics including patient engagement and data harmonization and exchange. Please see Appendix B for additional information on existing efforts, journal articles, and examples for each of the learning areas.

Each of these learning areas will then push their results to a dissemination and promotion group that will use this improved shared understanding to identify and promote high value opportunities where mHealth could make a significant difference in the assessment of patient outcomes.

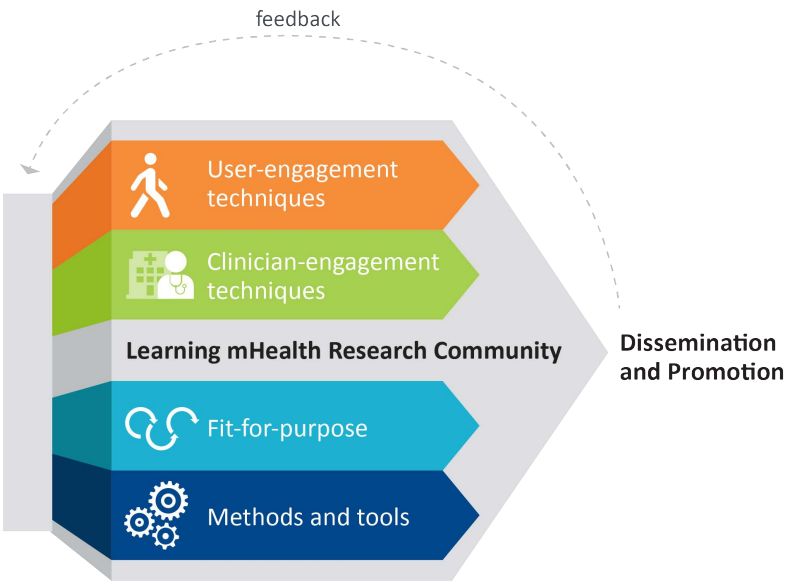


Figure 3. Proposed Structure of the Learning mHealth Research Community.
The Learning mHealth Research Community should consist of four learning areas, focused on patient/consumer engagement, clinician engagement, methods and tools for using mHealth data, and defining fit-for-purpose. These learning areas will consolidate information from existing efforts in this space and work to fill any gaps, and the Learning mHealth Research Community will need to be committed to synthesizing and disseminating information about where and how mHealth can have the most positive effect on health and value for researchers, patients/consumers, and other stakeholders.

Patient/Consumer Engagement Techniques

Behavioral research on patient/consumer engagement techniques

Research has shown the importance of mHealth design in initiating and maintaining use. Acceptance is often dependent on the characteristics of the population being targeted,[13] and the type of data (patient/consumer-reported, task-based measures, or active/passive sensing). Particular disease conditions may also affect behavior. However, many digital health applications and devices lack the necessary grounding in proven behavior and usability best practices.[14] The Learning mHealth Research Community should support regular landscape analyses of behavioral research approaches to determine best practices to support engagement in both the general population and in target subpopulations (e.g., people with rare diseases, children, the underserved, racial and ethnic minorities, and older populations)[15] for each type of data.

For example, Biogen and PatientsLikeMe gave activity trackers to 200 people with multiple sclerosis to monitor and manage their condition for a study.[16] Some used them as passive sensing devices, but others (after noticing personal patterns) used the devices to self-limit their activity in order to manage subsequent symptoms.[17] Sage Bionetworks analyzed nearly 3,000 participant responses to a daily prompt collected over six months within the Parkinson mPower app. Individual feedback suggested that engagement could decrease when people with a degenerative disease are confronted with symptoms they have not yet developed. Gamification may be a bonus for some people, but others didn't want their disease treated like a game.[18]

Payers and provider systems utilizing bundled payments may have special interest in increased patient/consumer engagement in mHealth made for clinical use. If their customers don't use mHealth tools in a sustainable way, they are unlikely to see returns on the investments made in mHealth.[19] As such, these systems may want to explore payment models that include measures on continued patient/consumer engagement. Potential funders that may have interest in supporting increased knowledge in patient/consumer engagement may include the drug and device industry, National Institutes of Health (NIH), Patient-Centered Outcomes Research Institute (PCORI), and groups such as the Robert Wood Johnson Foundation.

Clinician Engagement Techniques

Behavioral research on clinician engagement techniques

As discussed earlier, evidence suggests that many patients and consumers want their clinicians to value and incorporate their mHealth data to inform care decisions. This can increase patient/consumer engagement substantially. Most physicians say digital tools are advantageous to patient care, and the American Medical Association (AMA) recently voted to approve a list of principles supporting the use of mHealth technologies that are accurate, effective, safe, and secure.[20] However, physicians cannot effectively use these data yet because of both information overload and associated liability exposure. mHealth data must be presented in a useable format, preferably in a platform that can seamlessly integrate multiple sources of information for better decision-making.[21] User interfaces and form factors of digital devices also affect the quality of patient-physician interactions.[22] Better understanding is needed about how to effectively integrate mHealth into clinical workflows and define methods to store key data in EHRs. This learning area should identify best practices for mHealth clinical integration to support clinician-patient shared decisions and determine what specialties may be more receptive to mHealth integration. This learning area will likely overlap significantly with existing EHR and clinical workflow human factors research. Encouraging experts in these fields and potentially the Office of the National Coordinator for Health Information Technology (ONC) to participate in this learning area will be helpful.

Methods & Tools

Methods and tools for using mHealth data

Advances in data mining and predictive analytics allow researchers to use unstructured and varied data to predict important patient outcomes, such as cardiovascular events and seizures.[23] The Learning mHealth Research Community should identify the early adopters of these advanced methods and together pursue new methods that will optimize the integration of mHealth data in predictive models. Best practices are needed to minimize well-known mHealth study design and analysis issues such as reporting bias (specifically related to patient engagement techniques) and missing data. The rapid iteration of mHealth devices and data algorithms requires methods for dealing with lifecycle management of mHealth technology. Methods for determining and validating how mHealth data relate to clinical outcomes and conventional clinical measures are also needed. As with the patient/consumer engagement learning area, the best methods and tools are likely to differ significantly between the four data types. Establishing and maintaining a library of real-world evidence analytic methods, relevant data collection best practices, and lessons learned is critical to optimize future adoption of mHealth data in healthcare analytics. Current efforts in this space are listed in Appendix B3.

Fit-for-Purpose

Characteristics of data quality and fit-for-purpose

There is a wide range of variability in data from consumer technologies and therefore it is critical to consider when mHealth data are fit-for-purpose for specific research questions and study designs. This learning area should work with researchers and mHealth companies to clarify how to address these factors and identify groups already working on these issues. Data quality, the use of industry standard validations, and how the tool has previously been validated are key concerns when considering incorporating mHealth data into research. The "quality" of data needed for a particular type of study may vary widely. The relative importance of data characteristics such as missingness, accuracy, specificity, and reliability are affected by the specific research question being studied. This learning area should work to develop an overarching framework for methods of evaluating data quality from consumer and clinical-use mHealth technologies. The group should also define mHealth implementation methods that assure optimal and consistent data capture to support research integrity. Researchers would also benefit from comprehensive definitions of data quality measures and best practices based upon the intended use of the data. This learning area in particular should examine

and expand upon the existing efforts described in the earlier fit-for-purpose section and the efforts detailed in Appendix A.

DISSEMINATION AND PROMOTION

Learning in isolation only benefits a few. The Learning mHealth Research Community will need to be committed to synthesizing and disseminating information collected by the four learning areas. The Learning mHealth Research Community should identify and focus on priority areas where mHealth can have the most positive effect on health and value for different groups of patients and consumers, while remaining mindful to stay in the pre-competitive space. A common minimal set of standards for high-quality applications should be developed and publicized. Prioritization should be continuous and could be assisted by decision tools such as the one shown in Figure 4. Collaboration with the research community will help determine what measurements are most desirable. Registries and PCORnet could be early high-value opportunities where mHealth data could be included. Health insurers may be interested in promising examples of bundled or value-based payment models that utilize mHealth. Likely therapeutic areas include diabetes, cardiology, and orthopedics, which are areas where real-world evidence is already well accepted and there are already clinical-grade wearables and FDA-cleared/approved devices that record patient-generated data. Another area which

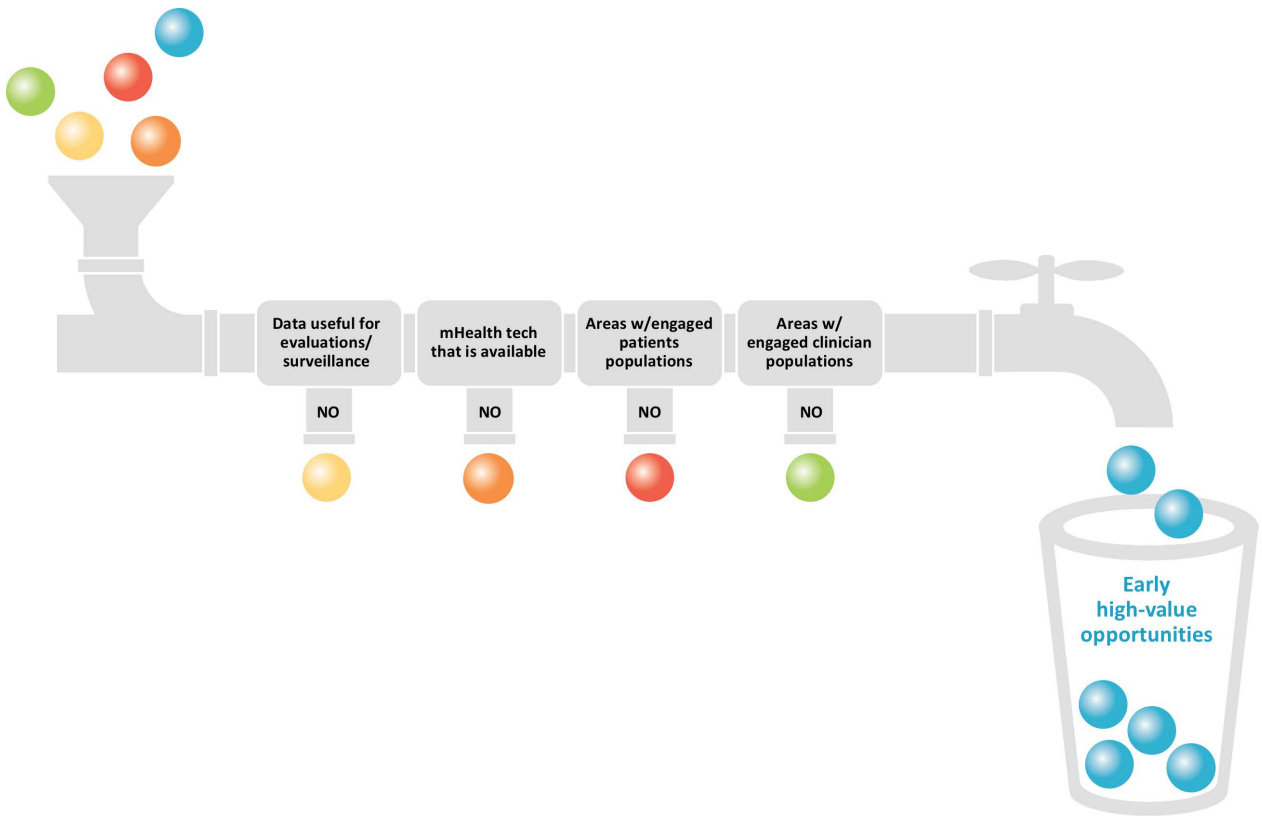
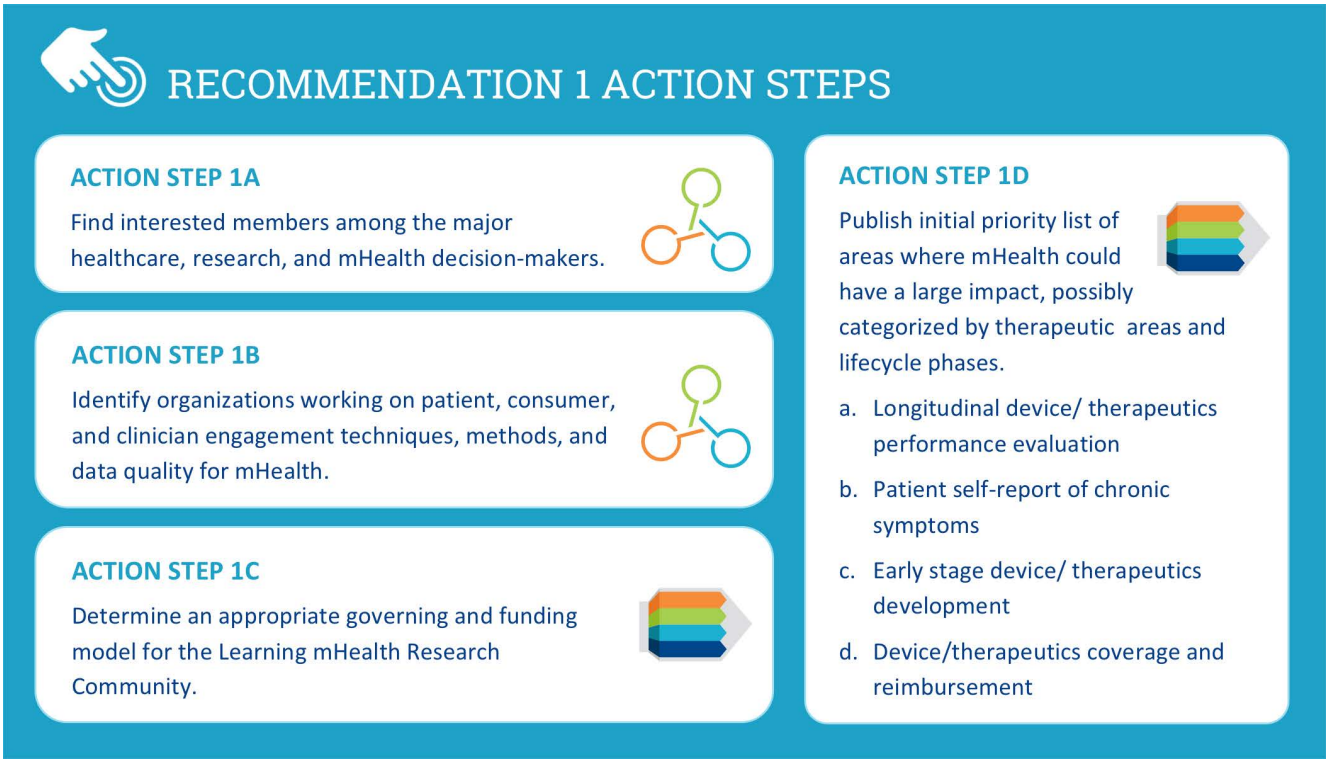


Figure 4. Evaluating and Prioritizing High-Value Opportunities for Promotion.
In a continuous process as the community grows and learns, high-value opportunities where mHealth could make a difference in patient outcomes will need to be identified. This figure portrays a method for systematic evaluation and prioritization of opportunities within the mHealth ecosystem. This method emphasizes finding opportunities where specific mHealth data would be useful for medical product evaluations and surveillance, mHealth tools to collect these data already exist, and in therapeutic areas with engaged patient and clinician populations that can see the value of mHealth. The Learning mHealth Research Community should then align its promotion and dissemination activity with these high-value opportunities.

could have utility to a broad number of stakeholders would be identifying mHealth tools that have the ability to detect and collect information on serious adverse events (SAEs).



Recommendation 2. Help mHealth companies save development time and increase marketability with a research-capable design

Interoperability, standardization, and regulatory compliance are essential for efficient sharing and use of mHealth data for secondary purposes, such as research. However, entrepreneurs in the pre-competitive space don't always realize they can leverage existing open source frameworks and standards (e.g., application programming interfaces (APIs) and software development kits (SDKs)) to save development time and enable efficient interoperability with other platforms, without compromising their intellectual property. Early-stage mHealth companies also can have difficulty understanding the complex relationship between their particular business model and the relevant legal and regulatory constraints. The information is available, but it is fragmented and often generalized.

A continuously updated implementation guide of pre-competitive information could help mHealth companies understand how to comply with interoperability standards as well as regulatory requirements. We propose that the guide be divided into different business models to show only the relevant information (see Appendix C for an illustrative example). To ensure that this guide will complement and increase the impact of other work in this area, hyperlinks to original source material should be used whenever possible (see Figure 5). It should include a layperson's guide to regulatory requirements, including a clear explanation of the laws surrounding health data privacy. Libraries of standardized medical term definitions, patient-reported outcome measures, performance measures, and other types of clinical outcome assessments should also be included. The Learning mHealth Research Community, described in the previous section, can be an important partner for updating priority needs and relevant libraries.

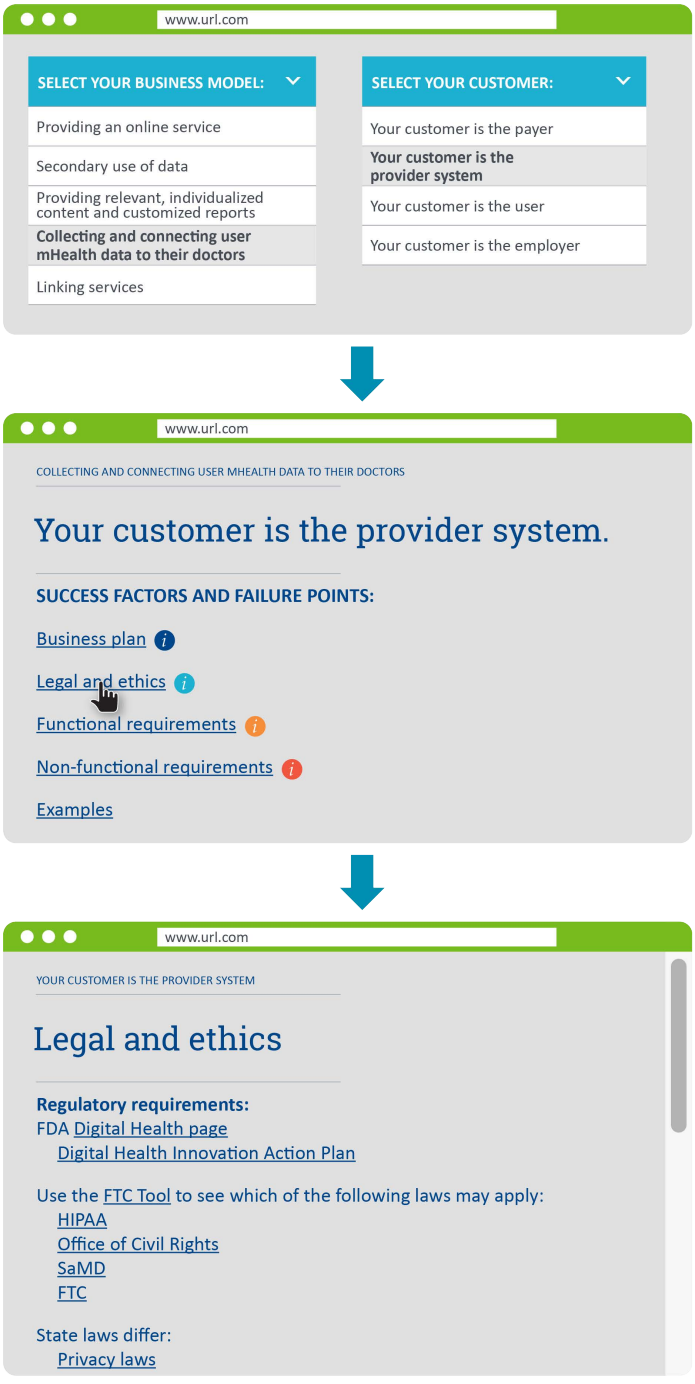


Figure 5. Foundational Knowledge Guide for mHealth Companies.
This online guide will serve as a centralized and continuously-updated source of pre-competitive information on the success factors and failure points for new mHealth developers and companies. The purpose of maintaining this guide will be to encourage standardization in the pre-competitive space and research-capable design that conforms to legal and ethical requirements. Information will be customized by business model, and organized into five categories: business plan essentials, legal and ethical requirements, functional requirements, non-functional requirements, and examples. The guide will link to appropriate external sources of information whenever possible. A detailed example of the type of information that could be provided can be found in Appendix C.

RECOMMENDATION 2 ACTION STEPS

ACTION STEP 2A

a. Promote and use entities such as Open mHealth, Github, ResearchKit/ ResearchStack, etc. that already provide open source information on technology standards such as APIs and SDKs.

b. Encourage those entities to promote submission of and highlight interoperability standards for apps with patient/consumer-reported data.

ACTION STEP 2C

HOW TO

a. Develop a sustainability plan for maintenance of the guide. Potential funding opportunities include pre-competitive consortiums (similar to MDIC), companies that specialize in consulting services for mHealth companies, advertising revenue, or being "adopted" into an existing project.

b. Set out the guiding principles needed to be an honest intermediary/catalyst.

ACTION STEP 2B

Form a planning group including the relevant stakeholders around sustainability and objectivity, as well as a diverse set of thought leaders.

ACTION STEP 2D

HOW TO

Start to define and prioritize the ecosystem of business models and implementation categories that will be included in the implementation guide.

Recommendation 3. Ensure efficient access to well-characterized, standardized, and robust patient/consumer-generated health data

While patient/consumer-generated mHealth data from apps and wearables are plentiful, uniform data capture, analysis, and transmission of that data can be challenging. Large volumes of patient/consumer-generated health data may exceed or overwhelm analysis capacity and have a negative effect on productivity. Moreover, the potential existence of inaccurate or inconsistent patient/consumer-generated health data could result in erroneous information that may adversely affect treatment. This lack of information integrity poses a clear risk to the quality of care, however mHealth information has the potential to provide better analytics and personalized outcomes for patients.[24]

RECOMMENDATION 3 ACTION STEPS

ACTION STEP 3A

a. Utilize and encourage continued development of standards through trade organizations, such as the Consumer Technology Association's standards for physical activity and sleep monitors.

b. Increase standardization of the structure and transmission of data by using and contributing schemas and APIs to Open mHealth, Xcertia, and similar frameworks and libraries.

ACTION STEP 3B

Funders should support, promote, and integrate the use of behavioral research and patient/consumer-centered design into development/adaptation of mHealth technologies targeting diverse populations to understand what value people find in day-to-day use (e.g., healthy, chronic conditions, acute recovery, older vs. younger).

ACTION STEP 3C

Patient groups should partner with researchers to learn how their populations may react differently to patient engagement techniques compared to the general population.

Recommendation 4. Use mHealth technologies to communicate with study participants to provide meaningful and understandable feedback of study progress and research results

It is rare for participants to receive information back from clinical studies in which they've participated. This one-sided relationship is not sustainable long-term, particularly for virtual studies where participants don't regularly speak with study coordinators. However, mHealth apps and devices provide researchers with a unique engagement and communication tool to engage with participants. Researchers can promote sustained engagement in research by learning how to communicate more effectively with participants. This could include periodic acknowledgment that the participant's data have been received, providing information on the progress of the study, and sending a meaningful and understandable explanation of the study results.

RECOMMENDATION 4 ACTION STEPS

ACTION STEP 4A

Individual researchers should start to send general progress information to participants. This could include acknowledging the receipt of data, touting study milestones such as conclusion of recruitment, and sharing information such as study demographics that may be interesting to the participant, but pose minimal risk to both the participants and the study.

ACTION STEP 4B

Funders and regulators should expect researchers to provide a plan to communicate with their study participants in an understandable and appropriate way, utilizing best practices.

ACTION STEP 4C

a. Academic journals should require a written dissemination plan to send information and results to study participants. This should be included in the methods section.

b. Academic journals should allow researchers to send study participants any resulting journal articles free of charge.

Recommendation 5. Use mHealth to promote easier participation in research through the awareness and adoption of standardized approaches for informed consent and patient privacy

mHealth can and should help patients and consumers have control over what health information is collected and shared with external parties, and under what circumstances. For research, the interactive nature and multimedia capabilities of mobile apps provide clear advantages over the standard process of obtaining informed consent.[25] App-based engagement methods could include interactive questionnaires to assist participant self-assessment or assess understanding, graphics and animation, explanatory audio and video clips, as well as links to additional, external information. This may have the advantage of shortening recruitment, due to decreasing the time per participant required from study coordinators, allowing studies to be completed faster, and potentially help in recruiting more diverse populations.

RECOMMENDATION 5 ACTION STEPS

ACTION STEP 5A

Adopt and share reusable mobile-ready frameworks such as the Eureka Research Platform, Hugo, and Sage's Participant-Centered Consent (PCC) toolkit for enrollment and informed consent.

ACTION STEP 5B

Regulatory agencies should explore incorporating appropriate guidelines for risk-based consent.

ACTION STEP 5C

Provide a clear explanation on what information is collected and shared with external parties, and under what circumstances. ONC's Model Privacy Notice and PatientsLikeMe's Privacy Policy are both good examples of this. Whenever possible, allow patients/consumers the ability to opt in and out of data sharing.

a. Identify current examples and opportunities (see Appendix D).
b. Explore ways to help understand why patients/consumers opt out of sharing.

Broad Challenges in Digital Health

Many of the obstacles that mHealth faces are also issues in the broader digital health field. In these areas, the mHealth community should work with the overall digital community to find solutions. Some of these broader challenges include, but are not limited to, data linkages and interoperability across platforms and with EHRs, cybersecurity, patient/consumer consent for data usage and sharing, and usability of health information technology (HIT). To effectively share digital health data there is a need for a widely adopted standardized framework for EHR interoperability as well as mHealth data sharing and aggregation across proprietary platforms. Cybersecurity is also key to cultivating engagement and trust within the digital health realm. Security, privacy protections, encryption, risk identification, and risk management are all necessary to long-term success. Finally, current informed consent forms fail to balance patient autonomy and privacy to productively promote longitudinal research, especially within emerging fields such as telemedicine.

Standardized consent frameworks for RWD collection and clinical trials are needed. We have listed resources for each of these issues in Appendix E. In order to make a real and lasting impact, the digital health revolution must continue to evolve and overcome these barriers.

Conclusion

This is an exciting time given the abundance of opportunities to use mHealth to support research and evidence generation. The development of novel outcomes and data collected in real time on the activities of daily life have the potential to evaluate outcomes that truly matter to patients. In particular, real-world evidence generation will be greatly enhanced by inclusion of data from apps and wearables to complement existing data sources. Mobile health apps and wearables can help fill data gaps by providing a wealth of real-time, high frequency, and longitudinal data.

The working group believes the recommendations and action steps outlined throughout this Action Plan can promote immediate use and support continued development of innovative, effective mHealth apps and wearables capable of collecting data appropriate for research. Two of the key recommendations in this plan will require collaboration. To establish the Learning mHealth Research Community, key leaders will need to be identified and an appropriate governing and funding structure will need to be developed. Organizations already working in the learning area spaces will need to be identified, and it is hoped that the resources in the included appendices will be a first step. There is general agreement that interoperability, standardization, and regulatory compliance are essential for efficient sharing and use of mHealth data for secondary research. Information exists, but consolidating the information that new mHealth developers will need to know in order to build research-capable products will shorten development times. Like the Learning mHealth Research Community, a planning group of key opinion leaders will be needed to select the appropriate host and develop a sustainability plan. In the meantime, leaders in the field should promote and contribute to open source technology standards.

Other recommendations can be followed by individual stakeholders, making research more efficient and ethical. Researchers need information about mHealth products and how to determine if these products are appropriate for specific target populations. Patient groups should help with this effort. Mobile health companies need to be more rigorous in determining the appropriate engagement strategies for their products by integrating behavioral research into their designs. Researchers should take advantage of the communication that can be enabled by mHealth technologies to improve informed consent, recruitment, and bi-directional communication with study participants. Funders, regulators, and academic journals should encourage and help researchers to do this. If stakeholders in the mHealth space can successfully address these challenges, lessons learned may also help solve challenges in the larger digital health arena.

Mobile health data for novel real-world evidence generation have the potential to transform healthcare. The steps described here can help harness the power of mHealth to achieve this transformation while balancing the needs of the patient/consumer, researchers, and the mHealth companies in a responsible, ethical, and empowering way.

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Appendix A: Determining Fit-for-Purpose

EXISTING EFFORTS

Critical Path Institute's Study Endpoint Considerations

- Provides an overview for endpoint measure qualifications and for when a PRO (patient-reported outcome) instrument is fit-for-purpose
- Guidance explains how FDA evaluates PRO measures for usefulness in characterizing treatment benefits as perceived by patient

CTTI's Official Recommendations for Developing Novel Endpoints Generated by Mobile Technology for Use in Clinical Trials

- CTTI has created a "Flowchart of Steps" of the iterative process and a "Detailed Steps Tool" that outlines possible approaches to completing those steps

FDA's Clinical Outcome Assessment (COA) Qualification Program

- Provides a roadmap to patient-focused outcome measurement in clinical trials
- Defines the four types of COA measures: patient-reported outcome (PRO), clinician-reported outcome (ClinRO), observer-reported outcome (ObsRO), and performance outcome (PerfO)

FDA's Medical Device Development Tools (MDDT)

- Guidance of tools that medical device sponsors can use in the development and evaluation of medical devices

LeadingAge CAST's Functional Assessment and Activity Monitoring Technology Selection Tool

- Comprehensive portfolio of resources that gives tools to providers to help them understand, plan for, select, implement, and adopt appropriate technology for innovative care models
- Tools include a selection guide, interactive guide, activity monitoring selection tool, activity monitoring selection matrix, and case studies

Xcertia mHealth App Guidelines

- Comprehensive effort to develop a framework of principles and guidelines to support consumer and clinician choice of mobile health apps
- Will incorporate feedback from members to advance knowledge around quality of clinical content, usability for consumers and health care professionals, privacy, security, interoperability, and evidence of clinical efficacy
- Involves the American Medical Association (AMA), DHX Group, American Heart Association, and HIMSS

CURRENT EXAMPLES

CTTI's Use Cases

- Provides four use cases to explore the development of novel endpoints using mobile technology for:
  - Diabetes Mellitus
  - Duchenne Muscular Dystrophy
  - Heart Failure
  - Parkinson's Disease

UCSF's Center for Digital Health Innovation

- Validation of technology solutions by evaluating usability, adoptability, and impact on clinical and educational outcomes
- Focused on interoperability and offers APIs, data analytics and storage, data and device interface standardization, EHR integration opportunities, and security/privacy services

ARTICLES & GUIDANCE	**Framework To Guide The Collection and Use of Patient-Reported Outcome Measures In The Learning Healthcare System** • Identified diverse clinical, quality, and research settings where patient-reported outcome measures (PROM) have been successfully integrated into care, routinely collected, and implemented • Describes implementation framework and steps that are best practices to guiding PROM capture and use **The Wild Wild West: A Framework to Integrate mHealth Software Applications and Wearables to Support Physical Activity Assessment, Counseling and Interventions for Cardiovascular Disease Risk Reduction** • Reviews the validity, utility, and feasibility of implementing mHealth technology in clinical settings and proposes an organizational framework for cardiovascular disease risk reduction interventions **Using mHealth App to Support Treatment Decision-Making for Knee Arthritis: Patient Perspective** • Conducted patient focus groups and clinician interviews to gather requirements and expectations for mHealth app development

Appendix B: Recommendation 1. Establish a Learning mHealth Research Community

Appendix B1: Patient/Consumer Engagement

EXISTING EFFORTS

BJ Fogg's Behavior Model

- Guide for designers to identify what stops people from performing behaviors that they seek

HIMSS' mHealth App Essentials

- Outlines keys to patient engagement, considerations, and implementation

CURRENT EXAMPLES

MedHelp & GE Healthymagination's I'm Expecting Pregnancy App

- Allows people to enter data about pregnancy, get useful information back, and crowdsource symptoms

monARC Bionetworks' Patient Research Network

- Members with Idiopathic Pulmonary Fibrosis (IPF) and of the Patient Research Network (PRN) can donate data to researchers and pre-qualify for clinical trials by downloading the IPF OneVue mobile app as well as consolidating medical records into Smart Health Record

Pfizer's Hemocraft Game, HemMobile® App, and HemMobile Striiv® Wearable

- Hemocraft, created in partnership with Drexel University and representatives from the hemophilia community, aims to help individuals, ages 8 to 16, to learn the importance of integrating treatment into their daily routine by utilizing gamification
- HemMobile Striiv Wearable is a wrist-worn device that tracks daily activity levels and monitors heart rate to measure intensity
- Wearable integration with the HemMobile® app allows users to log symptoms, monitors factor supply, and sets appointment reminders

ARTICLES & GUIDANCE

An Evaluation of Mobile Health Application Tools

- Nine categories of engagement for mHealth apps: changing personal environment, facilitating social support, goal setting, progress tracking, reinforcement tracking, self-monitoring, social presentation, social referencing, and other

Controlling Your "App"etite: How Diet and Nutrition-Related Mobile Apps Lead to Behavior Change

- Shows how apps can increase knowledge, improve dietary behavior, and lead to an enhanced benefits

eHealth for Patient Engagement: A Systematic Review

- Patient engagement outcomes are assessed and considered in eHealth interventions
- Outlines three dimensions (behavioral, cognitive, emotional) of patient engagement experience that are addressed by eHealth interventions

How Do Apps Work? An Analysis of Physical Activity App Users' Perceptions of Behavior Change Mechanisms

- Demonstrates that those who pay for apps may be more dedicated to using them due to financial investment or existing dedication to physical activity

Appendix B2: Clinician Engagement

EXISTING EFFORTS

UMMC's Remote Patient Monitoring

- Remote, far-reaching, and effective chronic care management delivered through a tablet computer
- Overall adherence is over 80%, diabetic medication compliance is over 90%
- Designed to be scalable

Xcertia mHealth App Guidelines

- Comprehensive effort to develop a framework of principles and guidelines to support consumer and clinician choice of mobile health apps
- Will incorporate feedback from members to advance knowledge around quality of clinical content, usability for consumers and health care professionals, privacy, security, interoperability, and evidence of clinical efficacy
- Involves the American Medical Association (AMA), DHX Group, American Heart Association, and HIMSS

CURRENT EXAMPLES

Validic

- A platform that scales, customizes, and integrates into provider system, linking external patient-generated data
- Delivers actionable, meaningful data to clinicians
- Provides analyses of system-level population health

WellDoc

- FDA 510k-cleared digital therapy that coaches adults with type 2 diabetes to self-manage their condition
- App that provides daily lifestyle support for people with diabetes

Wellframe

- Mobile platform that connects patient-facing, HIPAA compliant, proprietary mobile app to a care management dashboard
- Keeps users on track by delivering personalized programs directly to user's phone or tablet (could be as simple as a checklist)

ARTICLES & GUIDANCE

The Motivating Function of Healthcare Professional in eHealth and mHealth Interventions for Type 2 Diabetes Patients and the Mediating Role of Patient Engagement

- Cross-sectional study that demonstrates the role of the perceived ability of healthcare professionals to motivate a patient's initiative in improving the level of their engagement and activation in type 2 diabetes self-management

User's Guide to Integrating Patient-Reported Outcomes in Electronic Health Records

- Expands upon eleven key questions for integrating PROs into EHRs by outlining strategy, governance, engagement and training, outcomes, ethical issues, and so forth

Web-based Comparative Patient-Reported Outcome Feedback to Support Quality Improvement and Comparative Effectiveness Research in Total Joint Replacement

- Developed surgeon-specific comparative PRO reports based on user input for content, data elements, integration, and display

Appendix B3: Methods & Tools

EXISTING EFFORTS

A Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records

- Collaboration between Patient-Centered Outcomes Research Institute (PCORI) and the International Society for Quality of Life Research (ISOQOL)

BEST (Biomarkers, EndpointS, and other Tools) Resource

- Published by The FDA-NIH Biomarker Working Group, a collaboration of representatives from multiple FDA Centers and NIH Institutes in 2016
- Harmonizes terms and definitions and addresses nuances of usage and interpretation among various stakeholders.
- Includes examples of the various categories of biomarkers and their applications, and distinguishes between biomarkers and clinical assessments.

ePro Consortium's Best Practices for Migrating Existing Patient-Reported Outcome Instruments to a New Data Collection Mode

- Addresses issues that need to be considered when moving existing PRO instruments to available data collection mode (e.g., paper, interactive voice response system, tablet, web, handheld)

MD2K's Center for Excellence for Mobile Sensor Data-to-Knowledge

- Developing tools to make it easier to gather, analyze, and interpret health data generated by mobile and wearable sensors
- Goal is to reliably quantify physical, biological, behavioral, social, and environmental factors that contribute to health and disease risk
- Brings together researchers from twelve top universities and Open mHealth

MDEpiNet Methodology Center

- Develops and applies novel statistical and epidemiological methods to monitor the safety and effectiveness of medical devices
- Develops a set of methods to continuously evaluate pre- and post-market device data
- Located in the Department of Health Care Policy at Harvard Medical School

ONC's Policy Framework for Capture, Use, and Sharing of Patient-Generated Health Data

- ONC and Accenture project funded by the Patient-Centered Outcomes Research Trust Fund to develop a policy framework for the capture, use, and sharing of patient-generated health data in care delivery and research through 2024

Registries for Evaluating Patient Outcomes: A User's Guide (3rd edition)

- Intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes
- Developed by the Agency for Healthcare Research and Quality

CURRENT EXAMPLES

Children's Hospital of Wisconsin's Adoption of Key Process Analysis Application

- Application enabled neonatology group to dive deep into data and isolate certain conditions where there was variation in care versus variation inherent to patients they were taking care of
- Physicians were able to go through and validate data themselves
- Combines easy-to-understand dashboards with clinical, billing, and costing data

Evidation Health's Technology Platform

- Enables healthcare companies to partner with patients and consumers who are engaged in understanding and improving health outcomes
- Leverages digitally captured data sets as part of clinical trials and outcomes data collection

North Memorial Healthcare's Adoption of an Enterprise Data Warehouse (EDW)

- Visualization capabilities that allow and enable physicians to see how their care decisions affect length of hospital stay
- Discovered that it is easier to convince physicians to make needed changes by showing this data

Roche App Measures Parkinson's Disease Fluctuations

- Incorporates device in early stage of drug development program
- "This could be the first time that such an app has been used to measure disease and symptom severity in a medicine development program in Parkinson's disease"

THREAD Research

- Unified technology platform enabling remote patient research studies to be designed, launched, and managed
- Utilized by biopharmaceutical companies, academic researchers, and other research organizations to launch patient-facing mobile apps, research site portals, sponsor site portals, and HIPAA/21CFR Part 11 compliant cloud database
- Provides the technology, workshops, and processes needed to conduct mHealth studies supporting all key stakeholders

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ARTICLES & GUIDANCE

Beyond the Randomized Controlled Trial: A Review of Alternatives in mHealth Clinical Trial Methods

- Review on the methodology of mHealth studies: types of intervention, target groups, duration, and so forth

Clinical Validation of Heart Rate Apps: Mixed-Methods Evaluation Study

- Investigates and describes the necessary elements involved in validating and comparing heart rate (HR) apps against standard technology

Designing and Conducting Health Surveys

- Draws on recent methodological research on survey design and insights or implications provided by cognitive research on question and questionnaire design

Digital Biomarkers

- Multi-disciplinary journal spanning computer science, engineering, and bioinformatics' efforts aimed at improving health

Patient-Perspective Value Framework

- New way to assess the value of healthcare services by considering factors that matter to patients and weighing them in accordance with assessed patient preferences
- Comprised of five domains: patient preferences, patient centered outcomes, patient and family costs, usability, transparency, and quality and application of evidence

Rethinking Clinical Trials®: A Living Textbook of Pragmatic Clinical Trials

- Collection of expert consensus regarding special considerations, standards approaches, and best practices for pragmatic clinical trials from the NIH Health Care Systems Research Collaboratory
- Will continue to be added to and updated as a living textbook

SIS.NET: A Randomized Controlled Trial Evaluating a Web-Based System for Symptom Management After Treatment of Breast Cancer

- Explored novel methods of using PROs to potentially improve the quality and efficiency of follow-up care in patients with breast cancer

Patient-Reported Outcomes in Performance Measurement

- Good introduction to basic concepts about PROs and their role in performance outcome measurement

The mPower Study, Parkinson Disease Mobile Data Collected Using ResearchKit

- Clinical observational study about Parkinson disease conducted purely through an iPhone app interface

FDA Guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

- Explains the characteristics and sources of RWD and RWE that may be sufficient in making regulatory decisions for medical devices

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Appendix B4: Fit-for-purpose

Please refer to Appendix A.

Appendix C: Example of the Implementation Guide

This is an example of the type of information that might be found in the implementation guide for a technology that is designed to collect and connect patient mHealth data to their doctors, with the expectation that the customer will be a provider system. Note that the information is a combination of advice and useful links to external sources. When possible, this guide should also include examples of both successful implementations and early failures.

Business Plan

Define your product	• Think strategically
	• What is the product's purpose?
	• What is needed right now?
	  – Workflow improvement
	  – Relating data to outcomes
	• Don't build the "me-too" device — how is your product different?
	• Is your product a "nice to have" or a "must"?
	• Are you using BYOD design or device provisioning?
	• Can you show proof of efficiency?

What is the ROI for your customers?	• Does your product save money for your customer? • Does your product save time for your customer? • Does your product help improve your customer's product quality? • Does product help to increase revenue for your customer?
Do you have a plan to survive until your product makes money?	• Provider systems have long sale cycles • It is difficult to enter the largest systems
Have a game plan for strategic partnerships	• Particularly in the healthcare space, it is critical that that you have a broad array of expertise available – Convergence of exponential technologies • You need to know what you don't know

Legal, Regulatory, and Ethics

Regulatory requirements — depends on where you want to roll out first	• FDA Digital Health page
	  – Digital Health Innovation Action Plan
	• Use the FTC Tool to see which of the following laws may apply
	  – HIPAA
	  – Office for Civil Rights
	  – SaMD
	  – FTC (both unfair/deceptive practices and health data breach regulations)
	• State laws differ
	  – Privacy laws
	  – Telemedicine regulations
	  – Forthcoming CTTI recommendations and tools on Mobile Devices (expected February 2018)
	• International Medical Device Regulators Forum
	  – International SaMD guidance

Ethical requirements	• Privacy notices on sharing information
	  – ONC's Model Privacy Notice (MPN)
	  – Using clear and simple language (e.g., PatientsLikeMe)
	• Privacy by Design by Ann Cavoukian

Customer requirements	• Does your customer require additional protections for: – Privacy? – Storage? – Transfer? • Encryption and authentication standards • Federal customers are subject to FISMA • Xcertia
Research requirements	• Will your customer potentially want to use your data in research? – Quality improvement studies – Comparative effectiveness – Clinical research • Incorporating informed consent into your product: – IRB committees – Sage Bionetworks PCC toolkit – eConsent – PALM registry's informed consent – Electronic informed consent • HIPAA privacy controls apply to all research
Protection of intellectual property (IP)	• Different forms of intellectual property to be considered • IP can obstruct innovation • You will need an IP attorney – Expertise on what needs close scrutiny – Often comes with VC money • Execution is more important • Memorialize your prior art

Functional Requirements

Usability, user design, and user experience	• Identify the people who need to want to use your product (users) – Provider system C-suite – Clinicians – Patients • What can the user do and how easy is it for the user to do it? – Different for different categories of users
Sustained engagement	• Understand motivational science – BJ Fogg's Behavior Model • Return insights, not just data (or connect to a platform that can) for each category of user identified above • What are the requirements for long-term maintenance of the software? • Ability to collect longitudinal data
Validity	• Forthcoming CTTI recommendations and tools on Mobile Devices (expected February 2018)

Non-Functional Requirements

Storing user data **– Privacy** **– Security** **– Storage optimization and redundancy**	• mHealth developed specifically for clinical use generally falls under HIPAA • Storage is a design decision that must balance performance with security – Redundancy increases performance, improving accessibility, and decreasing the chance of losing critical data. But the more places you store data, the more places you need to protect from intrusion – Providers may not allow storage in servers abroad
Cybersecurity	• FDA's Cybersecurity • Blockchain • Post-Blockchain services
Scalability, supportability, and performance	• Understand your bandwidth and latency • Do you want to bring the analytics to the data? – Human factors issues with timing *People have set expectations about how long it should take for their data to display* • Where is the data being stored? – MITRE White Paper – Cloud-based, autonomous, edge-based? • What happens when your cloud goes down?
Receiving external data	• Standardized APIs • Understand access rights; who to push to and how to push? • Consumer apps need to understand how to deal with/convert to HIPAA-compliance • Data transfer agreements will be very specific on what you can give out and/or receive • GA4GH Consent Codes
Sharing data externally	• Start from industry standards that already exist and decide what are you trying to connect to first: – FHIR for connect to EMRs – AllScripts API – ResearchKit/CareKit SDK – ResearchStack SDK – Open mHealth – De-identified data has different rules
Semantics **– Using standard terms and coding**	• This proactively avoids interoperability problems later • What information needs to be included? • What does/will this connect or integrate into? – Medical terms – Acronyms – Backend definitions of data elements – Examples: Open mHealth Schema Library • What information needs to be included in your ontology? – Provenance/self-defining metadata *Hardware version* *Software version* • How do your various terminologies interact? – Reference terminology – Provider- and consumer-facing terminology – Interface terminology

Appendix D: Independent Recommendations & Action Steps

Recommendation 3: Sources for standardized approaches for informed consent and privacy

EXISTING EFFORTS

Android's ResearchStack

- Framework to building research study apps on Android by helping developers and researchers with existing iOS apps easily adapt to Android
- Designed to meet requirements of scientific research such as participant consent, input of tasks, and security and privacy measures needed for IRB approval

ELSI Research Agenda

- Uses the case study of mHealth research to provide an ethical, legal, and social implications (ELSI) research agenda for citizen science research conducted outside conventional research institutions

GA4GH's Consent Policy

- Outlines best practices to guide the sharing of genomic and health-related data in a way that respects autonomous decision-making while promoting international data sharing

ONC's Model Privacy Notice

- "Voluntary, openly available resource to help health technology developers who collect digital health data clearly convey information about their privacy policy to their users"
- The model privacy notice is a standardized snapshot of company's existing privacy and security policies, like a nutritional label, to encourage transparency and help consumers make informed choices when choosing products

PatientsLikeMe's Privacy Policy

- "Platform for patients who want to share their health information to create collective knowledge about disease, health, and treatments"
- Clearly outlines type of information collected and what data is shared or restricted in addition to how the data is used
- Explains the potential risks and benefits of sharing information

Sage Bionetworks' eConsent

- Includes a Participant Centered Consent (PCC) toolkit to transform the process into one that educates and allows participants to engage in consented studies through a visual dictionary of icons and animations, eConsent workflows, design documents and templates, as well as a frequently asked questions section
- Designed to be reusable, scalable, and customizable
- Apple's ResearchKit uses this eConsent process with a visual consent flow composed of animated screens of consent elements, links to "learn more," and a full consent form for review

CURRENT EXAMPLES

ADAPTABLE Trial's eConsent

- ADAPTABLE patient partners, or Adaptors, work alongside researchers in all aspects of the trial (protocol design, consent form, study portal, study materials, etc.)
- Adaptors are integral to development of participant-centered consent form and comprehension assessment
- Patients identified through EHR and contacted with trial information and link to eConsent
- Signed eConsent records are stored securely (encrypted for privacy with audit trails to track changes)

MyHeart Counts' Informed Consent

- App that gathers biometric and cardiovascular health data and initially walks the user through the informed consent process using an easily digestible, step-by-step process
- Advises participants that certain activities will be required, sensor and health data will be collected and processed, protected through a secure database, data will be stored and used, and mentions other issues to consider such as daily time usage

PALM Registry's eConsent

- Duke Clinical Research Institute's (DCRI) Prospective Assessment of Lipid Management (PALM) registry uses a tablet-based application that allows for all parts of the registry enrollment and PROs collection
- App offers study participants video informed consent, or eConsent, in a format designed to promote understanding and interest
- Digital platform allows for the use of advanced survey methodology (adaptive logic, embedded randomization of questions, sophisticated response categories)
- Designed to fit into the workflow of busy clinics by fitting into the "downtime" available which enables enrollment

ARTICLES & GUIDANCE

Formative Evaluation of Participant Experience With Mobile eConsent in the App-Mediated Parkinson mPower Study: A Mixed Methods Study

- Sought to identify participant responses related to comprehension, informedness, and voluntariness while capturing emergent themes in the eConsent process
- Participant responses reflected many of the same challenges reported within the "traditional" informed consent process

Informed Consent

- Multipart review that provides an overview of approaches to improving and expanding the informed consent process for researchers and participants
- Section focused explicitly on using app-based trials and informed consent for mobile health research

Recommendation 4. Information on usability and patient engagement

EXISTING EFFORTS

Direct-to-Patient Approach

- Provides an opportunity to meet key patient expectations and drive better outcomes for studies by using various strategies, tactic, and habits to facilitate meaningful patient engagement

Increasing Focus on the Patient in Patient Registries

- Defines patient-centered care and patient-centered clinical research while outlining challenges to incorporating patient perspectives over the registry lifecycle
- Supplement to the third edition of "Registries for Evaluating Patient Outcomes: A User's Guide"

Usability Testing using ISO 9421-11 Standard

- Quantitative usability study of mHealth diabetes system to evaluate patients' task performance, satisfaction, and relationship of the measures to user characteristics
- Used International Organization for Standardization (ISO) 9241-11 standard metrics to assess individual task success, errors, efficiency, satisfaction, and user characteristics of 10 patients
- Found that ISO 9241-11 measures of patients' experienced usability could serve as an exemplar for standardized, quantitative methods for usability studies for mHealth systems

CURRENT EXAMPLES

Apple Watch's Strategy

- Three-ring structure to encourage and subconsciously motivate users to meet self-entered goals for moving, exercising, and standing
- Users strive to get final ring to close instead of focusing on increasing numbers (i.e., goal-setting)
- Focusing on support and encouragement rather than leaderboards and competitions to foster sustained engagement

Health eHeart's Enrollment Strategy

- Rapid enrollment and sustained retention of study participants with easy to use online platform
- Participants complete online questionnaires that can be completed at their convenience and are filled out with basic demographic information, medical history, and lifestyle habits information such as exercise, sleep, alcohol consumption, and smoking history
- App connects to various participant-owned devices like smartphones, web-enabled scales, blood pressure machines, fitness trackers, etc.

Recommendation 5. Take advantage of mHealth technologies to communicate with study participants to provide meaningful and understandable feedback of study progress and research results

EXISTING EFFORTS

BWH's Research Dissemination Best Practices Resource Document

- Resource document compiled by the Patient-centered Comparative Effectiveness Research Center (PCERC) as a guide to research dissemination for Brigham and Women's Hospital (BWH) researchers interested in patient-centered outcomes research and comparative effectiveness research
- Easy to read format outlining frequently asked questions with corresponding answers and a checklist

Eureka Research Platform

- Digital research platform sponsored by the National Institutes of Health (NIH) designed to facilitate mobile and internet-based medical or health-related research for interested researchers
- Includes an engaging participant-facing "front-end," study management portal, a secure "back-end" for data storage and analyses, and a cohort of volunteers interested in contributing to research

Yale Center for Clinical Investigation's Strategies for Disseminating Research Findings

- Study participants receive a letter after study analysis has been conducted to thank participants for their time and provide an overview of how data collected and analyzed for the project will be used as well as where they can find it once it is available (e.g., newspaper articles, seminars, conference, presentations, journal articles, etc.)

CURRENT EXAMPLES

Fitabase

- Research platform, independent from Fitbit, that collects data from internet connected Fitbit consumer devices
- Aggregates, analyzes, and exports data from many devices
- Secure infrastructure that uses latest industry best practices

Fruit Street's Diabetes Prevention Program (DPP) Delivery Model

- Addresses limitations and barriers by allowing patients to attend DPP calls via group telehealth video calls
- Each patient is issued a Fitbit transmits exercise data back to registered dietitian, wireless scale that records the weight of patients throughout the DPP, and the Fruit Street mobile application that allows them to take pictures of their food and receive feedback from lifestyle coach
- Resulted from CDC's effort to deliver DPP via group telehealth classes and live video conferencing

Hugo's People Powered Data Partnership

- Helps people securely and confidently choose to share their EHR, user-reported, and wearable data with researchers and industry partners
- Consolidated, normalized, and automated health information platform

Noteworth's Platform

- Noteworth's reports continuously deliver clinically relevant, customized, patient-generated data to EHR
- App makes it easy for patients to send data back to clinicians
- Noteworth ships a kit of wearables and FDA-approved at-home clinical devices directly to the patient based on data types ordered by the clinician

SickKid's iCanCope Platform

- App assists with goal-setting and provides feedback or suggestions about how to manage pain
- Integrated smartphone app and website for adolescents and young adults with chronic conditions that will track pain, sleep, mood, activities, and exercise

WellDoc

- FDA 510k-cleared digital therapy that coaches adults with type 2 diabetes to self-manage their condition
- App provides daily lifestyle support for people with diabetes

Wellframe

- Keeps users on track by delivering personalized programs directly to user's phone or tablet (could be as simple as a checklist)
- Mobile platform that connects patient-facing, HIPAA compliant, proprietary mobile app to a care management dashboard

Appendix E: Broad Challenges in Digital Health

Appendix E1: Data linkages and interoperability

EXISTING EFFORTS

21st Century Cures Act Trusted Exchange Framework and Common Agreement

- ONC will hold a series of meetings and webinars in the coming months to inform work related to this framework, followed by a public comment period

A Framework for Measuring Digital Health Interoperability

- Working in concert with the HIMSS Interoperability & Health Information Exchange (I&HIE) Committee, the HIMSS Standards Advisory Task Force, which is comprised of specialized multi-stakeholder industry experts, reviewed and commented on the proposed framework

Clinical Data Interchange Standards Consortium (CDISC) Study Data Standards

- Standards to have study data in a format supported by FDA

Global Alliance for Genomics and Health (GA4GH) Data Working Group

- Concentrates on data representation, storage, and analysis of genomic data to develop approaches that facilitate interoperability

HL7 Fast Healthcare Interoperability Resources (FHIR) Argonaut Project

- Private sector initiative to advance industry adoption of modern, open interoperability standards
- Purpose is to rapidly develop a first-generation FHIR-based API and Core Data Services specification to enable expanded information sharing for EHR and other HIT based on standards

HL7 Mobile Health Work Group

- Creates and promotes HIT standards and frameworks for mHealth
- Mobile Health Application Interoperability Review
- Cross-Paradigm Implementation Guidance for Medical Device Data Sharing with Enterprise Health Systems
- FHIR for Device Data Reporting
- Consumer Mobile Health Application Functional Framework (cMHAFF)
- Mobile Framework for Healthcare Adoption of Short-Message Technologies (mFHAST)

IHE Mobile access to Health Documents (MHD)

- Working together with HL7 FHIR activities to revise and enhance the MHD profile

ONC's High Impact Pilots (HIP) Cooperative Agreement Program

- Implements HIT Standards Committee recommendations, continues ONC's investment toward implementing Nationwide Interoperability Roadmap, and fits in the ONC Tech Lab's focus on pilots for standards and technology

ONC's Proposed Interoperability Standards Measurement Framework (April 2017)

- Measuring progress toward nationwide interoperability in the areas of implementation and use of standards in health IT products and services

Personal Connected Health Alliance (PCHA)

- Publishes and promotes the global adoption of Continua Design Guidelines, an open framework for user-friendly, interoperable health data exchange in personal connected health
- Continua Product Certification for PCHAlliance members

Sync-4-Science program

- Collaboration among researchers at Harvard Medical School Department of Biomedical Informatics, EHR vendors (Allscripts, athenahealth, Cerner, drchrono, eClinicalWorks, Epic, McKesson), and the US federal government (ONC, OSTP, NIH)
- Will let patients retrieve their data from EHRs and share it with AllofUs and researchers

ARTICLES & GUIDANCE

Design Considerations and Pre-Market Submission Recommendations for Interoperable Medical Devices

- Provides manufacturers with design considerations when developing interoperable medical devices and recommendations about information to include in pre-market submissions or device labeling

Healthcare Information Technology Exam Guide for CHTS and CAHIMS Certifications

- Provides guidance on the skills and knowledge required to implement and support HIT systems in various clinical and healthcare business settings

A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy

- Seeks to identify gaps where new measures need to be developed and identify suitable existing measures by synthesizing available evidence from multiple stakeholders

Appendix E2: Patient/consumer consent for data usage and sharing

Please refer to Appendix D.

Appendix E3: Usability of Health IT

EXISTING EFFORTS

Agency for Healthcare Research and Quality (AHRQ)

- Focuses on the design and implementation of electronic health records (EHRs) so that they are more intuitive to use and more readily support clinical workflow
- Reduce documentation burden for physicians
- Make data within EHRs more usable for clinical decision-making
- Updated list of related projects and publications

American Medical Informatics Association - Usability Task Force

- A compilation of useful resources, papers, and meetings
- Standards activities

EHR Association

- Trade association of Electronic Health Record (EHR) companies
- Holds annual Usability Summits

HIMSS - User Experience in Electronic Health Records

- Resources that focus on user experience, usability, and user-centered design principles
- HIMSS EMR Usability Evaluation Toolkit

National Institute of Standards and Technology (NIST)

- Part of the U.S. Department of Commerce, NIST works to advance measurement science, standards, and technology in multiple fields
- Safety-Related Usability Framework

ARTICLES & GUIDANCE

FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices

- Finalized 2016
- Not HIT-specific, but meant to provide guidance in following appropriate human factors and usability engineering processes

Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records

- Provides detailed systematic steps for conducting validation studies

Appendix E4: Cybersecurity

EXISTING EFFORTS

FDA: Cybersecurity

- Updated FDA information and resource list regarding cybersecurity for medical devices
- Issued final guidance in December 2016: Postmarket Management of Cybersecurity in Medical Devices

Global Alliance for Genomics and Health: Security Working Group

- Focuses on technology aspects of data security, user access control, and audit functions
- Standards for data security, privacy protection, and user/owner access control

HHS Health Cybersecurity and Communications Integration Center (HCCIC)

- Announced summer 2017
- Educate health organizations and consumers about the risks of using HIT

HIMSS Cybersecurity Hub

- Updated hub of HIMSS information on cybersecurity
- Component of the HIMSS Innovation Center

Manufacturer Disclosure Statement for Medical Device Security (MDS^2)

- Standardized means for the device industry to disclose to healthcare providers the security related features of the medical devices
- Provides a comprehensive set of medical device security questions
- Allows for comparison of security features

National Health Information Sharing & Analysis Center (NH-ISAC)

- Trusted community of critical infrastructure owners and operators within the Health Care and Public Health sector (HPH)
- Focused on sharing timely, actionable, and relevant information with each other including intelligence on threats, incidents, and vulnerabilities

ONC's Blockchain Challenge

- Series of white papers on the topic of blockchain technology's potential use in HIT to address the privacy, security, and scalability challenges of managing electronic health record and resources
- Fall 2016

ARTICLES & GUIDANCE

NIST's 2014 Framework for Improving Critical Infrastructure Cybersecurity

- Provides details on managing cyber supply chain risks, clarifying key terms, and introducing measurement methods for cybersecurity
- Draft updated released in 2017
- Originally published in 2014