Building the infrastructure to accelerate evidence-generating mobile and wireless health research: National Institutes of Health and National Science Foundation perspectives

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Rapid scientific advances in computing, engineering, and technology have made it possible to improve human health in ways previously unimaginable. In the foreseeable future, it will be possible, for example, for every individual to carry a medical identification token, perhaps even subcutaneously, that enables them to share their up-to-date and accurate medical record information safely and securely. The complications and risks associated with being unable to remember or communicate important health information (e.g., medications, conditions, and treatment history) could be eliminated. This technological paradigm shift within health will also allow people to unobtrusively monitor their health behavior and the context in which they live, receive the information they want when they need it and in a way they can understand it, and have treatments targeted to their individual profile, prioritizing personal preferences and culture. Improvements have the potential to increase accessibility to healthcare and reduce health disparities as well as influence how we prevent, diagnose, and treat disease and modify risky health behaviors. These changes will potentially have a cascading effect increasing the likelihood of early detection, prevention, prediction, or lapse of both disease and behavior.

But for this vision of the future to become reality and ultimately translated to practice, new partnerships and investments are required. Both the NIH and NSF continue to support the development and evaluation of mobile and wireless technologies for behavioral research through a variety of grant mechanisms. These investments have resulted in the development of innovative technologies and the infrastructure to support them. In this article, we describe current NIH and NSF initiatives to develop mobile and wireless health infrastructures to further behavioral research.

MOBILE DATA TO KNOWLEDGE (MD2K)

The Big Data to Knowledge (BD2K) initiative was launched by NIH in 2012 to address the challenge of how to harvest efficiently and effectively the expanding wealth of biomedical data. One

of the national Centers of Excellence funded in 2013 by this program is the Mobile Sensor Data-to-Knowledge (MD2K) Center [1]. The Center has brought together researchers in Computer Science, Engineering, Medicine, Behavioral Science, and Statistics around the collection and analysis of high frequency sensor data to reduce hospital readmission in congestive heart failure patients and prevent relapse in abstinent smokers.

The MD2K Center has generated a number of resources that are or will be available to the wider research community. These resources can be accessed through the MD2K website or through GitHub, a social networking site that is used to develop and share software code, programs, and related documentation. For example, the modular, open-source software for collecting data from sensors through a mobile phone (mCerebrum) and the backend architecture for analyzing the collected data are now available through GitHub [2]. The software is compatible with a number of commercial and clinical grade mobile and wearable sensors, ecological momentary assessment, and other electronic self-reporting formats. This mobile health data repository allows researchers to store, share, and analyze these data more readily. The team also plans to make some of their hardware sensor systems more widely available. A number of studies are currently under way using this software and hardware that will help refine features such as data visualization, digital biomarkers, just-in-time adaptive interventions, and making the backend available as a cloud service. These studies incorporate a variety of behavioral and social science components including examining social determinants of health and smoking cessation, stress intervention, measuring physiological response in couples' interactions, eating behavior, health disparities among smokers, and oral health behavior.

MD2K also organizes a number of meetings and training events, including the mHealth training institute [3], an archive of webinars and lectures on mobile health (mHealth) research as well as the latest news in the field [4]. Having MD2K within the larger BD2K Centers Initiative encourages

data collaboration and coordination across a range of big data systems and analytics, further integrating mHealth into the broader health-related big data efforts. Behavioral researchers can take advantage of many of the components from MD2K. In addition to the various training opportunities available through webinars and the mHealth Training Institute, MD2K provides software development and analytical tools that should speed the development and evaluation of new applications that call on the sensors available in smartphones. Extensive use of the mobile health data repository by behavioral researchers will generate a data commons for behavioral data across studies that can be integrated, shared, and analyzed by all.

EUREKA PLATFORM

Another mobile and wireless health research resource funded by NIH is the Eureka Platform led by Jeffrey Ogin at University of California, San Francisco [UCSF] [5]. The goal of this project is to build a readily accessible, nimble, and sustainable infrastructure for investigators to conduct efficient and cost-effective mHealth research and a large, diverse cohort of engaged participants contributing data and willing to volunteer for additional data collection and randomized trials. Funded in the Fall of 2015, the team has developed a cloud-based multi-tenant platform and a complementary web interface and iOS application for enrolling, retaining and conducting studies with large cohorts. The software is modular to enable it to be tailored to the needs of individual studies, and the app can collect user-entered data from a growing number of compatible home-based, health-tracking devices. This platform can be easily tailored for any new study using a specifically recruited population or recruiting from the registry of participants on the platform. This registry of participants is currently more than 70,000 and expected to grow during the next few years. The platform also integrates with a number of other databases, is compliant with recognized security and privacy standards, and the team has worked to streamline the process for spinning up a new study. There are four pilot studies underway that will be used to test and optimize the platform before it is made more widely available to the research community. These studies include the relationship of diet and cardiovascular disease, stress management for smoking cessation, physical activity as potential surrogate assessment in neurodegenerative disease management, and diabetes management. When widely available, behavioral researchers will have an easily accessible test bed for rapid deployment and evaluation of new mobile applications. More details on the Eureka platform are available on the project's website (<http://info.eurekaplatform.org/>).

SMART AND CONNECTED HEALTH

While many behavioral researchers are cognizant of opportunities at the National Institutes of Health, some may not be aware of opportunities for research and collaborations in the fundamental sciences that apply to health at the National Science Foundation. For example, the Smart and Connected Health program [6], a joint NSF and NIH initiative, supports approaches that partner technology-based solutions with bio-behavioral research. The purpose of this program is to develop next-generation health solutions and encourage collaborations between existing and new research communities to focus on breakthrough ideas in a variety of areas of value to health, such as sensor technology, networking, information and analytics, decision support systems, modeling of behavioral and cognitive processes, as well as system and process modeling. Bringing together the community supports the development of effective solutions that satisfy a multitude of constraints arising from clinical, consumer, and community needs, intra- and interpersonal limitations, financial and cultural barriers to change, heterogeneity of data, semantic mismatch, and limitations of current cyber and physical systems. Such solutions demand multidisciplinary teams ready to address technical, behavioral and health issues ranging from fundamental science to public health.

By developing this multidisciplinary approach to smart health from the start, behavioral and social science researchers can have a key role in building a field that can move fluidly from prototype through translation. This will also enhance the probability that devices and techniques that are developed using state of the art behavioral and social science approaches will have the expected impact on behavior to ultimately improve health.

INCORPORATING MHEALTH IN THE *ALL OF US* RESEARCH PROGRAM

The *All of Us* Research Program is building an engagement and digital data platform with the goal of enabling thousands of studies on what will be one of the world's largest, most diverse biomedical data sets. *All of Us* will engage one million or more U.S. volunteers of all life stages, health statuses, races/ethnicities, geographic regions, etc., reflecting the rich diversity of the United States. Mobilizing rich and constantly evolving data—from electronic health records, biospecimens, and questionnaires, to physical evaluations, sensors, and other technologies—the program will support research at the intersection of lifestyle, environment, and genetics to produce new knowledge, leading to the development of innovative prevention strategies and treatments for foundational health challenges.

The *All of Us* Research Program aims to support a highly interactive research model, with participants as partners in the development and implementation of the research and with significant representation in program governance and oversight. Enrollment in the *All of Us* Research Program began in 2017 with the launch of a cross-platform participant portal accessible via responsive web and native iOS and Android smartphone applications. Participants will initially use the portal for account creation, eConsent, communications with the program, and contribution of self-reported data types including surveys. The evolution of the platform over the subsequent months and years will aim to incorporate innovative passive and active assessment methods and technologies from across academic and industry research and development communities.

Programs and projects such as BD2K, MD2K, Smart and Connected Health, and Eureka, present opportunities to leverage existing NIH and NSF investments to yield helpful lessons for the *All of Us* Research Program in data analytics and remote monitoring, among other areas. The base dataset generated from *All of Us* will provide a rich set of social and behavioral variables that can be integrated with genomics and clinical medicine data, and health behavior researchers should avail themselves of this rich dataset and also propose additional layers of data collection, including mobile and sensor data, for more in depth study in selected subgroups of the sample. Ultimately, data collected by the program will be broadly accessible to multiple stakeholder communities from researchers to citizen scientists and beyond.

OPPORTUNITIES AND CHALLENGES

The use of mobile and wireless health technologies provide both opportunities and challenges in translational research. For example, these technologies now allow us to collect longitudinal behavioral data within the context of participant's daily lives, however, this comes at the cost of data complexity and the need for advanced analytical approaches.

The opportunity to intensively monitor participant behavior and context and to share and integrate these data also raise significant challenges for ensuring participant privacy and the security of the data provided. These privacy and security challenges are also providing opportunities for participants to have greater control over the data they provide.

The implementation of mobile and wireless health technologies provide opportunities to advance science at both the population and individual level, but it is first necessary to understand how to make the data collected in these contexts meaningful and actionable. This requires collaboration among researchers from a variety of

backgrounds as well as training new scientists in behavioral medicine, technology, and advanced data analytics to ensure that the data obtained is consistent with our understanding of behavior, is reliable and valid, and can be analyzed to detect complex interactions of behavior and context. In addition, for data to be meaningful, changes in the measurements must be sensitive and specific to the underlying health or behavioral biomarker of interest, and the data must be machine-interpretable and have predictive power in order for it be used for making decisions.

These NIH and NSF efforts reflect the need not only to fund the development and evaluation of mobile and wireless health solutions, but perhaps more importantly to provide the research infrastructures that facilitate the development and evaluation of these solutions. The NSF and NIH Smart and Connected Health program integrates the health science and technical communities to develop innovative technologies applied to health. The Eureka Platform provides a readily available test bed to rapidly evaluate new programs, versions, and components as they are developed. MD2K provides a data repository (mCerebrum) for storing, sharing, and analyzing data from various sensors and software as well as advanced big data analytics to make optimal use of the data collected. The *All of Us* program will provide a large diverse cohort of participants to further validate mature technologies and evaluate their utility and effectiveness in behavioral interventions. By investing in these research infrastructures, the NIH and NSF facilitate mobile and wireless health research. The use of these resources as they mature by researchers should result in a more robust, rigorous, and rapid evaluation of these digital technologies applied to health relevant behavioral and social sciences.

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