White Paper

A Novel Approach for Conveniently and Securely Collecting Personal Health Data

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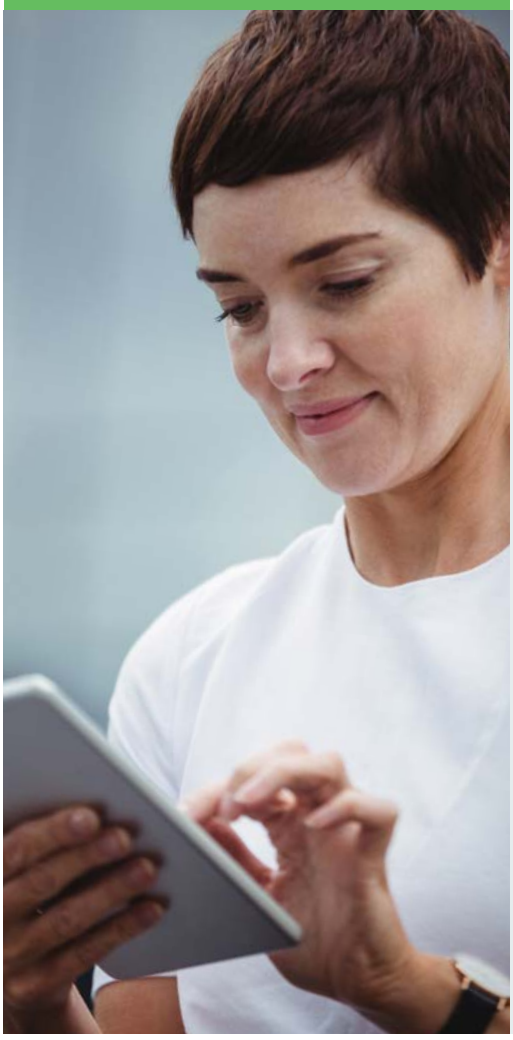


Abstract

Public health research faces declining participation rates, increased screening, and potentially more field challenges and costs. Widespread access to the internet, mobile computing, and the availability of health kiosks is altering the approach to conveniently interacting with research study participants. However, this access and convenience must be balanced against increasing privacy concerns over personal health data. This paper describes our experiment with using consumer wearable devices, health kiosks, and an internet-based data aggregation platform exploring potential opportunities to improve convenience and trust with study participants.

Introduction and Background

Public health research, clinical trials, and population surveillance—generally speaking, health studies assessing behavioral, health, and lifestyle-related outcomes—face declining participation rates. In some cases, less than one-third of clinical trials achieved their recruitment targets. Reasons for declining participation include confidentiality, inconvenience, protocol, and religious/spiritual objections.[1] At the same time, widespread access to the Internet, mobile apps, video-on-demand, texting, email, and social networking is creating a "society of convenience." This society of convenience can enable new activities which may, in turn, affect study participation in a positive fashion.

Declining study participation rates raise concerns that studies will become more expensive due to increased screening costs, less feasible to execute because of field challenges, and subject to more scrutiny about nonresponse bias. However, two of the four reasons noted above for declining participation—confidentiality and inconvenience—may be addressable in part through technological solutions. For example, certain data (e.g., physical measurements and blood pressure) may be collected with consumer wearable devices and health kiosks.[2] The popularity and availability of these devices has grown in the last decade, enabling consumers to monitor a range of activity and health measures.

A major benefit of these consumer wearable devices and health kiosks is that they capture health and lifestyle-related metrics (like daily blood pressure, exercise, and sleep) that are difficult to capture without an ambulatory visit or hospital admission. In other words, it is more convenient to capture this information than ever before. While these tools make data collection more convenient, respondent confidentiality and privacy remains an ongoing concern. As data becomes more accessible, consumers need to know that their health information will be managed properly. Thus, study participants need a simple way to authorize the use of their data, with the option to rescind access as they see fit.

This paper describes our experiment with using consumer wearable devices, health kiosks, and an internet-based data aggregation platform exploring potential opportunities to improve convenience and trust with "would-be" study participants.

Objective

Our learning objective was to test the feasibility of using an Internet-based platform to securely aggregate consumer wearable device and health kiosk data outside of clinical settings. Our experiment addressed two specific aims:

Aim 1: Demonstrate a secure mechanism for individuals to easily provide access to and securely control their wearable device and health kiosk data.

Aim 2: Evaluate the accessibility, quality, and structure of the data collected by the Internet-based platform.

[1] Brintnall-Karabelas J, Sung S, Cadman ME, Squires C, Whorton K, Pao M. Improving recruitment in clinical trials: why eligible participants decline. J Empir Res Hum Res. 2011;6(1):69-74. doi:10.1525/jer.2011.6.1.69

[2] Wunker, S. A new age for healthcare kiosks -- five ways next generation kiosks disrupt medicine and healthcare marketing. Forbes. July 16, 2013. https://tinyurl.com/y8luf3t5. Accessed October 26, 2017.

Criteria For Platform Selection

We used four criteria for selecting an Internet-based data aggregation platform. First, the platform had to be connected to a health kiosk with extensive geographic coverage in the United States to provide convenient access for survey participation. Second, because there were a number of consumer wearable devices on the market, we needed a platform that was currently managing device data for multiple common devices and could be easily extended for new devices. Third, the platform had to allow study participants to control who could access their health data. Finally, the platform had to allow for data exchange using the appropriate information security controls. The first two criteria focused on making it easier for study participants to contribute to a study. The remaining criteria addressed data privacy concerns.

Health Kiosks

The three companies with the largest market share of health kiosks are higi, PharmaSmart, and Pursuant Health, ordered by quantity of kiosks, with a total of more than 20,000 kiosks. According to publicly available information, as of October 2017, higi has over 11,000 kiosks, PharmaSmart has 7,000 locations, and Pursuant Health has over 3,600 locations. As the largest of the three companies, higi has more than 11,000 in the U.S. With kiosks located in grocery stores and pharmacies, higi facilitated the greatest access to the population. Roughly 75% of the U.S. population lives within several miles of a higi kiosk capable of measuring weight or blood pressure. Using higi's platform integrating personal health metric measuring devices, a study can easily collect and enable access vital information (e.g., fitness and lifestyle activities, measurements of weight, body mass index, height, fat ratio, fat-free mass, fat mass, hydration, bone mineral content (BMC) resistance, systolic/diastolic pressure, pulse, bone mass, muscle mass, heart pattern) without study participants visiting a doctor or hospital.

higi stations are equipped with advanced, quality-controlled health indicator measuring devices. In many cases, self-reporting this type of information is not considered acceptable research quality. However, higi owns the largest Food and Drug Administration-cleared, retail-based, self-screening network in North America, and therefore can provide data at sufficient quality for some studies.

Consumer Wearable Devices

Of the three leading providers of health kiosks, only higi has integrations with major activity trackers for consumer use. Each of these companies has engaged with pharmacy system and clinical system vendors aligning health data from the kiosk to health management, but this does not provide additional ongoing health data collected to the individual user. higi currently has 15 inbound integration partners covering over 80 devices, allowing users (i.e., study participants) to integrate their ongoing activity data and home tracking tools for a more comprehensive health view. higi currently connects with **Endomondo, Fitbit, Garmin, iHealth, Jawbone, Microsoft, Misfit, Moves, Nike+, Omron, Runkeeper, Strava, Under Armour,** and **Withings**, as well as **Foursquare** for identifying and rewarding check-ins at fitness locations.

Study Participant Control Over Data

As noted earlier study participants are concerned with confidentiality and privacy of their health data. There are competing protocols for allowing individuals to actively manage access to their data. Doing so requires a mechanism for study participants to enable each of their trusted health data systems to authenticate a study platform and what it has authorization to access. There are three identity protocols in use today: OpenID, Security Assertion Markup Language (SAML), and Open Authorization (OAuth).

OpenId and SAML are designed as single sign-on solutions, but do not provide the flexibility for study participants to authorize their data. These protocols are only designed to authenticate users of an application. In our experiment, we needed to authenticate the actual study management platform while enabling the participants to authorize use of their data managed on external systems. Using the OAuth protocol enables a dialog between our participants and consumers of their data, giving these participants complete control over what data can be accessed and the ability to stop at any time. In order to stop, these participants must take action (i.e., log in to the external system(s) and indicate their choice to discontinue our experiment's access), but they do have control. Because OAuth is the only protocol we found that meets our experiment's requirements, we chose its latest version, OAuth 2.0.

Secure Data Exchange

There are additional challenges in protecting study participants' privacy beyond giving them authorization control. Depending on the data being exchanged, many security controls may be required to protect the data at rest and in transit. HTTPS or HTTP over Transport Layer Security (TLS) protects the exchange of their data. TLS facilitates encrypting the data transmitted, authenticating data exchange partners, and preventing undetected loss or alteration of the data during transmission.[3]

Experimental Design

Through a data use agreement with higi, ICF and higi staff agreed to share data managed on their higi Data Aggregation Platform (DAP). Five ICF staff members took part in the experiment. The participants visited different, but not preselected, higi stations. Each one created an account on the DAP and enabled data sharing with their own personal devices. Participants authorized several devices or check-in apps, including Apple activity trackers, Fitbit, Garmin, Misfit, Foursquare Swarm, and higi. We observed their activity for two months.

We developed a study management platform prototype, including an email-based registration process to authenticate our experiment and grant ICF permission to access their data on the DAP (i.e., collected by physical stations or via other personal devices linked to their higi account). We used email to reduce effort only.

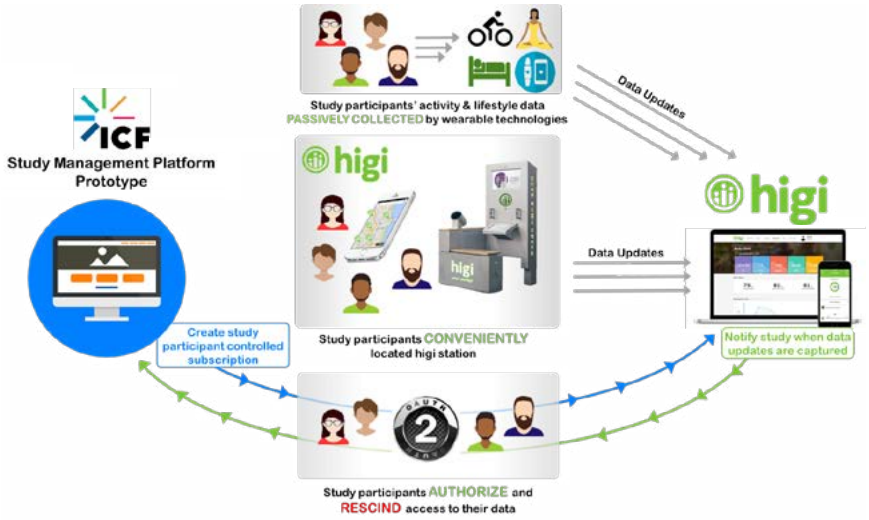
To simulate study participant registration, our participants received an email invitation with instructions how to authorize our experiment. The email contained a link to the DAP's OAuth 2.0 server. In a production study management platform,

[3] Dierks T, Rescorla E. The Transport Layer Security (TLS) protocol, version 1.2. https://tools.ietf.org/html/rfc5246. Published August 2008. Accessed October 24, 2017.

the same links would be provided within a secure study portal accessible on mobile devices or Electronic Medical Record (EMR) systems. After the participants clicked the link, they were redirected to the DAP requesting them to login. Upon successful login, the participants could choose which data to share with our experiment. During this step, our study was authenticated by DAP and the user decided what and how much data to share.

As illustrated in Figure 1, participants could share data through personal wearable devices. To incorporate blood pressure and or weight measurements into our experiment, participants found a conveniently located higi station using the higi app. As illustrated by the blue arrow moving left to right, when the study management platform receives notification that participants have authorized their data, it creates a subscription to each authorized data type for that participant. All data collected by either means is transferred to the DAP for processing and distribution to the subscriptions. As illustrated by the green arrow moving right to left, when data are received, notifications are sent back to the study management platform, indicating new data are available.

FIGURE 1. EXPERIMENT CONCEPT OF OPERATIONS ILLUSTRATING STUDY PARTICIPANT CONVENIENCE AND CONTROL



Upon receiving notification of the availability of new data, our study management platform must re-verify the authorization in case the participant has rescinded authorization. This ensures data privacy control remains with the participant.

Results

During the experiment, we observed participants successfully authorizing access to their kiosk-collected data and their wearable device data. We also determined that consumer wearable devices sample data at different frequencies, which may require analytic techniques to standardize and harmonize data. For our experiment, we did not access detailed sample data, and instead only had access to summary data. Primary data sources, such as Fitbit or Garmin, have different

data access implementations. The result of these implementations translates to different sampling frequencies for each device and non-uniformity in the level of detail that is accessible through the DAP.

According to higi, the majority of device or app data vendors support OAuth 2.0 subscriptions and in our experiment, all of the wearable devices used by the participants did integrate with the DAP using OAuth 2.0 subscriptions. However, for other wearable devices or apps that do not support OAuth subscriptions, higi would have polled the authorized participant device's data platform every two hours for updates.

Depending on the health and lifestyle metric recorded by the devices used, we observed different methods of higi data persistence models. In some cases, devices recorded measures as a daily summary, and in others, a series of updates to one or more records. When looking at the different information available from wearable devices, we see differences in frequency and aggregation. These variances depend on the type of information being observed. Based upon our experiment, we noted the following:

- **Step counting** devices like Fitbit and the Apple watch: higi received updates approximately between 22 and 24 times a day which immediately triggered notifications to our study management platform.
- **Health data updates:** higi stations notified our study platforms subscriptions immediately after measurements were recorded.
- **Lifestyle** updates from smart apps, such as FourSquare Swarm: notification was triggered by a check-in immediately notifying our study platforms subscriptions.
- **Fitness data**, such as a bike ride tracked by a Garmin device: notification was triggered at the on conclusion of the activity.

The DAP did not provide data at a shorter timescale than noted above. For instance, minute-to-minute steps or calories cannot be collected from the DAP. Although we could see the total number of calories expended over the duration of a bike ride, the updates did not provide finer levels of detail (e.g., calories expended during the beginning or end of the bike ride). In some cases, we observed activity data was available prior to the participant's authorization. For example, one participant authorized use of the data from a Garmin bike computer. We received activity summaries for that participant timestamped as far back as one year because we did not include date filters in the initial data request upon receiving authorization from this study participant.

Discussion

Aim 1: Demonstrate a secure mechanism for individuals to easily provide access to and securely control their wearable device and health kiosk data.

During this experiment, we successfully used the higi DAP to allow participants to securely share their fitness, health, and lifestyle data. Through the data subscription capability using OAuth 2.0, we were able to allow participants to easily opt in and out of sharing their data with our experiment. Participants did

not report any challenges with registration, using the health kiosk, or authorizing access to their consumer wearable device data. This successfully demonstrates two key issues to overcome with regard to study participation: convenience and study participant control of health data. For health studies where access to data that can be measured at a health kiosk and summary activity data are required, the use of an Internet-based data aggregation platform that provides convenience and study participant control over data access may satisfy protocol requirements.

While this experiment provided useful information to warrant continued study, there are a number of limitations that must be investigated before this approach can be applied on a larger scale or for a formal study. The experiment was only conducted with five individuals who worked for ICF and were cognizant of the experiment design and approach. Thus, not using a random sample of individuals, unexposed to the experiment objective, may have made certain aspects of the study easier for these individuals.

Aim 2: Evaluate the accessibility, quality, and structure of the data consumed by the Internet-based platform.

We experimented with a limited set of consumer wearable devices and did not rigorously establish a protocol for each participant to follow for when to use the consumer wearable device and when to visit a health kiosk. An important aspect of this is that we were not able to pull sample data. While summary data are useful for many applications, it may not have the level of detail for certain analyses required by a health study.

For studies where summary data from wearable devices or physical measurements from a health kiosk meet study quality and analytic objectives, our experimental approach to data collection appears to be a viable option. The flexibility of allowing for connections to a variety of devices creates participant convenience and may help to lower study costs. Yet with this flexibility comes the challenge of additional data management and the likelihood that data from different devices will need to be harmonized and validated to some agreed upon standard. Future research will look at ways to overcome the constraints we have listed.

Conclusion

The objective of our experiment was to test the feasibility of using an Internet-based platform to securely aggregate consumer wearable device and health kiosk data outside of clinical settings. The use of an Internet-based data aggregation platform proved viable in this small experiment warrant further studies, applications, and analyses. We believe that the availability of higi's health kiosks, in consumer shopping locations (e.g., grocery stores, pharmacies) provides a convenient means for study populations to engage with the study. Furthermore, the OAuth 2.0 protocol was demonstrated to be an appropriate method for securely controlling the transfer of electronic health data.

About ICF

ICF is a global consulting services company with over 5,000 specialized experts, but we are not your typical consultants. At ICF, business analysts and policy specialists work together with digital strategists, data scientists and creatives. We combine unmatched industry expertise with cutting-edge engagement capabilities to help organizations solve their most complex challenges. Since 1969, public and private sector clients have worked with ICF to navigate change and shape the future.

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Charles Akin, BBA, CEA, CSM is responsible for health research and development initiatives focusing on innovations in accessing/sharing health digital assets. He also oversees technical direction and adherence to overall delivery strategy for solutions proposed. He facilitates the creation of performance-based architecture, industry or sector regulations and standards, and the institutionalization of these ideas across the federal health market. He facilitates workshops with business owners demonstrating the importance of outcomes-based program direction and regularly meets with industry to uncover innovation that can make a difference in the health outcomes. Mr. Akin has more than 24 years of information management systems experience, with more than 14 years supporting the Centers for Disease Control and Prevention (CDC) with public health informatics and architecture. Mr. Akin serves as senior informatics specialist, providing consultation to CDC's National Syndromic Surveillance Program and the Laboratory Response Network Data Exchange focusing on hospital and laboratory electronic data exchange.

Jeff Barkoff is a health care strategist and leader with extensive experience across clinical, product, data/informatics, and marketing. As vice president, health solutions, he partners with leading health organizations to enhance the value of higi's core offering, extend the reach into new markets, and deliver new innovative solutions with retail pharmacies, providers, payers, and health care technology partners alike. Mr. Barkoff's expertise in driving innovative programs arises from his work at Catamaran (prior to its acquisition by OptumRx) in creating solution for the Clinical Analytics business unit, and at Truven Health Analytics (prior to its acquisition by IBM Watson) in launching forecasting solutions for hospitals and health systems.

Rafiya Javed, MD is a medical doctor and data scientist interested in using data-driven technology to improve the health care ecosystem. After earning a BS in physics from the University of Florida and an MD from McGill University, Dr. Javed is now earning her MS in computer science, with a specialization in Machine Learning, at Georgia Institute of Technology.

Lewis Berman, PhD, MS serves as a vice president at ICF, focusing on business development related to federal health projects. Dr. Berman is actively involved in research and development on electronic health data brokering and non-probability panel surveys. He also serves as the ICF officer in charge for the institutional review board. For over 25 years, Dr. Berman has been involved research and development activities related to medical and radar imaging and national and subnational epidemiological studies. Dr. Berman served as the deputy director on CDC's National Health and Nutrition Examination Survey. Before that he served at the National Institutes of Health and the Naval Research Laboratory.