Project HealthDesign: Rethinking the Power and Potential of Personal Health Records

EXECUTIVE SUMMARY

Project HealthDesign: Rethinking the Power and Potential of Personal Health Records, a Robert Wood Johnson Foundation (RWJF) national program, sought to expand the vision of personal health records beyond being essentially electronic copies of patient medical records that patients can view online, and to encourage the market to develop a variety of products that will meet the diverse needs of patients—by finding ways to use electronic technologies to put a wide range of useful, actionable information into their hands. Project HealthDesign’s leaders hoped not only to support the development of devices that would show the true potential of personal health records, but, more fundamentally, to demonstrate a novel, patient-centered approach to health information technologies.

In two rounds of funding, Project HealthDesign awarded grants to 14 interdisciplinary teams that completed a series of projects designed to stimulate innovation in personal health information technology. Project HealthDesign ran from February 2006 through June 2014. Over its eight-year duration RWJF funding totaled $9,447,565.

CONTEXT

In the first decade of the 21st century the American health industry was in the early stages of figuring out how to take advantage of the digital revolution. Some major health groups and hospitals had devised systems through which patients could access their health records—lab results, diagnoses, prescriptions, procedures, and the like—but their access was limited only to the records that resided in the files of that one group or one hospital. Having a centralized repository of health information from the entire spectrum of a patients’ health providers was a goal envisioned but not yet realized.
In the conceptual stages of Project HealthDesign, Stephen J. Downs, SM, RWJF’s chief technology and information officer, assumed that it was only a matter of time before that problem was solved. Soon enough, he believed, patients would have the ability to access a unified electronic repository of their health data from a variety of providers. (He admits now that confidence was premature—in many respects the health industry is still working on that basic problem well into the century’s second decade.) The question Downs and others in the industry began to ask at that point was whether giving patients the ability to read their medical records online was enough. Patients might find such an ability interesting, Downs said. What they could actually do with that information was another question.

“Being able to say, ‘My blood pressure in 2008 was 115 over 72 and last month it was 112 over 74’—that’s not very exciting,” Downs said in an interview for this report. “With Project HealthDesign we wanted to challenge the field of people who are working on this to think bigger.”

**RWJF’s Interest in the Area of Personal Health Records**

RWJF’s participation in the evolution of personal health records began with a series of grants made to support the Markle Foundation’s Connecting for Health project that was launched in 2002. Markle was working to facilitate the creation of a unified repository of electronically accessible health data from multiple sources.¹ Hoping to provide patients with more expansive, more actionable information, in 2006 RWJF funded a study in which researchers asked participants in a series of focus groups what sorts of health information they would find useful. (For more information, see Focus Group Researchers below.) That study not only informed the initial grants for Project HealthDesign, but also led to RWJF’s funding of OpenNotes, a project led by a team at Beth Israel Deaconess Medical Center in Boston to demonstrate the feasibility of giving patients access electronically to the notes their physicians make during office visits. RWJF issued a series of five grants to support OpenNotes from October 2008 to June 2015 for a total of $4,766,930.²

In a related health technology area, since September 2011, RWJF has supported the development of open source software architecture that could integrate data from a wide variety of mobile health (mHealth) applications (or apps) for smartphones and wearable electronic devices³ and translate that data into a cohesive, useful form for health care providers. As of September 2014, the project team has held a contest in which more than 40 developers created applications using the Open mHealth software, and used the Open

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¹ RWJF’s grants in support of Connecting for Health began in January 2004 and ran through June 2007. IDs 49834, 50781, 53537, 53539, 56712. For more information read the Program Results Report.

² Grant IDs 64990, 65921, 69488, 70632, 71082

³ Grant IDs 69997, 69215, 71540 ($2,874,094 in total, September 1, 2011 to December 31, 2015)
mHealth software to develop test applications to address problems related to post-traumatic stress disorder (PTSD) and type 1 and type 2 diabetes. For more information, read the Program Results Report.

THE PROGRAM

Project HealthDesign sought to expand the vision of personal health records beyond being essentially electronic copies of patient medical records that patients can view online, and to encourage the market to develop a variety of products that will meet the diverse needs of patients—by finding ways to use electronic technologies to put a wide range of useful, actionable information into their hands. Project HealthDesign’s leaders hoped not only to support the development of applications that would show the true potential of personal health records, but, more fundamentally, to demonstrate a novel, patient-centered approach to health information technologies. That philosophy is summed up in a phrase the program’s leaders repeated often: “It’s not the record that’s important—it’s what you do with it.”


Program Management

Downs supervised Project HealthDesign for RWJF. Patricia Flatley Brennan, RN, PhD, FAAN, FACMI,4 directed the program from the national program office at the University of Wisconsin-Madison School of Nursing. Gail Casper, PhD, RN, was deputy director.

Paul C. Tang, MD, MS, chaired a 16-member national advisory committee. During that time Tang also served as vice chair of the federal Health Information Technology Policy Committee and chaired that committee’s Advanced Health Models and Meaningful Use Workgroup, positions he still held as of late 2014.

For the full membership of the program’s national advisory committee, see Appendix 1.

Funded Projects

In two rounds of funding, Project HealthDesign awarded grants to 14 interdisciplinary teams that completed a series of projects designed to stimulate innovation in personal health information technology. For grant details and contact information, see Appendix 2.

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4 Brennan is the Lillian L. Moehlman Bascom Professor at the School of Nursing and College of Engineering at the University of Wisconsin-Madison.
Round 1

The nine teams receiving grants in Round 1 focused on developing designs for personal health record applications that would enhance the range of services and data available to patients. The overarching goal was to expand the conception of personal health records from “static repositories of information to dynamic, practical tools” (as project staff described it in a report to RWJF) that individuals could use to more effectively participate in their own health care.

These projects ran from December 2006 through February 2009. Brief descriptions of the projects funded in Round 1 follow.

- **Research Triangle Institute (RTI) (Research Triangle Park, N.C.): Personal health record system for at-risk sedentary adults.** Team members designed an interactive Internet site where patients can input information on their exercise levels (including data collected by a personal fitness device, such as a pedometer), lifestyle, and goals. Based on that information patients receive fitness plans customized to fit their daily routines. (Grant IDs 59885 and 64535)

- **Stanford University School of Medicine (Stanford, Calif.) and Art Center College of Design (Pasadena, Calif.): Living profiles: Transmedia personal health record systems for adolescents.** The research team designed a set of multimedia tools, “Living Profiles,” to help adolescents with a chronic disease (such as juvenile arthritis, systemic lupus, and hemophilia), who are transitioning out of the pediatric health care system, to assume greater responsibility for their health care through a better understanding of their illness, improved communication, and personalized treatment plans. (Grant IDs 59889 and 64534)

- **University of California, San Francisco: Transforming the process of care and the way information is used in breast cancer treatment.** The team designed a personal health application that integrates notices of doctor’s visits, diagnostic tests, and other appointments into patients’ personal calendars. It also displays information regarding treatment options. (Grant ID 64542)

- **University of Colorado Denver Fitzsimons Early Learning Center (Aurora): Developing a personal health record to assist older adults with transitions of chronic care.** Team members designed programs for a tablet-size computer, which could be given to older adults upon discharge from the hospital. The computer provides easy-to-understand information that helps them keep track of their prescriptions, including ordering refills and coordinating medication lists with their doctors. (Grant IDs 59880 and 64538)

- **University of Massachusetts Medical School Worcester (Worcester): Supporting patient and provider management of chronic pain with personal digital assistant applications linked to personal health records.** Team members designed an electronic diary to help patients closely monitor their pain levels together with their
medication regimens and physical activities. Patients enter data on a hand-held, touch-screen device that allows convenient entries throughout the day. The system will respond with customized medication advice based upon the available data. (Grant IDs 59887 and 64536)

- **University of Rochester (Rochester, N.Y.):** **Personal health management assistance focusing on management of heart conditions.** Researchers designed an electronic conversational assistant that allows patients to use voice-activated questions and answers or text-type chat to share information on their condition with health care providers. The system tracks and interprets data received and responds with personalized recommendations based on established guidelines. (Grant ID 59886)

- **University of Washington (Seattle):** **Development of a personal health record system for the home-based co-management of hypertension and diabetes between office visits.** The research team designed a system that enables diabetes patients to record glucose levels, blood pressure, food intake, and other information on their cell phones. They can then upload those readings to their health care provider wirelessly, via their cell phones, and providers can respond with feedback and advice. (Grant IDs 52601, 59882, and 64815)

- **Vanderbilt University Medical Center and Vanderbilt University School of Medicine (Nashville, Tenn.):** **Developing a child-focused personal medication management system.** Researchers developed a personal health application, My-Medi-Health, that helps children 6 to 12 years of age with cystic fibrosis take a more active role in managing their medications by reminding the child to take medications at established times and alerting parents and/or school personnel if there is no response to the reminder. (Grant IDs 59881 and 64537)

- **Walter Reed National Military Medical Medical Center (Bethesda, Md.):** **Personal health application for adult diabetes self-management.** Team members created a personal health application that helps adult diabetes patients self-manage their condition by capturing information about daily living needed for diabetes management, such as dietary and physical activity data, analyzing the data, and providing advice for self-care via users’ cell phones—all with a goal of reducing medication errors and increasing adherence to prescribed regimens. (Grant IDs 59888, 63415, and 64533)

**Round 2**

Project leaders encouraged the five research teams funded in Round 2 to build on the key lessons learned in Round 1. Chief among these was the understanding that the personal health information individuals find most valuable derives less from their medical records than from their own observations regarding their day-to-day activities and behaviors, what has come to be called observations of daily living. (For more information see Most Significant Finding, Round 1 below.) Round 2 grantees sought to demonstrate how
information on those activities could be effectively integrated into the clinical care process.

These grants ran from December 2009 to April, May, or June 2012. Brief descriptions of the projects funded in Round 2 follow.

- **Carnegie Mellon University School of Computer Science, Human-Computer Interaction Institute (Pittsburgh):** Recording observations of daily living to improve the care of older adults at risk for cognitive decline. Researchers created dwellSense, which uses in-home sensors to monitor routine tasks by older people (taking medication, making phone calls, preparing coffee) as benchmarks of cognitive function. These data are monitored by participants, caregivers, and clinicians in order to detect changes in day-to-day abilities. (Grant ID 67167)

- **Research Triangle Institute (RTI) (Research Triangle Park, N.C.):** Recording observations of daily living to improve the care of adults living with asthma and depression. The team designed a mobile application, called BreathEasy, that enables asthma patients to use their smartphone to collect daily data on their use of medications, symptoms, quality of life, and other measures. Health care providers review these data and respond to patients with suggested changes in treatment. (Grant ID 67162)

- **San Francisco State University Health Equity Institute for Research, Practice, and Policy:** Recording observations of daily living to improve the care and self-management of youths with obesity and depression. Researchers used mobile applications popular with teens and young adults as tools to help them monitor habits and conditions such as physical activity, food intake, socialization, and mood. Participants can use the applications, called the iN Touch system, to communicate with health coaches, therapists, and other health care providers in order to track progress, guide decisions, and set goals. (Grant ID 67166)

- **University of California, Berkeley:** Recording observations of daily living to improve the care of patients with Crohn's disease. Team members designed Chronology.MD, a mobile application system that enables young adults with Crohn’s disease to track pain, fatigue, gastrointestinal symptoms, and other information relevant to their condition, including mood. Patients are able to see important associations among health factors and make relevant changes such as getting more sleep and exercise as a way to feel better and reduce medication use. (Grant ID 67466)

- **University of California, Irvine:** Recording observations of daily living to improve the care of low-birthweight infants. Team members created a mobile application, Estrellita, that allows mothers and other caregivers of high-risk infants, following discharge from the hospital, to collect and report information on the babies’ conditions (fussiness, weight, urination, and bowel movements). The application also
collects information on the caregiver’s condition (stress, depression), and helps them coordinate and prepare for clinical appointments. (Grant ID 67163)

**National Program Office Support**

National program staff provided support to the funded projects in multiple ways.

**Direct-to-Grantee Support**

Staff led monthly telephone calls with individual project teams to receive updates and provide guidance. They also conducted monthly conference calls that included representatives from each project team to promote collaboration among the teams and share information and progress.

The deputy director, with at least one national advisory committee member and sometimes a technical consultant, visited each project site and provided on-site consultation.

An online forum designed to enable project teams to share their work with each other did not engage the researchers as hoped. Program leaders realized that they had failed to consider the reluctance of academic researchers to share work in progress with a national, nonacademic audience.

**Consultants**

In order to provide advice to the program overall and support to grantees in key areas, leaders of *Project HealthDesign* funded experts in a range of fields.

**Technical Consultants**

Previous generations of personal health records and devices had been limited by their inability to accept data from individual patients and also by their inability to communicate smoothly with one another.

*Project HealthDesign* contracted with technology consultants Sujansky & Associates to identify and implement technical requirements common to grantee projects in both Round 1 and Round 2 that addressed communications glitches. Sujansky’s experts also worked to develop a prototype of a publicly accessible common platform that would provide shared functions for a variety of personal health applications.

In addition, grantees attended design workshops, held two to three times a year, at the Vanderbilt University’s Vanderbilt Center for Better Health in Nashville. The workshops provided team members with technical advice and encouraged collaboration in order to further the goal of achieving data compatibility.
Regulatory, Legal, and Ethical Consultants

Making personal health records more accessible and more flexible offers patients many benefits, but also raises numerous concerns. Various regulatory and policy bodies as well as health care providers and public interest groups are wrestling with questions regarding patient rights and provider responsibilities in the digital age, chief among them privacy.

For advice on ethical, legal, and social issues, project leaders engaged experts from the University of Miami’s Bioethics Program, who worked with the grantees in Round 1. To provide advice on legal, regulatory, and policy questions to Round 2 grantees, project leaders engaged experts from the law firm of Manatt, Phelps & Phillips and the Center for Democracy and Technology.

Communications Support

Communications consultants from GYMR, a Washington-based public relations and social marketing firm, worked with grantees (under a separate RWJF grant) on external messaging. GYMR also worked with Daylight Design and the national program office to create and distribute visual stories featuring each Round 1 grantee’s applications and vision. A single, integrated video was produced for Round 2 that focused on the use of observations of daily living.

RWJF also provided program staff and grantees with Connect training. The Connect Project helps RWJF grantees and partners build or enhance relationships with members of Congress and other policymakers.

Focus Group Researchers

Aware that a key focus of the program was the usefulness of health data to individuals, RWJF commissioned, under a separate grant, a series of focus groups to solicit the views of consumers as well as some physicians. Participants were asked how personal health records and other emerging electronic technologies could enhance patient care. A team of researchers from Harvard Medical School, Beth Israel Deaconess Medical Center, Brigham and Women’s Hospital, and the Massachusetts Institute of Technology conducted the study, specifically to provide insights that would inform Project HealthDesign’s efforts.

In addition to this initial round of focus groups, individual project teams engaged with groups representing the intended users of the applications being developed in order to better understand the needs and desires of the population in question.

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5 Grant ID 70923 ($62,000, April 1, 2013 through April 30, 2014)
6 Daylight Design’s work was funded under two contracts, 59898-020 and 59898-024.
7 Grant ID 56392 ($178,651, September 1, 2006 to August 31, 2007)
Future Scenario Planning in Personal Health Technology Strategies

Under a second related, but separate, grant,8 consultants from scenario planning firm Global Business Network convened a scenario workshop in 2008 with representatives from the national program staff, the national advisory board, and RWJF to help program leadership adjust strategies as needed to ensure that the development of the next generation of personal health records remains relevant in light of the continuing evolution of the field.

Key insights generated by the workshop included:

- There may be a lack of clarity about the fundamental choice between the personal health record as a facilitative tool that follows health care system changes versus a transformative means to drive all system participants to the preferred system.

- While the “official future” for personal health records is one in which they are powerful forces that change health care practices and/or transform the system, there are plausible futures in which they are not.

- Personal health records are a solution that is unsure about which problem to solve—there is ambiguity about “precisely what it is they are supposed to do.” This uncertainty may be a partial explanation for the surprisingly low demand for them.

- Two interesting policy issues relate to two different scenarios for the future: (1) collective action, in which people need to connect to personal health records to comply with societal norms or requirements, so the critical policy issue is the construction of public health data sets; and (2) individual action scenarios, where there are fewer individual incentives for adoption, so the policy issue is to tie health coverage to the adoption of personal health records.

The Evaluation

A team of researchers headed by Deborah J. Cohen, PhD, MA, of the Oregon Health & Science University in Portland, Ore., conducted an evaluation of the five projects in Round Two of Project HealthDesign.9 For Findings, see The Evaluation & Its Findings.

8 Grant ID 63464 ($161,642, November 15, 2007 to November 14, 2008)
9 Grant ID 69909 ($200,000, April 1, 2012 to August 31, 2014)
PROGRAM FINDINGS

Most Significant Finding, Round 1

In a series of reports and interviews, leaders of Project HealthDesign cited one especially significant finding that emerged from the projects in Round 1:

Observations of Daily Living Turn Out to Be Most Meaningful

A central goal of the program from the outset had been to find ways to make personal health records more engaging for the individual person. As the grantees in Round 1 discussed with patient groups and others how to achieve that goal, it became clear that the information people found meaningful wasn’t so much clinical data as it was the experiences of their day-to-day lives.

Project leaders coined a term to describe these experiences: observations of daily living, or ODLs. What people observe will, by definition, vary by individual case, but might include details on sleep, diet, exercise, mood, energy levels, responses to medications, and the like. Thoughts, attitudes, and behaviors can also be observed.

According to National Program Director Brennan, observations of daily living, when integrated into personal health applications and correlated with other measures, such as test results and medication regimens, add significant depth and dimension to the clinical data in traditional health records.

“The concept of observations of daily living is an important and missing link in the health data panorama.”—Patricia Brennan, RN, PhD, FAAN, FACMI, Program Director

“People use very personally defined and idiosyncratic cues that give them the impetus to act on their health,” she continues. “These may range from how tightly their clothes fit to whether or not they have enough energy to run around after their grandchild. While these may not be indicators of any specific health problem, they are what the person attends to, and if you’re going to have person-centered health, you have to know what the people are paying attention to first.”

Additional Findings, Round 1

Other findings from Round 1 cited by program leaders included the following:

- Participants seemed willing to use a wide variety of technologies to record, enter, and receive data in their personal health records, from a smartphone to a Fitbit body monitor. However, Brennan eventually concluded that convenience dictates that in the long run it will be preferable to consolidate all the various functions of a personal health record on one general-purpose device, such as a smartphone or tablet.
• In some cases applications allowed patients to record observations of daily living in their own terms, using language meaningful to them.
  — The conversational assistant developed for heart failure patients by researchers at the University of Rochester, for example, used natural language processing systems that would record and respond to information spoken by patients.

• Having access to their personal health information and control over it seemed to be even more important to patients than privacy.
  — Project leaders compared this willingness to trade some degree of privacy in order to gain services to the public’s acceptance of online banking.

**Close-Up: Personal Health Application for Diabetes Management**¹⁰

Researchers with the Diabetes Institute at Walter Reed National Military Medical Center and the John A. Burns School of Medicine at the University of Hawaii wanted to help diabetes patients manage their conditions more effectively. They developed an application that would analyze data in a patient’s existing personal health record and then offer suggestions, in graphic or text form, for steps that could be taken to reduce symptoms and improve health. The program was available on the Internet and could be accessed securely via desktop computer or mobile device.

The prototype program responded to goals defined by each patient and tracked glucose levels, medication adherence, diet, and physical activity. Alerts were sent to the patient if trends in glucose levels suggested a problem. Patients were able to enter information about foods they intended to eat or activities they intended to engage in and the program would offer feedback on how those behaviors would affect their glucose levels. Another feature correlated a patient’s self-reported mood with his or her glucose level.

**Close-Up: The Colorado Care Tablet**¹¹

When discharged from the hospital, elderly patients with multiple chronic health conditions can be overwhelmed by all the things they need to do in order to maintain their health at home. They often find medication management especially confusing, and confusion can lead to adverse health consequences.

To address these concerns, a research team at the University of Colorado Denver Fitzsimons Early Learning Center designed a personal health application, the Colorado

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Care Tablet, that would help patients create and maintain a personal medication list. The list could compile prescriptions from multiple doctors, provide easy-to-understand information about medications, and alert the patient to conditions (e.g., a high fever) that could lead to hospital readmission.

Researchers supplied participating patients or their caregivers with a portable touch-screen tablet computer. To make entry of medication information easy, the application featured a bar code scanner that recognized medication labels. The application would then display information on those medications, including pictures of pills, potential interactions with other drugs, medication schedules, side effects to be aware of, and what to do if a dose is missed. Patients could also see information on preparing for doctor visits and when to seek assistance.

**Most Significant Finding, Round 2**

Once the value of observations of daily living had been recognized and developed in Round 1, the five Round 2 grantees focused their efforts on making the data collected by individuals accessible to their health care providers, and on finding ways to use personal electronic devices to foster two-way communication between clinicians and patients.

Their efforts in many respects met with frustration (see Challenges section, below) but also affirmed a basic conviction regarding the empowerment of the individual patient.

**Observations of Daily Living Can Improve Clinical Decisions**

The Round 2 projects demonstrated that combining observations of daily living with traditional clinical data gives physicians and other providers a more robust picture of a patient’s health, leading to improved clinical decision-making and saved lives.

The patient-clinician partnership is strengthened as well. Clinicians become aware of issues that might never have come up in regular office visits, while patients become more actively involved in their care. Treatments can be altered; costs reduced; lives saved.

“People are experts in everyday living. Physicians are experts in clinical care. Technologies bring them together.”—Patricia Brennan, RN, PhD, FAAN, FACMI, National Program Director
Additional Findings, Round 2

Other findings from Round 2 cited by project leaders included the following:

- **Observations of daily living are most often incorporated into the clinical workflow not by physicians but by nurses, health coaches, and other health care providers.**
  
  — Researchers at Research Triangle Institute, for example, found that the initial review of data submitted by asthma patients in their BreathEasy project would be performed by nurses trained to recognize data that called for physician attention and/or follow-up with the patient.

- **Technologies available now make it possible to track a patient’s progress with far more specificity than is possible with weekly or monthly visits to a doctor’s office.** Observations of daily living and clinical measurements (heart, exercise, and blood sugar levels, for example) can be recorded daily, hourly, virtually any time.
  
  — Patients dealing with chronic disease and their physicians found close tracking of their conditions especially useful in gauging responses to medications, diet, and other relevant factors.

- **Technologies available now allow clinicians and patients to customize applications, choosing not only what data are recorded, but how they are displayed.** This takes into account variations in the ways patients use technologies, as well as variations in conditions and treatments.
  
  — For example, researchers from the University of California, Berkeley, allowed patients with Crohn’s disease to continually revise their observations of daily living, with the goal of making each patient’s list as personally relevant as possible.

**Close-Up: dwellSense**

Researchers from [Carnegie Mellon University](http://www.cmu.edu) set out to track the daily activities of elderly patients as a means of watching for signs of cognitive decline. The team placed sensor devices in key locations in the Pittsburgh apartments of 15 elderly participants (12 of whom eventually completed the study). The sensors monitored such routine tasks as taking medications, dialing the telephone, and making coffee.

Data collected by these sensors revealed breaks or mistakes in these daily activities—a medication not taken, for example, or a misdialed phone call. Other sensors monitored restlessness in bed and movement within the apartment. Participants and their clinicians reviewed the collected data to gain insight into the participants’ changing physical and mental abilities.
The study monitored participant activities for eight months, dividing their subjects into two groups. One group received real-time feedback on a computer tablet in their apartments; the other group received long-term feedback at intervals of either two months, during one phase of the study, or four months, during another phase of the study.

In a report to RWJF, the research team said that participants who received real-time feedback showed a statistically significant change in improving their performance of tracked activities and sustained that improvement. Participants in the long-term feedback group showed a slight improvement in tracked activities after being shown results, but this improvement was not sustained.

**Personal Experience With dwellSense**

Rebecca (not her real name) is a 67-year-old woman who lives alone. She has multiple chronic health conditions, including arthritis, diabetes, and bipolar disorder. She is also a cancer survivor. The dwellSense study sensors were placed in her home to track when she took her medications as well as the accuracy with which she dialed phone calls and made coffee and she received a tablet-based display through which she received feedback from clinicians.

The dwellSense sensors and display gave Rebecca feedback on how she did on all three activities. The program also allowed her to print out her results so that she could discuss them during office visits with her primary care physician. The records showed that Rebecca had been keeping up with her medication regimen consistently—more consistently, in fact, than Rebecca herself had thought.

This helped the primary care physician discount medication management issues as a contributing factor in Rebecca’s mood swings or her diabetes. Instead she focused on what might be bothering her emotionally and on her diet. It turned out Rebecca had been upset by the death of her former husband, and her doctor recommended that she be more careful in keeping her psychotherapy appointments. The print-outs from the dwellSense program also showed that Rebecca had sometimes been making coffee late at night. Rebecca had complained that she had trouble sleeping. She agreed with her physician’s suggestion that late night coffee might be something to avoid, so she can get a good night’s sleep.

**Close-Up: iN Touch**

Researchers from San Francisco State University wanted to use mobile electronic technologies to help low-income youth deal with obesity and depression. Some 55 participants between 13 and 24 years of age used iPod Touch electronic devices to record observations on their exercise, diet, weight, and mood. They were able to upload
observations of daily living to the commercial health platform, TheCarrot.com. Collected data could be shared and discussed with health coaches and health care providers.

In a report to RWJF, the research team reported that participants achieved a significant improvement in waist size (an average reduction of 1.5 inches). Use of the iPods to record observations of daily living varied significantly: some participants recorded ODLs several times a day, others hardly ever. A guide for health coaches, developed later in the project, helped improve consistency by providing a weekly checklist for coaches and students to follow. Project leaders also resolved early problems with students not having Wi-Fi connections at home by arranging for permission for them to log on at school.

Health care providers reported that they found observations of daily living regarding mood especially useful, and that they found the data overall to be a good conversation starter in discussions with patients.

Personal Experience With iN Touch

Sarah (not her real name) is a prediabetic high school student with a history of obesity. During her first meeting with a health coach from the iN Touch team, she said she wanted to improve her exercise and eating habits (she regularly consumed fast food and soft drinks) but wasn’t sure how to go about it. Other bad habits, including cutting class, also concerned her.

Sarah began recording observations of daily living, including diet, exercise, social encounters, and mood, through daily posts to the iN Touch platform on TheCarrot.com. She and her iN Touch coach developed an exercise plan, complete with back-up exercises she could use if for any reason her regular routine was interrupted. She stayed in touch with her coach through texting and in-person visits, during which she discussed her progress, challenges, and strategies for staying on course. Meanwhile she continued to see her regular physician.

By the end of her sixth month on the program, Sarah had lost nearly 20 pounds and upgraded her exercise routine to include power walks using hand weights. She’d eliminated sugar from her diet, enjoyed looking up new salad recipes, and curbed her habit of cutting classes.

Findings From Consultants

Focus Group Researchers

The focus group researchers reported findings gathered from eight focus groups convened between November 2006 and January 2007 in an article, “Insights for Internists: ‘I Want the Computer to Know Who I Am,’ ” published in the Journal of General Internal Medicine in 2009. See the Consultants Bibliography for details.
Six of these groups consisted of consumers; two consisted of health care professionals. Researchers asked participants to describe their vision of a technology-enabled health care system and how personal health records and other technologies could change interactions between patients and clinicians.

Among their findings:

- **Consumers want full access to the health records kept by their health care providers.**
  
  — Said one, “I don’t know if I want to read [my entire medical record], but I want to have it.”

- **Consumer participants focused far more on the benefits of electronically available records than on concerns regarding privacy.**
  
  — Benefits cited include “rapid access and communication, particularly for those acutely or chronically ill.”
  
  — Patients become less concerned about privacy when they’re sick.
  
  — Professional participants expressed far more concern about privacy issues than consumer participants.

- **Consumers look forward to computers helping them avoid doctor visits by fostering self-care.** They expect electronic health applications to help them diagnose and manage common recurring conditions.
  
  — Consumer participants agreed most clinicians are stretched too thin. Most seemed unconcerned that the increased use of electronic health technologies might reduce their personal contact with clinicians in the future.
  
  — Participants thought that self-care that is enabled through technology will help to minimize delays in treatment, reduce costs, and free-up clinician time for more complicated care.
  
  — Although few participants expressed concern about the risks of this approach, one health care professional warned that society would have to “allow people to make bad decisions.”

- **Consumers have high hopes for more advanced health care technologies in the future.** These include body implants to monitor blood pressure and glucose levels and smart home technologies that would monitor air quality and other conditions.
  
  — Consumers envision a computer that will “understand” who they are and respond with appropriate information and advice.
Technical Consultants

Round 1: Developing a Common Platform

Technical consultants Sujansky & Associates worked with Round 1 grantees to develop a set of core software components comprising a common platform. Members of the Vanderbilt Center for Better Health and the project’s consultants on legal, regulatory, and ethical issues also contributed.

Development of the common platform yielded two important lessons, as reported in the Round 1 final report prepared by national program staff:

- A common technical platform can support a variety of personal health application tools.
- Centralizing common functions reduces implementation time and increases interoperability among personal health applications.

Features identified as necessary for such a system included:

- Medication list management, including the ability to record, manage, share, and provide advice on a patient’s prescribed medications
- Calendaring, including the ability to help personal health applications record, track, share, and remind patients of medical appointments and other events relevant to their health
- Observations of daily living, including the ability to store, aggregate, analyze, and share ODL data
- Identity management, including the ability to verify the identities of users and systems seeking use of patient data and patients’ ability to determine what users and systems will be allowed access to their data

In 2010 Sujansky & Associates’ article, “A Method to Implement Fine-Grained Access Control for Personal Health Records Through Standard Relational Database Queries” spelling out the basic elements of such a system was published in the *Journal of Biomedical Informatics* and made available to Round 1 grantees.

The project met with mixed success. As project leaders put it in their summative report to RWJF, “Although our technical consultant worked with grantees to identify the requirements for a common platform and built a prototype, we did not fully demonstrate the ability to store and retrieve patient generated data from this common external data repository.”

RWJF’s Downs points out that the important part of the common platform effort was the development of the specifications. The hope was that those specifications would influence the platform services that companies would build. The project took the further
step of building a functional prototype of the common platform and releasing the code under an open source license, but the demand for it was limited.

**Round 2: Projects’ Technical Challenges**

None of the research teams in Round 2 used the common platform. However, Sujansky & Associates continued to work with the grantees as they grappled with a variety of technical issues. Those issues included:

- **Difficulties integrating with third-party data repository systems.** These include:

  - **Limited options.** Of the existing systems, only Microsoft HealthVault and TheCarrot.com proved viable, based on grantees’ architectures and needs. One team used TheCarrot.com successfully, but a variety of restrictions thwarted teams choosing the Microsoft system.

  - **Data incompatibility.** When data for observations for daily living are recorded using custom data types and uploaded to a third-party repository, other applications using that repository will not be able to automatically use them, unless developers of those applications specifically build in the ability to do so.

- **Device power issues.** Loss of power can interfere with the collection and transmission of patient data. Grantees could not develop a fail-safe backup system that would protect data in case of device failure or power loss.

  - Smartphones and sensors often deplete their batteries in less than 24 hours. One research team scheduled weekly battery changes for its devices to avoid battery failure. Another team reconsidered its use of sensor devices to collect data because of the burden battery replacement would place on patients.

See the **Consultants Bibliography** for articles and reports from the technical consultants.

**Regulatory, Legal, and Ethical Consultants**

In a review of the regulations currently in place to protect the privacy of patient-generated health information, the legal consultants at Manatt, Phelps & Phillips concluded in an article published in *Personal and Ubiquitous Computing* that those protections are “spotty at best.”

Privacy provisions of the federal Health Insurance Portability and Accountability Act (HIPAA) apply to data generated by health care providers, not to data generated by patients. Some protection for patient-generated data is offered by statutes of the Federal Trade Commission, but these are broad and enforcement is uncertain.

As patient-generated data are increasingly included in personal health records, therefore, many questions regarding the rights of patients and the duties of caregivers remain. A series of journal articles authored by *Project HealthDesign’s* consultants on regulatory,
legal, and ethical issues summarized some of their findings in regard to those questions. See the Consultants Bibliography. Selected findings follow:

Privacy and Security

In an article in the *Journal of Biomedical Informatics* reporting their work with project teams in Round 1, members of the University of Miami Bioethics team noted the following privacy and security concerns:

- **In the new world of health technologies, patients themselves play an unprecedented role in safeguarding their own health information.**

- **Patients may not feel comfortable sharing all of the data in their personal health records with all of their health care providers.** Systems that don’t offer patients the ability to exercise granular selectivity of information access raise privacy concerns.
  
  — For example, a patient being treated for both diabetes and depression may not feel comfortable sharing information regarding her depression with everyone who has access to the information regarding her diabetes.

- **Minors are, in general, more apt to share personal data.** Whether release of that information via personal health records should be subject to parental consent is unclear.

Mobile Security

In a 2012 article in the *Journal of Healthcare Information Management*, consultants from Manatt, Phelps & Phillips, and the Center for Democracy and Technology reviewed special security concerns regarding data transmitted through smartphones and other mobile devices.

Findings and recommendations included:

- **The responsibility of health care providers for implementing security measures increases when the provider is supplying patients with mobile devices and encouraging them to share health information on them.**

- **Patients can be easily overburdened by security measures, both because they do not want to be inconvenienced and because their technical skills may be limited.**
  
  — Where possible, health care providers should offer patients education and training on the use of passwords and other advice on handling security on mobile devices.

  — Security measures should be of a level of difficulty that takes patient limitations into account. Patients often consider passwords, automatic log-offs, and other security features to be obstacles.
Data sent over mobile devices, including text and email messages, should be encrypted. Providers supplying mobile devices to patients should investigate preinstalling encryption capabilities.

Liability Concerns

In an article in the *Journal of Participatory Medicine* consultants from Manatt, Phelps & Phillips and the Center for Democracy & Technology reviewed liability questions generated by the experiences of clinicians working with Project HealthDesign’s Round 2 grantees. Questions included:

- **When do physicians become liable for failing to respond to information submitted by patients through a personal health application?**
- **Are physicians obligated to share patient-generated health data with specialists or others treating the patient?**
- **How do clinicians know that patient-generated data are accurate, or that some relevant data have not been lost or compromised in transmission?**

Also in the article, the authors enumerated a series of recommended steps, which evolved collectively through the experiences of Round 2 grantees, for clinicians to take when dealing with patients who are submitting personal information electronically. They include:

- **Work with patients to formulate agreements on what types of information patients will share, how the information will be shared, what members of the clinical team will be reviewing the information, and how often the information will be reviewed.**
- **Designate a trained member of the clinical team to monitor incoming data and respond appropriately.**
- **Make sure patients understand that medical data submitted electronically may not be reviewed immediately and that they must use traditional emergency measures when necessary.**
- **Determine what data submitted by a patient will be included in the physician’s medical record for that patient.** Definitions will vary, but none of the Project HealthDesign applications automatically included all patient-generated data.

Communications Results

Leaders of Project HealthDesign set system change as their priority, and communications played an important part in achieving that goal.

As they put it in their summative report to RWJF, “Our program was designed to push the boundaries of both health information systems and clinical data, with patients at the
center of the user group. Thus, our communications efforts focused on raising awareness rather than advancing specific solutions or products.”

Toward that end, project leaders pursued what they described as “a robust, multifaceted” communications program to advance their vision of personal health records to a variety of audiences, including health policy officials, clinicians, and the health information technology community.

Activities included:

- **Providing expert information and commentary.** Program Director Brennan provided expert information and commentary on personal health records to a wide variety of policymaking bodies. The project’s consultants and grantees also participated on occasion.

  Groups before which Brennan or others appeared or to which comments were submitted included:

  - Meaningful Use Workgroup of the federal government’s Health Information Technology Policy Committee
  - Office of the National Coordinator for Health Information Technology
  - President’s Council of Advisors on Science and Technology
  - National Institute of Nursing Research
  - U.S. Food and Drug Administration
  - Patient-Centered Outcomes Research Institute
  - National Institutes of Health
  - Centers for Medicare & Medicaid Services
  - American Health Information Community

- **Connecting with lawmakers.** In June 2008, seven grantees and several staff members of the national program office attended a day on Capitol Hill, speaking with congressional staff members on issues related to patient access to information and personal health data.

- **Building a Web presence.** With the help of communications experts (both on staff and consultants), the project maintained an active, visible profile on the Internet.

  - The *Project HealthDesign* website became the repository of information on a wide variety of activities, including updates from program leaders, project reports, consultant reports, blog entries, notices of journal articles published, copies of testimonies by program leaders before regulatory bodies, and more. RWJF plans to keep the *Project HealthDesign* website active at least through 2016.
— From April of 2009 through June of 2013, leaders, grantees, consultants, and others contributed dozens of entries to the Project HealthDesign blog. Subjects ranged from policy and privacy issues to conferences attended, project updates, and personal essays.

— Other Internet activities included webinars, podcasts, video interviews and profiles, a Twitter account, a SlideShare site, and a YouTube channel.

- **Convening a showcase conference.** On September 17, 2008, Project HealthDesign and RWJF hosted a one-day showcase conference in Washington titled “New Frontiers in Personal Health Records: A ‘Report Out’ from Project HealthDesign and Forum on Next-Generation PHRs.” More than 100 people attended. The conference featured presentations by Round 1 grantees and a series of panel discussions on various issues, led by numerous thought leaders from the health care and technology industries, government, foundations, and academia. The conference agenda is available [online](#).

- **Publishing journal articles.** Program leaders and grantee investigators wrote articles that were published in a range of peer-reviewed journals including a special supplement of related articles in the *Journal of Biomedical Informatics* as well as articles in journals such as the *Journal of Telemedicine and Telecare, Studies in Health Technology and Informatics, Telemedicine Journal and e-Health, Journal of Medical Internet Research, Journal of Participatory Medicine*, and the *Journal of Healthcare Information Management*.

- **Presenting at meetings and conferences.** Program leaders, consultants, and grantees also attended and sometimes made presentations at a number of other conferences, among them the mHealth Summit, AcademyHealth’s Annual Research Meeting, TEDMED, the O’Reilly Open Source Convention, the American Medical Informatics Association’s Annual Symposium, and Health 2.0.

- **Developing toolkits on various aspects of personal health records including the collection and use of observations of daily living.**

See the [Bibliography](#) for details and links to materials available online.

**THE EVALUATION & ITS FINDINGS**

The evaluation conducted by Cohen and colleagues focused on the benefits and challenges associated with the collection of observations for daily living (ODLs).

Evaluators interviewed team members from the Round 2 projects as well health care professionals, including clinicians and nurses. Evaluation activities also included a review of existing literature on ODLs, a review of documents and data from each of the five projects, reviews of interview transcripts from focus group sessions, and discussions with *Project HealthDesign* leadership from RWJF and the national program office.
Evaluation Findings


Potential Advantages of ODL Collection

The evaluation team noted a number of potential advantages to ODL collection. These included:

- Increased ability for patients to participate proactively in managing their conditions
- Increased patient awareness and understanding of how behaviors influence health
- Enhanced communication between patient and health care professionals
- Measurable improvement in treatments and conditions
- Reduced stress and worry for patients

Factors Affecting Successful ODL Collection

The evaluation team developed a model with six factors that explain patient motivation to collect ODL data. The evaluators expect that this model may be of use to researchers and designers developing new personal health technologies “to empower people to improve their health.”

Usability

Ease or difficulty of using program software can significantly impact patient ability or willingness to record ODLs. Factors reducing usability include:

- Difficulty using search tools
- Inability to protect against loss of data entered
- Inability to add ODL data for a previous day

Information Technology Infrastructure

Infrastructure issues that may affect ODL collection include:

- With any device, obstacles to accessing online programs (e.g., lack of Wi-Fi access) can hinder or prohibit successful collection of ODLs.
- Improvements in the technology of sensors that allow data to be recorded automatically have great potential for improving collection of ODLs, especially when
patients are not motivated to collect them. However, there are potential downsides to data collection by sensor. They include:

— Difficulties due to weak or sporadic Wi-Fi connections in patient homes
— Collecting an over-abundance of data, requiring too much effort on the part of health care professionals to sort the wheat from the chaff
— A risk that patients, because they are not actively involved in data entry, will be less attentive to what the data reveal. If this is the case, additional intervention may be required for them to benefit from the process.

Perceived Relevance of the ODL

Collection of ODLs is influenced by the motivation or lack of motivation on the part of both patients and providers. “The perceived relevance of ODL data is critical,” evaluators stressed.

Factors influencing motivation include:

● A patient’s personal situation, including the stage of the disease being treated, how long the patient has had the disease, and the stability or lack of stability of the patient’s condition
● Physician interest, support, and encouragement
● Sufficient flexibility in tracking methods to accommodate individual needs

Burden Involved in Collecting ODL

The greater the effort required to record ODL data, the less likely patients will record it. As described by evaluators in a report to RWJF, “The burden of using a tool to collect ODL data must not dramatically outweigh the potential or perceived benefits, including both short- and long-term burdens and health care outcomes.”

Factors influencing the burden of recording ODLs include:

● Manual data entry. Difficulties increase when data entry is expected several times a day, and if detail is required.
  — One student participant expressed strong distaste for the process, saying, “Writing down what you eat is just awful.”
● Time pressures. Participants who delay entering ODLs until later in the day may forget details.
  — Use of a snippet technique for ODL collection shows promise. This entails patients making more frequent short entries during the day that can be elaborated in the evening or other times when daily pressures have subsided.
• Learning how to use updated software or hardware. Changes in data entry protocol require a learning curve that can inhibit collection.

Emotional Activation and Variations in Health or Illness State

These two related factors were also important influences on ODL data collection. As level of health or the course of an illness varies over time the relevance of the ODLs can also vary. As patients’ health improves they may no longer feel that ODL collection is useful. More consistent tracking is likely when a patient does not feel well. “When I am not feeling well, I track every day; but if I am feeling well, maybe once a week or once every two weeks,” said one participant.

Evaluation Communications

In addition to the article published in *Personal and Ubiquitous Computing*, the evaluators presented findings at the North American Primary Care Research Group Annual Meeting in November 2014. See the Evaluators Bibliography for details. They also produced a literature search and summaries of Round 2 projects for their internal use and sharing with the national program office and grantees.

CHALLENGES

Brennan and Downs identified two major challenges, as well as others, that confronted Project HealthDesign as a whole:

Major Challenges

Keeping Up With Technology

The most obvious challenge encountered by leaders and grantees of Project HealthDesign arose from the remarkable speed with which health technologies evolved over the program’s life span.

A few benchmarks tell the story.

*Project HealthDesign* launched in 2006. Apple introduced the iPhone a year later, and two years after that the Android phone appeared. An explosion of smartphone apps, including many, many health apps followed—100,000 in the first quarter of 2014 alone—which was a doubling of that in the previous two and a half years—according to *Modern Healthcare*, even as a host of wearable fitness devices hit the market. Also a year after *Project HealthDesign*’s launch, Microsoft introduced an online health data platform

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called HealthVault. Other platforms that subsequently appeared include Dossia, Google Health (introduced in 2008, closed in 2011), and TheCarrot.com.

The number of health-related technologies has continued to grow since Project HealthDesign concluded. Notable developments include Apple’s introduction in 2014 of its Health app for consumers and its HealthKit programming interface for app developers. Also in 2014 Apple announced the Apple Watch, which when introduced in 2015 will include a series of health tracking features. Not to be outdone, in October of 2014 Microsoft introduced a wearable fitness monitor and online health service (called Microsoft Band and Microsoft Health, respectively) capable of tracking heart rate, sleep quality, and calories burned, among other things.

RWJF launched Project HealthDesign under the auspices of its Pioneer Portfolio, which is specifically dedicated to supporting adventurous new ideas that had the potential of significantly changing the health care landscape. Being ahead of the curve was part of its mandate. Being overtaken was not necessarily a bad thing—the goal has always been to see technology used to achieve positive change in health care, however that occurs—but no one wants to feel superfluous, either.

“It was hard to stay cutting edge,” Downs says. “Our vision for Project HealthDesign was pretty exciting when we laid it out in 2006. By the time our first round of grantees were ready to show their stuff, you could say, ‘Well, people are already building that.’ You can be ahead of your time at the beginning of a program and a little bit behind two or three years later. That was a challenge. In both rounds we tried to involve the tech companies that were starting to get more into this, but it wasn’t easy to do. So there was some feeling of, ‘They’re zipping ahead, and we’re constantly struggling to be relevant.’”

**Accommodating Technology**

New health care technologies have evolved far more quickly than the health industry’s ability to accommodate them. Even as they were demonstrating the clinical value of observations of daily living, the leadership and grantees of Project HealthDesign learned that numerous institutional barriers stand in the way of integrating those observations into clinical practice.

“We were unable to penetrate the electronic health record system, sending data in from the home,” Brennan says. “We attempted to demonstrate that you could monitor observations of daily living and transfer them through the clinical work flow and record system. And while that is technically feasible, there are institutional priorities that compete with taking on innovative practice activities such as these. Solving the data integration problem from the home to the clinic is going to require solving those issues.”
Competing Priorities

Brennan attributes some of the resistance to a lack of institutional will. By that she means that many hospitals, clinical practices, and other institutions were not prepared to dedicate the resources necessary to adapt their existing data systems to accept information supplied by patients. One reason for this was that many institutions and clinical practices were preoccupied during this period with trying to earn the incentives offered by the federal government for achieving meaningful use of their own electronic health records, a provision of the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.

The technical consultants Sujansky & Associates commented on this in a report on their work with the grantees in Round 2. Grantees found, they said, “that the medical groups and hospitals they are working in association with are in the midst of implementing new electronic health record systems. As a result, the health care organizations and their IT teams do not have the time or budget to develop custom interfaces to support integration with project teams.”

Openness to Change

Not all of the upheaval in the electronic health ecosystem was negative. Project HealthDesign unfolded during a period of great experimentation and openness to change, much of it directed at improving the use of personal health records and more directly engaging individuals in their own care. Examples included, in addition to the HITECH Act, the Strategic Health IT Advanced Research Projects (SHARP) program and the Health Information Exchange (HIE) through the Office of the National Coordinator for Health Information Technology, the Affordable Care Act, and RWJF’s Health e-Technologies, OpenNotes, and OpenmHealth programs.

As Project HealthDesign leaders noted in their summative report to RWJF, “These external events created a public dialogue and readiness for expansion of the idea of personal health records, and an acceptance that technological solutions could enable massive change in health care.”

Other Broad Challenges

Nonetheless, massive challenges remain unresolved. Among the most daunting of these are the technical compatibility problems to which Brennan referred. It’s one thing to have dozens of health data sources to draw on; being able to translate, combine, and consolidate that data so that it can be effectively used is something else.

Equally complex are the unresolved questions regarding patient privacy. Even though patients themselves seem open to sharing some data, protocols spelling out specifically what information can be shared, when it can be shared, and with whose permission it can
be shared have yet to be defined among patients, clinicians, hospitals, pharmacies, insurers, government agencies, researchers, and other players in the health care system.

**Specific Project Challenges**

In the course of their work, *Project HealthDesign*’s grantees encountered a wide variety of specific challenges, many of them manifestations of the broader issues cited above. Examples mentioned in reports submitted to RWJF include the following:

- **Complicated partnerships.** The projects’ cross-disciplinary nature—technology intersecting with clinical, commercial, nonprofit, academic, and nonacademic entities—ensured complications.

  Several grantees described delays they encountered when negotiations between institutional partners took longer than expected or when a project shifted from one institution to another. Researchers who were more accustomed to working with federal funders than with foundations also required special guidance.

- **Complicated technologies.** Not surprisingly, in the process of building applications as sophisticated as these, grantees encountered numerous technical problems. Issues mentioned in their reports included server communication issues, system maintenance issues, and (most often) code compatibility issues. An example:

  — During a test of their prototype, members of the University of Massachusetts Medical School team discovered a potentially serious technical problem with their chronic pain device. Errors in specifying medication doses and timing of medication, they found, could result in patients receiving repeated reminders to take their medications, possibly resulting in overdosing and serious injury. According to deputy director Gail Casper, the problem was resolved during the test phrase and no patient was at risk.

- **Clinician resistance.** Some grantees reported difficulty enlisting the cooperation of clinicians. Reasons cited included limited opportunities to secure appointments and physician skepticism that access to detailed health information would substantially alter patient behavior.

- **Fitting technologies in.** Helpful as they might be, technologies don’t always fit seamlessly into people’s lives, and the health care devices developed for *Project HealthDesign* were no exception. For example:

  — One of the mothers participating in the Estrellita project reported she did not always have time to enter observations for daily living on her twin infants because she was so busy caring for them and her two other young children.

  — Teenagers participating in the My-Medi-Health project did not always feel comfortable being reminded electronically to take their cystic fibrosis medications while at school.
— Researchers in charge of the iN Touch project spent a fair amount of time trying to track down the iPod Touch devices their young subjects had reported lost or stolen, and making sure the data on those computers was secure.

Meeting the Challenges

In a video report recorded upon Project HealthDesign’s completion, Brennan cited four basic issues that executives, practitioners, and officials throughout the health care system need to address:

- **They must recognize that traditional electronic health records no longer house all the important data relevant to patients’ health.** The existence of a broader “electronic health information ecosystem” must be taken into account.

- **They must find ways to ensure that the flow of information from patients to physicians, and vice versa, is accurate, so that parties on both ends know they can trust the information they’re receiving.** Errors in transmission can be dangerous, and therefore are unacceptable.

- **They must establish practice-permissive policies that enable clinicians to safely make actionable medical decisions based on information received from the patient electronically.** This will allow physicians to alter treatment regimens based on information received electronically, without requiring office visits.

- **They must find ways to expand confidentiality and privacy protections to accommodate the broader electronic health ecosystem as it has evolved.** These protections must apply, as Brennan puts it, “through the entire chain of transmission of information, from the moment it’s captured by the patient through its interim storage to its final use in the clinical practice setting.”

Brennan says these sorts of issues will take several years to resolve. Downs guesses 10.

“I think we’re going to get there,” he says, “but change is slow in the health care system. There’s an analogy to be made with the mid to late 1990s, when patients started bringing in printouts from Google searches into doctors’ offices. Doctors were going, ‘Don’t do that! It’s too much! You’ll worry yourself sick!’ But eventually that’s just become normal, and now doctors even encourage patients to be more aware of their conditions. So people are going to start doing more of that and over time physician practices are going to start figuring out how to take advantage of it.”

**SIGNIFICANCE OF THE PROGRAM**

Despite the frustrations of not being able to achieve all the technical advances they had aimed for, the leaders of Project HealthDesign agree that the program helped move the health industry as a whole in a positive direction.
The program, they believe, effectively demonstrated the importance of giving individuals more control over the information contained in their personal health records, thereby engaging them more directly in their own health care. It also firmly established that observations of daily living represent a clinically significant addition to that record.

As RWJF president and CEO Risa Lavizzo-Mourey, MD, MBA, put it during the New Frontiers in Personal Health Records showcase conference, “Giving people online access to their medical information is important, but it’s not enough to help them truly take charge of their health. They need smart tools that can interpret their data and provide customized feedback to guide their health decisions, day in and day out. By putting consumers at the center of the design process, we have demonstrated a powerful vision of how personal health records and new technologies can empower people to better manage their health and work together with their providers to get the care they need.”

Brennan emphasizes the influence Project HealthDesign has had in the deliberations of policymakers who are addressing personal health record reform. The voices of the program’s leaders, grantees, and consultants carried weight in part because they were ahead of the curve, she says—the goals they pursued anticipated many of the reforms policy makers subsequently identified as key objectives.

“Because of the work we had done on Project HealthDesign we were able to give an informed and principled input into that process,” she says. “The breadth and extensiveness of our work and the ‘first actor’ position gave us enormous referential influence.”

It’s more difficult, Downs believes, to pin down Project HealthDesign’s influence in the technology sphere. Just because personal health platforms, applications, and devices suddenly and dramatically evolved in exactly the direction the program’s leadership had envisioned from the outset—toward individual empowerment in personal health—doesn’t mean Project HealthDesign deserves credit for inspiring that evolution.

“In many ways you could say that these things were going to happen anyway,” Downs says. “In other ways, and maybe in smaller pockets of this, you could say we had a large influence. It’s hard to say.”

At the very least, Downs adds, “We sketched out an important vision, we demonstrated that it mattered, and we were able to document some key lessons about how to do it and the challenges associated with it.” By doing so, he believes, the project successfully helped energize those involved in personal health records to move in the direction of its vision, notably toward the incorporation of observations of daily living.
Both Downs and Brennan believe that defining the importance of observations of daily living will be a lasting contribution, one that has by now been adopted so widely within industry and policy circles that its origin is sometimes forgotten.

LESSONS LEARNED

1. **Build collaboration.** Project leadership decided early on that an open, collaborative spirit could enhance the work of the project teams, but they knew that this was not the way research often proceeded in the relatively isolated laboratories of academia. Holding design workshops—Brennan called them retreats—for team members two or three times a year at the Vanderbilt Center for Better Health helped foster collegiality, which in turn led to team members giving each other useful advice and support. (Program Director Brennan)

2. **Leave time for the machines to adjust.** Because of the technical complexities of the funded projects, program leaders made a point of leaving room in the schedule for adjustments. Initial plans submitted by grantees were considered vision and framework documents, with time set aside for refinement, especially as grantees were able to meet and discuss their ideas with each other and with the program’s leadership and consultants. (Program Director Brennan)

3. **Leave time for the humans to get the help they need.** Project directors learned that the cross-disciplinary nature of their projects meant that they also needed to allocate extra time to solicit and secure the help they needed from a wide variety of individuals and institutions. Activities that proved especially time consuming included recruitment of participants, staying in touch with participants, and dealing with institutional bureaucracies. (Project Directors, University of California, Irvine, and Carnegie Mellon)

4. **Invest in management.** Brennan and her colleagues learned that when running a program of this scope from a state university, there is danger of being overwhelmed by the minutiae of management detail. “There is a tremendous difference between how research funds and foundation funds are managed,” Brennan says, “and investment in staffing at the national program office was critical in making the program work.”

   This investment included hiring a full-time staff member to assist on contract and financial management. Program leaders also found that working with an outside public relations firm contracted through RWJF, proved too cumbersome. Hiring a part-time, in-house communications professional helped solve that problem. (Program Director Brennan)

5. **Seek experienced counsel.** *Project HealthDesign* benefitted tremendously from the advice Brennan and deputy director Casper received from people who had led similar initiatives in the past. Establishing early relationships with their counterparts at RWJF’s recently-completed *Health e-Technologies* program proved especially
helpful in getting Project HealthDesign started—developing an initial call for proposals, creating preaward webinars, and facilitating the review and selection of Round 1 applications. (Program Director Brennan)

AFTERWARD

As of late 2014, many of Project HealthDesign’s grantees are continuing their project work in various ways, though not with RWJF funding. Brennan continues her work in the field as a consultant. One of the projects Brennan is advising is the RWJF-funded Health Data Exploration Project,\(^\text{13}\) which Downs is helping supervise for the Foundation.

The Health Data Exploration Project aims to find ways to use the unprecedented quantities of personal health data being collected by individuals for research. With sufficient privacy protections in place, that data could be immensely valuable to, for example, epidemiologists hoping to trace the patterns of an epidemic, physicians trying to determine the effectiveness of treatments for heart disease, or nutritionists hoping to understand the impact of diet on diabetes.

Based at the University of California, San Diego, the Health Data Exploration Project will support a variety of studies to identify policies and best practices that would make data from wearable health monitors and smartphone apps available for the public good.

In addition, the work conducted by researchers in this program may be of interest to those doing work in the Real World/Real Time Data Opportunity Space initiative, in which nine projects are demonstrating the value and usefulness of data generated in real time and in the real world to patients, providers, public health officials, and researchers.

Prepared by: Doug Hill
Reviewed by: Mary B. Geisz and Molly McKaughan
Program Officer: Stephen J. Downs
Program ID: PGR
Program Director: Patricia Flatley Brennan; (608) 263-5247; pbrennan@engr.wisc.edu

\(^{13}\) Grant ID 71693 ($1,976,105, June 1, 2014 to January 31, 2017)
APPENDIX 1

**National Advisory Committee**

**Advisory Committee Members, Rounds 1 and 2**

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<tr>
<th>Name</th>
<th>Title and Affiliation</th>
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<tr>
<td><strong>Paul C. Tang, MD, MS (Chair)</strong></td>
<td>Vice President, Chief Innovation and Technology Officer, Palo Alto Medical Foundation, Los Altos, Calif.</td>
</tr>
<tr>
<td><strong>Michael Christopher Gibbons, MD, MPH</strong></td>
<td>Assistant Professor and Associate Director, Johns Hopkins Urban Health Institute, Baltimore, Md.</td>
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<tr>
<td><strong>David Ahern, PhD</strong></td>
<td>Associate Professor, Psychology, Harvard Medical School, Boston, Mass.</td>
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<tr>
<td><strong>Brandon H. Hull, MBA</strong></td>
<td>Co-Founder and Partner, Cardinal Partners, Princeton, N.J.</td>
</tr>
<tr>
<td><strong>Carmella Bocchino, RN, MBA</strong></td>
<td>Executive VP, Clinical Affairs &amp; Strategic Planning, America's Health Insurance Plans, Washington, D.C.</td>
</tr>
<tr>
<td><strong>Omid Moghadam, MS, MBA</strong></td>
<td>Director, Personal Health Record Programs, Intel Corporation, Santa Clara, Calif.</td>
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**Advisory Committee Members, Round 1 Only**

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<tr>
<td><strong>Helen Burstin, MD, MPH, FACP</strong></td>
<td>Senior Vice President, Performance, National Quality Forum, Washington, D.C.</td>
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<tr>
<td><strong>J. Marc Overhage, MD, PhD</strong></td>
<td>Adjunct Associate Professor, Indiana University School of Medicine, Indianapolis, Ind.</td>
</tr>
<tr>
<td><strong>David Lansky, PhD</strong></td>
<td>Director, Health Program, Markle Foundation, New York, N.Y.</td>
</tr>
<tr>
<td><strong>Alison Rein, M.S.</strong></td>
<td>Senior Director, Evidence Generation and Translation, AcademyHealth, Washington, D.C.</td>
</tr>
<tr>
<td><strong>Farzad Mostashari, MD, MSPH</strong></td>
<td>Assistant Commissioner</td>
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**Advisory Committee Members, Round 2 Only**

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<th>Name</th>
<th>Title and Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Veenu Aulakh, MSPH</strong></td>
<td>Associate Director, Community Clinics Initiative, San Francisco, Calif.</td>
</tr>
<tr>
<td><strong>Susannah Fox</strong></td>
<td>Former Associate Director, Internet &amp; American Life Project, Pew Research Center, Washington, D.C.</td>
</tr>
</tbody>
</table>
APPENDIX 2

Project List

Round 1

Personal health record system for at-risk sedentary adults
Research Triangle Institute (Research Triangle Park, N.C.)
ID 64535 (June 2008–February 2009) $49,764
ID 59885 (December 2006–May 2008) $293,963

Barbara Leah Massoudi, PhD, MPH
(770) 986-5062
bmassoudi@rti.org

Living profiles: Transmedia personal health record systems for adolescents
Stanford University School of Medicine (Stanford, Calif.)
ID 64534 (June 2008–March 2009) $50,000

Christy I. Sandborg, MD
(650) 723-8295
sandborg@stanford.edu

Art Center College of Design (Pasadena, Calif.)
ID 59889 (December 2006–July 2008) $300,000

Lisa Nugent
(626) 396-4210
lnugent@gmail.com

Transforming the process of care and the way information is used in breast cancer treatment
University of California, San Francisco (San Francisco, Calif.)
ID 64542 (July 2008–February 2009) $50,000

Laura J. Esserman, MD, MBA  
(415) 885-7691  
laura.esserman@ucsfmedctr.org

Developing a personal health record to assist older adults with transitions of chronic care  
University of Colorado Denver Fitzsimons Early Learning Center (Aurora, Colo.)  
ID 64538 (June 2008–February 2009) $46,967  
ID 59880 (December 2006–August 2008) $295,107  

Stephen E. Ross, MD  
(303) 724-2267  
Steve.Ross@ucdenver.edu

Supporting patient and provider management of chronic pain with personal digital assistant applications linked to personal health records  
University of Massachusetts Medical School Worcester (Worcester, Mass.)  
ID 64536 (June 2008–February 2009) $50,000  
ID 59887 (December 2006–August 2009) $300,000  

Roger Luckmann, MD, MPH  
(508) 856-4150  
luckmanr@ummhc.org

Personal health management assistance focusing on management of heart conditions  
University of Rochester (Rochester, N.Y.)  
ID 59886 (December 2006–November 2008) $288,011  

George M. Ferguson, PhD  
(585) 275-5766  
ferguson@cs.rochester.edu

Development of a personal health record system for the home-based co-management of hypertension and diabetes between office visits  
University of Washington (Seattle, Wash.)  
ID 64815 (January 2009–November 2009) $35,332  
ID 59882 (December 2006–February 2009) $300,000  
ID 52601 (September 2005–February 2009) $249,125
James D. Ralston, MD, MPH  
(206) 287-2076  
jralston@u.washington.edu

**Developing a child-focused personal medication management system**  
Vanderbilt University Medical Center (first grant) and Vanderbilt University School of Medicine (second grant) (Nashville, Tenn.)  
ID 64537 (June 2008–February 2009) $48,509  
ID 59881 (December 2006–November 2008) $298,211

Kevin B. Johnson, MD, MS  
(615) 936-6867  
kevin.johnson@vanderbilt.edu

**Personal health application for adult diabetes self-management**  
Walter Reed National Military Medical Center (Bethesda, Md.)  
ID 64533 (October 2008–February 2009) $50,000  
ID 59888 (December 2006–May 2008) $163,692

Stephanie J. Fonda, PhD  
Current contact information unavailable.

**Round 2**

**Recording observations of daily living to improve the care of older adults at risk for cognitive decline**  
Carnegie Mellon University School of Computer Science, Human-Computer Interaction Institute (Pittsburgh, Pa.)  
ID 67167 (December 2009–April 2012) $477,676

Anind K. Dey, PhD, MS  
412-287-9620  
anind@cs.cmu.edu

**Recording observations of daily living to improve the care of adults living with asthma and depression**  
Research Triangle Institute (Research Triangle Park, N.C.)  
ID 67162 (December 2009–May 2012) $480,000

Barbara Leah Massoudi, PhD, MPH  
770-986-5062
bmassoudi@rti.org

Recording observations of daily living to improve the care and self-management of youths with obesity and depression
San Francisco State University Health Equity Institute for Research, Practice, and Policy (San Francisco, Calif.)
ID 67166 (December 2009–May 2012) $478,381

   Katherine Kim, PhD, MPH, MBA
   (415) 405-2539
   kathykim@sfsu.edu

Recording observations of daily living to improve the care of patients with Crohn's disease
University of California, Berkeley (Berkeley, Calif.)
ID 67466 (March 2010–June 2012) $478,817

   Linda Neuhauser, DrPH, MPH
   (510) 643-9177
   lindan@berkeley.edu

Recording observations of daily living to improve the care of low-birthweight infants
University of California, Irvine (Irvine, Calif.)
ID 67163 (December 2009–May 2012) $480,000

   Gillian R. Hayes, PhD
   949-824-1483
   gillianrh@ics.uci.edu

   Karen Cheng, PhD
   323-357-3424
   kacheng@cdrewu.edu
BIBLIOGRAPHY

(Current as of date of the report; as provided by the grantee organization; not verified by RWJF; items not available from RWJF.)

National Program Office and Grantees

Articles


Journal of Biomedical Informatics. 43(Suppl. 5), 2010. Available online.

- “Project HealthDesign: Advancing the Vision of Consumer–Clinician–Computer Collaborations,” Johnson KB, i.


**Books and Chapters**


**Reports**


**Toolkits**


*Observations of Daily Living.* Information about the collection and use of observations of daily living (ODLs), with links to lists of ODLs and an e-primer, videos, blog posts about ODLs. Available online.

**Communications**

www.projecthealthdesign.org. Central website for Project HealthDesign, a repository of information on projects, resources, news reports, blog entries, artifacts, public comments, testimony, and more. Madison, WI: University of Wisconsin-Madison School of Nursing.

*Project HealthDesign Blog.* More than 200 posts, from April 2009 through September 2012, contributed by national program staff, project directors, consultants, and others. Available at http://projecthealthdesign.typepad.com/project_health_design/page/3.


*Project HealthDesign YouTube channel.* Thirty-six videos from national program office staff members, project directors, and consultants. Available at https://www.youtube.com/user/ProjectHealthDesign/videos?sort=dd&live_view=500&flow=list&view=0.

**Consultants**

**Articles**


**Reports**


**Evaluators**

**Articles**


**Reports**
