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HIT Policy Committee, Meaningful Use Workgroup

Panel 2: “Incorporating Patient-Generated Data in Meaningful Use of HIT”

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Thank you for the opportunity to testify today.

The HIT Policy Committee’s Strategic Plan Workgroup, of which I am a member, has recommended the nation’s health IT initiative be aimed at achieving four goals, including meaningful use of technology to create a learning health care system. We agree that technology can be a powerful tool for transforming the health care system into one that is more patient-centric, more responsive, and more effective.

However, to achieve this transformation, all patients will have to be more engaged in managing their own health, working together with their physicians and other health care providers. In essence, patients too must become “meaningful users” of health IT. This includes having timely access to actionable health information – which this Workgroup has already proposed in meaningful use criteria. But patient access to information is but one piece of the “patient meaningful use” pie.

Today, the health care system does not appropriately recognize the critical role that a patient’s personal experience and day-to-day activities play in treatment and health maintenance. Patients are experts at their personal experience; clinicians are experts at clinical care. To achieve better health outcomes, both patients and clinicians will need information from both domains– and technology can play a key role in bridging this information gap.

Project HealthDesign, funded by the Pioneer Portfolio of the Robert Wood Johnson Foundation, is forging a new vision of what personal health records can and should be and how they may be used by real people in their daily lives. The project is exploring practical ways to digitally capture and integrate patient-recorded observations of daily living into clinical care and testing this with real patients and real providers. My testimony today is drawn from lessons learned through the ground breaking work of 14 interdisciplinary teams and their hands on experiences with over 500 patients. I plan to address the relevance of patient-generated data and how it can effectively be used by both clinicians and patients to improve care.

Patient Generated Data Is More Than Just Clinical Data Captured in the Home

Patient generated data includes information about the patient’s recording of their own experiences. The vast majority of health and healthcare happens outside of interactions with the health system. It hinges on the choices and actions people take

every day—what they eat, where they live, how they feel, and with whom they interact.

One of Project HealthDesign’s key findings is that patients want to define the kind of data that is being used to measure their health. Patients are experts in their own experience. They don’t just want to fill in someone else’s chart—they want to decide what is measured and help interpret how it relates to their health generally. Personally defined health measures—what we call "observations of daily living" (or ODLs) are essential for making a complete and meaningful picture of the patient experience. Examples of ODLs include noting sleep-rest patterns, mood, or the effect of temperature changes in the lives of those with chronic pain.

Capturing, recording, interpreting, and making judgments based on ODLs is an area demanding a lot of attention in the health IT field. Creating interesting, unobtrusive approaches, such as sensors embedded in diaper fabrics or sound recordings that distort voices but monitor for changes in pitch and volume may be quite valuable. Examining patterns of food consumption and table talk tensions may hold the key to insulin control by a brittle diabetic.

Incorporating ODLs into clinical practice will only happen when technology provides the tools for interpretation and integration that afford clinicians an efficient glance into everyday life.

Observations of Daily Living Can Be Effectively Incorporated Into Clinical Care

In *Project HealthDesign*, we understand observations in daily living (ODLs) to be indicators of a person's experience that alert the person to take action (call the clinician, exercise more, adjust their fluid intake, etc.). Across our five current *Project HealthDesign* teams, clinicians, patients and designers are taking a “deep dive” on these ODLs --figuring out what indicators people attend to, which ones are meaningful, how computerized tools can make the capture and interpretation of them easier, and, importantly, what these ODLs tell clinicians and their patients about the person's health state.

ODLs may align well with clinician-recognized signs and symptoms, or they may serve as companion sentinels to the person to take action. Just because we might not understand them immediately doesn’t mean we should ignore them. We need to use them for what they are: indicators that something is going on related to our health.

In addition to serving as a call to action, ODLs are relevant to providers because they help inform therapies. For example, ODLs might help explain why prescribed therapies are not working, as in a patient who skips an anti-hypertensive because they have wrongly determined that the frequency of urinating indicated a problem with the medication rather than an expected consequence. By shedding light on everyday health experiences, ODLs might be just the thing to ensure that prescribed therapies are followed.

Some of our grantees have already created successful examples of the integration of ODLs into clinical workflow. For example, the University of Massachusetts Medical School team designed an application to help patients document their daily pain experiences and physical activities. The application, an electronic diary, supports collection of self-reported pain and activity data on a handheld device, and provides both patients and their health care providers with a menu of options for analyzing and displaying this data.

Patients and providers use the tool independently and also together during in-person appointments. Project HealthDesign Primary Investigator and internist Dr. Roger Luckman found that its use has significantly enhanced communication between clinicians and patients, enabling more precise and nuanced understanding of patient symptoms and the appropriateness of particular treatments. We are still investigating how ODLs may impact clinical workflow with the largest benefit.

To some people, the collection and use of ODLs by consumers of patients may sound impractical or futuristic, but it is already becoming mainstream. There are nearly 6,000 health applications in Apple's AppStore, ranging from those that track caloric intake or mood to measuring symptoms of chronic disease.

Implications for Meaningful Use

We believe that it is possible to incorporate patient generated data—including ODLs—into EHRs and into the Meaningful Use requirements without adding a significant burden. Achieving a paradigm shift to a more patient-centered health care system requires that patient generated data be captured, interpreted, and incorporated into clinical care – and we urge you to begin now to lay the necessary groundwork for that change.

Accomplishing this goal requires three things:

1. Health information technologies and policies that enable information selected and gathered by patients to be integrated into clinical care

As we've described, the flow of information about an individual's health should go two ways – not just from providers to patients but also from patients, who are experts about their daily activities, to providers.

Any health information systems architecture that supports electronic health records or electronic data exchange should have sufficient flexibility to accommodate changing ODLs and permit inclusion of a wide variety of patient defined, acquired and generated information types. This will require policies that preserve the integration of data elements as opposed to data storage environments and tolerate data storage from many different inputs.

2. Health information that is accessible to patients in a computable form

Project HealthDesign's grantees and numerous private sector companies have been

developing applications and services designed to let patients use health data in innovative ways, whether via PCs, mobile devices, online communities or other means. Emerging industrial solutions such as the data integrators may serve as repositories, but regulations should require that data generated by the health system (and also by PHR providers) be available to patients in a form that can be read by a computer program and manipulated and integrated with other information. Merely seeing health data on a screen, or downloading it in a PDF or other locked file format, will not let patients use information in ways that are most valuable to them.

3. Health information for patients must be actionable

Health information forms the basis of healthy action. This point is central to the *Project HealthDesign* overarching vision. Personal health information must be meaningful to patients as they make decisions about their own health care. Specifically, information in patients' personal health records must be available to them in terms they can understand and with tools that assist them in making good decisions about their health. Merely providing electronic access to raw data does not ensure that patients can use the information to make decisions about how to manage their health.

More specifically, this means that patients should have access to information in clear language that is accessible to those with lower literacy levels. Health data should also be accompanied by educational materials that translate raw numbers into a context patients can comprehend, as well as instructions about how to modify their own behaviors to support their health.

If a key purpose of the emerging regulations is to *"Provide patients and families with timely access to data, knowledge, and tools to make informed decisions and to manage their health"* – sufficient attention also needs to be paid to creating not only provider incentives and data exchange mechanisms, but the decision logic and visualization tools that help patients to understand the data. As the discussion about meaningful use continues we must all keep the focus on the ultimate user—the patient.

About Project HealthDesign

Launched in 2006, *Project HealthDesign* is a \$10-million national program of the Robert Wood Johnson Foundation (RWJF) created to stimulate innovation in personal health information technology. Whereas first-generation personal health records (PHRs) functioned primarily as data repositories, *Project HealthDesign* views PHRs as springboards for action and improved health decision-making. We believe the patient should be at the center of the design process and that PHRs should prioritize the health needs and personal preferences of the patient, and not simply adopt the procedures or contours of medical practice. Our hope is that ODLs will provide cues for both patients and their doctors to better manage health and find appropriate therapies.

Project HealthDesign Grantee Teams

Carnegie Mellon University

Pittsburgh, Pennsylvania

It is often hard to detect subtle changes in everyday activities – such as the loss of the ability to make a sandwich, dial a phone, or take medications correctly – that could indicate the onset of dementia or physical decline in adults who live alone. *Carnegie Mellon University* will develop and evaluate new technology that will monitor the routine of older individuals who have arthritis and are at risk for cognitive decline, providing trustworthy data for long-term functional assessment and treatment. The technology will monitor routine tasks such as taking medication, movement around the home and cooking. It will then present the information to key stakeholders including participants, caregivers and clinicians, so that they can detect and better understand the individual's changing cognitive and physical abilities. By identifying decline at an early stage, caregivers will have a chance to halt or even reverse deterioration that might otherwise result in an unsafe living situation and ultimately require the person to be institutionalized.

RTI International and Virginia Commonwealth University

Richmond, Virginia

Asthma is a common, chronic illness, affecting over 23 million adults in this country. In addition to respiratory symptoms associated with the disease, individuals with asthma are also more likely to experience depression and anxiety. *RTI International* and *Virginia Commonwealth University* will design a personal health record application, *BreatheEasy*, building on the latest clinical guidelines for treatment and self-monitoring for patients with asthma and depression. Patients will interact with the application through smartphone mobile devices and biomonitors to capture and report observations of daily living (ODLs) such as use of controller and rescue medications, symptom levels, quality of life and smoking. Clinicians will utilize a Web-based dashboard providing simple analysis and visualization tools that allow them to quickly view their patients' data, evaluate their health status and communicate any changes in treatment or monitoring. By providing a clearer picture of their health in everyday life, the ODLs will be used by both the patients and their clinicians to make lifestyle and treatment adjustments that will better manage their asthma and depression.

San Francisco State University

San Francisco, California

Youth from low-income backgrounds suffer disproportionately high rates of obesity. *San Francisco State University* will examine the potential of collecting observations of daily living (ODLs) via smartphones for low-income teens that are simultaneously managing obesity and depression. The project will utilize smartphone technology – wildly popular among young people – to make monitoring ODLs such as physical activity, food intake and mood easier and more convenient, thus making it more likely that they will enter the requested

data at the appropriate times. In addition, the technology will allow the teens to easily share the data with their care team in order to help set health goals, track their progress and ultimately improve their physical and mental health.

University of California, Berkeley

Berkeley, California

There are 600,000 people in the United States who suffer from the digestive disorder Crohn's disease. The disease is most prevalent in young adults ages 18 to 35 and can not only be complicated and expensive to treat but also has significant social and emotional implications. The *University of California, Berkeley* in partnership with *The Healthy Communities Foundation* and the *University of California, San Francisco* will help young adults who suffer from the disease create visual narratives of their condition and treatment to provide concrete feedback to providers about how they feel from day to day. The project will include patients tracking observations of daily living (ODLs) such as physical symptoms like diarrhea, bleeding and profound weight loss, along with more complex social and emotional observations. The information will then be shared with the provider and discussed during their clinical appointments to help the patient and clinician get a more accurate picture of what's happening between appointments with the goal of being able to reduce exacerbation of symptoms and undesired consequences of treatment, ultimately increasing the quality of the patient's life and care.

University of California, Irvine and Charles Drew University

Irvine, California

Early-life health decisions for pre-term, low birth weight babies can make a big difference in how well they do down the road. The *University of California, Irvine* and *Charles Drew University* will create a mobile device for collecting information from pre-term low birth weight infants and their primary caregivers that will allow them to more easily interface with their health care providers to improve care and communication. Caregivers will use a specially designed mobile device, *FitBaby*, to record observations of daily living (ODLs) such as the baby's temperament, exercise, feeding and sleeping schedules, as well as the caregiver's stress level and attitude swings. Providing nearly real-time data to clinicians will help alert them to early signs of health problems, which is crucial in treating low birth weight infants. The project is unique both in its goals of incorporating patient-generated information into a clinical setting and also because it collects information about the primary patients and their caregivers.

For more information, go to <http://www.projecthealthdesign.org>.