

**ACHIEVING THE PROMISE OF HEALTH INFORMATION TECHNOLOGY: IMPROVING CARE THROUGH PATIENT ACCESS TO THEIR RECORDS**

---

---

**HEARING**  
OF THE  
**COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS**  
**UNITED STATES SENATE**  
**ONE HUNDRED FOURTEENTH CONGRESS**

FIRST SESSION

ON

EXAMINING ACHIEVING THE PROMISE OF HEALTH INFORMATION TECHNOLOGY, FOCUSING ON IMPROVING CARE THROUGH PATIENT ACCESS TO THEIR RECORDS

SEPTEMBER 16, 2015

Printed for the use of the Committee on Health, Education, Labor, and Pensions



Available via the World Wide Web: <http://www.gpo.gov/fdsys/>

U.S. GOVERNMENT PUBLISHING OFFICE

96-259 PDF

WASHINGTON : 2017

---

For sale by the Superintendent of Documents, U.S. Government Publishing Office  
Internet: [bookstore.gpo.gov](http://bookstore.gpo.gov) Phone: toll free (866) 512-1800; DC area (202) 512-1800  
Fax: (202) 512-2104 Mail: Stop IDCC, Washington, DC 20402-0001

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

LAMAR ALEXANDER, Tennessee, *Chairman*

MICHAEL B. ENZI, Wyoming  
RICHARD BURR, North Carolina  
JOHNNY ISAKSON, Georgia  
RAND PAUL, Kentucky  
SUSAN COLLINS, Maine  
LISA MURKOWSKI, Alaska  
MARK KIRK, Illinois  
TIM SCOTT, South Carolina  
ORRIN G. HATCH, Utah  
PAT ROBERTS, Kansas  
BILL CASSIDY, M.D., Louisiana

PATTY MURRAY, Washington  
BARBARA A. MIKULSKI, Maryland  
BERNARD SANDERS (I), Vermont  
ROBERT P. CASEY, JR., Pennsylvania  
AL FRANKEN, Minnesota  
MICHAEL F. BENNET, Colorado  
SHELDON WHITEHOUSE, Rhode Island  
TAMMY BALDWIN, Wisconsin  
CHRISTOPHER S. MURPHY, Connecticut  
ELIZABETH WARREN, Massachusetts

DAVID P. CLEARY, *Republican Staff Director*  
EVAN SCHATZ, *Minority Staff Director*  
JOHN RIGHTER, *Minority Deputy Staff Director*

# C O N T E N T S

## STATEMENTS

WEDNESDAY, SEPTEMBER 16, 2015

Page

### COMMITTEE MEMBERS

Collins, Hon. Susan M., a U.S. Senator from the State of Maine, opening statement .....	1
Warren, Hon. Elizabeth, a U.S. Senator from the State of Massachusetts, opening statement .....	2
Murphy, Hon. Christopher, a U.S. Senator from the State of Connecticut .....	4
Alexander, Hon. Lamar, Chairman, Committee on Health, Education, Labor, and Pensions .....	27
Franken, Hon. Al, a U.S. Senator from the State of Minnesota .....	28
Isakson, Hon. Johnny, a U.S. Senator from the State of Georgia .....	30
Murray, Hon. Patty, a U.S. Senator from the State of Washington .....	31
Cassidy, Hon. Bill, a U.S. Senator from the State of Louisiana .....	33
Baldwin, Hon. Tammy, a U.S. Senator from the State of Wisconsin .....	36
Whitehouse, Hon. Sheldon, a U.S. Senator from the State of Rhode Island .....	37

### WITNESSES

Ratwani, Raj, Ph.D., Scientific Director, National Center for Human Factors in Healthcare, MedStar Health; Assistant Professor of Emergency Medicine, Georgetown University School of Medicine, Washington, DC .....	3
Prepared statement .....	6
Giusti, Kathy, MBA, Founder and Executive Chairman, Multiple Myeloma Research Foundation, Norwalk, CT .....	11
Prepared statement .....	13
Dishman, Eric, Intel Fellow, General Manager for Health and Life Sciences, Intel Corporation, Hillsboro, OR .....	15
Prepared statement .....	17



**ACHIEVING THE PROMISE OF HEALTH INFORMATION TECHNOLOGY: IMPROVING CARE THROUGH PATIENT ACCESS TO THEIR RECORDS**

---

**WEDNESDAY, SEPTEMBER 16, 2015**

U.S. SENATE,  
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,  
*Washington, DC.*

The committee met, pursuant to notice, at 10 a.m., in room SD-430, Dirksen Senate Office Building, Hon. Susan Collins presiding.  
Present: Senators Collins, Alexander, Isakson, Kirk, Cassidy, Warren, Murray, Franken, Bennet, Whitehouse, Baldwin, and Murphy.

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Good morning. The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

First, let me express my appreciation to our committee chairman, Senator Lamar Alexander, for asking me to chair this hearing. Also, let me welcome Senator Warren, who will be serving as the Ranking Member today.

Today's hearing is the fifth in a series of hearings that this committee has held on health information technology. We have heard about the problems with the HITECH Act, particularly regarding the ability of electronic health record systems to exchange and use electronic health information. Either systems are not talking at all, or they are doing so in a way that is not particularly helpful. We have also heard about the significant burdens posed by what is known as the meaningful use standards.

This committee has formed a Health IT Working Group to help identify ways that the Congress and the administration can work together to improve the exchange of health information, which continues to hold such great promise. But there remains a great deal of frustration to many physicians and other healthcare professionals, to hospitals and clinics, and, most of all, to patients.

Today, the committee is seeking the advice of our expert panel of witnesses on how to improve care through patient access to their own health records. We also want to get the insights of our panel into the challenges patients and providers currently face. Our fundamental question is this: How can electronic health records be improved to better serve patients?

With health IT, we have the potential to improve the patient experience and involvement in their own care, to strengthen care co-

ordination, to improve outcomes for patients, and to empower patients, if they so choose, to share their information with researchers to help drive the discovery, development, and delivery of new treatments and cures.

Yet, according to the Office of the National Coordinator for health IT's consumer survey, only 28 percent of Americans were offered access to online medical records in 2013, 54 percent didn't access their records, and 21 percent viewed them only once or twice. We're going to try to better understand why that is so.

Many patients are still filling out paper forms every time they visit the same doctor, and collecting their information in piecemeal fashion from each individual doctor visit and trip to the hospital, making monitoring health, sharing information with a family member, enrolling in a clinical trial, or requesting a correction an unnecessarily burdensome process. For those with chronic conditions and seeing multiple providers on a regular basis or for those facing a sudden and life-threatening illness, this can be particularly exhausting and frustrating and have consequences for the care that a patient receives.

An interoperable, patient-centered system could alleviate these frustrations. In the State of Maine, the health information exchange operated by HealthInfoNet is completing a pilot project on patient engagement. InfoNet has found that patients want access to all their information, not just static downloading of summaries, and that current data standards limit the types of information that can be accessed by patients.

They have also highlighted that the meaningful use provision that requires individual providers to have their own patient portals has led to fragmentation, patient frustration with having to access multiple portals, and a lack of incentives for investment in patient access capabilities that extend beyond a single provider.

To better serve patients, we need systems and flows of information and data that allow better communication and that have better utility for clinicians and for their patients. At the same time, the security and the privacy of patients' personal health information must be assured in an age where at least two major insurers, as well as government agencies storing sensitive personal information, have had their computer networks hacked.

I look forward to hearing from all of our witnesses and again want to thank the chairman for allowing me to chair this important hearing today.

I am now pleased to turn to Senator Warren for her opening statement before introducing our prestigious panel.

Senator Warren.

#### OPENING STATEMENT OF SENATOR WARREN

Senator WARREN. Thank you, Senator Collins, and thank you, Senator Alexander and Senator Murray, for calling this hearing and for asking us to preside here. I am very much looking forward to this.

This hearing is part of an ongoing series on health information technology. We've previously discussed the views of doctors, of hospitals, and of electronic health record vendors. Today, we're going to talk about how health IT can work for patients.

Patients want access to their own health data, and they should have an easy way to do that. Making sure that patients have access to their own information is also the best way to engage patients in their own healthcare and to improve outcomes.

We've come a long way from the time when doctors wrote all of their notes in paper charts and then filed them away until the next visit. But we still have ways to go before we have the kind of interoperable, consumer-friendly system that will make sure that patients can actually see their own information and that will give access to that information to different doctors, hospitals, and other healthcare providers.

In 1996, when Congress passed the Health Insurance Portability and Accountability Act, or HIPAA, it set important privacy standards, and it made clear that patients have a right to see their own medical records and a right to send their medical records to other physicians. In 2009, Congress expanded those rights with the HITECH Act, encouraging hospitals and doctors to set up electronic health record systems.

Today, after a Federal investment of more than \$30 billion, most medical records are digital. But there is a huge problem. The systems still don't talk to each other very well. That means that too many patients who try to access their records or who try to transfer from one doctor to another can't do so electronically. This lack of interoperability imposes other costs: wasted medical tests, wasted time, and wasted money.

A 2014 study from the University of Michigan found that emergency rooms that shared electronic health records through a regional information exchange ordered fewer duplicate medical tests. Patients in these ERs were 59 percent less likely to have a redundant CT scan, 44 percent less likely to get a duplicate ultrasound, and 67 percent less likely to have a duplicated chest x-ray than patients who visited unconnected hospitals. That's better care at lower costs.

We know that interoperability works. Individual health plans, hospitals, regional networks, and even big private companies like Intel have done it. The Federal electronic health records programs have taken us part of the way toward making sure that all patients and providers around the country have access to an interoperable system.

There's more work to be done, and here's what I think we still need to do. We need a standard format for recording and sending test results and other medical information. We need a way to accurately identify which records belong to which patient. We need incentives to encourage doctors and electronic health vendors to share information.

The Federal Government has invested billions of dollars in health information. It is now time to implement policies that create a system that works across the board.

I appreciate our witnesses being here today, and I'm looking forward to a discussion about how we can make sure that health information systems are efficient and that they work for patients.

Thank you, Madam Chair.

Senator COLLINS. Thank you very much for your excellent statement.

We're now going to hear from our panel of witnesses. I would note that we have excellent attendance today at our hearing, and to each Senator will be allocated 5 minutes for questioning of our panel.

First, we're going to hear from Dr. Raj Ratwani, the scientific director for Human Factors in Healthcare at MedStar Health. Dr. Ratwani has studied electronic health records and has significant expertise in the usability and usefulness of health information technology in meeting the needs of patients and clinicians.

Our second witness I am going to defer to Senator Murphy to introduce at this point, and then I will introduce our third witness.

#### STATEMENT OF SENATOR MURPHY

Senator MURPHY. Thank you very much, Madam Chair. We're really excited to have with us a fantastic leader on behalf of patients, Kathy Giusti. She's not only the founder and executive chairwoman of the Multiple Myeloma Research Foundation, which is based in Norwalk, CT, but she's also a multiple myeloma patient. The foundation has a really unique end-to-end system in precision medicine and is accelerating new treatments for patients.

Quite justifiably, she serves on the White House Precision Medicine Initiative Working Group and also serves at Harvard Business School as part of their Health Advisory Board. I'm really excited to have Kathy with us today.

Thank you, Madam Chair.

Senator COLLINS. Thank you.

Finally, we will hear from Eric Dishman, the general manager for Health and Life Sciences at Intel Corporation. Mr. Dishman, a cancer survivor, has been driving healthcare innovation in California companies for 25 years. He and his team are focused on developing pioneering technologies to enhance the patient experience.

I want to thank all of you for joining us today and ask that you try to summarize your statements in 5 minutes. We will put your full statements in the hearing record. If you go over a little bit, that's OK. People are chomping at the bit to ask you questions.

Dr. Ratwani, we will start with you.

#### **STATEMENT OF RAJ RATWANI, Ph.D., SCIENTIFIC DIRECTOR, NATIONAL CENTER FOR HUMAN FACTORS IN HEALTHCARE, MEDSTAR HEALTH; ASSISTANT PROFESSOR OF EMERGENCY MEDICINE, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, WASHINGTON, DC**

Mr. RATWANI. Good morning, Madam Chair Collins, Ranking Member Warren, Senators Alexander and Murray, and distinguished members of the committee. Thank you for the opportunity to speak with you today. I am Raj Ratwani, scientific director for MedStar Health's National Center for Human Factors in Healthcare, part of the MedStar Institute for Innovation, and Assistant Professor of Emergency Medicine at Georgetown University.

Our center is a unique collaboration between human factors experts and clinicians who focus on applying human factors principles to the Nation's most challenging healthcare issues. Human factors engineering is the science of designing systems to meet human capabilities, and the pressing issue of patient access to health infor-

mation that we're discussing today can benefit tremendously from a human factors approach.

Patients should have access to their own health information to improve health outcomes, facilitate patient and family engagement in care, and to reduce safety risks. The digitization of health information offers a tremendous opportunity. However, the usability of electronic health records, patient portals, and personal health records remains subpar, but is a challenge that can be overcome.

Usability of health IT systems impacts patient safety and is crucial to adoption and effective use. In most cases, patient portals and other health IT have not been designed to support patient needs and does not present information in a manner that is understandable and useful. Consequently, these technologies are underutilized by the public.

A more sophisticated approach to the design of this technology should be undertaken to realize the full potential of health IT. The application of user-centered design uses established iterative design methods to develop an understanding of the characteristics of the people who use technology. This includes what their information needs are, how they process the information, and how they'll use the information to make decisions.

A common misunderstanding is to think that usability is only about basic screen design, such as font size, color, and layout. A more critical aspect to good usability is the degree to which the functionality and design of the system supports the decisions and actions that are critical to the typical needs of patients and clinicians. Patients and clinicians are able to comprehend, reason, and gain insight from health information only when the systems work in concert with the way patients and clinicians think.

Three critical factors that have a tremendous impact on patient use of health IT are access, functionality, and information quality. All three are directly impacted by usability.

The first critical factor is access. Patients should be able to easily access all of their health information securely and in one place. Interoperability will be important for improving access as long as the information is integrated in a way that is meaningful for patients.

The second is functionality. The information and capabilities of the system must be useful for the patient. The design of system capabilities, such as patient-provider communication, should be intelligently integrated with the workflow processes of the clinician so the clinician can respond to patients in a timely manner.

The third is quality of information. Information must be accurate and presented in a manner that can be easily understood. This requires an in-depth understanding of how patients use their health information, recognizing that a diverse population with varying levels of health literacy may use this technology.

These examples are a brief snapshot of the usability challenges that require attention.

It's important to recognize user-centered design is a well-established method for developing effective software systems. Other high-risk industries, such as aviation and defense, have embraced human factors and user-centered design. Regulatory bodies in these industries closely inspect usability processes before any technology

is implemented. It should be noted that no technology enters the cockpit of an airplane before the usability is inspected and found to meet detailed standards.

It is promising that the Office of the National Coordinator has initiated efforts to mirror this in health IT with safety enhanced design. However, our research has shown that few health IT vendors have embraced this approach.

This represents a huge opportunity. In order to achieve the promise of health IT and advance health, the recommendations to the committee are, No. 1, to refocus certification requirements to implement clear standards and guidelines to ensure usability; No. 2, to encourage clear and transparent indicators of the usability of health IT systems to better inform the public, critically, providers, patients, and clinicians; and No. 3, to review barriers and identify opportunities to promote innovation that improves usability.

Thank you, and I look forward to questions.

[The prepared statement of Dr. Ratwani follows:]

PREPARED STATEMENT OF RAJ M. RATWANI, PH.D.

SUMMARY

Patients must have easy access to their health information to *improve health outcomes, facilitate patient and family engagement in care, and to reduce safety risks*. Critically, this information must be presented in a manner that is both understandable and useful. **One of the biggest barriers to patient access to their health information is the usability of current health information technology** (patient portals, personal health records, and electronic health records).

Usability is not only about basic screen design such as font size, color, and layout, but its functionality and design to support the decisions and actions that are critical to the typical needs of patients and clinicians. Understanding the needs of patients and clinicians is a difficult process that many vendors do not properly engage in. A more sophisticated approach to the design of this technology must be undertaken to realize the full potential of health IT. **Health IT vendors must embrace user-centered design, a process that focuses on understanding the characteristics of the people intended to use the technology, what their information needs are, how they process this information, and how they will use the information to make decisions.**

Shortcomings of current patient use of health IT include *Access, Functionality, and Information Quality*. All three are directly impacted by usability.

- *Access*. Patients should be able to easily access all of their health information, securely, and in one place. Interoperability is crucial in achieving access.
- *Functionality*. The information and capabilities of the system must be useful for the patient. The design of system capabilities, such as patient-provider communication, should be intelligently integrated with the workflow processes of the clinician so that the clinicians are able to support the patient in a timely manner.
- *Quality of information*. Information must be accurate and meaningful to the patient, presented in a manner that can be easily understood, and that will help them gain insights. This requires an in-depth understanding of how patients use their health information and recognition that patient portals serve a diverse population with varying levels of health literacy.

There are ONC certification requirements in place to promote usability under Safety Enhanced Design. However, many vendors have not embraced this approach and are not adhering to the certification requirements. Further, there are no formal guidelines for the design and development of patient portals as part of the EHR.

To make advancements we must (1) refocus certification requirements to promote true usability in design, development and implementation, with an understanding of industry constraints, (2) increase transparency around the usability of health IT systems, and (3) spur competition and innovation in the marketplace by making it easier for new vendors to develop products.

---

Good morning Chairman Alexander, Ranking Member Murray and distinguished members of the committee. Thank you for the opportunity to speak with you today.

I am Raj Ratwani, scientific director of MedStar Health's National Center for Human Factors in Healthcare, part of the MedStar Institute for Innovation, and assistant professor of emergency medicine at Georgetown University. Our Center benefits from a unique collaboration between clinicians and human factors experts who focus on applying the science of human factors to the Nation's most challenging healthcare issues. One of those issues is patient access to health information.

Patients must have easy access to their health information to improve health outcomes, facilitate patient and family engagement in care, and to reduce safety risks. Critically, this information must be presented in a manner that is both understandable and useful. The digitization of health information offers a tremendous opportunity to improve care, however, **the usability of electronic health records, patient portals, and personal health records remains subpar and is a significant challenge that we must overcome immediately.** While some have suggested that the low utilization rate of patient portals is from a lack of interest, we know that it is because in most cases the portals have not been designed using methods to optimize the system's responsiveness to patient needs. There is overwhelming evidence that usability of health IT systems impacts patient safety and that it is crucial to adoption and effective use. It takes a very deliberate and robust effort by specialized staff to develop health IT systems with good usability, and this fact is not always fully appreciated in the industry.

A more sophisticated approach to the design of this technology must be undertaken to realize the full potential of health IT. The application of **user-centered design**, in the development of health IT, uses established iterative design methods to develop an understanding of the characteristics of the people who use technology, what their information needs are, how they process this information, and how they will use the information to make decisions.

Other complex high risk industries invest heavily in this human factors approach, including aviation, defense, and nuclear energy. Healthcare has been slow to adopt the human factors approach and slow to make advancements that would facilitate a more aggressive adoption of this approach to optimize the safety, usefulness, and efficiency of health IT.

A common misunderstanding is to think that usability is only about basic screen design such as font size, color, and layout, the more critical aspect of good usability is the degree to which the functionality and design of the system supports the decisions and actions that are critical to the typical needs of patients and clinicians. **Patients and clinicians are able to comprehend, reason, and gain insight from health information only when the systems work in concert with the way patients and clinicians think.**

Three critical factors that have a tremendous impact on patient use of health IT are: Access, Functionality, and Information Quality. All three are directly impacted by usability. Without robust user-centered design processes that are led by trained professionals, naive, clunky systems are developed that don't serve patients needs, and are therefore underutilized by the public.

The first critical factor is *Access*. Patients should be able to easily access all of their health information, securely, and in one place. Interoperability is crucial for patient access.

The second is *Functionality*. The information and capabilities of the system must be useful for the patient. The design of system capabilities, such as patient-provider communication, should be intelligently integrated with the workflow processes of the clinician so that the clinicians are able to support the patient in a timely manner.

The third is *Quality of information*. Information must be accurate and meaningful to the patient, presented in a manner that can be easily understood, and that will help them gain insights. This requires an in-depth understanding of how patients use their health information and recognition that a diverse population with varying levels of health literacy may use this technology.

- For example, when a patient references their medication list in today's typical patient portal, the medications are listed in clinical jargon, and this fails to effectively communicate what the patient needs to know—which medicines to take at what time and for what conditions.

These examples are a brief snapshot of the usability challenges that require our immediate attention. There are well-established methods for developing usable software systems, and as a whole the health IT industry has not yet embraced them.

It is important to note that this is not just a theory. User-centered design is an established standard in other high-risk industries, and regulatory bodies in these industries closely inspect the usability processes used in development before any technology is implemented. No technology enters the cockpit of an airplane before

the usability is inspected and found to meet detailed standards. The Federal Government has initiated efforts to mirror this in health IT, with the implementation of what the ONC has termed Safety Enhanced Design. However, as described in studies from our Center, few vendors in the health IT industry have demonstrated evidence that they have embraced this approach. This represents a huge opportunity.

To make advancements we must: (1) refocus certification requirements to promote true usability in the design, development and implementation of health IT, with an understanding of industry constraints, (2) increase transparency around usability, and (3) spur competition in the marketplace by making it easier for new vendors to develop products.

The National Center for Human Factors in Healthcare has conducted research into both provider and vendor environments, reviewed existing literature, and analyzed current policies to make the following recommendations for improving the usability of electronic health records (EHR), patient portals and personal health records:

**1. Spur innovation in EHRs, patient portals and PHRs to foster improved usability.**

a. Many new vendors want to enter the marketplace of EHRs, patient portals and PHRs but are not able to because of the daunting certification requirements. This is inhibiting innovation and is limiting the ability for usability to be driven by a competitive market.

b. Poor interoperability and the lack of application program interfaces (APIs) is limiting the sharing of health information and preventing new vendors from entering the marketplace since they are not able to access existing patient health information for their products.

*Recommendation:* Reduce the barriers for new vendors to enter the marketplace so that vendors with better user-centered design (UCD) processes, which typically result in designs with better usability can innovate and bring new products to the market. This will shift the paradigm to a market that competes on usability.

**2. Refocus Safety Enhanced Design (SED) certification requirements.**

Currently the Office of the National Coordinator (ONC) has certification requirements in place to promote EHR vendor usability in eight high-risk EHR capabilities. The requirements stipulate that vendors must attest to a user-centered design process and conduct formal summative usability testing on the final product. Our research and analysis suggests:<sup>1,2</sup>

a. Many vendors are not adhering to the certification requirements and are not following industry testing standards, yet their products are still being certified.

b. The current summative testing requirements occur at the end of development of the product and any design flaws that are identified are unlikely to be addressed since the product has already been fully developed. Consequently, this requirement is unlikely to be effective at improving the usability of that product being released.

c. The summative testing requirement is overly burdensome for some vendors, particularly if a rigorous UCD process is employed with formative usability testing (i.e., iterative usability testing during the development phase). Over 90 percent of the design challenges are likely to be identified with the UCD process and formative testing before the summative testing stage. Requiring summative usability testing for vendors that have a rigorous UCD process can result in an unnecessary expenditure of limited vendor usability resources and may detract from the design of other aspects of the EHR. Our ONC-funded evaluation of a cross section of vendors and their UCD processes found that approximately  $\frac{1}{3}$  of vendors might meet this condition.<sup>1,2</sup>

d. EHRs undergo a customization process during implementation at each provider sight which often involves extensive changes, resulting in an EHR product that is vastly different from the product that was tested during summative usability testing. Consequently, the testing results may no longer be valid for the customized product.

*Recommendation:* It is our recommendation that the certification requirements be modified to provide two certification avenues: The first would require the vendor to show evidence of their UCD process and formative testing, which vendors should already be conducting given current certification standards which require vendors to attest to employing a UCD process. Vendors that are able to demonstrate a rigorous UCD process should be exempt from having to conduct summative usability testing. The second avenue would require that the final product undergo summative usability testing with no safety-critical use errors identified. For the vendors that do conduct summative usability testing, the ONC certification requirements should

be more explicit about testing methodology requirements such as number of participants and background of participants.

EHR vendors should be required to demonstrate evidence of their UCD process beyond the eight capabilities that are currently stipulated by the ONC so that broader usability coverage of the EHR products can be captured.

### **3. Encourage more rigorous usability practices for patient portals and PHRs.**

a. There is little patient involvement in the design and development of patient portals and PHRs. Patients are the intended users of this technology and without involvement during design and development it is difficult to develop a product that meets the needs of patients in a meaningful way.

b. There are currently no usability certification requirements for patient portals. In the existing health information technology literature there are studies that identify the information needs of patients and recommendations for improving usability and usefulness.<sup>3 4 5 6 7 8</sup>

*Recommendation:* Leverage our existing knowledge on how patients think about their health information to develop guidelines that can promote the usability of patient portals and personal health records. Invest in applied research to expand the knowledge base around patient health information needs to improve future products. Consider requiring vendors to demonstrate evidence of a user-centered design process in the development and optimization of their patient portal products.

### **4. Increase transparency of vendor usability.**

a. The Safety Enhanced Design (SED) certification reports for each vendor product that is certified must be made publicly available on the ONC's consumer health product list website. However, the information is difficult to access, difficult to digest, and not conducive for non-usability experts to consume. The format of the reports prevents direct comparison across different EHR products.

b. There are few, if any, formal usability evaluations of EHR products conducted by independent organizations. Consequently, purchasers cannot directly compare products based on metrics that measure the usability of the actual product.

*Recommendation:* The SED certification reports should be adjusted to present information in a standard format that can be easily consumed by all audiences to allow more informed purchasing decisions. Methods should be developed to foster independent usability evaluations of EHR products so that purchasers have more usability insight prior to purchase.

### **5. Improve the vendor access to usability resources.**

A good UCD process includes detailed data on the cognitive tasks, environments, and information needs of all potential user groups in different environments. Studies to generate this knowledge are resource intensive. Our analysis has demonstrated that many vendors do not have the necessary resources to employ a sophisticated UCD process and to conduct appropriate formative and summative usability testing.<sup>1 2</sup> This includes access to rigorous clinical use cases, clinician participants, and knowledge of how to conduct UCD given rigorous software development timelines.

*Recommendation:* Develop standard testing use cases for all vendors to utilize. Incentives may need to be developed for clinicians to engage with EHR vendors during the UCD process. In addition, detailed best practices around UCD and usability testing should be widely disseminated to all EHR vendors.

#### **MEDSTAR RESEARCHERS FIND LARGE NUMBER OF EHRS DO NOT MEET USABILITY STANDARDS**

A report by MedStar Health's National Center for Human Factors in Healthcare finds that a significant percentage of electronic health record (EHR) vendors failed to meet federally mandated user-centered design requirements and did not conform to usability testing standards for their EHRs, yet their products were certified as having met all the requirements of the government's meaningful use program for EHRs. The findings, reported in the September 8, 2015, issue of the *Journal of the American Medical Association*, are based on publicly available information supplied by the EHR vendors to the Office of the National Coordinator for Health Information Technology (ONC) between April 2013 and November 2014.

The investigators studied official reports submitted by the EHR vendors to the Federal Government attesting to the user-centered design (UCD) process they had followed to develop their products and providing results of usability testing they had conducted. Specifically, the study focuses on the computerized order entry function,

since it is primarily used by clinicians and presents significant safety hazards when not designed well. The authors conclude that enforcement of existing standards and oversight of usability processes are necessary to meet usability and safety goals for the next generation of EHRs.

The MedStar Health study found that among the problems were failure to adequately test the usability of an EHR and failure to document that an EHR was developed with a UCD process. Among the specific findings:

- Sixty-three percent of the vendors whose reported results were analyzed failed to enroll the recommended number of users—at least 15—in tests on their EHRs.
- Seventeen percent used no physician participants in testing systems intended for physician use.
- Twelve percent of reports lacked enough detail to determine whether physicians participated.
- Thirty-four percent of the vendors did not state, as required, the UCD process they had followed.

Researchers compiled their study by examining available reports from the top 50 EHR vendors, as measured by the number of meaningful use attestations made between April 1, 2013, and November 30, 2014.

#### MEDSTAR RESEARCHERS SHOW TREMENDOUS VARIABILITY IN EHR VENDOR USABILITY PRACTICES

A report by MedStar Health’s National Center for Human Factors in Healthcare finds that many EHR vendors do not have a rigorous user-centered design process in place. The findings, reported in the June, 2015 issue of the *Journal of the American Medical Informatics Association*, are based on the research team visiting 11 different EHR vendors to better understand their usability processes and barriers to usability.

The MedStar study found that one third of vendors have a misunderstanding of usability and user-centered design, one third of vendors have a basic user centered design process in place and only one-third of the vendors have a sophisticated process. Among the specific findings:

- Some of the largest EHR vendors (total revenue over \$1b) do not employ usability staff and do not have rigorous user-centered design processes in place.
- Many vendors only have a basic user-centered design process in place and require additional knowledge and resources to improve their process.
- The vendors that do have a rigorous process in place have developed methods to integrate user-centered design with their aggressive software development timelines.

The research identifies targeted ways to improve the usability processes of EHR vendors including: sharing of best practices, improving vendor access to clinicians to better inform their products, and developing standard use cases for testing.

#### ABOUT MEDSTAR HEALTH

*MedStar Health* is an academic health system which includes 10-hospitals, 20 diversified healthcare organizations, 250 outpatient sites, an air and ground EMS provider, and a population health insurance provider. MedStar Health is the largest healthcare provider in the Baltimore and Washington, DC region, and is a microcosm of the American healthcare system, representing the broadest possible spectrum of hospitals and patient populations. The 10 hospitals include large tertiary care/academic medical center hospitals, small community hospitals, and a university hospital (MedStar Georgetown University Hospital); inner city, suburban, and rural hospitals; teaching hospitals and hospitals staffed only by private attending physicians; and large, medium, and small-sized hospitals. MedStar Health has \$5 billion annual net operating revenues, and our resources total 3,300 licensed beds, 5,600 affiliated physicians, 166,000 annual inpatient admissions, and 2 million annual outpatient visits. MedStar’s six teaching hospitals, including MedStar Georgetown University Hospital, have a total of 1,100 resident physicians (the 11th largest GME organization in the United States).

*National Center for Human Factors in Healthcare’s* mission is to apply human factors research methods and concepts to the medical domain, with a focus on information technology, device design, and systems design. The Center is involved in patient safety, risk management, and systems engineering research sponsored by National Institutes for Health/National Institute of Biomedical Imaging and Bioengineering, Agency for Healthcare Research and Quality, Latham Foundation, Robert Wood Johnson Foundation, Emergency Medicine Foundation, American Diabetes Association, American Society for Healthcare Risk Management, Office of the National Co-

ordinator, and other sources. With 20 people including Ph.D. human factors scientists, clinical researchers, usability specialists, physicians, nurses, and support staff, the Center is the largest hospital-based human factors engineering center in the United States. The National Center for Human Factors in Healthcare is part of the MedStar Institute for Innovation.

*The MedStar Institute for Innovation* is a systemwide initiative to foster and catalyze innovation at MedStar Health, and is lead by MedStar Health's Chief Innovation Officer Mark Smith, M.D., who also serves as professor and chair of Emergency Medicine at the Georgetown University School of Medicine. Dr. Smith is the co-creator of MedStar Health's innovative Azzyxi clinical information system which is considered to be a highly innovative health IT application, as evidenced by its purchase by Microsoft, Inc.

*MedStar Health Research Institute (MHRI)* is the research center of MedStar Health, and provides a robust research support infrastructure, including a centralized IRB, grants management, biostatisticians, and other research support services. MHRI is in the top 20 percent of all U.S. institutions in total funding received from the National Institutes of Health, with over \$35M in sponsored work per year. There currently are over 500 externally funded projects, from 175 principal investigators, and 325 MHRI employees in support roles.

#### REFERENCE LIST

1. Ratwani, R.M., Fairbanks, R.J., Hettinger, A.Z., & Benda, N. Electronic Health Record Usability: Analysis of the User Centered Design Processes of Eleven Electronic Health Record Vendors. 2015 Jun 6. doi: 10.1093/jamia/ocv050. *PMID*: 26049532
2. Ratwani, R.M., Benda, N.C., Hettinger, A.Z., & Fairbanks R.F. Electronic Health Record Vendor Adherence to Usability Certification Requirements and Testing Standards. *JAMA*. 2015;314(10):1070–71. doi:10.1001/jama.2015.8372.
3. Hassol, A., Walker, J. M., Kidder, D., Rokita, K., Young, D., Pierdon, S., . . . & Ortiz, E. (2004). Patient experiences and attitudes about access to a patient electronic health care record and linked web messaging. *Journal of the American Medical Informatics Association*, 11(6), 505–13.
4. Ralston, J. D., Carrell, D., Reid, R., Anderson, M., Moran, M., & Hereford, J. (2007). Patient web services integrated with a shared medical record: patient use and satisfaction. *Journal of the American Medical Informatics Association*, 14(6), 798–806.
5. Haggstrom, D. A., Saleem, J. J., Russ, A. L., Jones, J., Russell, S. A., & Chumbler, N. R. (2011). Lessons learned from usability testing of the VA's personal health record. *Journal of the American Medical Informatics Association*, 18(Supplement 1), i13-i17.
6. Marchionini, G., Rimer, B. K., & Wildemuth, B. (2007). Evidence base for personal health record usability: Final report to the National Cancer Institute. *University of North Carolina at Chapel Hill*.
7. Archer, N., Fevrier-Thomas, U., Lokker, C., McKibbin, K. A., & Straus, S. E. (2011). Personal health records: a scoping review. *Journal of the American Medical Informatics Association*, 18(4), 515–22.
8. Kahn, J. S., Aulakh, V., & Bosworth, A. (2009). What it takes: characteristics of the ideal personal health record. *Health Affairs*, 28(2), 369–76.

Senator COLLINS. Thank you very much for your testimony.

Ms. Giusti.

#### **STATEMENT OF KATHY GIUSTI, MBA, FOUNDER AND EXECUTIVE CHAIRMAN, MULTIPLE MYELOMA RESEARCH FOUNDATION, NORWALK, CT**

Ms. GIUSTI. Good morning, Chairman Collins, Ranking Member Warren, Senator Alexander and Senator Murray, and distinguished committee members. My name is Kathy Giusti, and I'm the founder and chairwoman of the MMRF. It's an honor for me to be here today and represent all patients.

In 1996, at the age of 37, I was diagnosed with multiple myeloma. Hearing the word, cancer—yes, that's devastating. Hearing the words, 100 percent fatal, just 3 years to live—that's crush-

ing. Since my disease was uncommon, had no awareness or funding and no drugs in the pipeline, there was little room for hope.

As a patient, I could see the problems, and, as a business woman, I could see there were ways to solve them. I founded the MMRF so we could build business models that would advance scientific solutions quickly. Working with academia, government, industry, and technology, we did create an end-to-end system in precision medicine.

We built our own data bank to capture the genetic changes in patients. We made our data publicly available to every scientist. We built our own clinical network that conducted 60 trials of 30 drugs. We educate our patients on which trials to enroll in.

The results of this are unprecedented. We have seen seven drugs approved in multiple myeloma, with three more at the FDA right now. We have tripled the life span of the patients with this very uncommon disease because we were sharing data.

But myeloma remains fatal, and in today's world, health IT must accelerate new treatments and cures. So I'll discuss health IT from the patient's perspective in three ways.

No. 1, engaging patients. Access to health IT allows every patient to collaborate with their doctor and make the best decisions. We can review our test results, our lab tests. We can identify important trends that we see in the data. We can learn at our own pace when it's quiet, not when we're sitting in the doctor's office or the infusion room.

But the promise is so clear and the utilization so low. In another recent study, only 36 percent of Americans online were using portals. Thirty-five percent of those that weren't using them didn't even know they had one.

Let me contrast this for you with the data that we have from the MMRF, where our newly diagnosed patients—85 percent of them know they have a portal. Ninety-five percent of those patients are using their portal. They're looking at their electronic health records, because they know from us the importance of their data and their knowledge.

No. 2, integrating data. As a patient, I now have six electronic health records scattered from Dana Farber in Boston to the Mayo Clinic in Minneapolis, and I have no central place to integrate them. I can't make this information available to my healthcare team, and I can't possibly make it available to the researchers that desperately want to see my genome, my information that I want them to have.

To prove the point, I was just recently battling osteonecrosis of the jaw. The oral surgeons needed to see my treatment history. There was no way to possibly get it to them. The greatest efficiency in our healthcare system is going to come from integrating EHRs across the vast specialists that we all see.

No. 3, accelerating cures. The MMRF recently launched its own genomic initiative and CoMMpass trial. We are sequencing 1,000 myeloma patients from the moment of diagnosis and every single time they relapse. Our genetic studies have already identified a really important target in myeloma that nobody knew was there. It's also a melanoma target. We are already spearheading new

trials next year for BRAF positive patients that we can find through our own studies.

This is the world of precision medicine. This is where we all need to go. But the ability to understand, integrate, aggregate, and analyze EHRs is sitting on the critical path to research. It could make things happen so much faster and so much more efficiently.

The MMRF has shown the impact of sharing data in one uncommon, very fatal disease. But it's time for all of us to work together and do this across all diseases. We owe it to the patients we serve.

I thank you for the honor of speaking with all of you today.

[The prepared statement of Ms. Giusti follows:]

#### PREPARED STATEMENT OF KATHY GIUSTI, MBA

##### SUMMARY

Good morning Chairman Collins, Ranking Member Warren, and distinguished committee members. My name is Kathy Giusti. I am the founder and chairwoman of the Multiple Myeloma Research Foundation (MMRF). In 1996, at the age of 37, I was diagnosed with the blood cancer multiple myeloma. My cancer was uncommon, had no funding, no awareness, and no pipeline of drugs. As a patient, I could see the problems. As a business woman, I saw ways to fix them. I founded the MMRF to put those ideas into practice.

Working with academia, government, industry, and technology partners, the MMRF created an end-to-end system in precision medicine. We built our own data bank to capture the genetic changes in myeloma patients and their responses to treatment. We made this data publicly available to all scientists. We built a clinical network that has conducted 60 trials of 30 compounds. We educate our patients so they enroll in the right trial for them. Our community has seen seven new drugs win FDA approval, with three more expected in the next year. Our patients have benefited, nearly tripling survival from the 3 years when I was diagnosed to 9 years today. Myeloma, however, remains fatal. In today's world, health IT can and should accelerate new treatments and cures. So today, I would like to discuss the importance of health IT from the patient's perspective.

##### NO. 1: ENGAGING PATIENTS

Access to digital health information allows us to collaborate with our doctors and health-care providers and make better decisions. The promise is so clear, but the percentage of patients taking advantage of these technologies is too low. According to a recent survey, only 36 percent of Americans online were using patient portals. Thirty-five percent of Americans did not know they had a patient portal.

In contrast, when we looked at MMRF data, we found that 85 percent of our newly diagnosed patients know they have a portal, and over 95 percent use their portal. This shows the importance of trusted third parties in raising awareness and education amongst our patients. Physicians, hospitals, advocacy organizations, and the government must ensure that patients are educated on how best to use the technology.

##### NO. 2: INTEGRATING DATA

As a patient, I now have six electronic health records (EHRs) scattered from Dana Farber in Boston to the Mayo Clinic in Minneapolis. I have no central repository where I can aggregate, store, and access this information. The greatest efficiency will come from our ability to integrate EHRs across the vast number of specialized doctors and centers that patients now see. That data must be integrated into a centralized portal that we as patients feel like we own, share, update, and provide.

##### NO. 3: ACCELERATING CURES

The MMRF recently launched its own genomic initiative and our CoMMpass trial which sequences 1,000 patients at diagnosis and at every relapse to understand our disease heterogeneity. We have already identified a significant genetic mutation—BRAF—in myeloma patients. But there are many more targets to uncover, more efficient trials to run and new drugs to develop. The ability to understand, integrate, aggregate and analyze EHRs is on the critical path to improving outcomes and accelerating cures. We have shown the impact of data sharing in one uncommon, fatal

disease. Let's work together and improve patient outcomes in all diseases. Thank you for the honor of speaking today.

---

Good morning Chairman Collins, Ranking Member Warren, and distinguished committee members. My name is Kathy Giusti. I am the founder and chairwoman of the Multiple Myeloma Research Foundation (MMRF). It's an honor to be here today to provide a patient's perspective on the importance of health information technology (IT).

In 1996, at the age of 37, I was diagnosed with the blood cancer multiple myeloma. Hearing the word "cancer" was devastating. Hearing the words "fatal, 100 percent fatal", took me completely off guard. I realized my cancer was uncommon, had no funding, no awareness, and no pipeline of drugs.

As a patient, I could see the problems. As a business woman, I saw ways to fix them. I founded the MMRF to put those ideas into practice. Working with academia, government, industry, and technology partners, the MMRF created an end-to-end system in precision medicine.

We built our own data bank to capture the genetic changes in myeloma patients and their responses to treatment. We made this data publicly available to all scientists. We built a clinical network that has conducted 60 trials of 30 compounds. We educate our patients so they enroll in the right trial for them. Our community has seen seven new drugs win FDA approval, with three more expected in the next year. Our patients have benefited, nearly tripling survival from the 3 years when I was diagnosed to 9 years today.

Myeloma, however, remains fatal. In today's world, health IT can and should accelerate new treatments and cures. So today, I would like to discuss the importance of health IT from the patient's perspective.

#### NO. 1: ENGAGING PATIENTS

Access to digital health information allows us to collaborate with our doctors and health-care providers and make better decisions. We review our test results and lab reports on line, and identify and act on important trends. We can learn at our own pace—when it is quiet and convenient—not when we are stressed in the doctor's office or in the infusion room.

The promise is so clear, but the percentage of patients taking advantage of these technologies is too low. According to a recent survey, only 36 percent of Americans online were using patient portals. Thirty-five percent of Americans did not know they had a patient portal.

In contrast, when we looked at MMRF data, we found that 85 percent of our newly diagnosed patients know they have a portal, and over 95 percent use their portal. This shows the importance of trusted third parties in raising awareness and education amongst our patients. Physicians, hospitals, advocacy organizations, and the government must ensure that patients are educated on how best to use the technology.

#### NO. 2: INTEGRATING DATA

As a patient, I now have six electronic health records (EHRs) scattered from Dana Farber in Boston to the Mayo Clinic in Minneapolis. I have no central repository where I can aggregate, store, and access this information. And, I cannot make this information available to my healthcare team or scientific researchers. To prove the point, when I recently developed osteonecrosis, my surgeon needed my treatment history. There was no easy way to find it.

The greatest efficiency will come from our ability to integrate EHRs across the vast number of specialized doctors and centers that patients now see. That data must be integrated into a centralized portal that we as patients feel like we own, share, update, and provide.

#### NO. 3: ACCELERATING CURES

The MMRF recently launched its own genomic initiative and our CoMMpass trial which sequences 1,000 patients at diagnosis and at every relapse to understand our disease heterogeneity. We have already identified a significant genetic mutation—BRAF—in myeloma patients. And we are pushing drugs that target this cancer causing mutation into clinical trials. But there are many more targets to uncover, more efficient trials to run and new drugs to develop. The ability to understand, integrate, aggregate and analyze EHRs is on the critical path to improving outcomes and accelerating cures. We have shown the impact of data sharing in one uncom-

mon, fatal disease. Let's work together and improve patient outcomes in all diseases. Thank you for the honor of speaking today.

Senator COLLINS. Thank you very much for sharing your experience and for your eloquent testimony.

Mr. Dishman.

**STATEMENT OF ERIC DISHMAN, INTEL FELLOW, GENERAL MANAGER FOR HEALTH AND LIFE SCIENCES, INTEL CORPORATION, HILLSBORO, OR**

Mr. DISHMAN. Chairwoman Collins, Chairman Alexander, Senator Warren, Senator Murray, and our esteemed committee members here, I am honored to testify today as a data-grabbing, hyper-engaged cancer survivor, as a patient advocate for more than 1,200 families, myself, and as the leader of Intel's Global Health and Life Sciences business.

I can tell you that wearing all of these hats, I am quite confident in saying that we will not achieve sustainable healthcare by any name that you want to call it—the triple aim, personalized healthcare, N=equals-1 medicine, precision medicine—without two key foundations: deep patient engagement and full data interoperability.

I have spent my life trying to build these foundations for myself and others out of medical necessity, and I have spent my career doing the same out of business necessity. For the past 16 years, that career has been with Intel, where our way of life as a company is driving interoperability and standards into broad platforms that the world can innovate on top of, whether it's institutions or whether it's enterprising individuals.

In my own case, I was treated incorrectly for a rare kidney cancer for 23 years across six employers and health plans, 17 main hospitals and clinics, 38 specialty ones, and 67 different diagnosis codes. It was often as much a fight to get my own data and to be treated as part of my own care team as it was to fight the cancer.

When lack of data about my complex medications led to a near-death cardiac event because my four specialists were not paying attention and coordinating what off-label uses they had given to me, I fought to own all of my medication data from then on out. When I failed to be eligible for the first clinical trial ever for the rare cancer that they thought that I had because I nor an attorney on my behalf could get all of my paper and EHR data in time, I fought to own all of my clinical data from then on out.

When my cross-country oncology team worked with me recently to gather the terabytes of clinical, imaging, and diagnostic data over 4 long months while I was suffering in kidney failure to make sense of my whole genome sequence, I fought to get access to the tools to help me understand these new data types myself.

The end result: evidence now that 92 percent of the drugs I had ever been put on were biologically destined never to have worked, but one new round of individually targeted chemotherapy did. I am a lucky, living prototype of a proactive precision medicine patient who is cancer-free with 100 percent kidney function, and I'll be celebrating my 3-year transplant anniversary next week.

Across these personal and professional experiences, I've seen four main barriers to patients' accessing our data that the law says we

have a right to. First, organizations are hiding behind HIPAA as an excuse not to give us our data. Second, clinicians are lacking truly interoperable affordable tools to securely share our data even when they want to.

Third, skeptical paternalistic attitudes about patients having their own data are keeping us from getting it. And, fourth, increasingly these days everyone from providers to research organizations to software and device vendors are all hoarding patient data to try to monetize it for themselves.

The laws that are supposed to protect patients' privacy and access to our health information should not be the very ones that are used to block that access. Patients should not have to become practically hackers to access our own data, nor should clinicians have to become health IT experts or pay health IT experts to share data with each other and their patients. Strangers shouldn't get their returns from our data without us having the chance to use our own data, too. We must do better.

I know from numerous Intel employee and business programs that we have underway that we can do better, because we are making interoperability and patient engagement work. Our Connected Care employer ACO in New Mexico and Oregon has delivered true interoperability for our providers and our employees. Our collaboration with the Michael J. Fox Foundation has Parkinson's patients collecting their own wearable and clinical and other data to drive new discoveries.

Our YOU.24x7 Study of cardiovascular health is helping participants bring together wearable, clinical, and lab data for wellness applications for themselves as well as to donate to cardio researchers. Our Collaborative Cancer Cloud work with Oregon Health and Science University is showing ways to even securely share large genomic data sets.

I believe we can improve the standards of care to expect and assume that patients and families will be part of the care team and in the information loop, and I believe that we can improve the standards of data to expect and assume that interoperability is scalable and the norm is out-of-the-box for new software, hardware, and device tools that clinicians and consumers use.

In conclusion, I survived not only cancer, but an era of well-intentioned but data-poor imprecision medicine that didn't know what to do with me as a proactive patient who demanded my own data. Admittedly, patient engagement and data interoperability are two buzzwords that are easy to put on paper and Power Point but hard to put in practice. Thanks to ARRA and ACA and MACRA and ONC, NIH, MU, PMI, and an alphabet soup that I struggle to keep track of, I know that we can actually do this because there's early progress and momentum.

I look forward to your questions to explore specifics on how we can go faster so that N=equals-1 medical care that I was so lucky to receive can scale to N=equals-everyone.

Thank you.

[The prepared statement of Mr. Dishman follows:]

## PREPARED STATEMENT OF ERIC DISHMAN

## SUMMARY

**Introduction:** As a cancer survivor, a cancer patient advocate, a healthcare researcher, and an Intel executive, Eric is a lucky early prototype for the lifesaving potential of accessing your own health data and genome-based precision medicine. Whether to qualify for clinical trials or identify rare diseases based on genome sequencing or track daily vital signs for trending and medication management, he—like all of us—needs access to his/our own health information that’s convenient, timely, affordable, electronic, and secure. To achieve precision medicine for all Americans, the two pillars of **full data interoperability** and **deep patient engagement** are vital.

**Barriers:** Across Intel’s global research on patient & family member engagement, we see four primary barriers to accessing one’s own data: (1) Institutions **hiding behind HIPAA** & other privacy regulations/policies; (2) Clinicians **lacking affordable, interoperable tools** to share patient data due to **inadequate or poorly implemented standards**; (3) Widespread **beliefs that patients don’t have the abilities** to use their data safely; and last, (4) Institutions and companies trying to control patient data because **they want to monetize it**.

**Principle 1: Start with patient engagement by design:** The healthcare system today rarely considers how to include a proactive patient when designing software, quality metrics, expectations and training. We need to change the social contract for how an engaged patient interacts with the system to **achieve two-way data exchange and two-way responsibility for care**. The healthcare systems needs to improve the tools, data, and workflow—and first and foremost the *mindset*—to allow and eventually assume—that we patients *own our health*.

**Principle 2: Precision medicine’s foundation is secure shareability of diverse data types:** Four major data categories must be brought together to deliver an individualized, precise treatment or prevention plan: (1) **clinical/claims data**; (2) **diagnostic/device data**; (3) **omic data**; and (4) **consumer generated/mHealth data**. Securing the ability for individuals and institutions to safely, affordably decide who gets access to their information is crucial. We must use common data models and standards-based protocols for exchanging health IT data that extend beyond clinical data to include imaging, genomic, and consumer electronic device and smart phone data. With these new data types scaling now, we should *start* with commitments to—and validation of—interoperability standards from the outset so we do not recreate the problems seen with traditional EHR data.

**Intel Case Studies: For our employees and our business, we are demonstrating that Big Data analytics for precision medicine depends on patient and clinical access to comprehensive health records of diverse data:**

- **YOU.24x7 Study**, an early pilot using patient-generated data for research into health trends and behaviors to analyze cardiovascular risk factors. A Basis smart watch tracks sleep and activity, plus wireless blood pressure and weight scales in the home combined with EHR data, labs, and other key metrics give a more holistic view of the population and correlation insights, as well as insight into an individual’s cardiovascular wellness through 24x7 secure access to all of her or his information.

- **Intel’s Connected Care**, an employer ACO, demonstrates the value of interoperability to improve Intel employees’ and families’ healthcare experiences, outcomes, and reduce costs over time. This program has achieved EHR interoperability for our employees and their clinicians.

- **Intel and Oregon Health & Science University (OHSU) Collaborative Cancer Cloud**, a precision medicine analytics platform that allows medical institutions to securely share *access* to their private patient genomic & clinical data for potentially lifesaving discoveries, without giving up control of that data or violating privacy policies. This CCC program is part of our *All In One Day by 2020* campaign to challenge the computing and life science industries to work together to accelerate precision medicine analytics.

---

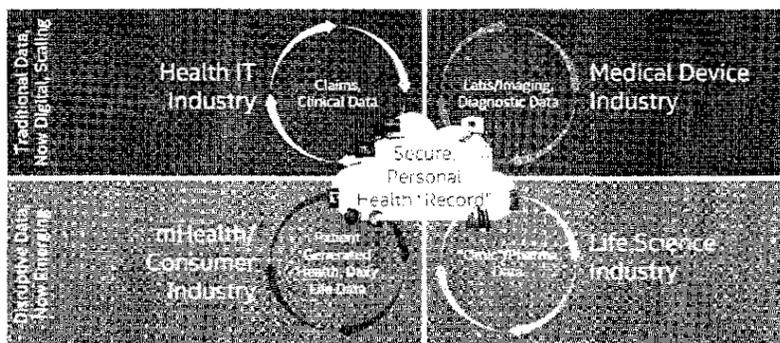
Chairman Alexander, Ranking Member Murray, Senator Collins, Senator Warren and members of the Senate Health, Education, Labor, and Pension (HELP) Committee, I appreciate the opportunity to testify today on behalf of Intel Corporation. I thank you for your leadership and appreciate the opportunity to speak today about the enormous—mostly untapped—potential of individuals to own their health and contribute positively toward national health transformation. This is a vital topic you have chosen for today. If we are to achieve the “triple aim” in America, then two

foundational principles must be delivered upon: full data interoperability and deep patient engagement.

I am a 23-year cancer survivor, a cancer patient advocate, an executive at one of the world's most innovative technology companies, a member of the President's Precision Medicine Initiative Working Group, and a lucky early prototype myself for the lifesaving potential of accessing your own health data and genome-based precision medicine. Wearing each of these hats, I have thought a lot about what must be done to make health care more customized, more connected and more coordinated. Because of demographic trends toward an aging population, it's not optional to take up this challenge of personal, precision healthcare. It is an imperative of our times, global in scale, complex in scope, and—at its very roots—it should be viewed as an opportunity for every individual.

Across all of my different roles, and backed up by 15 years of Intel's social science research worldwide, I have concluded that each of us must have better tools to participate in our own health and contribute to the well-being of others. Each of us needs access to our own health information that's convenient, timely, affordable, electronic, and secure. Each of us needs to work with our care teams to build care plans, with goals and accurate tracking. Each of us needs to *own our health*—but the healthcare systems needs to do a much better job of giving us the tools, data, and responsibility to do so.

Let's think of the constellation of our health data over the course of a lifetime. Most familiar are the **clinical and claims data** captured at clinics, hospitals, pharmacies, insurers, etc., including such information as diagnosis codes, prescriptions, program notes, claims, vital signs, and test results. Second, there is **diagnostic data** captured by medical devices and imaging equipment. Adding to this now are two new data streams that are rapidly increasing in importance and opportunity: **consumer-generated health data**, captured outside the traditional health system and including such information as patient diaries, observations of daily living, vital sign monitors, fitness wearables, online and smartphone apps, social media and gaming. And finally, there is **"omics"**—vast amounts of information contained in each person's genome (and proteome, metabolome) that will increasingly be used to attack disease at its molecular roots. By their very nature, these diverse data (coming from what we at Intel call the "Four Circle Model" depicted below) are collected at multiple sites, across long spans of time, and in a vast array of structured and unstructured formats.



The reality is that personal, precision health in the 21st century will need to make sense of all of this information for deeper insights into population health and individual treatment. These data tell us critical things about one of the most important aspects of anyone's life—our very health and well-being. To me, it's just unthinkable that we would architect a health system—a whole health economy—without facilitating each person's access to one's own data, as well as the ability to contribute meaningful data about oneself back to researchers and data scientists to gain insights into population health and wellness. Sharing of interoperable data must be the foundation of targeted, individual care.

My own life events—from the beginning of my battle with rare and unidentifiable forms of kidney cancer to the happy conclusion 23 years later—have shaped the passion I have for accurate, affordable, comprehensive and timely access to one's own health information. In the summer of 1989 before my junior year at UNC Chapel Hill, I was first diagnosed with a rare form of cancer, hurling me into more than

two decades of chemo, immune, and radiation therapy across 8 States, 6 employers and health plans, and 17 hospitals and clinics. To survive, I had to know my own history, carry my latest data with me, understand the latest clinical trials research, and be on top of promising new treatment options, oftentimes better than many of my oncologists and other specialists. But accessing my own data could be as challenging as surviving the cancer at times.

Five years into this journey, my first near-death experience came because four different specialists—none of whom had a complete view of my complex medication regimen—over prescribed off-label treatments that put my heart at risk. Luckily, a nurse and I finally figured out that the drug cocktail—really, a lack of sharing data—was the real culprit, not anything wrong with my heart. Fifteen years into it, the first clinical trial ever for the particular kidney cancer they thought I had at the time came out. After failed attempts for 3 months myself at pulling together my data to be eligible for the trial—and then 3 months more with an attorney doing so on my behalf—I couldn’t enter the trial because we couldn’t pull my records together in time. In my advocacy on behalf of cancer patients—1,220 people so far and counting—I still see this happening every week, even with new laws & technologies that should make it possible.

Much more recently, I was in full kidney failure and running out of options. On what I thought might be my last business trip as head of Intel’s healthcare group, I met a genomic startup company that offered to sequence my DNA. After half a year of shipping hard drives of data across the country between oncologists, computer scientists, and data experts, my medical team came back with a plan based on my molecular makeup. Within months, I was miraculously cancer-free and suddenly on the path to a kidney transplant that saved my life because, for the first time in 23 years, my oncologists had real and detailed data about me as an individual to act upon. I came back to Intel ready to help scale precision medicine to everyone.

In all of these examples, it was simply too hard to collect all of this information on a timely basis so my doctors could determine the best care plan for me. Across my experiences as a cancer patient and advocate—and in the studies of patient experiences Intel has done across more than 20 countries—I see four recurring barriers that often keep data out of the hands of citizens who want it:

- (1) Medical institutions using **privacy/security policies and laws like HIPAA as excuses** for why they cannot risk sending patients their data;
- (2) Medical professionals **lacking easy, affordable, interoperable tools to share patient data**, especially because app and device vendors fail to use—or correctly implement—standards;
- (3) Widespread **beliefs that patients do not have the abilities to use their own medical data safely**, which may be true in many or even most cases, but fail to give them the choice; and
- (4) A growing attitude among almost everyone in the patient data chain—hospitals, labs, payers, software companies, device developers—that **patient data sets are theirs to be monetized**.

Revisiting the four-circle model described earlier (which is over-simplified but useful for illustration), we can see that, despite a great deal of progress, each type of data is still not readily available to individuals—or even their clinicians—in most cases:

- **Electronic health record data and claims:** Under the Health Insurance Portability and Accountability Act (HIPAA), patients have a right to see and obtain a copy of their medical records. The American Recovery and Reinvestment Act (ARRA) extends those rights through modifications to HIPAA, requiring healthcare providers who utilize EHRs to give patients copies of their medical records in an electronic format, to another person or entity like a doctor, caregiver, a personal health record or mobile health application. The information is typically provided on paper or through a flash drive or CD, or an online clinic portal. Unfortunately, the regulations have two significant loopholes. First, patients can receive the information in their preferred electronic format *only if* the provider is capable of producing the copy in the requested format; and second, providers *have 30 days* (and an additional 30 if the information is stored offsite) to make the information available to the patient. (Certification for Meaningful Use Stage 2 is a huge improvement by requiring the information to be made available within 4 business days.) Congress must have envisioned a much easier and faster method for patient access to data. This could be much more readily achieved with today’s technology, particularly if more of the information was captured as common data sets in standardized formats.

- **Consumer-generated health data:** Today, there is a plethora of apps and services that collect health and wellness data from devices we wear, carry around

with us, or use in our homes and workplaces. However, generally speaking, each have different logins, different and confusing user interfaces, different calibration of sensors, different apps and services. Very few integrate with the systems used by clinicians who make up an individual's care team. And consumers have a very difficult time pulling this information into one repository, controlled by them, that will outlast the particular device, app, employer, or insurance company they are currently associated with. As a founding member of Continua (<http://www.continuaalliance.org/>), Intel supports a developing ecosystem of certified devices that “plug and play” to give consumer-friendly connectivity to individuals who wish to better manage their health and wellness no matter where they are. If industry adopts common standards, the information from the various devices can be curated and exchanged with the goal of helping individuals understand their information, track their progress, stay on track with their care plans, and generally take more ownership of their health. The potential is enormous for remote monitoring of patients with chronic diseases, with continuous feedback and more efficient, two-way communication between the patient and clinicians, but only if these data are securely shareable and interoperable.

- **Imaging and diagnostic data:** Medical images make up a large percentage—estimated as high as one-third—of all stored data in the world. The storage demands are very high. Fortunately, cloud-computing environments enable much more cost-effective storage of medical imaging, and there have been great strides in transitioning the hosting of medical images to the cloud for electronic retrieval through healthcare provider systems. However, providing *individuals* with convenient, on-the-go access to these often-large data files remains nascent. Think of the advantage to you as a patient if you were able to log on to access all your X-rays, MRIs, ultrasounds, etc., any time you go to a new provider or the ER, instead of filling out request forms and waiting for the files to be shipped, or paying for an expensive test to be unnecessarily repeated. Since these data types are not usually part of the official EHR per se, the progress on patient access to their own data misses important classes of personal information today.

- **Genomics and other “omic”:** The data from whole human genome sequencing are so large they are impractical to send back and forth across institutions, and we are in the early days of having tools for clinicians—let alone consumers—to make use of this data. I learned this myself when my own 5-terabyte files were being shipped across the country from oncologist to oncologist while trying to figure out the optimal way to treat my cancer. As these new data types begin to scale, it is important that we *start* with commitments to—and validation of—interoperability and standards from the outset so we do not recreate the problems that have plagued us with EHR data. Also, new tools for big data analytics are necessary to scale the potential for precision medicine, such as the Collaborative Cancer Cloud that I describe below.

Because each of these data streams are important to understand each person's whole health picture, providing the individual with access to parts of electronic health record (EHR) systems is necessary but not sufficient. As the National Institutes of Health builds out the extremely exciting Precision Medicine Initiative, the 1 million person cohort, and our national strategy to compete globally in the economic opportunity that precision medicine will present, let's make sure we build an architecture for individual access to personal health information from the beginning. It cannot be an afterthought, or it will never happen. We need to learn from the hard lessons from the Nation's multibillion investments in subsidies for EHRs and grants for health information exchanges. We must think about interoperability in much broader terms than merely the doctor-to-doctor exchanges of EHR data. We need to continue to support the concept of individual's having personal health records available to them and their care team, anytime and anywhere, and not tied exclusively to a particular institution or company.

To help show what's possible, I'd like to share what Intel is doing in its own journey to make health care more effective and affordable and to accelerate the possibilities for precision medicine for all.

#### INTEL'S CONNECTED CARE PROGRAM—AN EMPLOYER INITIATIVE FOR VALUE-BASED PURCHASING

The Connected Care vision is to improve Intel employees and families' healthcare experiences, outcomes, and reduce costs over time. EHR interoperability plays an important role to help Intel achieve this vision. In 2013, Intel launched the Connected Care program in Albuquerque, NM. It is essentially an employer-sponsored and -facilitated accountable care organization (ACO). In focus groups, we heard from our employees and families that they wanted streamlined access to primary care

and specialists. In response, Intel significantly changed its relationship with the healthcare system in the Connected Care Program. We contracted directly with the healthcare supply chain, removing middle men. We built a network of 11 primary care medical homes, including an onsite clinic, and medical neighborhood of specialists and facilities. To ensure timely access to care, Intel and Presbyterian Health Services agreed on protocols for call responsiveness and established acceptable levels of appointment availability. We contracted directly with Presbyterian Health System in an arrangement that aligned incentives and shared risk, with outcomes measured according to the following accountability metrics:

- **Right care:** Use of evidence-based medicine to improve population health, focusing on diabetes, hypertension and depression.
- **Right time:** Timely access to care in the optimal setting, including a nurse hot line.
- **Best outcome:** Patient satisfaction 100 percent of the time.
- **Right price:** Material decrease in the cost of care, per patient per month.
- **Best life:** Rapid return to productivity.

Employee response has been excellent: More than three in four eligible employees opted to join the Connected Care Program. So far, major successes have included greater member engagement with the healthcare system, very high satisfaction ratings, and statistically significant improvements in diabetes control. We have yet to demonstrate an improvement in costs. In the long term, we believe that promoting proactive primary care with deep patient engagement and accountability should improve health outcomes *and* costs as we iterate this program.

Successful preliminary results in New Mexico drove the decision to scale Connected Care to Oregon this year. The Oregon implementation had a deeper need for sharing of our employees' electronic health records because it included two large health systems—Kaiser Permanente and Providence Health and Services—in addition to ambulatory providers The Portland Clinic and Premise Health. With our partners, we addressed the data liquidity problem head-on first through contracts that focused on seamless care that required data sharing across institutional boundaries.

The Connected Care interoperability team at Intel selected the Direct messaging standard and the Healthway eHealth Exchange (recently renamed The Sequoia Project) to support the business and clinical requirements for coordinated care. The Connected Care data exchange model utilizes the HL7 Consolidated Clinical Documentation Architecture (C-CDA), which is a key part of the data interoperability specifications in Meaningful Use Stage 2. The EHR interoperability model in Oregon is nationally recognized for having an innovative approach for point-of-care access to electronic health records. New care coordination workflows are using data exchange with healthcare information coming to them in real time, resulting in quicker access to care with less work for everyone involved. Having the most up-to-date healthcare data means a more efficient model where physicians and patients can now make the best possible choices about their care planning, leading to lower costs over time. And, critically, this data exchange model is enabling consumer health pilots that will improve Intel employee experience and improve health engagement.

We relied upon the security, authorization and privacy measures governed by national standards (eHealth Exchange/NHIN and Direct messaging), and HIPAA for exchange of clinical records. This includes end-to-end encryption of data, authorization, PKI/digital signatures and appropriate access controls. The underlying technology standard is called SAML, which is used to assert authentication of the user. Members of the eHealth Exchange secure their communications using x.509 certificates whose chain-of-trust begins with the same Root Certificate Authority (CA), thus facilitating trust between organizations without the need to exchange certificates.

For more specific information on the interoperability challenges and the value provided from joining Healthway/Sequoia for a query-based system, Intel, Kaiser Permanente, and Providence Health and Services, The Portland Clinic and Premise Health have produced a white paper accessible at the following URL: <https://www-ssl.intel.com/content/www/us/en/healthcare-it/advancing-interoperability-healthcare-paper.html>.

#### INTEL'S WORK WITH CONSUMER-GENERATED HEALTH DATA

The Michael J. Fox Foundation for Parkinson's Research (MJFF) and Intel Corporation are collaborating on improving research and treatment for Parkinson's disease—a neurodegenerative brain disease second only to Alzheimer's in worldwide prevalence. The collaboration includes a multiphase research study using a new big

data analytics platform that detects patterns in participant data collected from wearable technologies used to monitor symptoms. This effort is an important step in enabling researchers and physicians to measure progression of the disease, improve medication adherence and speed progress toward breakthroughs in drug development.

With wearable technology, the potential to collect and analyze data from thousands of individuals on measurable features of Parkinson's, such as slowness of movement, tremors and sleep quality, could enable researchers to assemble a better picture of the clinical progression of Parkinson's and track its relationship to molecular changes. Wearables can unobtrusively gather and transmit objective, experiential data in real time, 24 hours a day, 7 days a week. With this approach, researchers could go from looking at a very small number of data points and burdensome pencil-and-paper patient diaries collected sporadically to analyzing hundreds of readings per second from thousands of patients and attaining a critical mass of data to detect patterns and make new discoveries. It is a dramatic shift from data-poverty to data-wealth—and in my view it signals the future of research and discovery.

MJFF and Intel share a commitment to increasing the rate of progress made possible by open access to data. The organizations' aim to share data with the greater Parkinson's community of physicians and researchers as well as invite them to submit their own de-identified patient and subject data for analysis. Teams may also choose to contribute de-identified patient data for inclusion in broader, population-scale studies.

We have also launched the YOU.24x7 Study, a 6-month observational pilot study of nearly 500 participants that uses an end-to-end prototype platform consuming patient-generated data for research into health trends and behaviors to analyze cardiovascular risk factors and potentially improve outcomes. Patient data are collected through a number of devices: a Basis watch to track sleep and activity, plus blood pressure and weight scales in the home. These data are combined with electronic medical record information, labs and other key metrics to give more holistic view of the population. Data scientists and cardiologists are using an advanced analytics platform created by Intel, looking at the de-identified data to gain trending and correlation insights into cardiovascular wellness. Meanwhile, the individual participant has 24x7 access to all of his or her own information through the secure personal health collaboration hub provided online by a company we helped to form called Dossia.

#### INTEL'S WORK IN PRECISION MEDICINE

Intel and Oregon Health & Science University (OHSU) recently announced the Collaborative Cancer Cloud, a precision medicine analytics platform that allows medical institutions to securely share insights from their private patient genomic data for potentially lifesaving discoveries. Intel announced that key technology components of the Collaborative Cancer Cloud (CCC) will be opened sourced. Hospitals and research institutions of all sizes could use the technology to advance personalized cancer research. They can also apply it to advance personalized research in other diseases that are known to have a genetic component, including Alzheimer's, diabetes, and more. Intel and OHSU also announced that they will partner with two other large cancer institutions to extend this capability in 2016.

The project combines next-generation Intel technologies and bioscience to enable solutions that can be used to make it easier, faster, and more affordable for developers, researchers, and clinicians to understand any disease that has a genetic component, starting with cancer. It will enable large amounts of data from sites all around the world to be analyzed in a distributed way, without having to move the data itself, preserving the privacy and security of that patient data at each site. The end goal is to empower researchers and doctors to help patients receive a diagnosis based on their genome and potentially arm clinicians with the data needed for a targeted treatment plan. By 2020, we envision this happening in 24 hours—a challenge to the computing and life science industries that we call *All in One Day*. The focus is to help cancer centers worldwide—and eventually centers for other diseases—share with one another the insights that reside in their private clinical and research data without having to share the data itself. This approach is designed to protect data privacy and the business models of the research centers while at the same time unlock the insights from far larger datasets to benefit research and inform the specific treatment of individual patients.

As an employer faced for years with unsustainable healthcare cost inflation for the 53,000 employees we are proud to employ in the United States and their 88,000 Intel Health Plan dependents, Intel has initiated these projects for business reasons—both to support a healthy, productive workforce and to grow the global mar-

ket for the powerful computing needed to scale precision medicine. We hope these programs can become examples for the rest of the country to build upon. And we believe congressional support of four key themes can help examples like these proliferate across the country.

**(1) Sustain momentum toward standards and interoperability.** As Intel's Connected Care Interoperability team demonstrated, a standards-based approach for health information technology enables quicker and more efficient deployments to share data from different sources. This provides scalability, interoperability, and innovation as new services can be built upon a common framework of standards, data models and clinical vocabularies. Intel supports an implementation specification compatible with baseline standards that are specific, well-documented, tested vigorously, and shared publicly, as described in H.R. 6, the 21st Century Cures Act.

**(2) Encourage patient engagement by removing obstacles for patients to access and share their data.** With the adoption of electronic health records comes enormous potential for creating value from data held in millions of patient records. Today, the use of this information is regulated by a series of highly regulated consent requirements constructed by not only the Federal Government, but by States. Intel invites policymakers to partner with industry to pursue a standardized machine readable consent form to allow patients to donate their data to ongoing research without the need for securing and faxing consent forms each time patient data is requested. The International Rare Disease Research Consortium has recognized this problem. The Consortium has assembled a task team from the Global Alliance for Genetics and Health to explore the machine readability of consent and its impact on data use and accessibility. PCORI has launched research into patient preferences for consent,<sup>1</sup> and The Broad Institute has launched "Count Me In", a patient consent effort to facilitate genomic research. Consistent with the 2013 memo from the HHS Office of Civil Rights,<sup>2</sup> individual access to personal health data could advance if personal health record organizations are allowed on the eHealth exchange network run by The Sequoia Project to collect information across provider systems on the patient's behalf. Credible personal health records should be allowed to securely capture and transmit patient consent electronically to the source systems and establish connectivity.

**(3) Continue to push toward value-based care.** We support the HHS goal announced this year to move 30 percent of care to alternative payment models by 2016 and to 50 percent by 2018. When incentives are aligned toward value-based care and managing population health, the demand for information-sharing goes up. Fee-for-service models work the opposite way, in which providers are paid based on the volume of service they deliver. Based upon Intel's experience with Connected Care, we have seen increased patient engagement and better outcomes based upon shared risk, shared goals and consistent metrics for success. As the U.S. healthcare system moves to outcome-based payments through the Medicare Access and Chip Reauthorization Act (MACRA), Congress can assist through providing funding for new care delivery tools for training and discovery until the 2019 implementation date. Specifically, pilots should be funded for remote patient monitoring (RPM), which remains mostly unpaid in today's fee-for-service environment in spite of studies showing as much as a 75 percent reduction in hospital re-admissions when provided to chronic care patients.<sup>3</sup>

**(4) Erase disparities.** Despite amazing advances in health and healthcare, many dimensions of disparity remain, particularly in health. The recommendations that we've outlined today—standards and interoperability, giving people access to their health data, lowering barriers for people to participate in and access precision medicine, and value-based purchasing must be achieved with a mindful eye on the diversity of our Nation, ensuring that solutions are a good fit for people across the array of incomes and ethnicities and in both rural areas and in urban ones. Achieving health equity means making sure that all Americans have a fighting chance to own their health, which is not possible if they can't first own and use their own health data.

<sup>1</sup> <http://www.pcori.org/research-results/2014/demonstrating-respect-and-acceptable-consent-strategies-what-matters-patients>.

<sup>2</sup> <http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/righttoaccessmemo.pdf>.

<sup>3</sup> <http://healthaffairs.org/blog/2014/04/04/the-role-of-remote-care-management-in-population-health/> [http://www.telehealthresourcecenter.org/sites/main/files/file-attachments/snell-smalley\\_hospital\\_physician-summit-feb-2013.pdf](http://www.telehealthresourcecenter.org/sites/main/files/file-attachments/snell-smalley_hospital_physician-summit-feb-2013.pdf).

## CONCLUSION

I am a lucky, living prototype of the precision medicine future that countries around the world are competing to develop for their own citizens and for their own economic growth through the invention and intellectual property of precision medicine. As a cancer survivor and kidney transplant recipient, I collaborate on improving my health (and lowering my costs) together with my care teams, and I am very engaged in owning my own care. At every step of the way in my health journey, access to my own health information has factored heavily in the difference between success and failure. But Congress and the health sector should not be designing our infrastructure, systems, and policies for me, a fortunate, well-educated, well-compensated Intel executive who has connections with health experts all over the world. We should design policies, standards and economic incentives to promote individual access to personal health information for people who have none of my advantages. We need to design for people with big health needs but low health literacy, and then those systems will work well for everyone. On behalf of Intel Corporation, thank you for your leadership and opportunity to speak today.

Senator COLLINS. Thank you so much for such an extraordinary story and for being here today.

Dr. Ratwani, we've just heard Mr. Dishman explain all of the inappropriate care that he got before, through sheer perseverance, he was able to secure the treatment that he needed. Studies show that some 400,000 Americans die each year as the result of medical errors, including 80,000 Americans who died because doctors are unable to easily access needed information.

You mentioned in your testimony that there's overwhelming evidence that health IT systems and whether or not they're effective affects patient safety. Could you expand specifically on what your advice to us, as policymakers, would be so that we can help Mr. Dishman, Ms. Giusti, not go through this struggle to get information that directly affects the efficacy of their care?

Mr. RATWANI. Senator Collins, that's an excellent question. A key component of this is patient safety. What we're finding with several of the health IT systems that are being designed, developed, and implemented across the Nation is that there are tremendous safety hazards that arise from these systems, things like wrong selection of the patient in the record, wrong medication orders, wrong laboratory tests being ordered.

A key component of this is dramatically improving the usability of these systems. We need to design these systems so that they're intuitive for clinicians to use, intuitive for patients to be able to adjust their information.

And, importantly, it's not just about the interaction pieces. It's also about how the information is represented. So if a physician is looking at a patient record and looking at laboratory results, it's important to ensure that those laboratory results are represented in a way where the critical values pop out to the physician, where the patients are able to understand why those values are important to their care. So it comes back to usability and visualization of that information to drive analysis, insight, and, ultimately, patient and clinician action.

Senator COLLINS. Ms. Giusti, you stated that an astonishing 85 percent of newly diagnosed patients participating in your research foundation programs know that they have a patient portal, and more than 95 percent of them are using it. As you mentioned, that is far, far higher than the population at large, where only 36 percent of Americans are using patient portals.

How did you do it? How did you educate patients about the portals and about using them?

Ms. GIUSTI. What we did was we educated patients on the value of knowing their own data, and I think that's one of the most important things we can say today. If patients understand the value of their data, they will understand the importance of taking the time to go into a portal and look at their electronic health record information.

What we found was by telling them that if you follow your own biomarker, your own tests in myeloma, you will be a more informed patient. You will know whether you are actually in a remission, a complete remission. You would know your genome so that if a child opened up for you, you could raise your hand for that child.

By explaining to them the power of numbers, not a huge list of numbers, but a few numbers that they can follow, we gave them the incentive to go on and become knowledgeable. In addition to that, what we also explained to our patients—it's really important—is if you know the data of yourself, you will improve your outcomes. But if you let your data be aggregated with others, you will improve the opportunities to know more about the biology of your disease and develop new treatments for your disease. When you see the value both ways, why would you not go on and learn this information?

Then we provide you with a website, a call center with nurses, chat rooms, gateways where you can go on and talk. You have to remember it's a little bit about reaching frequency to people. Tell them the value and keep explaining it a few times over. They will get there, and it will make a huge difference.

Senator COLLINS. Thank you.

Senator Warren.

Senator WARREN. Thank you, Senator Collins.

The Federal Government has spent more than \$30 billion supporting the adoption of electronic health records, and we did it because we know that exchanging health information and providing patients with access to their data can reduce healthcare costs and can improve patient outcomes, as you've just been talking about. We've come a long way, but today, many providers still can't exchange information, and, as Ms. Giusti and Mr. Dishman have just testified, many patients still can't easily access their information.

Mr. Dishman, I'd like to ask you about Intel's health insurance plan for its employees. I understand that in some areas, it provides highly coordinated care. As part of the coordination, Intel requires that any provider that's part of the Intel plan must be able to exchange patient health information, including tests or diagnoses, with any other doctor in the system.

Can you say something about how that requirement has affected the health of your employees, generally?

Mr. DISHMAN. Sure. For one thing, it started to produce the results that we wanted. Just in the first year, in New Mexico, where we rolled out this Connected Care program, as we aimed for the triple aim, the costs were held about the same, but we significantly improved outcomes in things like management of diabetes and the reduction of cost of diabetes.

Senator WARREN. So the same costs, but much better outcomes.

Mr. DISHMAN. Same costs, but much better outcomes. We had to write into our RFPs about the providers and their vendors, saying,

“We’re going to hold you accountable, not only for showing that you are saying that you are a standards-based EHR, but vigorously testing against it to actually prove it,”

and they did not get full payment unless they could actually show that they did this.

We’re a very engineering culture at Intel, so it’s not surprising. You might think, oh, were our employees surprised, and it was like no, they expected it. They said, “We’re a data-driven bunch of engineers who are expecting to have this information.”

The big surprise in the study so far, as we’ve rolled this out in Oregon and now New Mexico and California next, has been the clinicians. The clinicians across these multiple providers, multiple insurance companies, different versions of Epic implementations of their EHR, some of them using a different EHR with Greenway, were like,

“Oh, my gosh. Now that I’ve tasted interoperability, I can do what I’m supposed to do with my Hippocratic Oath, deliver high-quality care to my patients.”

Senator WARREN. OK. You’ve given us some idea of what we can get with interoperability. Let me ask you more about it.

As part of Medicare Access and the CHIP Reauthorization Act that was signed into law earlier this year, Congress set a national objective of achieving widespread interoperability by the end of 2018. The Department of Health and Human Services has recently proposed rules for the final stage of the Electronic Health Record Meaningful Use Program.

Mr. Dishman, I want to ask if you think that the proposed rule alone will ensure that health records can be easily exchanged and that patients in this country will have the same benefits that the employees at Intel have.

Mr. DISHMAN. First, I would say I know there’s lots of pressure from folks who want to delay. Don’t delay. This is a hard transformation. Keep it going in 2017 and 2018. We’re not done with meaningful use by that stage. We may call it something different out in time.

But the fact of the matter is if we want a complete medical record—what’s currently in the EHR today, the clinical data, doesn’t include the claims data, doesn’t include the imaging data, doesn’t include the genomic data that’s coming, and doesn’t include the consumer health data. We need to get out and establish standards for these new data types ahead of them—

Senator WARREN. Common standards.

Mr. DISHMAN. Common data models, common standards. Test and validate to make sure that those standards are actually being implemented and be ready to sort of understand that a complete medical record that I need to save my life with cancer, or that Kathy’s folks do with multiple myeloma, is not just what’s in the traditional EHR. We’re going to have to keep driving toward that innovation model, and it’s probably going to take us 4 or 5 more years to really get there.

Senator WARREN. All right. Thank you. I just want to underline what I'm hearing you say on this, that even though the Meaningful Use Program has had a lot of success in driving doctors and hospitals to adopt electronic health records, the final stage, as proposed, does not guarantee interoperability or true patient engagement.

This is really frustrating, because the technology to create a patient-centric interoperable healthcare system exists, as you are proving, and Intel and others have demonstrated that it can work. As the committee continues to look into this issue, I hope that we can find ways to build on the Meaningful Use Program to break down the remaining barriers to interoperability.

Thank you, Madam Chair.

Senator COLLINS. Thank you.

Senator Alexander.

#### STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. Thanks, Senator Collins.

I want to thank Senator Collins and Senator Warren for their leadership on this issue. They are very diligent members of this committee and have attended all the hearings that we've had on the subject. We've had five.

This is a subject which Senator Murray and I are trying to work on together in a bipartisan way to see if we can realize the promise of electronic medical records. Our goal is to put patients first. We want to make sure that these massive changes actually work to do that. We've formed a working group that is bipartisan to achieve that, and as you can see from the attendance at this hearing, there's a lot of interest in it.

Today, I'd like to use my time to make a statement before I ask a question. I might add that in our work together, we've also been working with the administration, with Secretary Burwell, with the Office of the National Coordinator, and my goal, anyway, is to make sure that we implement an electronic health record system as efficiently and effectively and as rapidly as we can in a way that genuinely helps patients, which leads me to my statement.

I believe we should delay until January 1, 2017, the making of the final rules for Stage 3 of the Federal Government's program to require doctors and hospitals to use electronic health record systems. I believe then that the Stage 3 requirements should be phased in at a rate that reflects how successfully the program is being implemented. I believe also that the modified rules already proposed for Stage 2 of this program should be adopted immediately, because it will help most doctors and hospitals comply with the government's requirements.

Patients need the interoperable system that we just talked about that enables doctors and hospitals to share their electronic health records. The government, doctors, and hospitals need time to do it right.

Some hospitals have told me they are, "terrified" by the prospect of Stage 3. These are some of the finest medical centers in the United States, some of those who have been the pioneers and leaders in electronic healthcare records; some of those who believe that

Stage 1 was very helpful in changing the habits of providers; that Stage 2 was difficult.

But even these leaders say that Stage 3, as proposed, terrifies them. It does not help patients to make these massive changes fast and wrong. It does help patients to do this deliberately and correctly, so that hospitals and doctors embrace the changes instead of dread them.

Since 2009, the Federal Government has spent more than \$30 billion to encourage the nearly 500,000 physicians and more than 5,000 hospitals who serve Medicare and Medicaid recipients to establish electronic healthcare records. About half of these doctors and most hospitals have established such systems. Beginning this year, the government is assessing penalties on those who haven't. About a quarter of a million physicians have begun losing 1 percent of their Medicare reimbursements, and 200 hospitals may be losing more than that.

All hospitals and most physicians met the requirements of the first stage of the so-called Meaningful Use Program. As I said earlier, most of them thought it was helpful in changing habits. Stage 2 requirements are so complex that only about 12 percent of eligible physicians and about 40 percent of eligible hospitals have been able to comply. That's why we should immediately adopt the proposed modifications to Stage 2 requirements so the physicians and hospitals have time to adapt to these huge changes, and we should delay, until January 1, 2017, making the final rules for Stage 3 so that we can do it properly.

I look forward to working with Senator Murray, with Secretary Burwell, other members of the committee, and the administration on finding the best ways to modify this program and these requirements so that we can realize the promise of electronic medical records. I would emphasize again that our goal is to help patients, and it does not help them to do this fast and wrong. It does help them to do it deliberately, carefully, and right.

Thank you, Madam Chairman.

Senator COLLINS. Thank you, Senator Alexander.

Senator Franken.

#### STATEMENT OF SENATOR FRANKEN

Senator FRANKEN. Thank you, Madam Chair.

This is for anyone. What is the No. 1 barrier to integrating electronic health records and interoperability? Is it that the leading companies in this want to keep their market share and don't want to share—you know, I've got a big part of the market, and if you stay with me, you'll be fine? And is there something we can do about that since we're a part of the lawmaking process in the country, I believe. Right?

[Laughter.]

Ms. GIUSTI. I would answer that question by saying that one of the greatest disconnects when you are a patient is who actually owns the whole patient. When we're seeing all different physicians for specialized care, there's not one person that gets rewarded on their overall health outcomes.

In addition, in today's world, where it's tough out there in healthcare and different centers want to maintain the patient pop-

ulation they have rather than lose them to other centers, there's not always an incentive for everybody just to share all of their data across every center. I do believe that the centers that work with the best vendors to build integrated and centralized areas where we can house our data—I believe those centers will win in terms of patients wanting to work more closely with them.

Part of this comes back to who has the responsibility for the overall health of the patient, and where are we looking to go for that central repository of integrated data.

Mr. DISHMAN. I would just add to it and say I believe that the software vendors have realized where the puck is going and are moving toward interoperability. Some of the standards are not specific enough and they leave too much leeway. That means you implement them differently, and then even software from the same vendor doesn't talk to each other unless you hire a bunch of health IT experts to do this—tightening the details on some of these things.

What we at Intel are referring to—and we recommended this for the House 21st Century Cures Act as well—is we need implementation specs. It's one thing to have the standard, but as part of what I mentioned in my testimony about the out-of-the-box experience, if you're adhering to the standard, but the clinician gets the new software after this huge investment, either from stimulus or from private sources, and it doesn't work out of the box because there's not a common implementation standard that's linked to the pretty much common standards of care that almost all clinicians need to do, this is like getting a car, but it's not yet ready to drive until you get somebody to put all the pieces together to actually use it.

An implementation spec that's very specific and that's common across all of these would help to drive the standards that are becoming real into actual practice.

The other thing we should just say—and this is the challenge of meaningful use. It's not just a technical challenge. This is a redefinition of the social covenant of what it means to be a patient and what it means to be a clinician and to have a coordinated care team. We're undoing 150 years of the doctor having the information as a lone practitioner, moving to the paradigm of coordinated care teams, where patients are part of it.

This is hard. Right? I had to fight to actually be a member of—a bona fide member of my care team. I teach the patients that I teach to do this today.

To step back from the technology for a moment, there are specific things we can do and realize. We're on a path to change the social covenant for a two-way interaction between patients and families and their care teams and a two-way exchange of data between the two of them. That requires re-education of the patient to have more responsibility. That requires re-education of the clinicians. That's why these things are hard. It's not just the technical pieces.

Mr. RATWANI. I would like to just briefly add the safety hazards and the inefficiencies that arise from these systems for both clinicians and patients is a critical issue. As we look to interoperability, it's critically important to have the exchange of information, but it's also critically important to ensure that the information is inte-

grated in an appropriate way so that there's no duplications that are going to pose issues, that the information is reconciled and represented so we can make sense of it. So interoperability is a key step, but so is the way that information is then integrated and represented.

Senator FRANKEN. The interoperability is not just about delivering high-value care and good care. It's about safety, too. It seems like it's incumbent upon us in this process, in this whole process that we've undertaken.

I want to thank the Chairman and I want to thank the Ranking Member for this series of hearings. It seems to me that we have to really take seriously—and I know we are—the approach that we do this so that we're fulfilling the promise of this, and we're doing it in a way that increases the value of care and lets patients have the access to their own information, and that it's interoperable so that we can get the real benefits out of this thing.

Thank you.

Senator COLLINS. Thank you.

Senator Isakson.

#### STATEMENT OF SENATOR ISAKSON

Senator ISAKSON. Thank you, Senator Collins.

I thank all of you for your testimony. You've testified to a great advertisement for Senator Warner's and Senator Isakson's bill on care coordination, which is in this committee now and is currently getting comments. We've had over 500 comments already, and we're trying to aggregate those in hopes the Chairman will look favorably upon it being a part of the omnibus bill that we bring in terms of care for our patients.

But care coordination is absolutely critical. Eighty-two thousand people a year die because of medical errors, many of them because misinformation is available rather than coordinated information.

What Senator Warner and I have done is said that we've created a reimbursement to Medicare doctors for care coordination for seniors with two or more chronic diseases. We think that will improve the quality of care to the patient and lower the cost because of the coordination. I think your testimony and the nodding heads I've seen from the committee members have all attested to that being a good thing to do, and I hope we can do it.

As one who has been managing Parkinson's for 3 years, I want to echo what you said, Mr. Dishman, and what you said, Ms. Giusti. The aggregate information that's available to you and the more you can get, the better you can manage a disease and the better you can notice those things that are triggers that your doctor should know about. The less information you have, the less healthy you're going to be. I commend the Michael J. Fox Foundation and the Parkinson's Foundation for the work they've done on that.

Not to do too much advertising, but Senator Murray and I have Senate bill 849, which is the registry for neurological diseases we're trying to bring forward to do exactly that, to see to it that we attract as much patient information as possible, aggregate it in a form that is risk—aware of the risk of doing that, but gets the patients the information they need to manage the diseases that they have.

I commend all three of you on your testimony. I commend both of you, in particular, on managing your disease and becoming a victor over what was a very dangerous disease.

Thank you, Madam Chairman.

Senator COLLINS. Thank you very much.

Senator Murray.

#### STATEMENT OF SENATOR MURRAY

Senator MURRAY. First of all, let me thank Senator Collins and Senator Warren for taking the time to lead this important conversation and for all of your work in our effort on this. We all know that strengthening our health IT infrastructure is really a critical part of continuing the progress we've made toward a healthcare system that really works for our families and for people. Empowering patients with information is such an important part of this.

Mr. Dishman, your personal story really illustrates why patients have to be able to easily access their data when they need it. I really appreciate you coming all the way out here. Thank you for sharing that with us. I listened to your testimony and your answers to questions, and it's a cultural battle as much as a technological battle, and we all need to appreciate that as we move forward on this.

Senator Franken asked you a little bit about this. In this committee, we've heard a lot of stories just like yours about the barriers that patients face in trying to get their electronic health information. You talked about fighting for it as much as you were fighting your cancer. That's just crazy. We just assume, especially on our end of the country, that people have access to information. So I really appreciate the battles that you are fighting.

Talk to me a little bit about, based on your experience, what the Federal Government should do to really address the barriers that you fought through.

Dr. DISHMAN. The first is to continue the drive toward value-based payment, because it's sort of prerequisite for everything that we're talking about. While Intel has had success creating our own ACO—and we are a tech company, so it's easier for us to make all of that stuff work together than somebody who's not, and that's what we want to get to. You don't have to be a tech company to be able to make this stuff work for your employees.

If the Federal Government had not driven and signaled that we were moving to value-based payment, I believe, even with Intel's size and clout, the providers would have ignored us and not done the work that they said when we said,

“We want a direct contract with you, and we want to hold you to some very aggressive quality metrics, so the folks who manage our FABS, who are very good at managing quality metrics, are going to build with measures with teeth.”

So that's a first.

Driving a common data model is key. At the end of the day, if we don't have common data elements that are designed the same and common data models and—let's do it for clinical and claims data and things that we know about, but let's go ahead and set up those common data models.

Kathy and I both served on the President's PMI working group, and one of the things that you'll see in our report that comes out tomorrow at 1 o'clock is recommendations that we've got to get the common data models in place for the new kinds of data types like omics, like consumer-generated data, so that that stuff can become a trusted part both to the clinicians and to the researchers.

I mentioned the implementation specs. It's not just having the standards. It's actually showing that there are implementation specs, that these things are ready to go out of the box.

One other is if we started auto pushing the EHR data into the relevant and authorized health information exchanges with all the security that we actually need and that is achievable and doable, there are tools on the exchange that I, as a consumer, can use, this would go a long way, and add the personal health tools that consumers use, whether it's a personal health record, to those exchanges. We have conceived of the exchanges as a clinician-to-clinician capability.

It's like there is no reason that consumers should not be able to use the exchanges to get access to their own data. If it's auto pushed from all of the EHR players into there, and now, suddenly, there are tools on the exchange that I, as a consumer, can use, then the exchange is not just about clinician-to-clinician, but about coordinated care teams having access to the same data.

Senator MURRAY. Excellent. I really appreciate your response.

Dr. Ratwani, you talked about certification requirements for health information technology needing a renewed focus on usability. I just heard about a woman who wanted the results of her pregnancy test, but her electronic health record reported her hormone levels rather than whether or not she was pregnant. So you can imagine how frustrating that is when you're trying to get accurate information and that's is hugely consequential, what you're looking at.

How user friendly is today's health information technology for patients?

Mr. RATWANI. Senator Murray, let me start by saying you're a tremendous leader in the area of health usability, so I appreciate the question. When we look at the usability from the patient side, if we look at the current safety enhanced design certification requirements, those requirements are focused on eight capabilities that are primarily medication-related and are provider facing, things like computerized provider order entry, medication reconciliation. There are currently no certification usability standards around patient portals, patient information, discharge paperwork. None of that is currently covered by the certification requirements.

What the committee could certainly look to do is leverage existing research and literature in the area and develop a set of guidelines that could be offered to the vendors to better facilitate usability of patient facing aspects of health IT.

Senator MURRAY. We need to really focus on that, what patients want, rather than how we are just putting information into a system. The doctors can talk to each other—important. Patients want information, too, and that's something we really have to think about.

Ms. Giusti, I'm sorry. I am out of time. Thank you so much for sharing your personal story and your expertise on this. I really appreciate it.

Senator COLLINS. Thank you.

Senator Cassidy, also known as Dr. Cassidy.

STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you, Madam Chair.

I agree with you all so much that it's a little bit hard for me to formulate a question, because there's nothing to challenge. Maybe we can illuminate.

We're working on a bill that would somehow—and I've spoken to vendors, to providers—I'm a doc—to insurers, and, frankly, the vendors have a point. They say,

“Listen, you go to Georgetown, and they always measure height in feet and inches, but we go across town and they measure it in centimeters, so we have to customize.”

The more customization, obviously, the harder it is to interface.

You spoke, Mr. Dishman, regarding how one Epic doesn't speak to another Epic. Epic will logically say, well, that's because they made it speak its own dialect, as opposed to—sure, it may go back to being Indo-European, but the fact is that many Indo-Europeans don't speak with one another.

I hate to talk to Dishman, because he's from Intel. Who in the hell—like, Intel is—of course, you can do it. You know what I'm saying?

[Laughter.]

My mom can't. She doesn't, by the way, and nor does her son.

I guess my question is if you come up with a standards committee, with stakeholders, it inevitably becomes somewhat bureaucratic, and probably somewhat dominated by people from Intel, who are, again, kind of three standard deviations out in terms of their ability to understand, or a businesswoman who is so incredibly motivated that, really, your ability to speak on a sixth grade level, as how you're supposed to write a medical consent form, has long been lost. I say that in no other way but to observe.

If we're going to come together with a working committee that's going to have standards, how do we prevent it from becoming a bureaucratic process in which the average person who reads on a sixth grade level will not be able to comprehend? I don't know. I'm asking your thoughts.

Ms. GIUSTI. I guess one thought I would have, No. 1, is if we're saying that these need to be used by patients for patients, then patients should be at the table as we try to bring all these disparate groups together to go over what we are actually looking for in the EHRs. The other piece—

Senator CASSIDY. Can I stop you for just a second? I want to ask a technical question.

Ms. GIUSTI. Yes.

Senator CASSIDY. My staff whispered to me API, the application program interface. I guess we don't really care about what the program itself does. We're just concerned about the API. Correct?

Ms. GIUSTI. Yes. We get into this whole discussion of what is—first of all, what is the patient seeing. You’ve got EHRs, and you’ve got everything that a patient sees. Even that can be a disconnect. The other thing that you’re hearing today is—we all just said the patients don’t know they have these. If patients—

Senator CASSIDY. I’ll tell you, I go into a doctor’s office—I take my mom to see her oncologist—do you want to see your medical records? I think it’s out there that you can access your medical record. It may not register.

Ms. GIUSTI. Right.

Senator CASSIDY. It’s out there that you can see your medical record.

Ms. GIUSTI. It’s out there, but as we can tell, quite a few are still not aware or not using it. If you have a chronic disease, or you have cancer, you have to keep going in and tracking your numbers. You’d be crazy not to. I think we tend to—

Senator CASSIDY. Yes, but I’m a physician. I don’t track my mother’s numbers. You know what I’m saying?

Ms. GIUSTI. Right. When we look at the data, what we’re finding is with the baby boomer group, we will go in and look at some of the data, if you are tracking some of it. If you look at the millennials, they’re actually going in to use these interfaces more to schedule appointments and actually learn health information just because that’s the way they learn.

At some point, we have to bring the different groups in to say, “Well, what’s everybody looking for in these tools, and how do we make them easy to use?” One of the concerns you’re hearing from Eric and me is there’s the ability of a patient to understand their health and their disease by looking at these EHRs and portals. There’s also the ability to use EHRs for research purposes and actually understand a lot.

Senator CASSIDY. Can I stop you there?

Ms. GIUSTI. Yes.

Senator CASSIDY. Mr. Dishman, you bring up one of the barriers that we have not discussed, which is institutions and companies trying to control patient data because they wish to monetize.

Mr. DISHMAN. Yes.

Senator CASSIDY. When I was on the Energy and Commerce Committee last year, we had a guy testify, and all these physicians plug in on all this data in order to do population health. As it turns out, it’s only available if you put down \$500,000 and you purchase it. The taxpayer didn’t finance this to create another business model for a provider of information. Do you agree with that?

Mr. DISHMAN. I agree. I’m helping a veteran right now who has Parkinson’s and cancer. He has eight devices, some provided by the VA and some that he self-purchased to monitor different aspects of his very complex health. I have been trying to help him get one simple view—because he’s not an engineer at Intel—of what’s going on with his data. We need patient accessible APIs to all of these devices. Some of the devices have been purchased by himself.

Senator CASSIDY. But that’s a different issue. Then the company holding onto the data and not sharing it with the population—

Mr. DISHMAN. No. That's the thing. They don't want to open up their APIs, because they have the raw data and they're trying to look across——

Senator CASSIDY. Do we need to legislate that people have a common API?

Dr. DISHMAN. If you purchase a device yourself or someone is using it, you as a patient ought to have a right to that data, not just the data that they have summarized into information using their algorithms, but the raw data that you're wearing on your body every single day.

Senator CASSIDY. Let me ask a question, and I'll finish with this. I don't know this, but you all have your own perspective. If you're an insurance company, and you have big data sets of de-identified patient data, should we mandate that that be made available to medical researchers of a certain qualification to do population health?

Right now, I'm told if you can put down \$500,000, you get it. But if you're at the School for Public Health at you-name-it, you cannot access it without that \$500,000, in which case it ceases to be proprietary and it becomes something of common usage. Any thoughts on that?

Mr. DISHMAN. Mandate that the patients can direct where their data goes.

Senator CASSIDY. That's different than what you said, ma'am, because you're saying why wouldn't you aggregate your data with others because it's only in the aggregation that it becomes most powerful for population research.

Ms. GIUSTI. Absolutely. I also agree that that's the decision of the patient. That's absolutely the decision of the patient. If they know, then they——

Senator CASSIDY. Then if the patient agrees to aggregate their data, and you have this aggregated data set, again, do we mandate that it be made available to researchers without paying \$500,000 or whatever the fee is? Do you follow what I'm saying?

Mr. RATWANI. I would like to add—yes, we need to reduce the cost of researchers to engage in these data. It's going to be the most meaningful way for us to make advancements here. When it comes to the APIs and people's own personal health information, if we want to see innovation in this area, we need to open up the APIs and allow third-party vendors to come in and innovate in this space.

I do want to come back to, Senator Cassidy, one of your other initial comments about standards and EHR vendors. It's important to recognize that this is not a new problem. Other industries have gone through this.

If we look to transportation, if I walk into any vehicle in this country, there's a hazard warning light that looks the same in every vehicle. The accelerator is in the same place in every vehicle. That industry has come to consensus on what those standards should be. Coming to consensus might be new for EHR vendors, but it's certainly not new to several of the high-risk domains that we embark on.

Senator CASSIDY. I'm way over time. I yield back. Thank you.

Senator COLLINS. Thank you.

Senator Baldwin.

STATEMENT OF SENATOR BALDWIN

Senator BALDWIN. Thank you. I want to really thank the witnesses, and you've given us an opportunity for another great discussion on this issue.

Mr. Dishman, you talked at the outset of your testimony about the goals of deep patient engagement and full interoperability. I wanted to share a brief, sort of, Wisconsin snapshot and maybe spur some discussion off of that.

In one of our communities in western Wisconsin, the city of La Crosse, a staggering, I'm told, 99.4 percent of patients at the end of life have an advanced care plan that is easily accessible in their medical record. This is thanks to a voluntary program called Respecting Choices that was pioneered back in 1991 by one of our leading health systems, Gundersen. They have—Gundersen had a robust electronic health record and a portal for patients and families to use to update and review the plans that they have on record.

I wanted to start with sharing this, because it really does combine this concept of deep patient engagement and full interoperability, at least for that system. We've talked more about interoperability in the IT side of this than we have about the deep patient engagement and the education around helping people find the value in that data and interacting with it.

I kind of use this example because I think you can't really do advanced care plans without really thinking—now, hypothetically, you might not be facing something imminently, but it requires you to really think about your future health and your treatment that you would like to receive under various different scenarios. If you do want to change your mind, it doesn't require that you go back in and alter those wishes.

I'm wondering if—I'd like to hear your comments about whether there are similar types of initiatives we could start, or communities could start, in order to engage people more deeply at an earlier stage, knowing that the thought that they give to their wellness and health will become a part of an electronic health record that will guide the medical professionals they interact with as it follows.

Mr. DISHMAN. I would mention that one pilot that we're doing right now is targeted toward—and we've done a lot of work at Intel with dual eligible populations and focusing on independent living and chronic care management for seniors. We're also trying to look at the other end of the spectrum that says let's take people who are young enough to still think that they're immortal, that, unlike me, they haven't gotten cancer at age 19.

We have this one study right now that's called YOU.24x7, and it's inviting people to really do preventive care and to really focus on cardiovascular wellness. It's a mix of a wearable, access to their clinical data if they've had any diagnostic data ever done, and giving them tools to actually engage with their providers on a shared care plan that both the patient and—or they're not a patient yet—the person and the clinician work on.

You heard from Kathy's point as well in response to Senator Collins' question. If you just give patients a bunch of access, there'll be 10 percent to 20 percent like me that are going to take hold of

it. You've got to wrap those things in a new relationship, a new program, like the one that you mentioned, where it's humans plus data infrastructure coming together to do things differently.

Senator BALDWIN. Any other comments on that?

Ms. GIUSTI. I would agree with it, and the thing we're finding is that when you actually have any third party that says, "Here's a reason to go into your electronic health record and look for something"—and it can be as simple as, in myeloma, you can track your disease with one biomarker. So we just say to them, "Follow that one number." If it's cholesterol, high blood pressure, whatever it may be, just teach a patient to track it. The moment you get them into that EHR looking at that data to track one number where they're not so overwhelmed, now they're in and they're working around it and they're starting to use it.

What we've found with the MMRF is that for our newly diagnosed patients, 75 percent of them felt they were highly knowledgeable, because they were getting these numbers. If they weren't working with the MMRF, only 45 percent thought they were knowledgeable about their disease.

You have to work with a lot of trusted third parties out there—there's many that are doing it—that can help raise awareness of this issue around EHRs. It's not just the doctors and the vendors. There are many people that can help with the problem.

Mr. RATWANI. The use of these systems is going to be critically dependent on the value that the patient actually receives from it. A concrete example of that—we were looking at a colleague's patient portal for their 5-year-old son, and in the patient portal, it lists social history, smoking, status unknown. Why is that relevant for a 5-year-old, and what parent wants to look at that in a patient portal?

That's the kind of information that does not need to be presented there, not in that format, not for that parent, and there's several examples of that. Another one is a vaccine, hepatitis, formula unknown. If I'm a parent, and I see "formula unknown," does that mean I need to call my provider? Does that mean there's something that's gone wrong here? So unless we make these tools absolutely useful for the patients, we're going to see a complete underutilization by the public.

Senator COLLINS. Thank you.

Senator Whitehouse.

#### STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Thank you, Chairman Collins. Thank you, acting Ranking Member Warren.

I have a recurring theme through these hearings with respect to health information exchange, and I've mentioned in prior hearings the concern I have that we have poured immense resources into the meaningful use support of information technology on the desks of providers, but we've been very parsimonious about supporting health information exchange.

We have one in Rhode Island called CurrentCare, which is as good as any in the country, and I think they've won every possible Federal grant that has come their way, and still it's such a struggle to sort through all the problems of information exchange, whether

they're legal or technical or have to do with making the information display in reasonable ways. I'm a strong advocate for health information exchange.

It's putting a lot on big provider groups to do their own health information exchange between each other. Many of them have pretty strong vested interest in not sharing information, as, unfortunately, we have heard here—kind of part of the business strategy sometimes.

Ms. Giusti, you've articulated so well that putting that on the patient is not only wrong, but it's bloody unfair, because you've got enough to think about without having to build your own health information data base for yourself. Today's conversation reinforces for me the importance of a really robust health information exchange and supporting the network, the infrastructure that provides that, and improving it. I'm trying to get it right.

In that context, I'd love to have your advice, looking specifically at the health information exchange mechanism. It's called Current-Care in Rhode Island. It's an independent organization, and it works closely with all the providers to maximize the utility of this information and to get as much information in as possible and to work automatically and efficiently and so forth.

What, from your experience, should be the things that we should take away? If we're going to push more emphasis onto the health information exchange piece of this, what should be the key patient-based safeguards you'd like us to be looking for, or the risks that we'd want to be staying away from? If you could just go right across the panel—and I only left you 2 minutes, so they'll have to be pretty quick answers.

Mr. DISHMAN. I'll just say Healthy Way health information exchange was key for us achieving our ACO, and our one suggestion is you will help the business models of exchanges if you do what I mentioned earlier, auto pushing data, with patients' permission to the exchange. The procedure is done. It's on the exchange for them so that anybody in the pool can actually do it. It will help—the exchanges have enough volume of data to where they can start to figure out their business models.

Senator WHITEHOUSE. Yes, which is the way we do it.

Go ahead.

Ms. GIUSTI. I would just say that, I think at this point in time, you have some areas that are doing very well in terms of making progress and others that are not. I would recommend looking at the best practices of what's going on out there and say these are working and then modify the incentives based off of what you're seeing and the information you've gotten from the hearings. I would do a potential reset.

Mr. RATWANI. I would say it's right information, right representation. We want to ensure that the appropriate information is available, it's accurate, it's up to date, and that it's represented in a way that the patient can actually understand. If I'm looking at a medication list, I certainly don't want three different medication lists in front of me.

How do we actually combine those to make sense so the patient is safe, understands, critically, what they need to do next, and is represented in a way that makes sense to the patient? If we are

saying for medications—in medical jargon, you might say, “Take three times daily.” What a patient cares about is when do I need to take it, breakfast, lunch, dinner? As we combine this information, we want to make sure it’s presented to the patient in a way the patient thinks about it.

Senator WHITEHOUSE. I suppose it’s safe to say that it goes without saying from all of you that it has to be clear and helpful to the provider that in the cases of patients who are severely disabled or don’t have the capacity to address their healthcare themselves are counting entirely on the provider’s ability to do this. You can’t sacrifice that in pursuing the patient integration piece.

Mr. RATWANI. Senator Whitehouse, I would like to comment on that. It’s important, as you point out, that we look at this as a system. It’s the provider and it’s the patient together.

Senator WHITEHOUSE. Yes.

Mr. RATWANI. As the committee looks to forward progress with health IT, the committee should ensure that the patient’s needs are able to be serviced by the provider. It fits with the way the provider works. It fits with their structure. That’s critically important as we move forward with this.

Senator WHITEHOUSE. Thank you very much.

And thank you to Chairman Collins and Co-Chairman Warren for the hearing today. I just want to thank Chairman Alexander and Ranking Member Murray for their continued focus on this issue.

This is really important, and we have to get this right, and there’s nothing really partisan about it. This is about getting it right and trying to make sure that the system does what we want it to do in an effective way and people aren’t cheating and all the usual stuff we have to deal with. The continued focus from this committee has really been terrific, and I appreciate it.

Senator COLLINS. Thank you. I’m going to suggest to my colleagues that we each have the opportunity for one final question before we adjourn this very interesting hearing. I’m doing so because I have a question for Mr. Dishman that I didn’t get to ask in the first round.

Mr. Dishman, you obviously are a technology expert. You’re very savvy. You live in a part of the country where access to the internet is very common, where the population tends to be younger. That’s very different from the State that I represent. Maine is the oldest State in the Nation. There are parts of our State where internet access is simply not available at all.

It’s one thing to say that patients should be accessing their portal and getting their medical information in California or Seattle or Massachusetts. It’s a lot harder if you are an elderly person without a computer, living in rural Maine, where access to the internet is very limited or non-existent. That’s one barrier that I haven’t heard anyone really talk about today.

The second barrier that I perceive is when you go online and look at your medical records, it’s like reading Greek for most people. If you’re getting regular blood tests for temporal arteritis and you’re having a regular blood test, but you don’t know what C-reactive protein and your sed rate means, then looking at every single week

that you have the test in your medical records, accessing it through the portal, really isn't very helpful.

I see two barriers that go beyond interoperability, that go beyond—is the provider's computer compatible with the computer at the local hospital, much less other medical centers or providers.

There's a basic, more fundamental problem of access, and I think one of the reasons that fewer than half of patients access their medical records and only 26 percent use that portal more than once is, if you get something that doesn't mean anything to you, or, worse yet, you can't get on in the first place, then you really—all the interoperability in the world is not going to help you. I would say that you're unusual in a lot of ways.

Mr. DISHMAN. I wrote that in my testimony, Senator Collins. I could not agree more. I said don't design it for me. Part of what we do at Intel—I just mentioned dual eligibles. When we go design technologies, we focus on dual eligibles in rural parts of the country, and if we can make those systems work for them and there, we know they're going to work elsewhere. That's what's called universal design. We follow this principle when we design and work on things.

The second thing I would recommend—and you're going to see this in the PMI report that comes out tomorrow from the committee. We keep saying it's not just about the data. It's about the information. We're going to need to aim these systems at probably 10 different levels of health literacy and make sure that we've got the tools in place.

I'm a social scientist at Intel, not a techie. I study doctor-patient interaction. I barely can understand these things myself. So the kind of usability that he's been talking about—we need to recognize there's probably 8 to 10 different levels of health literacy and make sure that we have the systems in place to do that.

Senator COLLINS. Thank you.

Ms. Giusti, I also want you to comment on this because you've managed to surmount this problem.

Mr. DISHMAN. She's much smarter about healthcare than I am. [Laughter.]

Senator COLLINS. Obviously, people of all ages are diagnosed with the disease. I suspect, though I haven't been on your website, that your website explains a lot of terms and treatments. Does it?

Ms. GIUSTI. We try. It's always a changing paradigm. The one thing that helps us, though, as I mentioned before, is the fact that you can follow specific numbers. We're like the concierge of so many patients that after a while, you get used to saying, "These are the three numbers you need to track when you have this cancer." Often, it really is three different things you're tracking.

Once you explain that to them, when they go on and look at their EHRs, they know what they're looking for. Otherwise, you're right. It's like drinking water out of a fire hose. You're so overwhelmed by it you may never go back. That kind of education—this is the important data for you to look for, and this is where to find it—is important.

The other trend we're seeing is for many people, they do have smart phones, and the challenge we're going to have is we're all

looking at it on our computers. The next generation is not going to do that. They're going to be looking at everything on their phones.

But one thing I want to add to this—and Eric touched upon it, too—is we spent months working on the Obama Precision Medicine Initiative. It's called precision medicine, but it could easily be called precision health as well, because it really is a 1 million cohort to everybody in this country, and it doesn't mean that you're sick. It's very healthy people, too.

This is an interesting time when we're trying to build awareness of the importance of precision medicine and building a million-patient cohort. It's very apropos to what we're trying to do here, too, which is know your data, make sure you're getting the most robust data set you can, integrate it, aggregate it, and we'll all benefit. I think the two things are going to go hand-in-hand.

Senator COLLINS. Dr. Ratwani, does this also require a cultural change on the part of some physicians who really have not been trained to open up all of the medical records to their patients? Does that make some physicians uncomfortable? Do they feel they have to be more careful about what they write? Are they willing to make their patients true partners?

Mr. RATWANI. It's difficult for me to comment on how many clinicians would feel about this. Clinicians are deeply involved in the care of their patients. They care about seeing their patients get better. As we look at how we can improve access, as we look at how we can make sure that the terminology used in patient portals and the information is represented in the right way, it's going to take input from patients and clinicians to make all of that work.

The user-centered design methodology is exactly about that. It's about engaging patients, providers, and any users of this technology early and often, doing it in an iterative way so that we get people's feedback on what these systems should like, how they think about the problems, and, ultimately, it will lead to the most effective product, system, interface that can be developed.

Senator COLLINS. Thank you.

Senator Warren.

Senator WARREN. Thank you. I want to ask about medical research. We all know of the importance of medical research and now the digitization of health information opens up tremendous potential for facilitating clinical research.

Ms. Giusti, some of your testimony about this is truly amazing. You have made the point that many patients and their families want to participate. They want to be part of this. When we talk about what serves patients, we talk about what serves them one at a time to track their own numbers, but we talk about it in terms of medical research and how the aggregated information is far more valuable for creating new research opportunities. I want to ask two quick questions about this.

I want to start, Mr. Dishman, if I can, with you. Could you just identify some of the barriers that researchers face when they conduct clinical research using self-reported patient data?

Mr. DISHMAN. Let's take cancer for an example. First of all, you have to understand that there's so little data out there for people who do cancer research. Fewer than 1 percent of cancer patients have actually had a whole genome sequence.

If you go look at the data that researchers have access to in something like cancer, 4 percent of the data that's out there is sitting in the public data sets where the data has been curated so that they can actually make meaningful research out of it. The other 96 percent is sitting in the private data centers of the hospitals, clinical centers, and cancer centers that are out there.

The ability to tap into what's below the iceberg and do research on that is the key, and the only way that's going to be facilitated is through secure sharing. Once you have the secure sharing infrastructure, you can start to combine self-reported data, consumer-generated data from things like wearables, omic data, and clinical data. It is the triangulation of those data sets against one another where the truth may lie.

A lot of the resistance for researchers sometimes in using the self-reported data is they just don't have enough of the data sets to triangulate all of these pieces. One of the things that's starting to happen is let's create a stream where patients themselves can contextualize their clinical data, not change it in the record, but actually put a stream next to it that says,

“Hey, I don't really have asthma. It was a response to a chemo side effect that I was on for 3 months. But now everybody believes I have asthma.”

That kind of data could help both the future clinicians looking back at it, but also can help the researchers make sense of the self-report data against the stream of clinical data.

Senator WARREN. I get your point about a data repository, and I get your point about multiple data sets. If I could just ask you one more—the role of standards in reporting. Can you just say a word about that?

Mr. DISHMAN. Yes. This is back to standards at all levels and security at all levels. There are many known self-report measures now that have been clinically proven, if they're executed in the standard way, to be reliable self-report measures. So the notion that you can't make clinical outcomes or research outcomes out of self-report is just not true.

Senator WARREN. Good.

Maybe I can followup, then, with Ms. Giusti, and you can talk just a little bit about how the foundation has overcome many of the barriers to doing research in multiple myeloma.

Ms. GIUSTI. Right. You could tell that I was very focused on a trial we were calling CoMMpass, where we sequenced 1,000 myeloma patients and built our own data bank. The barriers we had to overcome in CoMMpass itself were we needed all the academic centers to share. Otherwise, we'd never build a critical mass of data. Every center sees some myeloma patients, but not enough to get that critical mass.

By the way, myeloma is not alone. Most diseases are breaking down into smaller and smaller types of diseases.

The second one is we had to allow everybody to give up intellectual property so that they would be able to share all this data. And the third was the importance of maintaining all the patients in getting the longitudinal data. We have to keep them in this data set over time, and the way you do that is by sharing the data with

them and aggregating the data and telling them what they're learning from it.

But, importantly, for EHRs, one of the most expensive pieces of this was developing the protocol, but also the case report forms by which to study the CoMMpass trial over an extended number of years and the money it cost to do the trial, which was \$40 million for a small nonprofit like ours to raise. Looking forward, if you had good standards, and if we could integrate all of this information, you could, No. 1, use EHRs to start to identify—especially if you have genomics—what's going on in these diseases.

Second, think about this. If you're a patient that goes on and knows your genomics, when the trial opens, you can raise your hand. Like I mentioned to you before, finding patients for clinical trials and accruing trials quickly is the No. 1 obstacle in drug development. If you can do this wisely, not only do you improve outcomes and improve drug development, but you build in so much efficiency, and that's why it's so important.

Senator WARREN. Thank you both so much. I thank our entire panel.

Researchers are on the cusp of so many great discoveries, and we need to make sure they're not slowed down by data systems that are just working in siloes, that are not sharing the information. The work done by the Multiple Myeloma Research Foundation, by Intel, by other partners working to overcome these data barriers and their success in using patient data, really shows us the future.

I hope that as this committee continues to focus on health information that we're going to make sure that we're building an approach to data that will support a 21st century research enterprise.

Thank you all so much, and thank you, Madam Chair.

Senator COLLINS. Thank you.

Senator Baldwin.

Senator BALDWIN. What a treat to get a second opportunity. There's so many things I'd like to discuss, but I wanted to try to limit myself.

There was a conversation earlier about how this health IT has sort of developed around usability for the medical practitioner, around doctors, not patients. You could make an argument that there are almost—many doctors I talked to would make the argument that they're really made for the billing department, and, really, that the choices, whenever they were made, to acquire a certain health IT was so that in that medical system that existed at the time—but we've obviously gone through quite a lot of changes—but was purchased so that the right bill was generated for the patient, the insurer, the supplement, whatever it is.

That's why the comment, Mr. Dishman, that you made about really continue your—no, it was somebody else who—really continue your work toward value-based payment models—or was it you—because that's going to, hopefully, align all of that usability for each of—you know, for the patient, for the doctor, and for the setting in which that practitioner has their practice.

I wanted to just ask a couple of questions. You had a discourse with Senator Cassidy about APIs, which is rather a new term for me. In terms of driving patient engagement, it seems like this is a huge opportunity, whether it's condition-specific or disease-

specific devices that are user friendly for the patient and they engage in on a routine basis because they're motivated to do so, and it makes sense, and it deals with a number of the issues that have been raised.

We've been talking about interoperability between the major health IT platforms. To what degree is it necessary for us, at this point, to start engaging in the interoperability issues about all of these, the wearables, the other devices that assist patients?

You were talking about some of the VA programs. I had a conversation with a constituent over the August recess who said that, really, the health buddy program that he's dealing with has been essential to him. Any comments on that for driving greater patient engagement and interoperability?

Mr. DISHMAN. About 8 to 10 years ago, when my team at Intel started building things for independent living for seniors, we said,

"You know what? There's going to be a whole wide range of wearable devices, and there's going to be phones that even have medical diagnostic, great equipment built into them, and that world is coming very quickly."

Senator BALDWIN. If I can interrupt, phones, not internet-based—

Mr. DISHMAN. That's right.

Senator BALDWIN [continuing]. So that it can serve our constituents who have less reliable internet service or none.

Mr. DISHMAN. That's right. That's right. That world is coming, and we helped to form something called the Continua Health Alliance that said just as we've struggled because we did not have standards at the outset for what we've created for the medical equipment side of the world, as the consumer health side of the world emerges and these two start to combine, we need to make sure that we have standards in that place.

We would do well—we would serve the country well by making sure that these new data types, like omics and consumer-generated data, start to have standards. If you're a diabetic today, you can go on an app store, whatever OS that you use, and find thousands of diabetes apps, which ones are high quality, which ones are used, which ones were downloaded more than once and actually sort of sustained.

The art of design for developing a consumer experience that will sustain your behavior change is the key to fundamental healthcare reform. Making sure that these devices that we're going to have on our persons and are going to be around us and part of our everyday life technologies—we need to get ahead of that now and not let it become the same bogged down data swamp that we have now in trying to pull clinical data into the era of interoperability.

Ms. GIUSTI. You're already starting to see this happen in startup companies left and right, where we're seeing companies that will step in and say,

"We'll look at the employer groups. We'll look at certain companies. We actually will sequence their genomes, and we'll actually coach them and follow them, and we'll require them all to wear a Fitbit, and we're tracking their data. When things go awry, we just coach them and reign them in on health, so

that we're not here trying to pay for disease, but we're actually trying to prevent disease."

Many, many companies are already looking at this and using wearables as a huge part of it. The more time that goes by as we try to build EHRs and make them as strong as they possibly can be, the one thing we're facing is that technology is growing so fast that almost the needs are changing.

You're hearing us say you have to educate the patient. There's also amazing needs in research, because genomic sequencing is taking off like crazy, and now you're asking a slightly different question, which we all dealt with on the Obama PMI piece as well, which is, yes, but now everybody's got wearables and sensors. How is that data being brought in, too? It's a challenging time.

Mr. RATWANI. If there's time, I'd love to comment. The EHR vendors are generally the ones that put forward the patient portals, and we've seen from research that we've done that. Oftentimes, EHR vendors are not meeting the certification requirements for the usability guidelines that are in place now, which are focused on, generally, provider or clinician facing aspects. It's unlikely that many vendors are investing in usability resources for patient portals.

As we look to APIs and open APIs, it'll spur innovation in the area. It'll allow new entrance into the market that consumes that data. That will build really great products that will serve patients' needs. As we do that, it'll also be important to have other health information consumer health products that feed that. The more data that we can bring together, there's going to be a stronger data source for us to better understand health outcomes and encourage good health.

Senator COLLINS. Thank you very much.

Let me thank each of our panelists today. You truly have been extraordinary and have added immensely to the committee's deliberations on this very important issue. We're trying to figure out how giving access to electronic health information can improve patient care and what the challenges are from the perspective of both providers and patients. We want a patient-centered system. That is our goal.

We have a better understanding of the challenges as a result of your testimony and the work that you've been doing, and we very much appreciate your sharing your insights with all of us.

I want to thank all of the members of the committee, but particularly my Ranking Member, Senator Warren, for their participation today.

The hearing record will remain open for 10 days. There may be some additional questions that are submitted by members of the committee, or if you have something more that you want to tell us, feel free to send that in as well.

The next committee hearing is being planned for October 1.

Thank you, and this hearing is now adjourned.

[Whereupon, at 11:39 a.m., the hearing was adjourned.]

○