

MARCH 2014

IGNITING AN INTEROPERABLE HEALTHCARE SYSTEM

HCI|DC 2014

HEALTHCARE INNOVATION DAY

Washington, DC February 6, 2014



westhealth.org



healthit.gov

Executive Editor

Dr. Joseph Smith

Contributing Editors

Dr. Doug Fridsma

Dr. Michael Johns

Mark Lealey

Bakul Patel

hcidc.org



[#IGNITEinterop](https://twitter.com/IGNITEinterop)

Nick Valeriani of @WestHealth: We believe interoperability deserves a national dialogue. @FierceHealthIT

The "West Test" Is your healthcare good enough for your mother? Valeriani @dahern1

West Health CEO calls for healthcare that is simple, streamlined and smart—and made possible by interoperability. @MHjlee

Watching #HCIDC live webcast—awesome #igniteinterop sessions. http://bit.ly/1kgMmnX @ahier

How much longer are we going to use humans as "middleware" to machine interfaces? @Transformatics

@Jacobr Time for questions. Make them good. @ONC_HealthIT

At #hcidc today, learning about electronic health records and why medical devices don't talk to each other. @clararitger

One takeaway from #IGNITEinterop panel: On data, providers have a foot in two boats—some records are electronic, but many still on paper. @ddiamond

To see my story, just google 'ward miles' and there will be a link to Ward's film. @benjaminscot

Michael Johns—If we don't accelerate (#igniteinterop) our children will look back and say 'Those old fogies let us down.' @ONC_HealthIT

NEWS: @FDA will put out draft guidance on #interoperability this year. @ONC_HealthIT

We need participation by diverse stakeholders (med #tech #biz & gov). @lela_winston

A bit of humor frm Michael Johns of Ctr for Med interoperability—3 Bs: be brief, be brilliant, be gone! Nicely done! @SwissGator

Gladwell: I have a rule: Never talk about something your audience knows more about than you do. @ONC_HealthIT





Malcolm Gladwell: Nothing happens unless everyone has a sense of urgency that interoperability MUST happen ASAP. @FierceHealthIT

@timbenson We used to talk to providers on tidiness of uniforms & scrubs about message it sends. Old IT can send same message. @nickdawson

@Gladwell: "It is the synergies between the technologies & tools that bring about profound change." @LIVESTRONG

RT @westhealth Thanks to everyone who attended, participated, spoke at and was a part of our #HCIDC #IGNITEinterop conference! @ONC_HealthIT

HCI-DC: Igniting Social Media

	#IGNITEINTEROP	#HCIDC	@westhealth	@ONC_HealthIT
 tweets	2,496	812	127	99
 retweets			227	174
 impressions	8,410,971	2,490,638		
 mentions			415	334

Most of the results were obtained from Symplur for activity on February 6, 2014.

About the West Health Institute The Gary and Mary West Health Institute is an independent, non-profit medical research organization that works with healthcare providers and research institutions to create new, more effective ways of delivering care. We're wholly funded by philanthropists Gary and Mary West as part of West Health, four organizations with a common mission—pioneering new and smarter technologies, policies and practices, to make high-quality healthcare more accessible at a lower cost to all Americans.

Along with the Institute, West Health includes the Gary and Mary West Health Policy Center, a non-profit resource in Washington, DC, providing policy education and proposals; and the for-profit Gary and Mary West Health Investment Fund and West Health Incubator, providing investments and expertise to businesses that share our mission. For more information, find us at www.westhealth.org and follow us [@westhealth](https://twitter.com/westhealth).

About the Office of the National Coordinator for Health Information Technology The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration's health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve healthcare. ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS). ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. The position of National Coordinator was created in 2004, through an Executive Order, and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009. For more information, visit healthit.gov and follow [@ONC_HealthIT](https://twitter.com/ONC_HealthIT).



A MESSAGE FROM NICK VALERIANI, Chief Executive, West Health and KAREN DESALVO, MD, MPH, MSc, National Coordinator for Health Information Technology, ONC



We are pleased to present this report from Healthcare Innovation Day 2014: Igniting an Interoperable Healthcare System, co-hosted by the West Health Institute and the Office of the National Coordinator for Health Information Technology. On Feb. 6, 2014, we hosted 1,700 stakeholders critical to driving interoperability and dedicated to transforming the nation's healthcare system. This report presents what we learned at the conference. It highlights, most importantly, that achieving interoperability is a shared responsibility for all stakeholders. It also synthesizes the findings from the conference into our Call to Action, which lays out a vision for the path ahead and the key milestones to achieving an interoperable healthcare system.

Why interoperability? Because patients are waiting. You will read here about patients who experienced problems due to the lack of interoperability: devices that won't work together; healthcare providers forced to pay more attention to technology than to patients; and treatment decisions made in the absence of critical information trapped in systems that can't communicate. We learned during the conference that we can do better. We have a shared goal of a healthcare system that is simple, streamlined, and smart. We want healthcare that's good enough for our patients, our parents, our children, ourselves.

Healthcare is the one industry that's been the slowest to adopt the intelligent methods we have in most other parts of our lives. How did the communications revolution that transformed industries such as banking, entertainment and telecom somehow leave healthcare behind?

The West Health Institute and Gary and Mary West Foundation recently helped create and establish the Center for Medical Interoperability to address the many challenges associated with the lack of interoperability. The Center will be led by hospitals and health systems and is currently seeking members. Its goals are to serve as a neutral environment to identify technical solutions to interoperability challenges; engage technical experts; work toward protocols for testing and certifying; and facilitate education on solutions and best practices.

ONC envisions a health system in which all patients, their families and providers have consistent and timely access to accurate and reliable information that can be securely shared and meaningfully used across the continuum of care. The agency is working with the healthcare and health IT industries and patients and healthcare providers to achieve adoption of electronic health records and secure information exchange for the effective use of health IT. ONC's major focus in the next three years will be on ensuring the right policy standards and incentive environment necessary to see that data is flowing along with, and in support of, patients.

Bringing seamless functional interoperability to healthcare is as complex as it is essential. It is going to take leadership, creativity, innovation, and perseverance. It is going to take all of us working together to ignite an interoperable healthcare system.

Nick Valeriani
Chief Executive, West Health

Karen DeSalvo
National Coordinator for Health Information Technology, ONC



Contents

Executive Summary: Igniting an Interoperable Healthcare System page 3

Patient and Provider Perspective: Stories from the Point of Care page 13

Hospital and Health System Perspective: The Business Imperative for Interoperability page 16

Regulatory Perspective: FDA and ONC page 18

Lessons from History: Malcolm Gladwell Tells Three Tales of Interoperability page 20

Outsider Perspective: What We Can Learn from Other Industries page 22

Vendor Perspective: Innovation and Collaboration page 24

Research Perspective: Big Data for Better Healthcare page 26

Acknowledgements

The West Health Institute and the Office of the National Coordinator for Health Information Technology would like to acknowledge all of the individuals and organizations that provided input into HCI-DC 2014 and for their commitment to advancing interoperability and transforming the nation’s healthcare system.

We are particularly grateful to the following individuals for their service on the editorial board of this publication:

Executive Editor

Joseph Smith, MD, PhD, FACC, Chief Medical and Science Officer, West Health Institute

Contributing Editors

Doug Fridsma, MD, PhD, Chief Science Officer & Director, Office of Science & Technology, ONC

Michael Johns, MD, Chairman, Center for Medical Interoperability

Mark Leahey, President and CEO, Medical Device Manufacturers Association (MDMA)

Bakul Patel, Senior Policy Advisor to the Center Director, Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA)

Writer/Editor

Jill Schlabig Williams

Layout

Ruth Moyer

Photos (unless noted)

Kaye Evans-Lutterodt/PRNewswire

Published by

The West Health Institute
10350 N. Torrey Pines Road
La Jolla, CA 92037

1.858.535.7000

westhealth.org

© Copyright 2014 Gary and Mary West Health Institute

Permission is granted to distribute or reproduce this report in its entirety for noncommercial and educational purposes. For other uses, or to order reprints of this report, contact Tim Ingersoll at the West Health Institute, tpingersoll@westhealth.org.

Igniting an Interoperable Healthcare System

Interoperability—the ability of systems to exchange information and to use the information that has been exchanged—can help solve the healthcare crisis. The West Health Institute’s HCI-DC 2014, co-hosted by ONC, brought together experts from across the healthcare community to consider how interoperability can cut costs, improve efficiency, reduce errors, and improve health. Interoperability across systems and care settings can empower patients, help doctors make better decisions, and allowing all healthcare providers to spend more time with patients. It can accelerate innovation and free up technology resources in hospitals so that they can focus on improving care in the community.

It is by implementing standards-based technology that we can achieve interoperability between systems. Standards can help by moving us away from proprietary solutions and toward open source solutions. Commonly adopted standards will eliminate the custom interfaces required today, lessening associated costs, risks and time. Interoperability supported by standards-based exchange and semantics will help us finally harness the power of information technologies to improve healthcare.

The real catalyst to transforming our healthcare system is all of us. Because we are all patients and we all deserve better healthcare. Together, we can create the tipping point we need to ignite an interoperable healthcare system.

—Karen DeSalvo, MD, MPH, MSc, National Coordinator for Health Information Technology, ONC



The experts at HCI-DC 2014 considered what we must do to tap into the information technology revolution that has transformed other industries to solve some of healthcare's thorniest problems. Their deliberations have been consolidated into the Call to Action offered in this document. Their key message: All of us must work together now to ignite an interoperable system. It is a burning issue. Our patients are waiting.

What is interoperability?

Interoperability in-ter-op-er-a-bil-i-ty, *noun*.

The ability of two or more systems or elements to exchange information and to use the information that has been exchanged.¹

For example, functional medical device interoperability refers to the ability of medical devices to exchange information with each other and with patient data repositories such as electronic health records (EHRs). In the context of device and EHR interoperability, it refers to information sharing from one device to another or between devices and EHRs.

To have a truly “semantically” interoperable healthcare system, the receiving system must be able to use the information it receives. Both systems must speak the same language. Functional interoperability would enable clinical medical devices to communicate in a consistent, predictable, and reliable way. It allows for the exchange of, and interaction with, data from other medical devices and with patient data sources and repositories, such as EHRs, in order to enhance device and system functionality. Data can also be shared across hospitals, health systems, and providers, following the patient across settings of care. Interoperability also creates a plug-and-play connectivity and automatic discovery between different medical systems that reduces errors and saves time spent on configurations, again, to the benefit of the patient.

Why is interoperability needed?

Today, our nation's healthcare system is piece wise excellent, but chaotic and dysfunctional in the aggregate. Clinicians are often left to rely on stale and incomplete information. Many innovative, life-saving device technologies cannot share vital data about their function or the patients they are treating. Information, the lifeblood of healthcare, is often fragmented and siloed, effectively blocked in its flow to the very sites where it is most needed: to patients and the clinicians who are treating them.

If healthcare could bring to bear the power of truly interoperable systems, imagine what may be possible. Interoperability is a key element in enabling connected and coordinated healthcare across the community: the right care, at the right time, in the right place. We could see smarter systems, fewer errors, and fewer injuries. We could unleash the full potential of our clinicians and our many different healthcare technologies in a coordinated and connected healthcare delivery system that puts patient needs first. In addition to improved outcomes, interoperability could reduce waste and improve efficiencies in healthcare. A recent analysis identified \$30-\$40 billion in annual savings that could be attained by implementing standards-based technology that achieves interoperability between systems.²

Take all of these extraordinary tools and bring them together so they can speak to each other, and who knows what extraordinary changes that will bring about.

—Malcolm Gladwell, Author and Keynote Speaker at HCI-DC 2014

Breakdown of Estimated Benefits from Medical Device Interoperability



Source: The Value of Medical Device Interoperability: Improving Patient Care With More Than \$30 Billion in Annual Health Care Savings.

Without interoperability based on standards, our healthcare workers are being stretched to their human limits. Today, about 35%³ of a nurse's shift time is spent on documentation. With interoperability, much of that time could be returned to providing care. Let's use technology to support caregivers, not burden them. When you consider that hospitals spend two-thirds of their budgets on labor costs⁴ and only 6% of their budgets on devices⁵, it becomes clear that interoperability could significantly reduce those labor costs.

Without standards-based interoperability, hospitals and healthcare systems are forced to spend significant time and effort creating and configuring custom interfaces, sometimes device by device. We need to significantly cut the cost and time of connecting these systems.

Patients are demanding the information and the ability to play an active role in their own care. They can't afford to wait one or two or three years while stakeholders debate this issue. They need better care now. We cannot wait for a perfect system, or ever eliminate all risk. We are all patients, and we all deserve better care. We must accelerate this process now for the benefit of everyone in the nation.

What gap does interoperability fill?

Healthcare has been the slowest industry to adopt the intelligent methods that we have in most other parts of our lives. In the plug-and-play world of consumer electronics, demand for simple and seamless functionality has driven convergence on a few common standardized interfaces and platforms. Today, from almost anywhere in the world, you can securely access your financial accounts, check your email, and more.

Such a revolution has not yet occurred in healthcare. The purchasers of medical devices and health IT systems—our nation's hospitals and health systems—do not have a consistent means for achieving interoperability. As a result, many vendors use distinct proprietary and closed communication methods, even among their own devices or systems. Much of healthcare data is trapped in machines that cannot or will not communicate. Hospitals, health systems, and physician practices have made significant investments in IT systems and often feel trapped by their choices, which too often do not support the free flow of data that will help to better manage patient care.

Even where data is being shared electronically, much of this data is “lazy” or unstructured. Today, a printer and a scanner too often represent the state of the art for record sharing among much of the healthcare community. While sharing a PDF electronically is certainly better than sharing no data at all, this data is of limited use

“Give me the ability to make the decisions that I need to make to manage my disease 24/7. We need interoperability now. We can't afford to wait.”

—Anna McCollister-Slipp, Type 1 Diabetes Patient

¹ IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries. New York, NY. 1990.

² West Health Institute. The Value of Medical Device Interoperability: Improving Patient Care With More Than \$30 Billion in Annual Health Care Savings. West Health Institute, La Jolla, CA. March 2013. Available from: www.westhealth.org/institute/interoperability/abstract-value-of-medical-device-interoperability.

³ Hendrich A, Chow MP, Skierczynski BA, Lu Z. A 36-hospital time and motion study: how do medical-surgical nurses spend their time? *Perm J*. 2008 Summer;12(3):25-34.

⁴ American Hospital Association. *The Costs of Caring: Sources of Growth in Spending for Hospital Care, June 2012 Update*. Available at www.aha.org/research/policy/2012.shtml.

⁵ King, R and Donahoe, G. *Estimates of Medical Device Spending in the United States*. Figure 2, page 3. July, 2012. Available at <http://advamed.org/res.download/291>.

and prevents harnessing the full power of today's analytical tools to solve healthcare's problems. This part-paper, part-electronic world is dangerous. We must demand the same benefits of interoperability in healthcare that have already accrued to banking, commerce, telecommunication, entertainment, and most other parts of our world. The time to act is now.

Why don't we already have interoperability?

The lack of industry-wide commitment to use open standards-based communication strategies has contributed to the lack of interoperability.

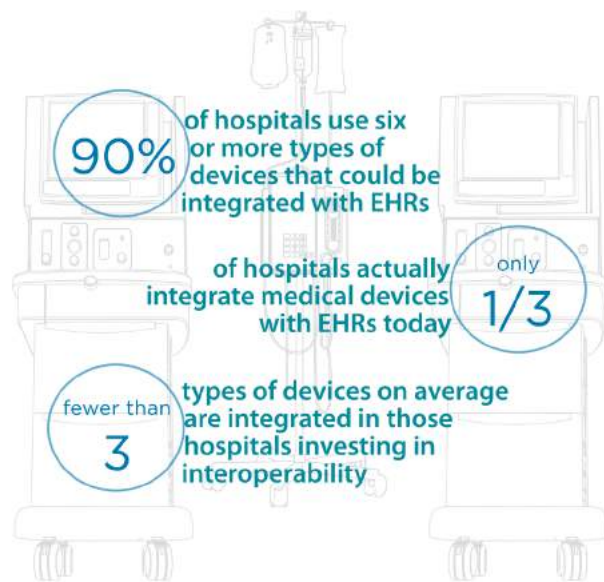
The lack of interoperability is a problem of our own creation. It is not at all like the lack of effective therapies for specific diseases where researchers and clinicians are tirelessly exploring the details of specific causes. The lack of industry-wide commitment to use open standards-based communication strategies has contributed to the lack of interoperability.

Interoperability standards do exist, and some are even being recognized by regulatory bodies such as the U.S. Food and Drug Administration (FDA), but many are loosely specific, with a number of options for configuration, meaning that even devices using similar standards may not be able to communicate without further customization. Development of standardized nomenclature for medical data—an enormously complicated task when undertaken after the deployment of multiple dissimilar systems—is also still underway. It is expected that the FDA will soon provide guidance for manufacturers on medical device interoperability, an essential milestone along the path.

Today, even in the absence of unambiguous and open standards-based interoperability, it is possible to cobble together interfaces that allow data to be imported from medical devices into enterprise EHRs. Yet, only a third of hospitals that could be integrating medical devices with their EHRs actually do so. Those that are investing in this limited form of interoperability typically integrate only a fraction of the devices that could be integrated.⁶

Why? One reason is because of the high cost and complexity of this post hoc medical device integration, which has been estimated at as much as \$6,500 to \$10,000 per bed in one-time costs, plus annual maintenance fees.⁷ These investments are a substantial undertaking for hospital systems. Furthermore, many providers continue to work without even this limited form of interoperability because they are unaware of the cost savings and safety improvements that could result.

Currently, providers who are integrating systems bear the costs and do not work with medical device companies to follow specific standards. In the absence of this demand, medical device and health IT companies have lacked the incentives to use open interfaces to establish seamless functional interoperability. It is time for the purchasers of these systems to require their vendors use a consistent means for achieving interoperability.



Source: *The Value of Medical Device Interoperability: Improving Patient Care With More Than \$30 Billion in Annual Health Care Savings.*

⁶ West Health Institute. *The Value of Medical Device Interoperability: Improving Patient Care With More Than \$30 Billion in Annual Health Care Savings.* West Health Institute, La Jolla, CA. March 2013. Available from: www.westhealth.org/institute/interoperability/abstract-value-of-medical-device-interoperability.

⁷ Moorman B. True costs of device connectivity. Presented at: Meeting of the Association for the Advancement of Medical Instrumentation, June 2010.

A Call to Action

Without interoperability, our healthcare system is limping when it should be speeding along the information superhighway. Let's work together to remove the barriers and achieve the promise of interoperability. The following are key actions essential to igniting an interoperable healthcare system:

Action #1: Recognize that the lack of interoperability is a crisis and advocate for rapid change.

Achieving interoperability has evaded us for too long. The public and private sectors must collaborate now to solve this problem. No one stakeholder owns this issue; all must be engaged. All must be educated on the importance of achieving interoperability in order to solve the crisis in safety, efficiency, and healthcare costs. We must create a national imperative, an understanding that the lack of interoperability is a crisis.

HOSPITALS, HEALTH SYSTEMS, AND CLINICIANS

- › Insist upon open standards-based interoperability for new purchases. Don't buy systems that don't connect.
- › Be intolerant of proprietary systems and, where possible, discontinue investment in one-off interfaces.
- › Use interoperability to support a multivendor environment, with its inherent advantages of interchangeable functional elements and lower barriers to entry for innovative market entrants.
- › Commit and invest to make patient data interoperable across systems so that patients have real freedom to seek care rather than being captured in a network due to lack of interoperability.

PATIENTS

- › Don't be afraid to ask questions and advocate for the safety, quality and convenience of the healthcare you receive.

REGULATORY AGENCIES

- › Declare EHR and medical device interoperability to be an imperative; incentivize it where possible.

HEALTHCARE TECHNOLOGY VENDORS

- › Commit to developing, testing and providing products that meet customer and patient needs with respect to interoperable healthcare information.

STANDARDS DEVELOPMENT ORGANIZATIONS

- › Quickly identify gaps and convene stakeholders to create standards to support interoperable systems.
- › Accelerate efforts to improve technology and data standards to support interoperable systems.

INVESTOR COMMUNITY

- › Invest your resources in companies that are making interoperable solutions and following the patient-driven roadmap.

PAYORS

- › Help make interoperability an imperative by focusing on outcomes-based payment models that promote quality care and patient safety.



Action #2: Frame the interoperability problem correctly: Everyone is in the business of gathering and sharing data to best serve patients.

Amazing tools are at work in today's hospitals and healthcare systems, generating an unprecedented amount of data that could be applied to improve healthcare across populations. What's missing? These tools are largely disconnected; they cannot share information. We must demand a reliable way of sharing common sets of data across devices, across health systems, across continents.

HOSPITALS, HEALTH SYSTEMS, AND CLINICIANS

- › Set a predictable technology roadmap for your vendors, highlighting the central role of data sharing and functional interoperability.
- › Require that vendors share information to assure effective execution of interoperability standards and sharing of data.

PATIENTS

- › Work with your providers to get access to and understand your health information.

REGULATORY AGENCIES

- › Encourage development of plug-and-play systems to support gathering and sharing of data.

HEALTHCARE TECHNOLOGY VENDORS

- › Embrace the open sharing of data and the roadmap to interoperability that your customers request.

We must demand a reliable way of sharing common sets of data across devices, across health systems, across continents.

Action #3: Accelerate the full adoption of unambiguous, open standards for interoperability.

Interoperability standards do exist today, but may be insufficiently specific, or incomplete, providing an impediment to widespread adoption. We must tie together the remaining fragmented, disparate efforts, and accelerate them to completion. Commonly adopted standards will support the move toward greater interoperability and reduce the costs. We must move to open source solutions rather than proprietary solutions.

HOSPITALS, HEALTH SYSTEMS, AND CLINICIANS

- › Participate in standardization efforts to ensure your needs are being met.

REGULATORY AGENCIES

- › Support development of technology and data interoperability standards, working with other stakeholders.
- › Recognize existing interoperability standards, call out where specific gaps exist, and support development of related test beds.
- › Recognize certification/validation tools to support the use of health IT.

HEALTHCARE TECHNOLOGY VENDORS

- › Participate in technology and data standardization efforts and test beds with a sense of urgency commensurate with the opportunity to improve care, prevent errors, and save lives.
- › Support and help fund standards development organizations (SDOs) to drive toward open, standards-based interoperability.
- › Rely on open platform solutions, not pairwise agreements, to achieve interoperability.

STANDARDS DEVELOPMENT ORGANIZATIONS

- › Develop unambiguous and testable standards that can support interoperable solutions.
- › Keep standards and technical approaches modern so we do not lock in old technology and impair innovation and advancement.
- › Provide a migration path to these new technical approaches.

RESEARCHERS AND DEVELOPERS

- › Support efforts to standardize clinical data elements.

The West Health Institute and the Gary and Mary West Foundation recently helped establish the independent Center for Medical Interoperability to address the many challenges associated with the lack of interoperability.

New Center for Medical Interoperability Invites Hospitals, Health Systems to Join Interoperability Efforts

The West Health Institute and the Gary and Mary West Foundation recently helped establish the independent Center for Medical Interoperability to address the many challenges associated with the lack of interoperability. The Center will be member-led by hospitals and health systems. Its goals are to:

- › Benefit the public by improving patient safety, assuring security and confidentiality of health information
- › Enhance access to care, care efficiency and affordability for the general public through the establishment of a centralized laboratory
- › Serve as a neutral environment for health system stakeholders to identify technical solutions to the challenges associated with medical interoperability
- › Engage technical experts to develop common standards-based architecture, specifications, and reference designs
- › Work toward protocols for testing and certifying that member-specified requirements are fulfilled, and
- › Facilitate education concerning solutions and best practices related to medical interoperability.

All hospitals and health systems are invited to join in this effort. Learn more at medicalinteroperability.org or email info@medicalinteroperability.org.



Michael M. E. Johns, MD, former chancellor of Emory University, is the founding chairman of the board of the Center for Medical Interoperability. Prior to his role as chancellor, Dr. Johns served as the executive vice president for Health Affairs and chief executive officer of the Robert W. Woodruff Health Sciences Center of Emory University.



Healthcare workers are often forced to pay more attention to technology than to treating patients. Interoperability initiatives should aim to reduce complexity at every opportunity.

Action #4: Align stakeholder incentives to drive interoperability.

To date, there has been a lack of industry-wide commitment to use open standards-based communications strategies to achieve interoperability. Providers, payers, EHR developers and vendors, medical device manufacturers and the government must collaborate to promote the development and adoption of seamlessly interoperable devices. We must create market demand, remove disincentives, and align regulatory efforts. We must engage hospitals, healthcare systems, and top executives to drive the interoperability imperative.

HOSPITALS, HEALTH SYSTEMS, AND CLINICIANS

- › Engage top executives, clinician leaders, and nurse champions in interoperability efforts.

REGULATORY AGENCIES

- › Provide proper governance and structure for an interoperable healthcare system.
- › Provide guidance to vendors regarding software upgrades that advance interoperability and minimize the regulatory burden.
- › Work to align incentives for interoperability; be mindful of the impacts of regulation and work to avoid the inadvertent creation of economic disincentives for interoperability.
- › Improve regulatory clarity.

HEALTHCARE TECHNOLOGY VENDORS

- › Transition from proprietary systems to ones that enable/support open standards-based interoperability.
- › Embrace interoperability as a market strategy to attract customers.

STANDARDS DEVELOPMENT ORGANIZATIONS

- › Involve all stakeholders in standards development efforts with a sense of urgency commensurate with the opportunity to improve care; prevent errors; and save lives, time, and money in our healthcare system.

Action #5: Ensure validity, privacy, and security of data.

Data must be validated to ensure its accuracy. It must be kept private and secure for the protection of patients.

HOSPITALS, HEALTH SYSTEMS, AND CLINICIANS

- › Use a systems engineering approach to ensure safety, privacy, and security in your health IT systems.

REGULATORY AGENCIES

- › Ensure an open dialogue regarding the benefits and risks of connected systems and encourage the development of solutions to address the unintended risks.
- › Help to ensure that health information remains private and secure.

RESEARCHERS & DEVELOPERS

- › Develop and use better methods to audit and validate data as well as to help ensure privacy and security of data.

STANDARDS DEVELOPMENT ORGANIZATIONS

- › Consider validity, privacy, and security of data in standards efforts and support development of test beds to support these efforts.

Providers, payers, EHR developers and vendors, medical device manufacturers and the government must collaborate to promote the development and adoption of seamlessly interoperable devices.

Action #6: Reduce technical complexity for hospitals, health systems, and healthcare workers.

Hospitals and health systems attempting device integration today are struggling under the weight of too much complexity, too much expense, too much time and too many barriers. Healthcare workers are often forced to pay more attention to technology than to treating patients. Interoperability initiatives should aim to reduce complexity at every opportunity.

HOSPITALS, HEALTH SYSTEMS, AND CLINICIANS

- › Be persistently intolerant of technologies that increase the burden or complicate the workflow of caregivers.
- › Adopt systems engineering and human factors engineering approaches, consider workflow, and test implementations to ensure usability.

REGULATORY AGENCIES

- › Provide incentives for reduced complexity in technology implementations.

HEALTHCARE TECHNOLOGY VENDORS

- › Integrate interoperability as a benefit to the ecosystem, including customers.
- › Consider data applications and interoperability as an integral part of the original design process of a medical device.

RESEARCHERS & DEVELOPERS

- › Develop new analytical tools and platforms to provide unique visualizations of health data for decision making.
- › Develop effective, thoughtfully designed user interfaces.

STANDARDS DEVELOPMENT ORGANIZATIONS

- › Drive to simpler, easier to implement, easier to use, more modular standards.
- › Create standards to support the linking and access/viewing of information in a consistent way.

Action #7: Develop new ways to use data streams that will result from interoperability to drive an adaptive system that will improve patient health.

Our advanced healthcare technologies are creating new data streams at an unprecedented rate. We must convert that raw data into usable information. Advanced analytical tools will be needed to successfully tap into the potential of those new data streams to improve healthcare.

HOSPITALS, HEALTH SYSTEMS, AND CLINICIANS

- › Support efforts to use these interoperable systems to manage better care for patients.
- › Teach patients how best to understand and use their own healthcare information, and build within them and their families an expectation of having and using such information for their collective benefit.

REGULATORY AGENCIES

- › Encourage that information flows to the patients, caregivers, and researchers to support their care in a timely manner.

RESEARCHERS & DEVELOPERS

- › Develop new data tools to process continually flowing data, which has perishable attributes and new processes to speed up big data computations.
- › Expand opportunities to mine health data to answer health questions.
- › Rethink practical uses of data to achieve continuous improvement of the healthcare delivery process.
- › Rethink practical uses of data to achieve the health and wellness of patient populations.
- › Convert “lazy,” “dark” or siloed data to structured, useful data.
- › Support training and hiring of more data scientists to support analysis efforts.



“What does it take at this point to look at the number of patients in harm’s way and start to make those rather substantial, courageous movements to drive this notion of interoperability?”

—Joseph Smith, MD, PhD, FACC, Chief Science and Medical Officer, West Health Institute

Action #8: Guarantee secure access to data for patients, researchers

Patients have a right to access their healthcare data. Healthcare workers and researchers who can use that data to improve and innovate better treatments must also have access to the data with safeguards for privacy.

HOSPITALS, HEALTH SYSTEMS, AND CLINICIANS

- › Make data securely available to patients and to researchers for outcomes research.

PATIENTS

- › Access to healthcare data is a patient’s right. Demand that your information be shared seamlessly so that you get the best care. Switch providers if you don’t receive access to your data.
- › Demand that healthcare providers and insurance carriers give you secure access to information in electronic format.
- › Agree to share your properly de-identified healthcare data to support research toward better care.

REGULATORY AGENCIES

- › Ensure that patients have the ability to securely view, download, and send the information to recipients of their choosing.

HEALTHCARE TECHNOLOGY VENDORS

- › Make data available to patients and researchers in a standardized, secure, low-cost data format.

RESEARCHERS AND DEVELOPERS

- › Develop processes to bring analysis to de-identified data to improve treatment.

Stories from the Point of Care

Why interoperability? Because patients are waiting, and so are frontline healthcare workers. Nearly every speaker at the day-long HCI-DC 2014 had a personal story to share about the difference interoperability would have made to them, their loved ones, or their patients.

Is This Interoperability?

This is an actual photo of the intensive care unit room of a West Health employee’s father. It’s hard to imagine that this is the standard of care for patients in our country. There are more than 10 devices in this room and they are not seamlessly sharing information. Does this look like smart healthcare?

—Nick Valeriani, Chief Executive, West Health



Technology is Keeping Us from our Patients

When I started out as a young physician, I recognized that I wasn’t capable of being the physician that I thought I was going to be. I knew the importance of giving patients our full attention and worked to train myself to listen to them fully.

Yet, in that disorganized, disruptive, analog world of paper records, paper results, paper things to keep track of, I found that I wasn’t capable of doing my job, of staying on top of all the knowledge that I needed to acquire because—“Where’s that chart?” And “Where’s that lab test we did last week?” And “I don’t remember what cardiologist I saw seven years ago, do you?” No.



And it frustrated me. I realized this isn’t the healthcare that I signed up for, and it was the beginning of my path toward getting really involved in health IT.

—Jacob Reider, MD, Chief Medical Officer, ONC

My Devices Won't Work Together

Interoperability of medical devices is something I deal with on a daily, hourly, sometimes minute-by-minute basis. I have Type I diabetes, which is complex and difficult to control. I use four prescription medical devices 24/7, two of which are attached to my body: an insulin pump and a continuous glucose monitor. These are amazing machines with incredible technology, and the care of diabetes has improved dramatically because of them.

However, one of the most important things for me in terms of managing my disease is understanding patterns. Because all of my medical devices use different data formats and different data standards, they don't communicate, so the data cannot be combined for analysis. Even though it's electronic, even though it's all downloadable in one form or another, it's all in different platforms, computing systems, and it doesn't

work together. I'm sure well-intentioned CIOs, policy circles in DC, and medical device developers are saying, "We'll get there next year, or in three years." Three years is a really long time in the life of a patient to wait.

—Anna McCollister-Slipp, Co-Founder, Galileo Analytics



Lack of Information Hinders Decision Making

As an emergency room (ER) physician, problems with lack of interoperability affect me on a daily basis. An ER is a fast-turnaround area, where a large number of patients must be evaluated and moved to the right place as quickly as possible. Waiting for information is difficult. Without interoperability, we frequently have to make decisions without all of the needed information. We may need to get information from a private practice office that is not connected to our health system—I really have no way of getting their information except to make a phone call. I may need to access a database in Richmond that tracks narcotic prescriptions, but there's a problem with my password, and I can't access it. And even within our large integrated system, I still don't have access to everything I need. We are moving forward, but we are not moving forward at a pace that I would like to see as a physician.

—Neal Chawla, MD, emergency medicine practitioner who is also the Chief Medical Information Officer for the Inova Health System in Fairfax, VA.



Struggling to Access Data for a Second Opinion

My mom received a diagnosis, wanted a second opinion, and needed to get information from her specialist to make decisions about what to do next. The information was not flowing. So my parents decided to take matters in their own hands. They contacted the lab and were able to get an electronic copy of the results downloaded. The lab, unfortunately, used unsecure e-mail, but nevertheless, my mom received the information and was able to share it with the specialist. She was able to keep her appointment,

and avoid unnecessary lab tests and a delay in needed surgery.

—Jodi Daniel, JD, MPH, Director, Office of Policy and Planning, ONC



A CALL TO ACTION What Patients Can Do

- › Don't be afraid to ask questions and advocate for the safety, quality, and convenience of your healthcare.
- › Work with your providers to get access to and understand your health information.
- › Access to healthcare data is a patient's right. Demand that your information be shared seamlessly.
- › Demand that healthcare providers and insurance carriers give you access to information in electronic format.
- › Agree to share your properly de-identified healthcare data to support research toward better care.

Hurricane Katrina Cuts Off Patients, Providers

Before joining ONC, I served as the New Orleans Health Commissioner and the Senior Health Policy Advisor to New Orleans Mayor Mitchell Landrieu. In 2005, Hurricane Katrina visited New Orleans and wrought some horrific disaster. In St. Bernard Parish, just southeast of New Orleans, every single structure in the community was flooded and the entire community displaced, some permanently. Doctors took to spray painting their phone numbers on the outside of their office practice as a means of reaching their patients; very few doctors' offices had web-enabled electronic health records. It was the largest displacement of health professionals in U.S. history. There



Photo courtesy of Karen DeSalvo

to use interoperability, and to use technology such as telehealth to connect patients with their caregivers.

—Karen DeSalvo, MD, MPH, MSc, National Coordinator for Health Information Technology, ONC

107 Days in NICU Highlight Struggles with Technology

My son Ward was born 15 weeks early and spent his first 107 days in the hospital. He was our first child. As a parent, when you go into a hospital room and see all of the devices surrounding your baby, you're just scared to death. The nurses keep you informed about what's going on. You can see them working day in and day out, breaking their backs to care for your baby. Alarms are going off and they're going crazy managing the equipment and charting everything. Many of the nurses stay over after their shift just to write down all of the numbers. They have to keep track of all this data and manually enter it into the computers. It wears on them, and they can't do what they need to do to the best of their abilities. In that environment, anything that can be done to make the nurses' lives easier is worth it. It should be easier for nurses to spend more time with your child and less time worrying about writing stuff down.

—Benjamin Miller, photographer, father of Ward Miller



Photos by Benjamin Scot Miller

upstairs, we wanted to facilitate bonding, so we got the baby out to let the parents hold him, which is critical. But, because of all of the equipment, it's nearly impossible to get those babies out.

We are a referral hospital and many of the babies come from delivery hospitals. Problems with information flow can interfere with treatment, especially because some of the care we provide to the babies is very time-specific. Without interoperable records, you are relying on word-of-mouth from their

physician, through our transport chain. In that whole time-sensitive process, it's a horrible game of telephone.

Without interoperability, technology gets in the way of giving direct patient care. From a nursing standpoint, interoperability would give us more time to directly take care of the patients and to facilitate bonding between the parents and their babies. We could spend less time charting data; maybe there would be less machinery to manage; and maybe there would be fewer treatment delays for these very fragile babies.

—Sarah McGregor, RN, Ward's neonatal nurse, Nationwide Children's Hospital

Caring for Technology Rather than Patients

I admitted Ben's son to the neonatal intensive care unit the day he was born. It was a whirlwind of a day. He came over from one of our referral hospitals and we had to take him down for a procedure. As we were heading down, in my head, I was thinking, "I haven't done my admission labs, I haven't charted." When we got back

The Business Imperative for Interoperability

Only a third of hospitals are working today to integrate medical devices with EHRs, according to a report by HIMSS Analytics¹², and even those hospitals are typically integrating fewer than three types of devices on average. One reason for limited interoperability is the high cost and complexity of medical device integration. In this conversation, health system executives discussed the path to interoperability.

What challenges are your health systems facing due to the current lack of interoperability between medical devices and electronic health records?

JONES: All hospitals are on a journey to transform ourselves. We have great changes started, like bar code medicine administration, lab specimen collection, and automated blood pressure monitoring. If we had better interoperability, they would all talk to the EHR. These real-life examples increase the cost of healthcare and slow down the speed of transformation.

SCHATZLEIN: One of our tenets is enriching the lives of caregivers. The lack of interoperability is sapping those caregivers—not only the efficiency, but also the energy and the enthusiasm of nurses and doctors. That may be an unappreciated cost of the complexity we've developed.

TOBIN: If you could drop the cost of interoperability by a few orders of magnitude, so many new things would

be possible. If no vendor had the ability to prevent you from tying things together in the right way, we could accomplish great things.

What is driving your passion about interoperability?

JONES: It is huge on our priority list. We know that current costs are unsustainable. The cost and time required to build interfaces, of adding interoperability one device at a time, is huge. If we had plug-and-play on everything, it would be easier and faster. That time and cost is preventing this transformation.

SCHATZLEIN: Americans would be surprised, if not appalled, if they knew the degree to which treatment took place every day in this country in the absence of all of the relevant information necessary to care for a patient. We are living in a particularly dangerous world right now because we're part paper, part electronic. There's a real urgency on my part to get data into the computer and get

¹² HIMSS Analytics. Medical devices landscape: current and future adoption, integration with EMRs, and connectivity [Internet]. Chicago: HIMSS Analytics; 2010 [cited 2012 Oct 25]. Available from: www.himssanalytics.org/docs/medicaldevices_landscape.pdf.



MODERATOR:
Glenn Tobin, PhD,
Chief Executive Officer,
Crimson, The Advisory
Board Company



Michael Schatzlein, MD,
Tennessee/Indiana
Ministry Market Leaders,
Ascension Health;
Chief Executive Officer,
Saint Thomas Health



Michael Johns, MD,
Chairman, Center for
Medical Interoperability



Stephen Jones, FACHE,
Chief Executive Officer,
Robert Wood Johnson
University Hospital

it right. But, it has to be done in a way that doesn't sap caregiver energy.

JONES: The patients need ways to connect to us. We want them to understand the information we share with them. We want the information that comes back from them to populate our systems and to be used to help us manage the population.

JOHNS: Usable information must flow back and forth accurately and seamlessly so we can manage the population. With the penalties for readmissions, we must be able to manage patients at a distance more efficiently and effectively, keeping them out of the hospitals.

How do you see leveraging your purchasing power to try to get the type of outcomes that you want here?

JONES: We have market power. Our vendors know who we are and they are responsive to us. If we together—hospitals, vendors, regulators—develop interoperability standards, we'll demand them when we write the specifications for buying new medical equipment.

JOHNS: The Center for Medical Interoperability is based on the idea of bringing the hospitals together to establish the architecture they need to provide the right kind of patient data flow. It has to be a collaborative effort.

What steps are you taking to ensure that your purchases can accomplish the type of objectives that we're talking about?

SCHATZLEIN: Our purchasing group is looking at the IT space. If we have true interoperability, we can use any vendors; we could put standards in our RFPs rather than standardizing on a particular vendor. The interface option has increased complexity. Interfaces are not the answer.

TOBIN: Interoperability will allow you to support a multivendor environment and bring more innovation to your system. We can move from a single system that's supporting everything to a much more distributed approach where items from various vendors can work together.

JONES: Interfaces are a work-around. We know that the way to take waste out of the system is not to develop cooler work-arounds. We need to eliminate that waste. We need open architecture and interoperability. There's great innovation going on in the vendor side and in the hospital side, but time and cost is huge for us. There are ten things out in the community that could be done through mobile health services that could speed care, but we don't have enough innovation and we're not reducing costs fast enough to do all of those things.

What policy items should be pushed higher on the agenda to help us accomplish some of the objectives in interoperability?

JONES: It is great that ONC has promoted the expansion of health IT. Now, we have an opportunity to take that to another level, working with the FDA and other regulators to set the standards.

JOHNS: We need to accelerate this process for the benefit of the people of this nation. It's not a simple solution, where we can snap our fingers and it will all be fixed. But we have to address it and move it forward. Otherwise, we're letting down the next generation behind us.

Who owns the data that's generated from your healthcare system?

SCHATZLEIN: The patient does.

JOHNS: I agree, the patient does. I can take my bank card all over the world and I can look up my information. On my iPhone, I can see all of my banking results. They convert the currency to the currency I understand. Why can't that happen with patient data?

How urgently should the relevant people who know how to solve these problems be going after them?

JONES: It is urgent. We need interoperability to allow us to transform healthcare. The public is demanding it, government is demanding it. We need to move healthcare into the community. We've got the right players involved in coming up with the solution. It's a huge issue. It's billions of dollars that we can't afford to waste, especially when we're not improving value for the patients.

JOHNS: I would simply say, our patients are waiting. They are waiting.

A CALL TO ACTION What Hospitals and Health Systems Can Do

- › Insist upon open standards-based interoperability for new purchases. Don't buy systems that don't connect.
- › Set a predictable technology roadmap for your vendors, highlighting the central role of data sharing and functional interoperability.
- › Participate in standardization efforts to ensure your need are being met.
- › Use a systems engineering approach to ensure safety, privacy, and security in your health IT systems.
- › Make data securely available to patients and to researchers for outcomes research.

We are going to put out draft guidance in the coming year on how we think about interoperability and recommendations for how device developers should think about it.

—Jeffrey E. Shuren, MD, JD, Director, Center for Devices and Radiological Health, Food and Drug Administration

FDA Efforts Toward Interoperability



Jeffrey Shuren, MD, JD, Director, Center for Devices and Radiological Health, Food and Drug Administration

The FDA does not see a need for additional regulatory requirements in interoperability. We think a number of other things are important: Standards, technology, and test beds.

Interoperability is important for innovation. It truly gives us the opportunity to share and aggregate data between technologies and also to pull from them, to support the move to big data and improving healthcare. It can help enhance existing functionality, and it can help create new functionality.

Interoperability is also important to the ability to provide care in different settings.

First, standards are a critical underpinning. Consensus standards are important because developers need to understand what they might need to communicate with other technologies. Standards give us the opportunity to have connections that we didn't even imagine beforehand. Second, technology is key. One solution beyond just the standards is the ability to have nonproprietary plug-and-play backbone systems, which allow you to put things in and put things out. Third, we need test beds. Can I kick the tires, can I truly connect with other technologies and test them to ensure there is conformance with standards? We at the FDA would be interested in seeing that happen.

FDA's role is to provide the regulatory environment to promote interoperability. The value of consensus standards is that we can say: If you conform with these standards, we're viewing you as having met the regulatory requirements. We are not telling you that you must conform, but if you do and we have adequate assurances, that's good enough for us. We would say that if a test bed—an independent third party—certifies you, that is good enough for us. We're looking to provide the incentives to move toward that approach.

Last year, we adopted 21 standards for interoperability. We are reviewing more this year. We are working with the community to develop the standards. That involvement allows us to use those standards for purposes of meeting regulatory requirements.

We are going to put out draft guidance in the coming year on how we think about interoperability and recommendations for how device developers should think about it. We are looking at increasing cybersecurity—not with the big hammer of regulation, but by working with the community for the smart ways to mitigate risk.

Another item will come out from FDA this year: We are clarifying that, if patients want to see their data, manufacturers can provide that data. FDA is not standing in the way of patients receiving data. Patients do have the right to their own information and they should receive it.

A CALL TO ACTION What Regulatory Agencies Can Do

- › Declare EHR and medical device interoperability to be an imperative; incentivize it where possible.
- › Encourage development of nonproprietary plug-and-play backbone systems to support gathering and sharing of data.
- › Support development of technology and data interoperability standards, along with certification/validation tools, and build them into the approval/claims process.
- › Help to ensure that health information remains private and secure, and flows to patients and researchers.
- › Provide incentives for reduced complexity in technology implementations.

ONC Efforts Toward Interoperability



Doug Fridsma, MD, PhD, Chief Science Officer and Director, ONC

ONC is looking to align all of the incentives across the systems for consumers, providers, vendors, and regulators. We are going to use horizontal integration, focusing on ways we represent meaning, extend

information, and move information around. We want to serve as the coordinator or facilitator to get consensus standards in place. We are engaged with the standards development organizations; organizations that are not driven by the vendor community but by the users—the CIOs, the CMIOs, the consumers—are an important addition to our ecosystem.

We listen to the user community to find out what problems need to be solved. Interoperability is defined by the use of information. Interoperability must be grounded in the things that you want to accomplish and the functionality that you want to see. Our role is to attack it from the middle out. What are the important pieces that can be leveraged by innovation but that provide some consistency? There are some fundamental pieces upon which we can build the infrastructure.

We are looking for a path of least regret as we go forward, because we don't know what the future is going to hold. We don't want to go down a path that will lead us to a dead end. So, we are constantly scanning for new technologies and new ways to do things. What are the fundamental building blocks we need?

In order to make a change, you have to take a risk. We've seen that the status quo is unsustainable. Can we afford to take the time to make sure we get it absolutely right? Or, should we get started, put interoperability in place, and build on it and improve it? Patients are waiting. This isn't an academic exercise.

The current state of the art for interoperability is two devices: a printer and a scanner. We've got to fix that. We can't accept that any longer as being sufficient. We have to build our systems in ways that say we recognize that a PDF is inadequate for where we want to go with this.

The current state-of-the-art for interoperability is two devices: a printer and a scanner. We've got to fix that.

—Doug Fridsma, MD, PhD, Chief Science Officer and Director, ONC

But at least it's a place to start. We have to structure and organize the building blocks such that we can start with something we know will get the ball rolling, and swap that out for something that's better and better over time.

Making Health Data Available Across the Continuum of Care



Jodi Daniel, JD, MPH, Director, Office of Policy and Planning, ONC

Although we typically think about healthcare as one patient and one provider, even the healthy among us have multiple healthcare providers and seek care in multiple healthcare settings. Healthcare is a

continuum of different experiences and different clinical settings over a period of time. The power of technology to improve outcomes and to improve care really increases when we share information across that continuum.

Now that the majority of providers and hospitals have adopted health IT and electronic health records, ONC is focusing more heavily on the exchange of information across the continuum between primary care providers and specialists, but also between providers and consumers. How can information be developed in communities to support care during times of need like disasters and epidemics?

Interoperability is the key to facilitating health information exchange. Government has a role in setting the rules of engagement for interoperability, by supporting the establishment and oversight of a common set of behaviors, policies, and standards to enable electronic exchange of health information among participants. We want to change the gridlock to one of smoothly flowing information. We don't want information stuck with one system or in one setting. We want that information to flow with the patients to support their care in a timely manner.

The power of technology to improve outcomes and to improve care really increases when we share information across that continuum.



Malcolm Gladwell Tells Three Tales of Interoperability

We can consider the notion of interoperability using three crucial lessons. The first has to do with culture; the second has to do with framing; the third has to do with consequences.

The greatest transformation brought about by technology is when you connect these various pieces and have them work together in combination. It is the synergies between these tools that bring about the greatest changes.

Culture: The Bekaa Valley Turkey Shoot

The Bekaa Valley Turkey Shoot in 1982 is one of the most lopsided victories in the history of modern warfare. It started because the Israelis were increasingly concerned about Syria's movement of several surface-to-air missiles near its borders. In June of that year, the Israeli air force attacked. By the time the fighting ended a week later, all of the Syrian missile batteries and 87 Syrian planes were destroyed, compared to one Israeli helicopter downed as a result of a routine accident.

The keys to the Israeli success were three new digital technologies: drones, an Airborne Warning and Controls System (AWACS) plane, and precision-guided missiles that hit their target 95% of the time. The combination of these three technologies gave them device interoperability. Using the latest tools of the digital age in combination, letting them talk to each other and coordinating them in real time resulted in a quantum level increase in the effectiveness of the Israeli fighting force.

The Soviet military developed the concept for this military approach, but they did not have the technology. The technologies used were all developed in America, but the American armed services never put the technologies together. So why was the Israeli army the first to put device interoperability into action in a battle?

The Israelis did not have the research of the Soviets or the resources, wealth, and technological know-how of the Americans. What they had is something that ended up being far more important: They had a sense of urgency. They had a problem that needed an immediate solution. That attitude turned out to be far more useful to them than having the brainpower of the Soviets or the resources of the United States.

There's an important lesson here for the revolution in healthcare. You don't want to be the Soviet Union; the time for deep thinking about this is over. Nor do you need to be the U.S. military—the technologies are already there. What you need to be is Israel. What you need to do is what they did, which is to act. Nothing happens unless all of you, and the general world of which you are a part, is convinced that we have a crisis.



Framing: Shipping Containers

Malcom McLean, born in 1913 in North Carolina, started a trucking company during the Great Depression. He was frustrated at having to spend two days waiting for his truckload of cotton from the South to be unloaded. As he discovered, during the middle part of the 20th century the docks in America and around the world were the real choke point of the economy. Goods were brought in on trucks or rail cars and each piece was moved and packed individually. This process was so expensive that 50% of the cost of shipping something by sea was bound up in the cost of loading and unloading. International trade was profoundly constrained.

By the 1950s, McLean had built a sizable trucking company and decided to solve this problem that he had identified 20 years ago. He bought a small shipping tanker and tried various solutions. Finally, he came up with the idea of having a big metal box on the back of the trucks, and retrofit the tanker so he could slide the big aluminum boxes on to the ship. In 1956, one of his tankers became the first container ship ever to sail in the world. He cut the cost of loading and unloading his ship from \$5.50 a ton to \$0.15 a ton.

McLean did not invent the shipping container. Others had tried it for years and run into problems. The difference was that he built an entire system around the container, making the container one part of a completely interoperable system that he redesigned from top to bottom. He had to redesign the trailers on the trucks, develop special cranes, strengthen the most important docks in the United States, build railroad lines alongside the piers, weather a longshoreman strike, and change the management culture within the shipping industry.

McLean saw that the whole issue was about moving cargo. Because he was able to frame the problem correctly, to see the big picture, he was the only one who came up with a truly successful interoperable solution.

Nothing happens unless all of you, and the general world of which you are a part, is convinced that we have a crisis.

To create interoperability in healthcare, you have to make sure you understand what you're trying to do and what problem you're trying to solve. You have to make all of the different parties in this particular conversation realize they are no longer in the business of solving the narrow and specific task that they thought they were in the business of solving. They're actually part of something much larger. This has to be framed so that everyone is in the business of gathering and sharing data.

Consequences: MP3 Players

The digitalization of music began with the first MP3 player in 1998. By 2007, Apple had sold 100 million iPods. Digital music gives you musical interoperability. It used to be the case that music was a prisoner of the device on which it was played, and music was not easily interchanged between mechanisms. With digital music, you can take your music anywhere and play it in any form you wish.

What happened when you introduced interoperability into the music marketplace? It had far greater consequences than anyone imagined, and created an extraordinary revolution that was foreseen by no one. Everyone underestimated the impact of interoperability in the world of music.

The greatest transformation brought about by technology is when you connect these various pieces and have them work together in combination. It is the synergies between these tools that bring about the greatest changes. Take all of these extraordinary tools that we have out there and bring them together so they can speak to each other, and who knows what extraordinary changes that will bring about.



What We Can Learn from Other Industries

Its goal was not to supplant individual companies' products and services, but to support those products and services overall with interoperability and standards.

—William Check, PhD, Senior Vice President, Science and Technology Chief, National Cable and Telecommunications Association (CableLabs)



MODERATOR:
Harry Greenspun, MD, Senior Advisor for Healthcare Transformation & Technology, Deloitte Center for Health Solutions

People often ask, what does the future of healthcare look like? It looks a lot like the present day of almost any other industry. Other industries have solved these interoperability problems. Here, industry leaders from outside healthcare talk about challenges they faced, lessons learned, and ideas for innovation that could benefit our healthcare system today.

CHECK: CableLabs is the research and development consortium for the cable industry. In the 1980s, digital cable started to appear, with new equipment and new services. The cable industry knew it didn't have interoperability or industry standards, and that it needed an overall industry approach to be competitive. So the CEOs of the industry came together and founded CableLabs to develop new technology across the cable industry. Its goal was not to supplant individual companies' products and services, but to support those products and services overall with interoperability and standards.

KATZ: The financial industry also relies heavily on interoperability. One of the earliest interoperable networks was a system started in 1853 to help banks cash checks. A robust teletype network called FedWire was introduced in 1915 to allow banks to exchange financial and balance information; later, a large credit card network was formed. Banks had a sense of urgency and a sense of enlightened self-interest. Companies created the standards, companies created the processes, and eventually the networks were regulated, but the regulations largely ensured that the standards and processes that were in place were being enforced.



William Check, PhD, Senior Vice President, Science and Technology Chief, National Cable and Telecommunications Association (CableLabs)



Sid Fuchs, President and Chief Executive Officer, MacAulay-Brown Inc.



Steve Katz, Founder and Owner, Security Risk Solutions LLC

It was a matter of highly enlightened business self-interest. Banks wanted to attract the greatest number of customers. It required operating across an entire sector, not within a single corporation.

—Steve Katz, Founder and Owner, Security Risk Solutions LLC

FUCHS: In the intelligence world, there is a need to collect a vast amount of information and share it with very specific people or organizations, and to keep the bad guys from getting the information. Multiple levels of security are very important. We learned after the 9/11 terrorist attacks that many intelligence agency systems didn't work together. The 9/11 attacks created that sense of urgency and a mandate to make things work together.

When you build these large data systems, you must ask, what is broken? What was broken in the intelligence community was that these agencies could not share information. So once a national mandate was created and a sense of urgency was created, we knew what we were trying to fix.

It's not technology that keeps us from sharing information. Technology was the easy part. What is hard is the culture and the governance. People don't want to share. Until you have one source selection authority, it is very difficult to drive interoperability.

CHECK: When CableLabs was founded, the decision was made to focus and make the members of CableLabs just cable operators. It allowed a real focus on finding technological solutions for the cable industry. A decision was made to place only CEOs on its board. With CEOs on the board, they made it very clear that their organization worked through CableLabs, and their contracts with vendors required them to also use CableLabs. Very quickly, CableLabs became the industry-centric solution.

When it comes to your own industry, whether it is healthcare or the cable industry, there are certain specific standards of interoperability that you need to make it work for your own industry. CableLabs works with the engineers of the member companies and then it works with the vendors to find the right solutions for the specific problems, from the evolution of digital television to the development of technology for cable modems.

KATZ: The development of automated teller machines (ATMs) in the banking industry is an example of interoperability driven by customer demand. Banks are good at understanding that, while they are intensely competitive for customers, the sector itself has to succeed. Banking was no longer a self-contained system where a single customer goes to a particular bank. Banks knew that if they opened up their own internal branch networks, they had a greater chance of getting customers. Then, they set up corresponding relationships with other banks in other cities, again, to serve their customers. It was a matter of highly enlightened business self-interest. Banks wanted to attract the greatest number of customers. It required operating across an entire sector, not within a single corporation.

FUCHS: People have a false sense of security that the more information I own, the less I share, the more powerful I am. The truth is the opposite. Sharing and empowering others is where the real power comes from. If you realize you can use IT or data sharing as a competitive advantage, you are going to be way ahead of those who don't see it that way.

CHECK: You can't solve everything at once. You have to take it in baby steps. CableLabs focuses on different "themes" that they think are the highest priority projects. Through your R&D organization, you develop a path that brings everyone together over time, so you are all on the right path.

FUCHS: The intelligence community rallied around the need to share information. They went to their vendors and shared their requirements: Here are the system conditions; here's how it will operate. Here is what is broken: We have no way of sharing common sets of data. That's the one thing we're going to fix. How do we take this massive data we're collecting and share it? It was an open system, not a proprietary system. They went out to the market, because the market can drive innovation faster than any government organization can.

Innovation and Standards: Are They in Conflict?

A Challenge to the Vendors

Jacob Reider, MD, Chief Medical Officer & Director, ONC, issues a challenge to the vendors:

REIDER: My mother lives in Boston for the summer and in California for the winter. She sees doctors on both ends. The California system is a Cerner system, the Boston area system is moving to Epic. She wants to know, “Are you going to make it work so that my doctors can get my records in both places?”

CASSEL: Yes. There is an implementation between Cerner and Epic that’s live. We are at the standpoint of rolling out the connections and the ability to connect to more and more different endpoints. We need to look at the next step, how do we bring all of these efforts together and unify them as one ecosystem?

M^CCALLIE: The Commonwell belief is that we shouldn’t have to depend on pairwise agreements between sending and receiving systems to get interoperability. It should be built in. We share the same goal, but we may take different routes to get there. We are invested heavily at Commonwell to make sure that problem doesn’t exist. Everyone is an equal around the table; interchange flows through all of the vendors.



Dave Cassel, Senior Interoperability Engineer, Epic Systems

Meaningful use has done a great job at spurring activity on the interoperability front, getting that investment to be made. Right now we are at the point where the cables have been laid, the pipes are in the ground. Now, we can really start to see that investment paying off.

When you need to get information from one system to another, standards are absolutely essential. We do not have the development resources as a company, as a vendor community, or as a nation to negotiate interfaces every time we need to connect two systems. Standards, far from reducing innovation, free up development resources that are otherwise stuck implementing custom interfaces. They free up resources for what I call real innovation.

For EHR developers, the primary goal is not to revolutionize how to move data back and forth across a pipe. Our goal is to use that data to provide more access, more functionality, and better work flows for our users who, by the way, include patients. We are in the business of improving healthcare with data.

Regulatory requirements stem from safety, quality, and consistency goals, important public health considerations. They are not intended to promote innovation, but rather to help us meet a public policy goal. We do have to be mindful of the impacts of regulation. The danger is disincentivizing someone from going over the bar; with disincentives, you lose some of the market-driven innovation that you might otherwise have. There’s a balance somewhere, and we need to try to strike that.

The real challenge around technical standards is in the temptation to change them. Standards are required when you’re investing in infrastructure. You need some time to make it work and realize the advantages of the investment. We’re at the point now where we’ve made the investment, and we are on the cusp of being able to do more with it.

Our goal is to use that data to provide more access, more functionality, and better work flows for our users who, by the way, include patients. We are in the business of improving healthcare with data.

—Dave Cassel, Senior Interoperability Engineer, Epic Systems

Collaboration in the Vendor Community



David McCallie, Jr., MD, Senior Vice President, Medical Informatics; Director, Cerner Medical Informatics Institute

I’d like to address how vendors have responded outside of government pressure to address perceptions of market failure. There are three examples where

vendors agreed to collaborate because they wanted to see a problem fixed.

The first is **Direct**, a vendor-led reaction to the perception in the early days of the IT standards community that there’s wasn’t a good, simple, open, standards-based way to move messages securely from one provider to another. The vendors got together, agreed there was a problem, and in a matter of months crafted a new approach to using secure email to solve this problem. ONC has since adopted that approach and it’s now part of their Stage 2 requirements.

The **Commonwell Health Alliance** is a multi-vendor effort designed to manage patient identity, manage a patient locator service, and track the consent of the patient. It is an opt-in service that provides the adopter with an identifier and says, “Please use this to link my records together so that wherever I go, the data can follow me.” All of the Commonwell vendors agree to build in this connectivity so that any site they turn on has the easy option of being prewired into that network.

Third, Cerner is working to create a device bus infrastructure. We set out to build a bus-based implementation for IT standards and devices that gives bidirectional control of devices. We did it in a proprietary fashion, but we licensed it to 50 device manufacturers. Now 900 device drivers have been written to plug into the bus. The bus is decoupled from the EHR, so it can be deployed in non-Cerner sites.

In these three examples, industry either acted as a single vendor who wanted to solve a problem or, better, collaborated with other vendors to address the gaps and move forward. It’s not a rosy picture yet, but it’s far from a bleak picture.

We see the future of innovation and interoperability as the EHR becoming a platform against which innovative devices and services can be deployed.

—David McCallie, Jr., MD, Senior Vice President, Medical Informatics; Director, Cerner Medical Informatics Institute

We see the future of innovation and interoperability as the EHR becoming a platform against which innovative devices and services can be deployed. The innovation occurs around the edges.

Cerner is in the process of turning its proprietary **MPages** framework into an open framework that we will publish using existing standards, application programming interfaces (APIs), so that any person or group who wants to develop an app can do so and plug it into any EHR system that operates on open protocols. The core protocol that makes this possible is **FHIR**, or fast healthcare interoperability resources, a draft standard that is rethinking the core way we move data around the enterprise. We could get consensus to achieve a new kind of interoperability that we think will open the floodgate of innovation for people who want to build apps that plug into the EHR space. The potential is unlimited.

A CALL TO ACTION What Healthcare Technology Vendors Can Do

- › Commit to developing, testing, and providing products that meet customer and patient needs with respect to interoperable healthcare information.
- › Embrace the open sharing of data and the roadmap to interoperability that your customers request.
- › Participate in technology and data standardization efforts and test beds; support and help fund SDOs to drive toward open, standards-based interoperability.
- › Transition from proprietary systems to ones that enable/support open standards-based interoperability.
- › Make data available to patients and researchers in a standardized, secure, low-cost data format.

We are at our limits as a profession and what we can do as humans. We are ready for innovation, for technology solutions to come into our environment and help.

—Gregory Moore, MD, PhD, Chief Emerging Technology and Informatics Officer and Director of the Institute for Advanced Application, Geisinger Health System

Big Data for Better Healthcare

Aggregating Data + Adding Analytics = Better Care



John Halamka, MD, MS, Chief Information Officer of Harvard Medical School, Chief Information Officer of Beth Israel Deaconess Medical Center

In the last two years, my father died; my wife was diagnosed with breast cancer and is now in remission; and my mother broke her hip. If you look at these three experiences with healthcare, you see why the notion of aggregating data and providing a layer of analytics would markedly improve the healthcare experience.

My father had multiple sclerosis and a variety of cardiac issues. We had a great deal of data, but no one could tell me how he was doing. We need a platform to provide unique visualizations of the data that might be used by patients and families to make decisions. When my wife was diagnosed with cancer I wondered, for all Asian women age 50 with this kind of cancer, what kind of treatments did they get and what were the outcomes of those treatments, or the side effects? I was able to send our question to [i2b2](#), Informative for Integrating Biology at the Bedside, an NIH-funded National Center for Biomedical Computing. We were able to discern a combination of three drugs that would work well. It melted the tumor and she is in remission and doing fabulously. My mother's story is about the challenges of getting data to flow in a liquid way. After she broke her hip, there was no way to use certified software in a meaningful way to reconcile her medications. She wound up with a beautifully reconciled list, but it was completely inaccurate for what she needed for therapy.

In terms of practical uses of data, we are now running an accountable care organization. I'm being reimbursed for keeping patients healthy rather than for episodic sickness. We are using big data to take the experience from all places in the community, aggregate it, and identify gaps in care. We can then proactively reach out to the patient with home care or monitoring. In this new economic world, we have to completely rethink the appropriate practical uses of data to achieve continuous wellness if we're going to survive as a business.

Aggregating data and providing a layer of analytics would markedly improve the healthcare experience.

In this new economic world, we have to completely rethink the appropriate practical uses of data to achieve continuous wellness if we're going to survive as a business.

—John Halamka, MD, MS, Chief Information Officer of Harvard Medical School, Chief Information Officer of Beth Israel Deaconess Medical Center

Leveraging Big Data for Continuous Learning



Alistair Erskine, MD, Chief Clinical Informatics Officer, Geisinger Health System

I am a pediatrician and an internist, and went into IT a few years ago out of a sense that there's a better way to practice medicine. We have many new sources of data. Can we find patterns in the data? Would it

be possible to curate, analyze, and restore all this data? It would take far too long. Healthcare data carries perishable attributes that extinguish over time. Data tools are not designed to continually process this data flowing from sensors and other sources.

Several barriers stand in the way of using big data in healthcare. One is competition. Healthcare remains a cottage industry, mired in technology. Competing organizations have their own sequestered data silos that don't share information that could improve patient care. Also, big data is going to require big storage. Are leaders going to be willing to spend money on that? There will be a shortage of people who understand data science. In addition, there is still "lazy" or "dark" data, despite efforts to digitalize healthcare. The vast majority of data we record is dormant, unstructured. And, as we get our big data, security must be implemented. Data needs to be available, audited, secure, and protected. We will need new policies and procedures to address privacy concerns. Data and any correlations will need to be validated. Our monolithic EHR filing cabinets have a long way to go before adequately helping clinicians and patients sort through all that data.

Big data teaches us more about what patients really want and how they want it. Those committed to healthcare will begin to leverage big data and continuously learn from every single encounter.

The Challenges of Big Data: Putting It into Action



Gregory Moore, MD, PhD, Chief Emerging Technology and Informatics Officer and Director of the Institute for Advanced Application, Geisinger Health System

If a family practitioner was to do everything needed for all of their patients—the wellness care, the routine care, the care for illness—

we have given them 18 to 20 hours of work a day. As a practicing radiologist, in a typical day I might spend ten hours a day reading images. There are now between 600 and 1200 images per patient. If I take care of 50 patients per day, I will have to look at 40,000 images. Our nurses are also busy trying to document everything they need to do with the patients they are caring for. We are at our limits as a profession and what we can do as humans. We are ready for innovation, for technology solutions to come into our environment and help.

We must standardize how we store that data to get it out of silos and make it functional. We must take that "lazy" data and move it into action. How? Companies must work in data visualization, in helping patients and providers look at their data at a glance and get a sense of how the patient is doing. We can define populations with that data and let the computer manage patient groups by taking that data and putting it into action.

To enable big data in healthcare, we need clinician leaders and nurse champions, along with data scientists. We need user interfaces that are effective and thoughtfully designed, for both patients and providers. We must scrub and validate that data, so we can have confidence in it. Finally, we need patients to engage and activate with the data.

Sharing Data for Research: Technical Issues Impacting Genomics & Cancer Research

These technologies produce raw data that is truly enormous in scope . . . it can take up to a week to do a full analysis for one patient.

—Joe Gray, PhD, Associate Director for Translational Research, Knight Cancer Institute, Oregon Health & Science University



Joe Gray, PhD, Associate Director for Translational Research, Knight Cancer Institute, Oregon Health & Science University

Today, we have the imaging and genomic-based tools that reveal, in detail, the abnormalities of the individual cancers. We hope to use this information to optimize the treatment of individual tumors. We can ask what treatment is best suited to the individual patient and we can ask, in theory, how drugs can be best combined to produce durable

responses. A decade ago, generating these kinds of data was a \$1 billion exercise. Today, the tools are sufficiently low-cost so we can now consider them for use in a routine clinical care. It brings us to the point of thinking realistically about the precision management of human cancers.

So what's the problem? These technologies produce raw data that is truly enormous in scope, possibly petabytes of data for the 2 million new cancer patients and 14 million cancer survivors each year. Analyzing these data is computationally intensive; it can take up to a week to do a full analysis for one patient. We have to speed up that part of the process, which brings us to the need for better data analytics.

The research community is making good progress on establishing standards for interexchanging data. But in order to be able to make proper use of the genomic data that we generate, we have to be able to compare those to the clinical data elements. And we have no consensus, no ability to actually get adequate clinical elements to be able to do those associations. Our data sets are too big to move, so we need to standardize our analysis process so we can bring the analytics to the data. As we go forward, we also have to deal with issues like energy considerations to power these computer centers.

Many of the cancer patients that we have to manage don't have time to wait. We need a way to quickly process through all of the materials that we've got for each individual patient and make a call on how to use that information. We need access to these data, and we need to maintain high data security.

Our data sets are too big to move, so we need to standardize our analysis process so we can bring the analytics to the data.

A CALL TO ACTION What Researchers and Developers Can Do

- › Support efforts to standardize clinical data elements.
- › Develop and use better methods to audit and validate data as well as to help ensure privacy and security of data.
- › Develop new analytical tools and platforms to provide unique visualizations of health data for decision making.
- › Rethink practical uses of data to achieve continuous improvement of healthcare delivery processes and the health and wellness of patient populations.
- › Develop processes to bring analysis to de-identified data to improve treatment.

Resources



improve patient care and safety.

An analysis released by the Gary and Mary West Health Institute estimates that medical device interoperability could be a source of more than \$30 billion a year in savings and



understand the major challenges to interoperability and provide insight and practical guidance to the healthcare technology management community.

A free publication from the Association for the Advancement of Medical Instrumentation (AAMI) can help healthcare delivery organizations



with the U.S. Food and Drug Administration that identifies steps to improve device interoperability and enhance patient safety.

A free publication from the Association for the Advancement of Medical Instrumentation (AAMI) reporting on a two-day event cosponsored

External Organizations

Many organizations play a role in the advancement of medical interoperability. The following external links may be helpful in obtaining more information regarding interoperability. These organizations are not affiliated with West Health Institute or ONC, which are not endorsing or promoting such organizations or the content of the following organizations.

Association for the Advancement of Medical Instrumentation (AAMI). The Association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization founded in 1967. It is a diverse community of nearly 7,000 healthcare technology professionals united by one important mission—supporting the healthcare community in the development, management, and use of safe and effective medical technology.

Continua Health Alliance. Continua Health Alliance is a non-profit, open industry organization of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare.

The U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH). The U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health by assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.

Healthcare Information and Management Systems Society (HIMSS). The Healthcare Information and Management Systems Society (HIMSS) is a global, cause-based, not-for-profit organization focused on better health through information technology (IT). HIMSS leads efforts to optimize health engagements and care outcomes using information technology.

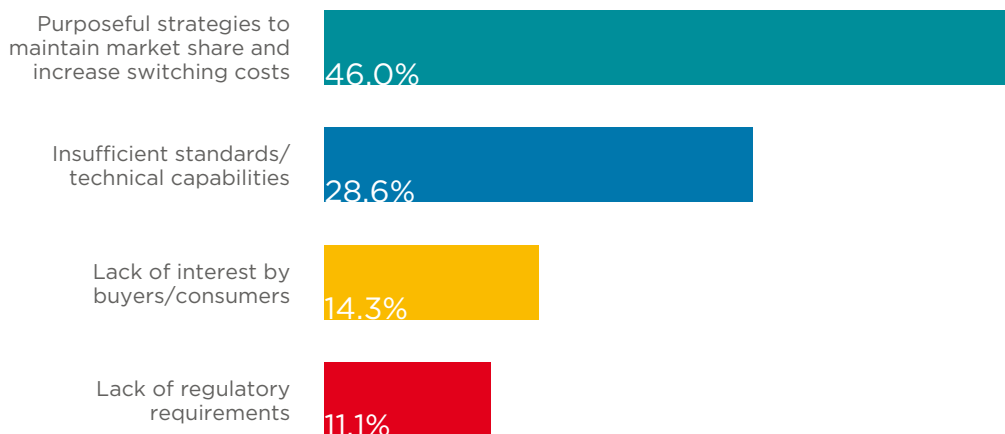
Health Level Seven International (HL7). Health Level Seven International (HL7) is an accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information.

Integrating the Healthcare Enterprise (IHE) USA. Integrating the Healthcare Enterprise (IHE) USA serves as a voice representing U.S. health IT interests and key partners in national health IT efforts for fostering the national adoption of a consistent set of information standards to enable interoperability of health IT systems.

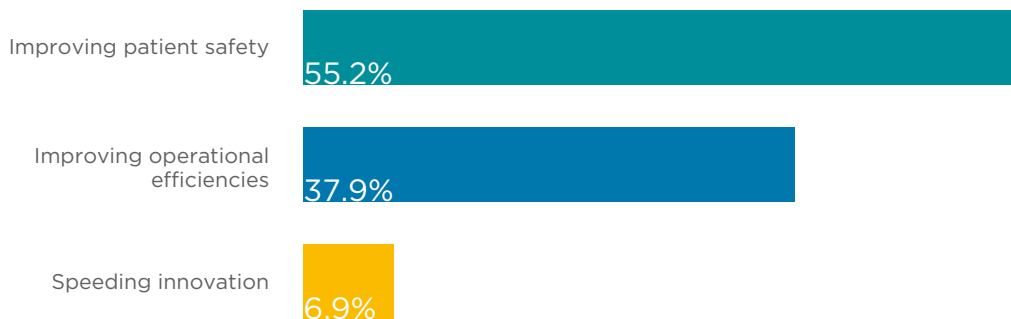
Medical Device "Plug-and-Play" (MD PnP). The Medical Device "Plug-and-Play" (MD PnP) Interoperability Program is promoting innovation in patient safety and clinical care by leading the adoption of patient-centric medical device integration.

The audience responds . . .

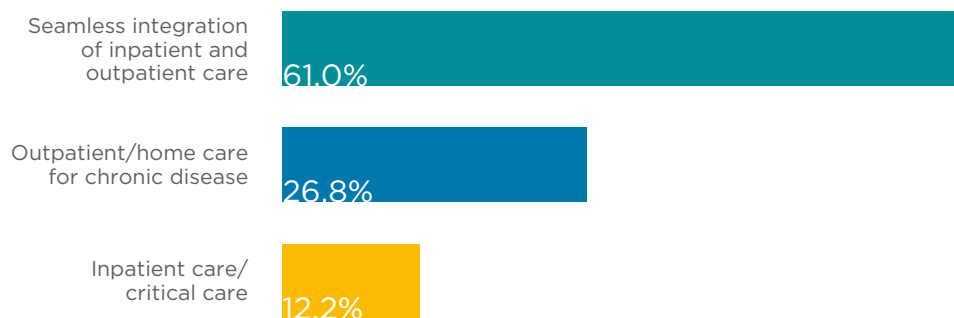
LIVE POLL #1
What do you think is preventing functional or seamless interoperability in medical devices and information systems?



LIVE POLL #2
How will interoperability impact healthcare devices/information systems?



LIVE POLL #3
What aspect of healthcare delivery has the most to gain from functional/seamless interoperability?



Live poll results taken from audience at HCI-DC14 using the event's mobile application.