Meeting Report

American Health Information Committee
September 12, 2006

The American Health Information Community (AHIC), a federally-chartered advisory committee formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within 10 years, held its eighth meeting on September 12, 2006, at the Department of Health and Human Services (HHS), 200 Independence Avenue, SW, Washington, DC, 20201.

The purpose of the meeting was to bring together Community members to achieve the mission of providing input and recommendations to HHS on how to make health records digital and interoperable and assure that the privacy and security of those records are protected in a smooth, market-led way. The meeting's discussions focused on: (1) a state health information exchange (HIE) panel; (2) a presentation on a health information technology (HIT) adoption survey; and (3) an overview of personalized medicine and its application to HIT.

HHS Secretary Michael O. Leavitt chairs the Community, and Dr. David Brailer serves as Vice Chair. The remaining 16 members, selected by Secretary Leavitt, are key leaders in the public and private sectors who represent stakeholder interests in advancing the mission of the Community and who have strong peer support. Members serve 2-year terms.

A summary of the discussion and events of that meeting follow.

Call to Order

Joining Secretary Leavitt counterclockwise around the table were:

David Brailer, MD, PhD, Vice Chair, AHIC

Colin Evans, Director, Policy and Standards, Digital Health Group, Intel (Mr. Evans represented Craig Barrett, PhD, Chairman of the Board, Intel)

Nada Eissa, Deputy Assistant Secretary, Department of the Treasury (Ms. Eissa is serving on an interim basis following the resignation of Mark J. Warshawsky, Assistant Secretary for Economic Policy, Department of the Treasury. She was represented by Jason Brown, also of the Treasury, for part of the meeting)

Robert Kolodner, MD, Chief Health Informatics Officer, Veterans Health Administration (Dr. Kolodner is serving on an interim basis following the resignation of Jonathan Perlin, MD, Under Secretary for Health, Veterans Health Administration)

Nancy Davenport-Ennis, CEO and President, National Patient Advocate Foundation and the Patient Advocate Foundation

E. Mitchell (Mitch) Roob, Secretary, Indiana Family and Social Services Administration

Charles N. (Chip) Kahn III, President, Federation of American Hospitals

Robert Cresanti, Under Secretary for Technology, Department of Commerce

Linda Springer, Director, Office of Personnel Management (OPM) (Dan Green, Deputy Associate Director, Center for Employee and Family Support Policy, OPM, represented Ms. Springer during part of the meeting)

Scott Serota, President and CEO, Blue Cross Blue Shield Association (Justine Handelman, Director, Federal Relations, Blue Cross Blue Shield Association, represented Mr. Serota for part of the meeting)

Lynn Steele, Director, Emergency Preparedness and Response Division, CDC (Dr. Steele represented Julie Gerberding, MD, Director, Centers for Disease Control and Prevention (CDC)

Kevin Hutchinson, CEO, SureScripts

Douglas Henley, MD, Executive Vice President, American Academy of Family Physicians

Lillee Gelinas, RN, MSN, Vice President, VHA, Inc.

Mark McClellan, MD, PhD, Administrator, Centers for Medicare and Medicaid Services (CMS) (Tony Trenkle, Director, Office of E-Health Standards and Services, CMS, represented Dr. McClellan for part of the meeting)

William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs, Department of Defense

Introductory Comments

Secretary Leavitt opened the meeting by thanking Community members and Office of the National Coordinator for Health Information Technology (ONCHIT) staff for their continued efforts related to AHIC's mission. Three weeks before this meeting, President Bush signed an Executive Order that will bring the full weight of the federal government behind the Community's work. This Executive Order requires the following from government departments and agencies involved in the procurement of health care:

- Adopt health information technology standards that will be at the level of interoperability that exists.

- Work with common quality measures that will be adopted to engage the quality of the care that is being purchased with tax dollars.

- Begin making price and quality information about the care that they purchase and provide transparent to their consumers.

- Create positive incentives to reward those who offer and those who purchase high-quality, competitively priced care.

Secretary Leavitt indicated that these requirements—which depend on systems that can manage large amounts of information seamlessly and securely—will help achieve the vision of value-based competition. He reiterated the fact that HIT is the backbone of HHS priorities, and AHIC's work is critical to moving these priorities forward.

The reality of personalized medicine based on the human genome, and personalized health care in general, is closer than most think, Secretary Leavitt commented. In the future, health care providers will

need to consider genomic information in conjunction with the pharmacology of the medicines that they provide. This will enable the health care system to be based on treating individuals rather than averages. Although the costs associated with conducting genomic research are decreasing, carrying out this work on a large scale requires systems capable of managing large volumes of information about individual patients—this information will need to be managed in a standardized way to be used effectively. Secretary Leavitt noted the possibility of incorporating the capacity to store genomic profiles as part of an EHR, adding that if this activity can progress now, before emerging standards compete, it will greatly help in terms of organizing and speeding development in this area.

Following Secretary Leavitt's opening comments, Dr. Brailer reminded the AHIC members that this eighth meeting of the Community represents its 1-year anniversary. AHIC now has seven workgroups, two of which were created recently (the Confidentiality, Security, and Privacy Workgroup and the Quality Workgroup). More than 100 individuals are actively working within AHIC's workgroups. Dr. Brailer described the Confidentiality, Security, and Privacy Workgroup, noting that these topics surfaced in every other AHIC workgroup. This Workgroup was chartered to examine common policy and activities around confidentiality, security, and privacy. The Confidentiality, Security, and Privacy Workgroup's broad and specific charges are as follows:

- *Broad Charge:* Make recommendations to the Community regarding the protection of personal health information in order to secure trust, and support appropriate interoperable electronic health information exchange.

- *Specific Charge:* Make actionable confidentiality, privacy, and security recommendations to the Community on specific policies that best balance the needs between appropriate information protection and access to support and accelerate the implementation of the consumer empowerment, chronic care, and EHR-related breakthroughs.

This AHIC Workgroup includes 16 individuals and co-chaired by Paul Feldman of The Health Privacy Project and Kirk Nahra of Wiley, Rein, and Fielding, LLP. Jodi Daniel from ONCHIT is the senior staff support person for this Workgroup. Future AHIC meetings will include reports from the Confidentiality, Security, and Privacy Workgroup that will focus on key "protections-versus-accessibility" issues found in the four immediate breakthroughs underway in the other AHIC workgroups.

The other newly formed AHIC Workgroup, the Quality Workgroup, also has 16 members and is co-chaired by Carolyn Clancy of the Agency for Healthcare Research and Quality (AHRQ) and Rick Stephens of The Boeing Corporation. The Quality Workgroup's broad and specific charges are as follows:

- *Broad Charge:* Make recommendations to the American Health Information Community so that HIT can provide the data needed for the development of quality measures that are useful to patients and others in the health care industry, automate the measurement and reporting of a comprehensive current and future set of quality measures, and accelerate the use of clinical decision support that can improve performance on those quality measures. Also, make recommendations for how performance measures should align with the capabilities and limitations of HIT.

- *Specific Charge:* Make recommendations to the American Health Information Community that specify how certified HIT should capture, aggregate, and report data for a core set of ambulatory and inpatient quality measures.

In addition, Dr. Brailer explained that based on AHIC recommendations related to emergency responder EHRs, a recommendation letter has been sent from the Community to Secretary Leavitt. He also noted that the next AHIC meeting will feature a strategic planning exercise to help guide AHIC's future endeavors and link them to the strategic directions of ONCHIT and HHS. As part of this exercise, AHIC

workgroup leaders already have begun working with facilitators to guide how the workgroup charges fit into the health care system. Key steps to drive technical planning will be identified and discussed at the next meeting.

Approval of August 1, 2006, Meeting Minutes

Minutes from the August 1, 2006, AHIC meeting were distributed, reviewed by Community members, and approved unanimously with no changes.

State Health Information Exchange (HIE) Panel

State-Level Health Information Exchange Initiatives

Linda Kloss, CEO of the American Health Information Management Association, explained that this project, which was completed in just under six months, began by selecting nine state-level HIE initiatives for study, with a focus on: (1) governance, (2) financial and operational characteristics, (3) HIE policies, and (4) short- and long-term priorities. Project leaders developed guidance for state-level initiatives and hosted a consensus conference in July 2006 that included more than 130 representatives from states across the country to refine this guidance. This effort resulted in a publication, the *State Level Health Information Exchange Development Workbook: A Guide to Key Issues, Opinions, and Strategies*. Following the consensus conference, a plan was developed to disseminate key findings, and recommendations were made for follow-on and policy work related to this effort.

The project team includes a project staff, lead Principal Investigator Victoria Prescott, as well as Steering Committee members and other state-level HIE staff, technical advisors, representatives from the National Conference of State Legislators, representatives from ONCHIT and AHRQ, and liaisons to other organizations.

Ms. Kloss reviewed the following key project findings:

- Important innovation and learning are underway in many states.

- There is no single model for state-level HIE initiatives, nor should there be.

- States are uniquely positioned to engage stakeholders for coordination of HIE efforts.

- States play a critical role in the Nationwide Health Information Network (NHIN) and must be more fully engaged in partnering with the federal government in its development.

- Even the most experienced organizations face significant barriers.

State-level initiatives have many evolving roles. For example, state HIEs can serve as conveners, educators, and facilitators to inform stakeholders about strategies and communication between local/regional efforts and the state as well as providing consumer engagement in encouraging HIT adoption. State-level initiatives also can help move toward adoption of standards and uniform policies; state-level HIEs are uniquely positioned to engage state governments on key issues being considered by AHIC. Other critical roles filled by state-level HIEs include providing technical assistance and serving as a bridge between the states and nationwide efforts.

4

Ms. Kloss described some of the barriers facing state-level HIEs. These include: (1) funding for organization-building and sustainability, (2) a lack of consensus on the most effective role for state government in HIE, (3) minimal participation and support from private payers, (4) non-aligned stakeholder interests, (4) a lack of shared experience about strategies for success and high impact start-up projects, and (5) there is no roadmap for how state-level HIE relates to federal NHIN programs, including how contiguous states should relate to one another.

A second document released by Ms. Kloss's group, the *Development of State Level Health Information Exchange Initiatives Final Report*, expands on the following recommendations:

- Build mechanisms to promote strategic synergy among states and between state and federal efforts. This includes establishing a coordinating body for active, ongoing collaboration, and developing a roadmap to make that linkage explicit.

- Create salient financial models for sustainable HIE.

- Engage and leverage public and private payers.

- Advance the understanding of how state policymakers and government agencies should be involved.

- Develop vehicles for support and knowledge-sharing among state-level HIE initiatives.

Kelly Cronin, Director of Programs and Coordination within ONCHIT, discussed activities underway across the country and across states. At present, 38 states are participating in a statewide or regional collaborative related to HIT and HIE. Of those, 21 states are convening stakeholders for planning, communication, and coordination. Sixteen states are providing staff to plan or manage these activities, and 17 are providing funds to support regional efforts. In addition, Governors in 10 states have created Executive Orders intended to enable improvements in health care through the use of HIT. Given the large amount of momentum and activity building in the states, the federal government's role in supporting this activity needs to be defined.

Based on Steering Committee recommendations, ONCHIT is funding additional work to:

- Identify barriers with federal solutions.

- Recommend HIE cost models that have generated revenue.

- Determine the involvement of state Medicaid programs.

- Examine the flexibility of sate Medicaid programs to facilitate HIE.

- Explore how and when to engage CMS and other public payers.
- Examine the role of the VA, Department of Defense (DoD), and other federal employee health benefit programs.

- Create explicit links and coordination mechanisms between the work of AHIC and ONCHIT and state-level HIEs.

ONCHIT also is supporting the formation of a new state collaborative, mirroring the role of AHIC at the state level to address: (1) long-term solutions to ensure privacy and security, (2) state law practice of medicine barriers to HIE, (3) governance models, (4) sustainable business models for HIE, (5) the role of private payers, and (6) integration of state public health and health care programs.

Health Information Exchange in Rhode Island

Laura Adams, President and CEO of the Rhode Island Quality Institute (RIQI), described the environment in Rhode Island, highlighting the following: (1) Rhode Island is a small market with 1.1 million people, 16 hospitals, and 3,000 doctors; (2) the state faces cost pressures on all fronts (as do all states); (3) there are digital divides (hospitals, physicians, community health centers, etc.); and (4) the state benefits from strong leadership from its Governor. Two recently enacted pieces of legislation are helping to enable HIE in Rhode Island. The first is a health care quality and cost transparency law that expands previously existing legislation for the public reporting of outcomes from hospitals and nursing homes to include community-based care. The second involves a regional health information organization (RHIO) designation and a funding potential law that has been enacted in the state.

Ms. Adams explained that the RIQI is trying to achieve significant improvement in health care quality, safety, and value, while serving as the "community table" for those issues that include consumers. She also provided Community members with examples of HIE activities ongoing within Rhode Island, such as a $5 million AHRQ contract award to the Rhode Island Department of Health, promoting the statewide adoption of electronic prescriptions (with the goal of having 75 percent of prescriptions within the state sent electronically by the end of 2007), enabling administrative data exchange, promoting standards, developing the business case and sustainability plan, and planning for coordination of public health record efforts.

As an example of market-driven activity related to HIE activities in Rhode Island, Ms. Adams described how hospitals are connecting with their partners, such as EHR vendors, laboratories and imaging centers, and ambulatory care providers. A budget article for a $20 million revenue bond in the state calls for an officially designated RHIO that would be eligible for financing HIE through a state bonding authority. The state itself will pay its proportionate share (e.g., state employees, Medicaid) if other sectors participate.

In terms of RIQI governance, Ms. Adams explained that the RIQI Board (a strong public/private partnership with the state) makes most of the decisions. Options and recommendations are brought before the Board in an open, public forum for vote, with each organization represented on the Board having one vote. Key issues are identified by the Board or by RIQI's Committee of Chairs. Workgroups and *ad hoc* committees that include Board members are formed when needed. Ms. Adams commented that Rhode Island's Governor is personally and deeply engaged in HIT activities, and has worked with others to align the health care agenda with HIT efforts in the state. Ms. Adams also outlined RIQI's recommendations for a federal role in the adoption of HIE:

- Advance the work of the NHIN prototypes and cost estimates to determine how HIE will be sustainable.

- Ensure federal HIT initiatives support state and regional initiatives, and, with dialogue, create a more actionable federal agenda.

- Assist states in aggregating their market power—employers, Medicaid payers, and regulators should work together.

- Answer the question of "who benefits?" based on real-world experience.

- Rapidly advance a national prescription drug history.

Health Information Exchange in Massachusetts

Ray Campbell, Executive Director of the Massachusetts Health Data Consortium (MHDC), discussed features of the Massachusetts environment as related to HIE. The state has approximately 6 million people and a compact geography. Massachusetts has a dense cluster of world-class health care institutions and a sophisticated technology economy. Local non-profit organizations dominate the provider and payer communities, and there is a long-standing, established tradition of HIT collaboration within the state. In addition, Chapter 58 of the Acts of 2006, the Health Reform Law, should bring the percentage of citizens in the State of Massachusetts who have health insurance to more than 95 percent.

Mr. Campbell noted that a "virtual" RHIO has been created in Massachusetts to facilitate the HIE activities occurring within the state. This virtual RHIO includes the following five organizations working in collaboration:

- Massachusetts Health Data Consortium – This group is the "convener" and is involved in education, facilitation, and incubation of HIE-related projects. It also is responsible for policy development activities related to HIE and HIT.

- New England Healthcare Electronic Data Interchange Network – This group carries out administrative HIE between provider and payer organizations. As a free-standing, self-supporting corporation owned by its members, the Network processes approximately 50 million administrative transactions per year.

- MA-SHARE – A subsidiary of the MHDC, this organization is charged with creating community utility for clinical data exchange (common technologies and tools that can be used by any organization in Massachusetts).

- Massachusetts eHealth Collaborative – This effort, funded by Blue Cross/Blue Shield of Massachusetts, is examining the effects of provider use of electronic medical records (EMRs). The project includes 450 providers and 200 practice sites across three communities.

- MassPRO – This serves as the quality improvement organization for the Doctor's Office Quality Information Technology Pilot Program.

The MHDC has been convening state health care entities for the past 28 years, contributing to a deeply ingrained culture of collaboration on HIE within the state. Having this virtual RHIO in place with multiple organizations allows for tailored governance, and each organization has a large, inclusive Board of Directors that overlaps with the other partner organizations in the virtual RHIO.

Mr. Campbell outlined some potential state roles in facilitating HIE activities, such as providing encouragement, support, and thought leadership; having state representation participate on each of the Board of Directors; and providing financial support for certain initiatives (e.g., providing ongoing support to the MHDC and providing developmental costs associated with MA-SHARE). He noted that there is no perceived need for any legislation or Executive Orders to move these projects forward at present. In terms of the federal role, Mr. Campbell offered the following suggestions:

- Provide thought leadership.

- Use the "bully pulpit" to drive change and get buy-in.

- Remove federal barriers to HIE.

- Help align incentives to foster a market for HIE.

- Avoid proscriptive mandates—providers and payers need flexibility to adapt to local circumstances.

- Be cautious about truing to force a resolution—it will take time and iterative learning before reaching the ultimate goal.

Health Information Exchange in Colorado

Lynn Dierker, Director for Community Initiatives at the Colorado Health Institute, opened her presentation by noting that the environment affecting HIE activities in Colorado is significantly different than that in Rhode Island and Massachusetts. She characterized Colorado as being a "classically Western" state that has a distinct preference for the market solution as opposed to the government solution. Colorado has an interesting and changing demographic, both economically and in terms of the populations within the state. The state has a rising uninsured rate, has undergone a decade of severe budget restraints, and has a highly competitive health care market. An upcoming gubernatorial election is expected to bring change to this environment, but for the time being, Colorado is in a "holding pattern" in terms of what policymakers can do with regard to HIE.

Despite this "holding pattern," a clear goal is emerging in the state to create a federated, interoperable system, and multifaceted technical developmental efforts related to HIE. For example, Colorado is participating in an AHRQ state/regional demonstration project. The state also is participating in a Health Information Security and Privacy Collaboration (HISPC) project focused on privacy and security analysis and solutions, and is collaborating with NHIN on HIE-related activities.

Ms. Dierker noted that one of the major drivers for HIE in Colorado is at the local level, with early adopters and HIE leaders found in different parts of the state who are developing local RHIOs. Various sectors and providers are implementing various levels of clinical messaging and other types of HIE throughout the state. There are concerns, however, about the level of adoption. Colorado has many rural small solo practices as well as safety net providers who are interested in various HIE activities. For the most part, however, these practices and providers are watching, waiting, and trying to identify points of leverage for how they can increase their capacity.

Ms. Dierker characterized Colorado as having an emerging state-level HIE. A coalition of about 40 individuals from all sectors are supporting the development of the Colorado Regional Health Information Organization, or CORHIO. The state faces the challenge of needing an organization that will serve both to pull entities together in a virtual fashion while playing a role in operations. To push HIE forward in Colorado, an independent entity that can provide services is needed to provide a Web-enabled record locator service master patient index to serve the statewide exchange and to convene a divergent group of stakeholders. The Colorado Health Institute has been leading these activities as an independent, non-profit information analysis center. The Institute serves as the incubator for Colorado's RHIO.

HIE leaders in Colorado have reached consensus on some principles and future directions, with the goal of "putting the stake in the ground" by the end of the year. Efforts in this regard include determining the value proposition and political will, establishing governance, building a viable economic model, leveraging emerging resources in other states, etc. Challenges include increasing the level of state engagement and investment, gaining clarity and consensus, leveraging prevailing conditions, and building national momentum.

In terms of the state role in these activities, Ms. Dierker explained that there has been a low level of participation to date. Conversations have been held with the state's Medicaid agency, and there is interest and participation in the CORHIO Steering Committee (participation has been at a fairly low level, however). The Colorado Department of Public Health has been active and is developing pilot projects. Despite the Governor's support for HIE-related activities, given the upcoming election and impending change in leadership, Colorado still faces the "holding pattern" Ms. Dierker described previously. Even so, the state legislature is aware of things like telemedicine and is becoming increasingly aware of nationwide activities; growing interest and momentum among state policymakers is expected.

In closing, Ms. Dierker described four major roles at the federal level:

- Leadership, to bring Medicaid and other health plans to the table, and to increase the synergy among national-level initiatives/federal programs.

- Communication, to send a clear message about the importance of state-level HIE.

- Build more effective working partnerships with states, to obtain ongoing input and guidance from states and find creative ways to help states and channel resources at all stages.

- Strive to put the federal house in (more) order, to expand the timeframes for action and support from the federal level and coordinate/streamline efforts among multiple federal agencies/programs impacting states "on the ground."

State Health Information Exchange

Dr. Kala Ladenheim, Program Director at the Forum for State Health Policy Leadership, opened her presentation by noting that her comments reflect research from this project and not National Conference of State Legislatures official policy. In discussing collaboration within and among states, she noted that there is a variety of coordination activity among state health programs. These typically start as joint purchasing with public employees and Medicaid programs, efforts focused on quality, etc. Dr. Ladenheim participated in a project evaluating state efforts to combine quality efforts in Medicaid and public employees. One major challenge is that legal requirements differ among the programs. As states try to coordinate among programs, they face the challenge of these types of conflicting frameworks. There are positive existing models of joint public policy settings and collaboration at the state level that may be advantageous to build on, however. Coordinated activities across the government and public/private organizations often center around employee purchasing, and there are, for example, state public employee programs participating with private employers in projects related to transparency. In Massachusetts, Medicaid was one of the earliest participants with one of the public employer purchasing coalitions focused on quality and purchasing.

Among the states, there are geographically based collaborations that often relate to environmental and economic development issues. Issue-driven collaborations among states often are created and carried out in a number of ways, ranging from developing common standards to creating model legislative language and contracts.

Intergovernmental associations, such as the National Conference of State Legislatures, are important mechanisms for disseminating information and sharing effective models among the states. They also can facilitate the development of best practices and comparative data evaluation, and differentiate/define state and federal roles. Dr. Ladenheim noted that because it is difficult to obtain funding within one state to evaluate across programs in other states, the participation of the federal government and philanthropic organizations in these activities is critical.

In describing lessons learned, Dr. Ladenheim noted that states vary greatly in their capacities, resources, and preferences. They also can provide a buffer between national policies and national decisionmaking that takes into account regional differences in preferences for the roles of government as related to the private sector and for differences in the infrastructure capacity of the state governments. She also explained that history matters in two respects: (1) experience that has taken place that may be unique to a state in terms of sunk costs and/or relationships, and (2) in terms of developmental models and stages of adoption. States look to the federal government for guidance on standards and models. States are anxious about HIT initiatives, particularly because Medicaid dominates state budgets, and they are particularly anxious to know what is coming out of CMS related to the rules of reimbursement tied to

Medicaid and HIT. Dr. Ladenheim emphasized that there is no strictly state or strictly federal role regarding HIE initiatives. Whatever policies are adopted will require a partnership—attention to how that partnership is defined at the time the policies are developed will help shape future direction.

Dr. Ladenheim concluded her presentation by describing the following issues related to the importance of state-federal partnerships:

- Significant interdependencies exist between states and federal government to realize policy, political, and market environments for HIE.

- There is a need for states to understand federal HIT initiatives to align efforts.

- Partnerships can be synergistic if agendas are coordinated and information is shared.

- States are instrumental to developing a nationwide interoperable infrastructure for HIE.

- AHIC and ONCHIT need to consider state implications in all recommendations.

Discussion Highlights

"I would be interested to know what the relationship [is] with the health information exchanges and the quality collaborations that are going on in most states. Are they the same organization or are they working together?" – Secretary Leavitt

"For Rhode Island, it is one and the same. Our RHIO is a subset of our quality and safety initiative…we now need to turn to some of the things that we've been doing, such as our statewide ICU collaborative. We have every ICU in the state working on reduction of ventilator-associated pneumonias and central line infections, and [they are] enabling some of these things alongside the development of our information health technology." – Ms. Adams

"In Massachusetts, there's certainly points of connection between the health information exchange organizations and the quality improvement organizations…there is a cluster of different organizations…that are active in the quality space. And so we're always looking for opportunities to work together, but the two agendas are not explicitly linked." – Mr. Campbell

"There are people working on quality and quality agendas in different silos and pockets, and so pulling in all of these efforts together is really an emerging role." – Ms. Dierker

"My sense is that some of the challenges that we face in the rest of these arenas [have] to do with standardization, getting us going in the same direction, whether it's public reporting, whether it's pay for performance. All these kinds of things benefit from public agreement and community agreement."
– Ms. Adams

"To what extent, in your states, and in the states generally, are there competing organizations?"
– Secretary Leavitt

"We have organizations who are doing pieces of things. While right now perhaps they're not competing there's really the big possibility for competing… The question becomes: who reports, who does all this, where do we set the standards for what quality reporting looks like? And that's the point about this piece of infrastructure that we're talking about at the state level, is a standard setter, is a convener, it's getting everyone to play and those functions are what's needed across a lot of these." – Ms. Dierker

"The state health information exchange initiative can be the group that insists that national standards be followed. There's a concern that we will have 1,000 flowers blooming in regional health information organization initiatives and that this could be one role of the states: to convene the organizations to follow at least a set of minimum exchange standards." – Ms. Kloss

"There's technical interoperability or technical standards, but there is also policy interoperability. And I think that in some ways that's the more challenging issue… we think that it's an important part of our role as the convener in the Massachusetts e-health community to make sure there's a focus on the policy framework, that it will support health information exchange, so that we don't have organizations, one pursuing opt-in, one pursuing opt-out, one having this approach to privacy, another having a different approach. We want to make sure that to the extent possible, we harmonize our activities at a policy level so that those barriers to interoperability don't rise up and don't create problems farther down the road."
– Mr. Campbell

"The technical standards need to be nationwide in order for there to be national interoperability. I think that from a policy perspective…different states approach these issues in a different way. And I think that it's probably on the policy level where you can have more flexibility." – Mr. Campbell

"We need help significantly at the national level with helping states understand their role and how to energize and engage the states, and some of those policies I think, come down from the national level better than they do than being developed state-by-state in terms of describing that role and perhaps standardizing that role in some way. Certainly, some local flexibility is needed. We specifically feel that local flexibility will be an absolute requirement for things like how these data will be used." – Ms. Adams

"Medicaid is both a state and a federal issue together…at the federal level it's an example of how you can really use the leverage of a big payer and bring Medicaid to the table and really advance infrastructure and demonstrating through Medicaid how to really integrate quality and health information exchange, and build it… And then we need our state policy makers to really understand how to use a program like Medicaid as a source of leverage. So it's a really important example where a lot can be done."
– Ms. Dierker

"Under current law and with the approach that we've taken at the agency, there is a lot of flexibility for states to redirect their Medicaid dollars. They have to meet, as always, a budget neutrality test overall. But we have been working with a number of states to implement reforms that rely on supporting interoperable health IT. And we expect to continue to do so… I think it's the right time for us to highlight the approaches that states can take under the new flexibility and Medicaid financing to redirect the dollars to promote quality, prevention-oriented care as opposed to costly and duplicated services that we see too often in the Medicaid programs today." – Dr. McClellan

"If we design these systems without the consumers' viewpoint in mind…it will take more time rather than less time. We'll run into further difficulties down the road. In Massachusetts, we've made a number of decisions about how we implement health information exchange that are designed to preempt some of those objections, so for instance, we don't believe in centralized databases of medical records, we're following a very decentralized architecture. And secondly, in all the projects we've done so far, we've followed a very strong opt-in approach as opposed to an opt-out." – Mr. Campbell

"I think the big challenge is how to really describe to people what we're doing and to take this whole technology, HIT, HIE, arena and talk about it. Even people supposedly doing it and in the business of it aren't really on the same page…Some creative financing options about how to drive adoption [are needed], and that's where perhaps there's a real interesting role for state government, even in a market-based approach to really think about how to do that. And I think that's what's upcoming for our state."
– Ms. Dierker

"I think some places where we see states sort of start towards doing something and backing away had to do with consumer concerns around issues like privacy and security." – Dr. Ladenheim

"The projects we did on medication histories allowed us to inventory all of the state laws…and one of the things we discovered that was very problematic was that the health plans are forbidden by law from sharing information, even with the patient's consent, for medications relating to HIV, behavioral health issues, sexually transmitted diseases, substance abuse, and so even if the doctors in the emergency room had a conscious and competent patient in front of them saying 'I consent for you to pull down my entire medication history,' they were not allowed to do so. But interestingly, if the data had been coming from pharmacies, they could have. Because the law was specific to health plans." – Mr. Campbell

"The founding fathers may have been brilliant in that they created the perfect form of government for the information age. But we're having to invent something entirely different…we're sort of inventing 'net-eralism'…In a way, a network is a perfect metaphor…The states and local communities have to be PCs. They have to have the ability to operate independently and to capture their own sense of agenda and do what they think is best…But there has to be an operating system. You can't have a network without an operating system. And the federal government very clearly has to lead in an aggressive way. And I think our capacity to pay and our capacity to lead has to be evident here." – Secretary Leavitt

"It's clear to me that the connection between the quality collaborations and the health information exchanges isn't what it needs to be…I sense that there's a fairly heavy appetite among the states for the federal government to have a strong role in being able to bring sense of order to this. And yet we don't want this to be a government-dominated kind of proposition." – Secretary Leavitt

"In the quality initiatives…we have six pilots…and the network will be working with the AQA and HQA, which are the quality-adopting organizations for hospitals and ambulatory care. This network would have three functions. The first is cross-pollination. The second would be harmonization, and the third would be to charter many more like them and to nurture them." – Secretary Leavitt

"In terms of the federal government taking a leadership role, I think…probably the most important thing that can be done is the transparency agenda you have been talking about." – Mr. Campbell

"It's very clear to me what's ultimately going to drive this is a need to have pay-for-performance functioning and working…And it's a true and profoundly important concept that I believe will ultimately be adopted in the statute at some point. And we're all going to have the responsibility both in terms of the market driving it and legislation driving it to make this work." – Secretary Leavitt

"As it stands today, quality measurement in this country is a nurse who comes in on a Saturday morning and goes through a 2-foot stack of files to try to figure out who got their aspirin when, and whether or not people had a blood check. And to fix that, we've got to get through adoption…We've got to have standards. And the level of urgency that I'm feeling to get this into place is profound."
– Secretary Leavitt

HIT Adoption Survey Presentation

Dr. Brailer introduced a panel addressing progress made in HIT adoption and tackling the issue of scientifically understanding how best to move forward. Dr. Sara Rosenbaum, Hirsh Professor and Chair of the Department of Health Policy at George Washington University School of Public Health and Health Services, noted that the HIT Adoption Survey is a collaboration between George Washington University and Massachusetts General Hospital, and that a joint endeavor that included the Robert Wood Johnson Foundation added value to this project. The purpose of this work is to create a definitive, public baseline for measuring the rate of HIT adoption. Panel members were asked to present a discussion on

measurement, why standards for measurement are needed, and how to establish and implement an appropriate adoption measurement system. Dr. Rosenbaum added that in addition to selecting methods used to measure adoption, decisions must be made to identify what to measure. Some of these critical decisions include which practice settings command the most attention, which types of actual or perceived barriers will be examined, and the extent to which adoption is reaching the communities and populations that stand most to benefit from improved health care quality.

Adoption of EHRs: Where Are We, Where Are We Going, How Can We Know?

Dr. David Blumenthal, Director of the Institute for Health Policy at Massachusetts General Hospital/Harvard Medical School, explained that he and his colleagues have been working to understand, based on existing evidence, the current status of HIT adoption. He provided the Community with some estimates that their expert consensus panel has vetted based on an examination of the currently available HIT adoption literature, with a focus on EHRs in three sites: (1) individual physician practices, (2) physician group practices, and (3) hospitals.

Based on the group's best estimates and the review process that the expert consensus panel undertook, it is estimated that at present, approximately 17 percent of American physicians have access to an EHR. This estimate includes 13 percent of solo practitioners and almost 40 percent of physicians in groups larger than 20 doctors. Dr. Blumenthal and colleagues were unable to find credible information on EHR adoption in hospitals, but it is believed that computerized physician order entry is present in a minimum of about 5 percent of American hospitals.

Based on trends observed from surveys conducted between 2001 and 2004, a 3 percent annual increase in physician office adoption of EHRs was seen. Dr. Blumenthal's group extended this trend in the context of the President's 2014 goal for overall adoption, noting that by 2014, the current trend projects to a 45-50 percent adoption rate. If the 3 percent adoption rate is increased to 6 percent, by 2014 it would result in overall adoption in the 70-75 percent range.

There are significant problems associated with the existing EHR adoption data used to make these estimations. To improve these data and more effectively track EHR adoption over time, the following issues need to be addressed:

- The definition of the EHR needs to be clarified and established. The expert consensus panel has agreed that the Institute of Medicine's definition, which lays out eight key functionalities, is probably the most desirable definition. For survey and data collection purposes, the panel modified this definition to include four key functionalities that constitute the core of an EHR.

- It is essential to define what is meant by the term "adoption," because adoption has three components: (1) the acquisition of HIT or EHR, (2) its installation, and (3) its use.

- Reliable, objective, and reproducible data collection methods need to be designed. Some such data collection methods are in place through activities undertaken by the federal government through the National Ambulatory Medical Care Survey (NAMCS) as well as through the American Hospital Association and others. These efforts could be complimented by additional data collection activities to yield an even more complete picture.

Dr. Blumenthal also offered some recommendations for gaining a better understanding of the value, barriers, and incentives associated with EHR adoption. For example, there is a need to define measures of value, in terms of the aspects of quality that might be influenced by HIT. One major experimental challenge is developing approaches to compare the value and efficiency of care, both with and without operating EHRs. There also is a need to clearly identify the barriers and incentives to adoption so that measures of these barriers and incentives in regular data collection activities can be defined.

Tracking Use of Electronic Medical Records

Dr. Jane Sisk, Director of the Division of Health Care Statistics in the National Center for Health Statistics (NCHS), CDC, presented the Community with data collected in two routine surveys conducted by the NCHS, the NAMCS and the National Hospital Ambulatory Medical Care Survey (NHAMCS). These annual surveys sample 3,000 office-based physicians (NAMCS) and 500 hospitals (NHAMCS) that are selected to generate nationally representative samples of those providers across the country. The NAMCS includes nonfederal office-based physicians and excludes radiologists, anesthesiologists, and pathologists. The NHAMCS includes nonfederal, general and short-stay hospitals with emergency departments or outpatient departments.

In terms of data collection for the NAMCS and NHAMCS, a survey goes to the provider's office, conducts a face-to-face induction interview, and takes a sample of visits that are going to occur in the coming days and abstracts those medical records to get information about the patient and the clinical management of the patient once those visits have occurred. Response rates for both surveys have been high (65 percent for the NAMCS, and 90 percent for the NHAMCS). Relevant data from these surveys go back to 2001, when NCHS first added questions about the use of EMRs to the NAMCS and NHAMCS. Dr. Sisk noted that in the pretest, all of the respondents indicated that they understood that EMRs meant keeping documentation in computerized files rather than using paper files.

Between 2001 and 2003, diffusion of EMRs appears to have remained constant, at a rate of approximately 21 percent for emergency departments and 29 percent for outpatient departments. For individual physicians over that time, the rate was approximately 18 percent through 2003. Starting in 2004, the use of EMRs by physicians surveyed increased to 21 percent, and then rose to 24 percent in 2005. NCHS also surveyed physicians in practices having three or more physicians and found that EMR use rose to 23 percent in 2004 and almost reached 28 percent in 2005. Dr. Sisk noted that the characteristics of the practice, such as number of physicians in the practice, the ownership of the practice, and geographic region have a significant association with whether or not the practice has EMR systems. Dr. Sisk added that individual physician characteristics, however, such as age, gender, and specialty do not have a significant relationship between whether or not the practice reports EMR use.

NAMCS data from 2005 indicate that of all physicians surveyed, approximately 24 percent reported full or partial use of EMRs. Solo physicians reported much lower use (16 percent) compared with physicians in group practice, with almost half of physicians in groups of 11 or more reporting EMR use. Additionally, the data indicate that if a physician or physician group owns the practice, the rate of EMR use is significantly lower than if an HMO owns the practice (20 percent versus 66 percent). Dr. Sisk noted that the categories in which physicians are most likely to report using EMRs also are the categories that have the fewest numbers of physicians (e.g., although 66 percent of physicians in practices owned by HMOs report using EMRs, only 3 percent of physicians surveyed are in these practices). In terms of geography, physicians in the Northeast report much less use of EMRs than do physicians in other parts of the country.

NCHS also examined the characteristics of patients whose primary care providers used EMRs. Of patients surveyed who saw primary care providers in 2003 and 2004, about 17 percent had physicians that reported using EMRs. This percentage did not vary by patient characteristics such as age, gender, race, ethnicity, language ability, geographic region, urbanicity, source of payment, income, and education.

Dr. Sisk also provided information on the EMR features physicians reported having or not having in their systems (keeping in mind that only about 24 percent of physicians surveyed reported using EMRs). 2005 NAMCS data indicate that the most common EMR feature, demographics reporting, was reported by 21.4 percent of physicians who use EMRs. Physician notes and laboratory results were the next two most common features used, at 17.7 percent and 17.2 percent, respectively. The least commonly used or available feature was public health reporting (5.4 percent).

Sustainable High Value Care for All: Searching for Solutions

Dr. Michael Painter, Senior Program Officer at the Robert Wood Johnson Foundation, used a narrative device—a fictional story about a family in a town 10 years from now—to describe components of this measurement assessment project and related efforts. The story involves a Mr. Richard Romero, who lives in the fictional town of Liberty, U.S.A. Mr. Romero, with family origins in the Dominican Republic, has a strong family history of diabetes. Mr. Romero is very happy with his decision to move his family to the town of Liberty because it lives up to its motto of being the "best place to live to have a high-quality, healthy life."

However, Mr. Romero remembers a time when American health care was getting more and more expensive. The quality was variable, poor for many, and access to care was out of reach for many, as well. For example, the 2005 *National Healthcare Disparities Report* noted that nationwide, Hispanics had poor quality care for 20 of 38 important core-reported measurements of quality. Hispanics also had poorer quality of care than other racial and ethnic groups. For instance, Hispanics were 16 percent more likely than non-Hispanic whites to receive poor quality care. They were less likely than non-Hispanic whites to receive preventive services like mammograms and pneumococcal vaccines. If they had diabetes, they were less likely to receive strongly recommended services for diabetes than non-Hispanic whites. Additional research found that the town of Liberty surprisingly had one of the highest amputation rates among diabetic patients of any city in the nation.

Dr. Painter continued the telling story, explaining that as Liberty's health care community gathered and reported additional information, patients and providers learned the worst about health care in the town of Liberty. It was somewhat worse than the national average, both overall, and for some racial and ethnic groups, particularly Hispanics. All of this information was very concerning to Mr. Romero and his family, and to the leaders of Liberty. Ten years later, the town of Liberty is a different place. Liberty is now living up to its commitment to high-quality, affordable care for its citizens. For instance, the quality of Liberty's health care has dramatically improved, including the equity dimension of that care. Liberty's average hemoglobin A1C measure is now 7.5 percent communitywide, and there are no disparities in this measure of Liberty's diabetes care. Liberty now has the lowest amputation rate for its diabetic patients of any other municipality in the country, and importantly, past disparities are closed. There are no differences in the amputation rate by racial or ethnic group. Mr. Romero knows this because he follows these and other rates for Hispanics closely—he can follow these rates because Liberty made it easy to access and understand this information. In addition, Liberty physicians now report information about the results and outcomes of the care they provide publicly. This public reporting means that Mr. Romero, all of Liberty's other health care consumers, and the town's physicians and other providers can see which providers or groups are providing the overall best results for medical conditions (e.g., diabetes in this case).

This information is valuable to Mr. Romero as he decides where to get his care. He combines this information about results with the price information that Liberty's providers also report. With that information, he and his family can determine the highest value for their health care dollar. Liberty did not just look to the medical community to develop its community health care information; the town also took the somewhat radical step of getting consumers—including consumers from every racial and ethnic group—to help design the public reporting system. That assured that reported performance data were much more useful to patients, and because more patients understand the data, it is helping them to think more about their own role in their health care.

The changes in Liberty came about in large part because the community came together to implement and adopt EHRs and push for interoperability so that health information flowed privately and securely but efficiently to serve Liberty's patients. A standardized approach to national measurement of EHR adoption identified potential gaps and disparities in this EHR adoption; Liberty was able to use that information and make sure that all providers in town got the help they needed to implement, adopt, and

connect their health information systems. Liberty came together under strong leadership with projects to align market forces to drive and sustain quality. The town also developed a system of public reporting on performance, outcomes, patient experience, and price. The community's efforts resulted in dramatically increased health care value.

Liberty providers embraced the goal of quality improvement. Furthermore, they recognized that in many ways, they were ultimately going to compete on outcomes and results, so they all needed to understand how to redesign their practices to deliver these results. They built sustainable mechanisms, capacity, and capability that allowed them to improve the care they provide and meet the interests and demands of Liberty's consumers. Dr. Painter concluded this fictional account of Liberty by adding that the town engaged all of its consumers, including those of every racial and ethnic group, to help them understand the publicly reported information, and help them think about their own role in health care.

Dr. Painter commented that components of this fictional story have critical implications for EHR adoption measurement. HIT and EHR adoption are vital ingredients to almost all aspects of this vision. A standard, consistent, regular report card is needed to monitor the adoption trajectory. As noted in previous presentations, a standard definition of what is meant by the term EHR is also needed. There is a need to ensure that all important vulnerable groups are included in this effort, so that certain communities, areas of the country, types of practices, etc. are not left behind. Finally, there is a need to understand and find ways around potential medical, cultural, financial, and technical barriers to implementation.

Discussion Highlights

"The Robert Wood Johnson Foundation has generously complemented the support that the ONC has provided to produce a report on the state of HIT adoption. We think that that report will be released in the early to mid part of October. It will summarize our findings across the set of questions that we have addressed… There will also be a heavy focus on disparities in adoption and what the best information is up to this point, and then some recommendations going forward for how to continue the measurement process…We are hoping that at the same time we can arrange publication of some of this material in a peer-reviewed form that will increase its availability and dissemination to the community at large."
– Dr. Blumenthal

"Ultimately, I think that adoption in this country may be to some degree influenced by the role of the consumer in defining its importance and their demand for that level of service. So, the more we have consumers that are saying 'I only want to be treated within a facility or a practice group that has an EMR,' the more we're going to see these practice settings move to the EMRs." – Ms. Davenport-Ennis

"Consumers are surveyed much less frequently than other groups…It would be very desirable to have the kind of data that we're developing about providers also on the consumer side. And hopefully that will be forthcoming over time…If people come into doctors' offices with the expectation that an electronic health record will be used, that it will have a major influence on both institutions and on physicians."
– Dr. Blumenthal

"Barriers and incentives…come in four flavors. The first is economic, and that's referred to often as the lack of a business case for adoption. The second is legal or regulatory…[The third is] technological, uncertainty about which forms of electronic health record work and how well whether they'll be compatible with other forms. And then finally organizational. This is, I think an extremely important type of barrier or incentive, as witnessed by the fact that groups tend to be much more frequent adopters than individual practices." – Dr. Blumenthal

"Understanding how to categorize the barriers and tying consumer expectations with physician expectations or hospital expectations and concerns begins to uncover important insights that I think are going unnoticed at this point." – Dr. Rosenbaum

"Obviously, there's this problem with economic equation where people who pay for it don't necessarily get the benefit. And we've got to work heavily on that. But we can't afford to wait—this has got to be exponential, and it's got to happen in a 3- or 4-year period or we're not going to get [a] critical mass."
– Secretary Leavitt

"The greatest single story I can think of about the speed at which adoption can happen when this Department stands behind speed is how quickly every hospital in the United States came into compliance with Title 6 of the 1964 Civil Rights Act. After Medicare was enacted…as a condition of participation in the program, hospitals [had]to be in compliance with Title 6. And it took 6 months for every hospital in the country to come into compliance with Title 6." – Dr. Rosenbaum

"The most single powerful tool you have for incentivizing compliance or adherence adoption of this technology and then essentially moving it out to all other payers is the use of federal authority over both conditions of participation in federal programs and federal authority to clarify the conditions under which that participation and the adoption and financial support for the ongoing operation of the system is a recognized, federally allowed expenditure." – Dr. Rosenbaum

"There's got to be some macro changes in health financing that will accommodate this—I'm not just talking about Medicare and Medicaid…If we really believe, as I think everyone at these tables would, that there are substantial efficiencies to be gathered, then that shift in macroeconomics ought not to be an unhappy event. It ought to be a very happy one." – Secretary Leavitt

"Physicians right now don't see [HIT as being] essential to practicing the way they see the examining table, and the tuning fork and the reflex hammer, or the X-ray machine. Getting past that will be important; it's by no means insurmountable if the federal government puts its mind to it and if payers put their minds to it… It's very helpful to have your hand held for a considerable period of time [after implementation of an EHR]…I think that's another ongoing cost that needs to be built in."
– Dr. Blumenthal

"One of the reasons early on [that] we identified interoperability as being one of the key essences of our effort was not only that it lowered the cost to make these tools more plug-and-play, and it raised the value, as you've heard, for reporting or consumer portability, but…it had the potential to create a network effect in adoption, not unlike the internet or a fax machine. That the more people begin to adopt, the more it becomes easier and required for other people in the economy to do so." – Dr. Brailer

"Solo practitioners make up a bit more than a third of the physicians across the country. They make up two-thirds of the practices. They are, as you saw, at a level of about only one-sixth [of those] who have use of electronic medical record systems." – Dr. Sisk

"Whether it's the individual physician or other practitioner in solo practice or in a very small practice, they represent the small business community in this country. They're fiercely independent…and they want to do the right thing…There's a huge opportunity here…the ability of this group, the small and medium practitioner group, to respond to their peers, who have already gone through this process, and can know and understand what the challenges are up front but how those challenges can be overcome even in their environment is huge. And we certainly have learned that in the surveys with our members."
– Dr. Henley

"The early adopters…often represent the respected peers in communities because they take the first step, whether it's a new clinical process such as EHR or a new clinical treatment, whatever the case may be. And they take it to their peers and it presents a very important opportunity, I think, to stimulate this group. My concern is that we may be getting to the end of the early adopter community, and what about the next 30 percent which represents, perhaps, a bit of a greater challenge?" – Dr. Henley

"We are better off creating a culture of improvement rather than a culture of blame. A culture of positive incentives as you have alluded to earlier with issues of pay for performance and so forth…It's important to understand that this is no less than culture change and practice redesign change. And we are challenging our members to understand that and know what those challenges and barriers are. But also to appeal to their sincere professionalism in the sense that, regardless of specialty, what the RAND data shows, regardless of specialty, is that we're only doing it right about 54 percent of the time." – Dr. Henley

"As you go to look at where is the return, whether it's reduction of duplicate tests or reduction of errors, or improved decisionmaking, I'm concerned about the level of evidence base out there…where are we in terms of building that evidence base and who's got the data and how do we get that out there as sort of fuel for accelerating the adoption?" – Dr. Winkenwerder, Jr.

"I find the evidence less than I like it to be. But I would say if I had to put the evidence in kind of regulatory terms, that are familiar to the federal government, if IT were a drug it would be approved for marketing. You might do some postmarketing surveillance. But there's good enough data to me to demonstrate its efficacy. The data about cost saving, I think is not as firm as the data on perhaps its ability to improve quality." – Dr. Blumenthal

"I can tell you without any hesitation, with a lot of experience in this space, those physicians today that are using electronic health record systems, once they reach a first phase of interoperability, their value and their own estimations of the ROI, the use of EHR goes tremendously up." – Mr. Hutchinson

"I would submit, based upon my past experience as an EHR vendor and now my experience as running a pharmacy network, that if you're going to get to the next tipping point of adoption for physicians, those early adopters would put up with the lack of interoperability for better documentation and for better workloads in their practice. But if we're going to move this ball over to the next phase it's not adoption. We have to start with interoperability…And one of the things I would encourage us to do as a group, and as an organization, as a government, is get rid of the exception within the Medicare Modernization Act for faxes, that allow faxes to be an exception to the rule of standards, because it goes directly against our desire to drive interoperability." – Mr. Hutchinson

"There's a real challenge in hospitals. Hospitals vary in size; some are pretty big. You can get an EHR functioning on the outpatient department, but have nothing in the inpatient side. Does that mean that you've got adoption? I don't think it does…The American Hospital Association is working on this and we are working with them. They do a terrific annual survey. And I think they're going to start including some questions in the near future on this topic and so we should have better data going forward."
– Dr. Blumenthal

"IT as an enabler, is knitted in to how we deliver care. And we actually use it more than the exam table and more than a stethoscope. It is used in every encounter and that's a different way of thinking, but it's a process change that takes time." – Dr. Kolodner

"So what I'm seeing in my mind over time is a bunch of positive incentives that get us to a substantial critical mass and then at some point people have to get on board or they become a drag to the system. And that's when negative implications make some sense to me." – Secretary Leavitt

"We're not anywhere near a tipping point…we still are looking at the mountain. We haven't climbed half way up, I think." – Mr. Kahn

"One thing that has been noted in many regulatory exercises, not just health care, is that after a certain rate of adoption of a certain practice or behavior, that it's actually those parties who have already done it that call for regulation or an intervention in the market to take away the unfair advantage that those who lag may have." – Dr. Brailer

"As long as we can have a momentum moving forward with positive incentive, that's what we want to do…Every one of us in the United States is, indeed, a patient. We may not have lived that journey yet, but we will at some point. But there's an incentive that we've talked about in this committee before. And the incentive is a realization that in moving to EHRs, we reduce medical errors. And as I think of the solo practitioners particularly, I'm very sensitive to the benefit that can accrue to them when we begin to talk to them about the value of reducing medical errors. And I'm hoping this indeed will be an area of attention that will be used to promote return on investment, because it clearly does."
– Ms. Davenport-Ennis

"Those organizations that can find ways of getting information to doctors or to patients in the system, in a clear and crisp way, I think will end up being advantaged as we go forward. And I think about what it took for the internet to be adopted…People spent money to build the infrastructure; FedEx built lots of systems to ship packages, but they didn't ask for the government to provide money to do that. It was the best way for them to run their business. And I think the more organizations can get into that frame of mind, that we can incentivize those kinds of things, the more we will spear adoption." – Mr. Evans

Personalized Health Care – Considerations for the American Health Information Community

Dr. Brailer noted that this presentation will be followed by a full panel discussion at a subsequent Community meeting. Dr. Gregory Downing, Director of the Office of Technology and Industrial Relations, National Institutes of Health, informed Community members that he was representing the Personalized Healthcare Team from across HHS. He described what the Department sees as a framework for enabling medicine to be tailored to individuals' needs based on biology and many aspects of their health care. The confluence of rapid advances in science, driven in large part by fundamental discoveries in molecular biology and the human genome project that have set the stage to explain and address individual differences in health states. HIT is transforming the health care system by establishing the means for patient-centric care. Furthermore, the integration of HIT and genetic information will be transformative in health care practice, and contributes to the critical opportunity for anticipating and planning for the future.

Dr. Downing presented a pyramid of personalized health care. At the base of this pyramid, are the fundamental elements of understanding the basis of disease, and the human genome project has been a major contributor towards that. An equal partner in this foundation is HIT capabilities. Building towards personalized health care, these capabilities will be viewed in product development and review of the critical path process that the U.S. Food and Drug Administration has underway in developing enabling tools, many of which are based on these technologies that will have an impact on clinical management. The next steps in terms of disseminating these technologies and capabilities in the health care system also will be critically dependant upon HIT. Ultimately, at the pinnacle of this pyramid is the achievement of personalized health care.

Emerging opportunities for personalized health care include the following:

- Many health care systems and public resources are now beginning to incorporate genetic tests into their framework.

- Some practical applications of genetic tests are already emerging, such as identifying risk for disease, confirmatory diagnostic tests, and selection of appropriate therapies (pharmacogenomics).

- The technology platform costs for genomic tests are decreasing and becoming feasible for medical use. Some of these technologies are already in place at the bedside or in the clinic.

- Multiple standards for the technologies are emerging to facilitate market entry. The process for enabling these to become either regulated or part of clinical care requires some elements of standardization of the platforms themselves, and this is already underway.

Dr. Downing discussed some examples of gene-based tests that already are in use in medical management. Risk factor determination for ovarian and breast cancer in the use of BRCA1 genetic testing has been in the health care setting for a number of years now, and has opened the door for selective estrogen receptor modulation as a means of delaying the onset, or preventing, in some cases, the occurrence of these diseases. The selection of appropriate therapies for managing particular diseases also is becoming common in the field of oncology. Many of the molecular pharmacotherapies for various types of cancer are based on the appropriate test to determine whether a patient has a specific type of cancer. It also is possible to select drugs based on whether an individual's metabolic pathways will enable them to take certain drugs and avoid adverse events through some genetic tests. One commercial product has the capability of testing for drug metabolizing enzymes to guide individualized patient dosing regimens of various drugs.

In terms of other disease areas, there are new pathways underway that enable clinicians to examine eight genetic markers for patients who are at risk for macular degeneration and other forms of eye disease. In addition, all states have a form of newborn metabolic testing that is standardized in many of the laboratories and reported in a very efficient fashion across the health care setting.

Dr. Downing described a framework for building an interface of HIT, genomics, and health care. One commonality is that the HIT system is built on a digital framework; so is the genetic basis of biology, in that there are four nucleotides that make up DNA, this provides a great deal of utility and power. Building on that, the scientific enterprise has been moving quickly to develop a common, harmonized nomenclature system for genes and diseases. Communities already exist that are developing standards for the technology platforms for medical tests, but they lack the framework to harmonize their efforts. The stage is being set for integrating genetic test results into the medical system and EMRs. The results of these efforts will benefit patients, and ultimately impact on the quality and effectiveness of how their health care is delivered in the future.

Discussion Highlights

"Dr. Brailer, is there any workgroup that's going to consider this to drive it forward? In other words, when Secretary Leavitt announced the first responder work, that went to the appropriate workgroup, is there a workgroup that will help support this?" – Ms. Gelinas

"We are currently considering how to organize the Community's part of that, whether it's an independent Workgroup or part of another as we're looking at how to frame this issue in a much deeper way."
– Dr. Brailer

"As I understand the way you have organized it, it's an HHS enterprise, but we would offer to join you and [provide] support at DoD for a couple of reasons. One, our IT system is on the clinical side, but also we maintain a very large DNA repository and a tissue repository that goes back 80 years…We need help on this too, and I think we could also offer some technical support, and we'd just like to join you on this."
– Dr. Winkenwerder

"VA would like to be at the table too." – Dr. Kolodner

"There will be a workgroup…Its relationship with AHIC is the question. I'm going to [accept] the offers of help from VA and DoD, and we're going to be proceeding on this. And so, the question is: do we manage it inside AHIC, or do we just instruct them to say, 'keep a very close eye of what's going on at AHIC, because victory is defined as standards that can be harmonized with everything else that AHIC is

doing.' The question is a matter of workload here at AHIC in terms of being able to manage workgroups." – Secretary Leavitt

Public Input Session

No members of the public came forward to offer comments during the public input session.

Closing Remarks

Before adjourning the meeting, Dr. Brailer thanked Community members for their attendance and participation, reminding them that the next AHIC meeting is scheduled for October 31, at 8:30 a.m.