The Community

American Health Information Community

November 13, 2007
10:30 a.m. - 3:30 p.m. [Central]

Sheraton Chicago Hotel & Towers
301 E. North Water Street
Chicago, IL 60611

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A G E N D A

17th Meeting of the
American Health Information Community

November 13, 2007

10:30 a.m. - 3:30 p.m. [Central Time]

Sheraton Chicago Hotel & Towers / Cityfront Center, Ballroom 6

301 East North Water Street, Chicago, IL 60611

10:30 a.m. **CALL TO ORDER**

- *Secretary Leavitt*

10:35 a.m. **Introductory Comments**

- *Secretary Leavitt*
- *Chairman Kevin Martin, Federal Communications Commission*

10:55 a.m. **Comments**

- *Kerry Weems, Vice Chair, Acting Administrator, Centers for Medicare and Medicaid Services*

11:05 a.m. **Comments**

- *Robert M. Kolodner, National Coordinator for Health IT*

11:15 a.m. **NHIN Trial Implementations**

- *John Loonsk, Office of the National Coordinator for Health Information Technology*
- *Liesa Jenkins, CareSpark*
- *Margaret Gunter, Lovelace Clinic Foundation*

12:00 p.m. **CCHIT Update**

- *Mark Leavitt, Certification Commission for Healthcare Information Technology*

12:15 p.m. **Health IT Physician Adoption Survey**

- *Karen Bell, Office of the National Coordinator for Health Information Technology*
- *Jane Sisk, National Center for Health Statistics,*

Centers for Disease Control and Prevention

- *David Blumenthal, Partners HealthCare*

12:45 p.m. **BREAK**

Presentations on Re-Uses of Health Data

1:30 p.m. **Advancing the National Framework for Uses of Health Data**

- *Don E. Detmer, President & CEO, AMIA*
- *Charles Safran, Harvard Medical School, CDC*

2:15 p.m. **Enhanced Protections for Uses of Health Data: Recommendations to HHS on a Data Stewardship Framework**

- *Simon Cohn, Chair, National Committee on Vital & Health Statistics*
- *Justine M. Carr, Co-Vice Chair, Work Group on Uses of Health Data*
- *Harry Reynolds, Co-Vice Chair, Work Group on Uses of Health Data*

3:00 p.m. **Public Comment**

3:15 p.m. **ADJOURN**

Draft Meeting Report

American Health Information Committee
September 18, 2007

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within 10 years, held its 16th meeting on September 18, 2007, 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 continue discussion of steps toward ways to achieve its 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 focused on: (1) a Nationwide Health Information Network (NHIN) trial implementation update, (2) a report on clinical decision support, (3) recommendations from the Population Health/Clinical Care Connections Workgroup, (4) a presentation from the State Alliance for e-Health, (5) a discussion on the AHIC successor, and (6) findings from the *Enhancing Data Quality in EHRs* Report.

HHS Secretary Michael O. Leavitt chairs the Community. 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 two-year terms.

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

Call to Order

Joining Secretary Leavitt around the table were:

Robert Kolodner, MD, National Coordinator for Health Information Technology

Kerry Weems, Acting Administrator, Centers for Medicare and Medicaid Services, and Vice-Chair, AHIC

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

Howard Isenstein, Vice President of Public Affairs and Quality, Federation of American Hospitals (Mr. Isenstein represented Charles N. (Chip) Kahn III, President of the American Federation of Hospitals)

Dan Green, Deputy Associate Director, Office of Personnel Management (Mr. Green represented Linda Springer, Director of the Office of Personnel Management)

Craig Barrett, PhD, Chairman of the Board, Intel (Dr. Barrett was represented by Brian DeVore, Industry Affairs Manager for Intel's Digital Health Group, for part of the meeting)

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

S. Ward Casscells, MD, Assistant Secretary for Health Affairs, Department of Defense

Kevin Hutchinson, CEO of Surescripts

Lillee Gelinas, RN, MSN, FAAN, Vice President and Chief Nursing Officer of VHA, Inc.

Robert Cresanti, Under Secretary of Commerce for Technology, U.S. Department of Commerce

Nancy Davenport-Ennis, founder of both the National Patient Advocate Foundation and the Patient Advocate Foundation

Jorge Ferrer, MD, Office of Health Informatics & Information Resources (Dr. Ferrer represented Gail Graham, Director of Health Data at the Department of Veterans Affairs, Veterans Health Administration)

Steve Lampkin, Vice President, Benefits, Compliance, and Planning, Wal-Mart (Mr. Lampkin represented John Menzer, Vice Chairman, Wal-Mart)

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention

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

Introductory Comments

Secretary Leavitt opened the meeting by welcoming Community members and other participants. He recognized two special guests at the meeting—Governors Phil Bredesen of Tennessee and Jim Douglas of Vermont, who provided the Community with recommendations from the State Alliance for e-Health during the proceedings. The Secretary applauded the State Alliance for undertaking the difficult task of developing commonality across state lines on different state laws, particularly regarding the complex and sensitive issues of privacy and security in health care. He reminded Community members that at the last meeting, he emphasized the following three activities he hopes to have accomplished before the current administration ends: (1) complete the agenda that has been laid out for the current AHIC (also referred to as AHIC 1.0), (2) create and implement AHIC's successor entity (also referred to as AHIC 2.0), and (3) secure the connection between AHIC 2.0 standards and the ongoing flow of how health care is financed, practiced, and organized.

The Secretary commented that the NHIN will soon implement awards related to contracts for trial implementation. These awards will go to state and regional health information exchanges (RHIOs) that will begin to form the "network of networks" that has been previously discussed within the context of the NHIN. Both the Office of the National Coordinator (ONC) and Centers for Disease Control and Prevention (CDC) will be making awards that will build on the progress of the NHIN and support biosurveillance and public health reporting. Secretary Leavitt emphasized that a sustainable business model for this network of networks is not one of a steady stream of CDC and HHS grants. These grants have to be connected to the overall financing vehicle of the industry; these grants will be an important step in starting that process.

Secretary Leavitt announced that Kerry Weems has taken over as Acting Administrator at the Centers for Medicare and Medicaid Services (CMS). In addition, Mr. Weems has been appointed as the new Vice Chair of AHIC.

Before moving forward with the agenda, Dr. Kolodner, announced that Deven McGraw, Chief Operating Officer at the National Partnership for Women and Families, will be serving as the new Co-Chair of the Confidentiality, Privacy, and Security Workgroup (sharing that leadership position with Co-Chair Kirk Nahra). Dr. Kolodner also noted that the ONC has issued a contract to the Institute of Medicine (IOM), which has been hearing testimony and evaluating AHIC's first cycle of standards. The IOM will report back to the Community at the next AHIC meeting, which will be held in Chicago on November 13, 2007, in conjunction with the annual meeting of the American Medical Informatics Association.

Approval of July 31, 2007, Meeting Minutes

Minutes from the July 31, 2007, AHIC meeting were distributed, reviewed by Community members, and approved unanimously with no changes.

NHIN Trial Implementation Update

Dr. John Loonsk, Director of ONC's Office of Interoperability and Standards, discussed the status of the NHIN, describing the Network as an effort to advance services for the secure exchange of health information. The NHIN has been looking to support and advance health information exchange (HIE) entities, which are central to building the "network of networks," that will comprise the NHIN. These entities are critical for moving data from and to EHRs and PHRs, supporting longitudinal patient records, and advancing quality initiatives that are based on clinical data (and, potentially, claims data).

From a process standpoint, the work of the NHIN has been laid out in three main steps. The first step was last year's prototyping work. The second step involves trial implementations, which will finish the specification of the work needed to be done this round. These specifications will, by the end of the year, demonstrate HIE and the associated core capabilities needed to move data between jurisdictions. Efforts also will be made to establish the market for these HIE services nationally so that an EHR, hospital, or ambulatory care setting can access network services and take advantage of economical support for this type of HIE. The third step is production. Dr. Loonsk and colleagues are driving toward reaching production services for the NHIN in the 2009/2010 timeframe. He explained that there was a very encouraging response to a previously issued Request for Proposals, with a very strong applicant pool of HIEs. As many of these HIEs as possible will be brought into what is being called the NHIN Cooperative, which will continue moving HIE efforts forward.

The NHIN Cooperative will finish the specifications, develop the data exchange, and support agreements. These agreements are complicated, involving not just one-to-one data sharing, but "one-to-many" sharing, with pooled activities in the Cooperative and the establishment of trusting relationships. These efforts represent the beginning of the foundation for the NHIN, and for many other activities. Approaches to helping these HIE organizations develop their business case and their sustainability are being pursued in a collaborative environment. Dr. Loonsk explained that within the two weeks following this meeting, two major announcements will be made that will involve a number of HIEs nationally that will be participating in forming the initial steps of the NHIN.

Discussion Highlights

"The first half of this first year will be focused on the additional specification work that needs to be done for these groups to work together. They will be focused on these core services and focused on the use cases that we also asked them to consider as part of their proposals. By the end of this year…we are actually going to demonstrate data exchange. So you will be able to, for example, in one jurisdiction, do a look up on a patient's record and have that not only find the information inside of that…but share that with another health information exchange, which will then find the information that's relevant to that patient there as well, to be able to move, to push data across and importantly, to be able to share summary records around a patient." – Dr. Loonsk

"This idea of a summary record moving between different providers, between providers and PHRs is going to be one of the key steps. It's very hard to standardize all the data in a health record, but now that we have a harmonized standard for a summary record, we think that can play a very important role." – Dr. Loonsk

"The summary record is touched on by a number of different needs, but it represents demographic data, it represents the diagnoses of active problems, and a series of other data; lab results, and medication history, and other data that comprise a limited but essential core of what the status of that patient is." – Dr. Loonsk

"We're going to be offering grants to a number of health information exchanges. You expect that at the conclusion of their work product, which you anticipate would be next year, we will actually have the capacity to demonstrate the exchange of data, based on standards that we have established among and between systems that have that are AHIC compliant, in essence?" – Secretary Leavitt

"Exactly right. And that that will be around some of these core activities, and around some of the activities, the more specific initiatives, such as biosurveillance, in conjunction with the CDC." – Dr. Loonsk

"We're at a very critical point here where we could develop a series of independent networks doing specific things to accomplish different activities. On the other hand, if we join together and push in the same direction through the framework of the Nationwide Health Information Network, we can establish and foster these health information exchanges. We can provide these core kind of capabilities, but also build a foundation for these other activities that will help move the entire agenda forward." – Dr. Loonsk

"If I have a PHR, and I don't want to have to populate that on an ongoing basis, ultimately, I could create a permission for my PHR to go out and seek information from various electronic health records that would be configured in a similar way. They could seek the data, bring it back, and populate my personal health record." – Secretary Leavitt

"One of the core services is to be able to say 'this is the address of my personal health record,' and for that to be managed, and so that becomes a target for where those data can be put for that patient…Having that point to deliver those data could be significant in fostering the consumer's access to information." – Dr. Loonsk

"You're in essence talking about really pushing the content to test the networks exchange. How much of it is actually computable data, clinical computable data?" – Dr. Ferrer

"We're pushing the overall structure. We are pushing some content, and not pushing others. And it is a difficult balance, because we do know that most of the information that's out there is in text form, if it's electronic at all. And so we need to accommodate that. And that's one of the things that the summary

record does. It allows for text to be exchanged. On the other hand, you do need to have agreement on some of the data about that text…so it's definitely an intermediate step…but an important step in terms of having a realistic target for a significant amount of information that can be processed, and a practical accomplishment in terms of sharing textual data as well." – Dr. Loonsk

"Today, there are over 40 EHR vendors that have the capability to import and export that data from one vendor to another. The CCR [continuity of care record], in fact, was used as a standard for the Dossier Project that Intel and Wal-Mart and others announced, which is a PHR-based product, that would allow that exchange of information. And it is exactly the information that consumers and providers need to have knowledge about what the critical data that a patient represents and presents to their clinician or provider at any point in time, at any location, for medical care that they need." – Dr. Henley

"I must commend the CCR effort for a couple of things. One, it really focused on a business need of identifying what should be in a summary record, and for advancing a standard in the context of the CCR that represents that. At the same time, what the Health Information Technology Standards Panel did was to recognize that that this has to work in a broader ecosystem of other standards. And in this case, this was one of the more contentious areas of discussion between the HL7 standards, including the CDA, and the CCR. And that's why this harmonization product of the CCD is such a significant step forward. It takes the scoping of what a summary record could be for electronic health records." – Dr. Loonsk

"The CCD, as a harmonization product, was a significant HITSP accomplishment, and I think we have yet to see the full impact of a summary record. It is not necessarily something that has a direct analogue in paper records, but it's one that we think is going to be very critical in moving the electronic health agenda forward." – Dr. Loonsk

"In terms of how you exchange that information, the current system, with no network, requires that there be understandings and arrangements between any receiving entity and any sending entity, and that gets very complex as you add the number of entities. The simplification that the NHIN is intended to do is to make that more widespread. And so right now, while there may be abilities to exchange the information between certain entities, this will broaden it in a more generalizable fashion, which is why we have been pursuing the NHIN." – Dr. Kolodner

"[Dr. Loonsk] mentioned the sensitive fragile nature that some of the HIEs are in now. Are you seeing a common business model bubbling up with these HIEs or are you seeing strengthening of these business models that exist for the HIEs? And if so, what is that business model that seems to be bubbling up?" – Mr. Hutchinson

"There are differences, it's fair to say, in terms of the HIEs that have shown that they're sustainable. And the first lesson, I think, is that they need to think of themselves as a business activity. And I think one of the lessons that HIE work has demonstrated, and other work that ONC has advanced, is that they need to be very practical about considering themselves a business to advance that need." – Dr. Loonsk

"Dr. Henley mentioned the capability exists for this kind of data exchange, but are there disparate systems right now that are actually exchanging data? Is this a promise that's being actualized, and if so, are there a couple of big users of that that we might be able to look at and understand the practical aspects of making these systems work?" – Dr. Gerberding

"There are a number, not a large number, but a number of health information exchanges that are actually exchanging data mostly at a regional level, some at a state level, nationally. What they exchange is sometimes different where they came from. Some came from the claims world, moving into the clinical data world. Some developed around a single institution that had a particular presence, and in regard to

informatics and clinical activities. They're different, but there are examples of practical data exchange that are being advanced. We're seeking to reinforce them with the NHIN, and to build on them, to meet other needs as well." – Dr. Loonsk

Report on Clinical Decision Support

Dr. John Glaser, Vice President and Chief Information Officer of Partners HealthCare, defined clinical decision support (CDS) as: (1) providing clinicians, staff, patients, and other individuals with knowledge and person-specific information, intelligently filtered at appropriate times, to enhance health and health care; and (2) encompassing computerized alerts and reminders, clinical guidelines, order sets, patient data reports and dashboards, documentation templates, diagnostic support, and clinical workflow tools. Several studies have documented the ability of CDS-enabled EHRs to reduce errors, improve care quality, and reduce costs. However, other studies have found limited or no impact or adverse impacts. Dr. Glaser explained that overall CDS adoption is low, due mostly to limited EHR adoption. Specific challenges to increased CDS adoption include EHR technical limitations, a lack of CDS adoption incentives, challenges associated with workflow integrations, and the difficulty of acquiring and managing CDS-based knowledge.

Dr. Glaser noted that an analysis commissioned by the ONC in collaboration with the Agency for Healthcare Research and Quality (AHRQ) developed a roadmap for clinical decision support that identified the following six strategic objectives for promoting CDS adoption within the broader framework of interoperable health information technology (HIT):

- Represent clinical knowledge and CDS interventions in standardized formats.
- Collect, organize, and distribute clinical knowledge and CDS interventions.
- Remove policy/legal/financial barriers and create additional support and enablers.
- Improve clinical adoption and usage of CDS interventions.
- Assess and refine the national experience with CDS.
- Advance care-guiding knowledge.

Dr. Charles Friedman, Senior Advisor to the National Coordinator for Health Information Technology, ONC, emphasized that CDS is cross cutting—five of the AHIC workgroups have explicitly expressed interest on this topic and the Personalized Healthcare Workgroup recently held a meeting that focused on the issue of CDS. In addition, the ONC has formed a public-private *ad hoc* planning group to address CDS and identify priorities; the Office also has commissioned a study by the Gartner Group to: (1) provide an overview of the current state of adoption of CDS, and (2) help the ONC understand how some of the chronically challenging aspects of CDS were being addressed in both vendor systems and the locally developed solutions within certain institutions. The Gartner Group was asked to address cutting-edge areas such as knowledge management, decision support modes, genetic/genomic knowledge, advanced CDS functions, studies on practice behavior, and shareable CDS content. The Gartner Group summarized that although the combination of deploying EHR solutions with CDS capabilities offers great potential, the near-term reality of deploying CDS is much more limited. The adoption of CDS is still in the early stages within hospital and integrated health care delivery systems. Current challenges include

limitations in: (1) the availability and acceptance of decision support content, (2) how to effectively engage but not overwhelm the clinical user, and (3) organizational readiness to support CDS.

The ONC also has been conducting a scan of CDS activities within federal agencies. To date, more than 25 individuals who play varying roles across eight federal agencies (HHS, AHRQ, CDC, CMS, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, Department of Defense, and Veterans Administration) have been targeted for telephone interviews. So far, 11 interviews have been completed, representing the four agencies. The agendas for these interviews vary and depend on each agency's role as either a funder, implementer, or facilitator of CDS. Interview questions include, but are not limited to, issues such as: (1) the level of priority for funding, or importance in the strategic plan; (2) examination of the usability and workflow; (3) interoperability of CDS tools; and (4) future steps planned for CDS funding, deployment, or policy development.

In terms of moving forward, ONC's *ad hoc* CDS planning group will continue to coordinate deliberations and recommendations across AHIC Workgroups and to identify problems that need to be addressed through a coordinated way approach. As a complementary effort to these activities, a government "collaboratory" co-sponsored by the ONC, AHRQ, and the Personalized Healthcare Initiative, is being formed. This "collaboratory" will build on ONC's government agency scan and focus on funding and implementation activities.

AHRQ Director Dr. Carolyn Clancy described her Agency's involvement in CDS activities. She explained that AHRQ's core mission is improving health care quality and value, noting that getting the right care to the right patient at the right time requires the right information for the right person at the right time. The Agency views CDS an important vehicle for disseminating the information coming out of the roadmap efforts it has undertaken with the ONC as well as for disseminating information related to the comparative effectiveness of treatments, so that patients can access information customized to their needs and preferences. In addition, AHRQ's involvement in the AHIC Quality Workgroup includes a strong focus on decision support, with the concept that EHRs will be linked with the capacity to provide clinicians with the correct information when they are making decisions.

Dr. Clancy noted that AHRQ's Health IT initiative has been ongoing since 2004 and includes a broad portfolio with a strong focus on exporting the lessons learned from ongoing AHRQ grants and demonstrations. In the area of diffusion of knowledge, AHRQ has a dual interest, in terms of both the practical use as well as assuring that content is updated and reliable. Dr. Clancy emphasized that filtering patient-specific information is an incredibly important tool for clinicians, because what is right for one patient may not be right for the next patient. Being able to provide patients with the appropriate information in real time about benefits and harms is an important advantage in moving forward. CDS is an important tool for improving quality and is not a "one size fits all" strategy. Prior research has shown that CDS works very well in some domains (e.g., in preventive care). CDS can even remind clinicians to initiate conversations with patients about end-of-life care planning. However, Dr. Clancy commented, CDS has not been found to be as effective in the hospital setting. Working with guideline developers is important; to that end, AHRQ has begun engaging these developers to that when their recommendations are written, they are in a format suitable for being imported into CDS. Dr. Clancy also emphasized that the workflow issues associated with CDS adoption are significant and have yet to be adequately addressed.

To help advance understanding of how best to address the issues surrounding CDS adoption, AHRQ will be announcing two new contracts focused on addressing clinical practice guidelines in the areas of further improvements in preventive care and improving care for people with multiple chronic illnesses. The initial thrust of these efforts will be in the ambulatory setting and will require certified HIT systems. Contract awardees will be working closely with stakeholders from across a number of communities and

will be forming important guidance for guideline developers, those who develop quality measures, IT vendors, and clinician professional organizations.

Discussion Highlights

"DSS is alive and well in a lot of areas, and a lot of complex areas. For example, if you look at a operating system from Microsoft, it's probably more complex than the human body in the health issues. I'm just wondering how much learning you're getting from the other areas where decision support systems have been used for many, many years, and very effectively?" – Mr. Barrett

"About two years ago, [Partners HealthCare] surveyed how many instances of decision support do we have here…and the answer is 26,000. And so now we have a problem of managing that base of knowledge and making sure that it's internally consistent, coherent, et cetera. So we recognize there are unique aspects to the patient-provider relationship and to health care and the medical domain. Nonetheless, I think it's a fair point that we leverage, often, the work of other industries, and the complexity, and the solutions that they come up with." – Dr. Glaser

"People have attacked this issue in a very systemic fashion for very complex systems to do decision support. And we ought to be importing as much of that from the industrial world into this area as possible." – Mr. Barrett

"With these grants, we've got to figure out how to do clinical decision support at the most frequent point of care, which happens to be in small and medium-sized practices, and not in integrated systems, and not in hospitals…So I hope these grants and these projects, as they move forward, will take that environment into consideration and make sure that those practices and those sites are part of this." – Dr. Henley

"We couldn't agree with you more, and two communities that we see as quite vital are physicians in small and medium sized practices, and as you know, we sponsor a research network of those folks with reach to over 7,000 practices. So clearly, we will be hearing from them and including them, as we move forward. And I think the other site that is of great interest to the nation is actually community health centers. And we have been working very closely with them as well." – Dr. Clancy

"I just think this consumer-driven area is getting ready to explode. Do you have a sense of what are the most reliable sources of information? What can we do to help [patients]? Because in my practice, the errors that the patients make are not trivial. They're numerous. Because after all, they're not trained. And the doctors don't have time to hear about it. So that we have a gulf still, and I'm wondering how the patients are bridging that gulf…Is there any way this body can help the patients get good information?" – Dr. Casscells

"I can only stress the importance of the increasing amounts of information for patients that are appearing on Web sites of the various NIH Institutes and the other sites that the NLM, itself, is maintaining. I can't cite you the latest statistics on the use of those…but the use of those, the ratings of those, the feedback from patients that many NIH agencies are receiving from those has been extremely positive." – Dr. Friedman

"I think the fear of consumers is that they want to have the information around comparative effectiveness, but they do not want an independent third party determining for them what is the most effective protocol to be used. So there is some degree of concern around what relationship will their health plans have with that particular information, and will the health plan engage, in a positive way, the consumer, in reimbursement decisions around the most appropriate protocol to be used. And that is a major concern for consumers." – Ms. Davenport-Ennis

"Consumers will often go to the Internet; they will often get flawed information. They may look at television at a direct consumer ad. They may, again, walk into a physician, and they may be demanding a service or a support good that is not appropriate for their treatment protocol. So from the point of view of consumer empowerment, I think we will look at great interest with how you will move forward with the comparative effectiveness, and how the patients can intersect with that in a very positive way."
– Ms. Davenport-Ennis

"Understanding that the content—and so that any clinician or patient knows that the content is valid, and reliable, and up to date—is going to be incredibly important. And that gets into a whole array of issues that I don't want to distract us with right now, except to assure you that it's very much on our minds."
– Dr. Clancy

"At least in our state [Indiana], about 60 percent of the individuals suffering from chronic illness are suffering with either primary or secondary diagnosis of mental illness. And we have not made the progress in this group, on a development of an EHR for mental illness. And that will be a big problem, as we try to deal with chronic illnesses, because they are very connected to mental illness, sometimes causal. Sometimes one causes the other. But it's a factor, and I think we need to focus on that." – Mr. Roob

"We have supported a fair amount of work, which is largely descriptive in nature, that confirms everything that you're just saying, that your costs are higher and your outcomes are worse, if you are one of the people with multiple chronic illnesses. And one of those is a mental health diagnosis. Interestingly, I think the current drive for transparency is an important tool to improve value in healthcare. It's going to be a very important factor, motivating the development of better tools for people with mental health disorders. I'm at least optimistic on that front, because then, I think that gives us the important content that we're going to need." – Dr. Clancy

"There will come a point where clinical decision support and the payment system, both public and private, begin to collide, and then interdigitate. I'm wondering what the timeline looks like for that. We've heard from a number of people that the payment system can be a great motivator. As you look at your roadmap, when does that collision begin to occur, and how do we manage it? As you look at your demonstrations, have you included the effects of the payment systems?" – Mr. Weems

"I think payment will be potent rocket fuel here. And I do think that the clear intersections are going to be around which measures are used or required for accountability. So what are we acquiring from hospitals, various long term care facilities, physicians practices, and so forth. So getting those measures right is going to be very important. But at the same time, it's not just about more, better, faster report cards. It's also about how do we actually get the care better. So that's where, I think, the real potential is." – Dr. Clancy

"Clearly, a lot of physicians are moving fast to participate in the physician quality reporting initiative from CMS, and I think there is a huge amount of interest in a variety of private sector led pay-for-performance initiatives. Having said that, at the moment, there is not a huge incentive in any of these on the table. That's not to disrespect CMS' efforts by any stretch of the imagination, but right now, many small to medium-sized practices don't have the infrastructure or the capacity to participate. It's just not worth their while…So I would guess it's going to take the next 3 to 5 years to see this at a very big scale."
– Dr. Clancy

"Right now, our peak primary care docs have ten percent of their income at risk, based on these types of contracts; one of which is related to the drug spend, one of which is related to the radiology spend; both of which go right at the heart of decision support to guide choices, in both of those cases. In the next

round, which we're gearing up for, we may move from 10 to 20 percent. We're dealing with actual management per established hemoglobin A1C levels, and you can see all kinds of decision support opportunities to help our doctors meet those goals, both for care reasons, but increasingly for financial reasons. So I think there are pockets—and we happen to be an example, but we're not the only one—where that coming together is occurring. And it has a huge effect on EHR adoption and the use of decision support, because the incentive just went up to a different level." – Dr. Glaser

"I think the collision is actually around the small and medium-sized practices where the question of timing is if you are giving some financial incentives for better improved care that's higher value, will those incentives be enough for those physicians to invest in the infrastructure that they're going to need to actually be able to participate effectively? And I think that's an open question." – Dr. Clancy

Population Health/Clinical Care Connections Workgroup Recommendations

Before starting her opening remarks for this session, CDC Director and Population Health/Clinical Care Connections (PH/CCC) Workgroup Co-Chair Dr. Julie Gerberding introduced Dr. Les Lenert, the new Director of CDC's National Center for Public Health Informatics. Dr. Gerberding noted that Secretary Leavitt's four pillars of value-based health care translate well into the realm of public health. For the first time, the Association of State and Territorial Health Officers, the National Association of City and County Health Officials, and the CDC have developed a single strategy for their future work supporting health system transformation.

PH/CCC Workgroup Co-Chair Dr. John Lumpkin of the Robert Wood Johnson Foundation reminded the Community that the Workgroup's broad charge is to make recommendations to the Community that facilitates the flow of reliable health information among population health and clinical care systems necessary to protect and improve the public's health. The specific charge of the Workgroup is to make recommendations to the Community so that within 1 year, essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems can be transmitted in standardized and anonymized format to authorized public health agencies within 24 hours. Dr. Lumpkin also explained that governmental public health structure includes approximately 3,000 health departments at the local level, 57 state and territorial health agencies, and a handful of federal agencies, with CDC taking the lead (at least from the perspective of the many of the programs that state and local health agencies have to implement).

Dr. Lumpkin then presented the following recommendations of the PH/CCC Workgroup:

- **Recommendation 1.0 (Overarching):** CDC, in collaboration with AMIA and the PHDSC, and working with schools of public health and other informatics fellowship programs should enhance ad promote the public health domain of the AMIA 10X10 initiative, the Partnership for Workforce Public Health Informatics Training, and similar programs to advance public health informatics workforce development. The public health informatics competencies developed by the University of Washington and CDC, and other applicable work, should be used as a basis for this initiative.

- **Recommendation 1.1 (Overarching):** HHS should work with CDC, HRSA, CMS and other federal agencies to include language in contracts, grants, and cooperative agreements that ensures that:
  - Funds from a variety of programs can contribute to an informatics capacity and technical architecture that invests in advancing information systems and IT infrastructure required to support their implementation and interoperability. This language should explicitly include

systems and infrastructure that support public health labs, registries, surveillance systems, as well as other systems that receive data used for population health purposes.
  - In order to meet the requirements of the Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs, funds can be used for technical support, to cover the cost of on-going system maintenance, and for updates and enhancements to provide functionality and adhere with interoperability specifications.
  - Metrics should be collaboratively developed with state and local public health partners to assess the ability of public health information systems to investigation and response. These metrics should measure and monitor interoperability, usability, flexibility, quality, completeness and timeliness of data, as well as system functionality to support: outbreak and event management, countermeasure allocation, tracking, distribution and administration, integration of laboratory information, and bi-directional exchange of data across clinical care and public health.

- **Recommendation 2.0 (Outbreak and Event Management):** By March 2008, CDC with ASTHO, NACCHO, CSTE, APHL and other appropriate groups, should update and refine criteria for functionality, security, and interoperability of systems that support outbreak management at local, tribal, state, and federal levels. The criteria should:
  - Be minimal but sufficient to support the needs of managing complex outbreaks.
  - Ensure interoperability with other systems (such as other outbreak systems, laboratory information systems, systems that manage countermeasures, fatality management tracking systems, monitoring tools for quarantine and isolation, EHRs, and surveillance databases).
  - Provide a starting point for a freely distributable software implementation and ongoing development and maintenance.
  - Use as a starting point the AHIC Use Cases, the HITSP Interoperability Specifications, and PHIN Functional Requirements for Outbreak Management.

- **Recommendation 2.1 (Outbreak and Event Management):** CDC, with input and assistance from state and local public health should support the development and testing of software systems designed to manage public health investigations (e.g., CDC Outbreak Management System, state or commercially-developed systems), including identification of important exposures, laboratory diagnostics, contact tracing and indication for preventative countermeasures such as infection control, isolation, quarantine, prophylaxis or treatment.
  - Facilitate the development of standards, shared architectural components and implementation guidance for possible and confirmed case exchange and make available to public health partners by October 2008.
  - Develop, or commission the development or acquisition of, and support the maintenance of a freely distributable software implementation to support local, tribal, state and national agencies to manage outbreaks. The criteria for this software implementation would be based on the collaboratively defined criteria defined in recommendation 2.0 above. This software should be available no later than March 2009.
  - Develop test sites to measure the level of interoperability between EMR, LIS, surveillance and software developed for outbreak management.

- **Recommendation 3.0 (Laboratory Response):** By June 2008, CDC in collaboration with APHL, CSTE, ASTHO, NACCHO, and other appropriate organizations should identify any types of data, codes and relationships needed (beyond those specified in the HITSP EHR/Biosurveillance lab result message), necessary to support:
  - Test orders to and result reporting from public health labs.
  - The coding of public health conditions in the HITSP lab message.
  - Result reporting of veterinary and environmental data.
  - Unambiguous linkage of laboratory data to clinical and public health records.

- **Recommendation 3.1 (Laboratory Response):** HHS in conjunction with state and regional health information exchanges, public health and clinical laboratories, should develop the infrastructure and architecture for unambiguous unique identification of medical service providers in association with the NHIN initiative. This should include ensuring that registries of medical service providers exist and that registry lookup capability is developed and available to laboratories for routing laboratory data back to the originating requestor, and to other appropriate parties to support national electronic laboratory data exchange.

- **Recommendation 3.2 (Laboratory Response):** By October 2008, HHS, in collaboration with APHL, private laboratories, and other federal laboratories, should establish regional or national capabilities to receive and route laboratory results to all appropriate recipients simultaneously.
  - Define the processes and approaches for consolidated receipt and routing of laboratory results.
  - Support a proof-of-concept demonstrating an efficient regional or national mechanism for the acquisition of laboratory test order information as well as dissemination of test results to appropriate public health and clinical care providers.

- **Recommendation 4.0 (Countermeasure Allocation, Distribution, Administration):** By March 2008, CDC with ASTHO, NACCHO, CSTE, APHL, FDA, and other appropriate groups, should update and refine criteria for functionality, security, and interoperability of systems that support countermeasure apportionment, tracking, distribution and administration at local, tribal, state and federal levels. The criteria should:
  - Be minimal but sufficient to support the needs of managing countermeasures during a response.
  - Ensure systems are interoperable with other systems (such as outbreak systems, vendor managed inventories, point of distribution software, fatality management tracking systems, monitoring tools for quarantine and isolation electronic medical record (EMR) and surveillance databases).
  - Provide a starting point for a freely distributable software implementation and ongoing development and maintenance.
  - Develop a series of detailed use cases that support interoperability for countermeasure and response. Use as a starting point the AHIC Use Cases, the HITSP Interoperability Specifications, and the PHIN Functional Requirements for Countermeasure Response and Administration.

- **Recommendation 4.1 (Countermeasure Allocation, Distribution, Administration):** By April 2008, CDC should convene a meeting to include representation from clinical partners, manufactures, and distributors to understand the resources that are available in the private sector and develop strategies to exchange information on the availability of and demand for resources at any given time.

- **Recommendation 4.2 (Countermeasure Allocation, Distribution, Administration):** CDC with HHS, and through the national agenda, should support the harmonization of standards and development of implementation guidance and shared architectural approaches for the exchange of countermeasure information. These products should be made available to public health partners by December 2008. Following the implementation of countermeasure response solutions, support the establishment of test sites to measure the level of interoperability with electronic health records, outbreak management systems, registries, and surveillance systems.

- **Recommendation 4.3 (Countermeasure Allocation, Distribution, Administration):** By June 2008, HHS should facilitate the development of national administrative or legal approaches for routine and emergency inter-state data exchange of countermeasure and immunization information.
  - Address business propriety data concerns of relevant commercial supply chain entities.
  - Develop a blanket agreement to provide federal support for sharing of data and resources when it is necessary.

- Communicate with and educate hospital risk management staff and privacy and confidentiality officers in clinical care settings to alleviate concerns about public health access to clinical data.

- **Recommendation 5.0 (Automated Integration With Registries):** By March 2008, CDC should convene a group of public health registry experts such as immunization, cancer, trauma, donor, chronic disease, and others to determine how the established capabilities and unique attributes of existing registries could be used in public health response.

- **Recommendation 5.1 (Automated Integration With Registries):** By October 2008, CDC should develop a communication plan based on discussion and recommendations from the March 2008 meeting referenced in Recommendation 5.0. The overall goal of this plan is to communicate to public health officials the available registry resources for use during an emergency response.

Discussion Highlights

"To actualize the full vision of what we are talking about here, this is not going to happen fast. This is a tremendous investment and a tremendous transition." – Dr. Gerberding

"It would be interesting with the recommendations, to kind of see a broad-brush timeline of when partial implementation, full implementation would occur. The words are great, but just from a layman's point of view, I look at this, I can't figure out how fast you're going to get there, and what capability you'll have in any given timeframe." – Mr. Barrett

"The first step is have some guidelines and standards for interoperability...having a standard that we can all build to is a major innovation that needs to be in place." – Dr. Lumpkin

"[At the] local level, the dollars that are spent at a local level on average are roughly one-third generated at the local level, one-third at the state level, and then one-third state funds that are flowing in. The decisions to build these systems go beyond just a national decision. Fifty states, the district of Columbia and six territories have to also decide to allocate funds...What we can do at the federal level is create the conditions that enable that national system to be built." – Dr. Lumpkin

"One of the lessons that we're learning is that it's very difficult for us to build this system from the inside out. It's hard to change what you have and morph it into what you wish it would be, and where we could have some conversations that would benefit from people like you is to look at this from the outside in. How can we invent this new approach to things, using the state-of-the-art tools, state-of-the-art data systems approaches, and not necessarily just try to improve the way we've always done things?
– Dr. Gerberding

"And one of the strongest incentives is, I think, going to be the same thing that's incentivizing the change in the healthcare delivery system, if we realign the payment system to support what we want to accomplish, we'll be far more likely to move things in that direction." – Dr. Gerberding

"You have collaboratively designed a big vision here, and there is need for that, and I think we could all agree this is a very important and positive proposal. [Mr. Barrett] has pointed out the need for a timeline. I would also point out the need for us to figure out how much this is going to cost, and how it will integrate with other HHS priorities, and how you split the cost up among the various participating entities, because there will need to be a shared burden with the states and locals and so forth." – Secretary Leavitt

"This big vision needs to link into the other activities of AHIC…It seems to me we need to take these recommendations now, and go back and lay a timeline against them, and lay a budget framework, and

begin to think through how we would execute toward this vision…before we can accept them as recommendations, I think we ought to go back and now put some HHS time into what's this going to cost, and what's the timeline, and what has to happen next so there is a perk chart and a budget applied to it." – Secretary Leavitt

"If you currently add up the aggregate investment that the federal government is making in these component parts right now, it's substantially greater than you would realize, but it's parsed out into a number of categorical silos, and in order for us to actualize the benefit of that investment, we have to rethink the way we apportion the resources in our grant. That's going to take some legislative support as well as appropriation support." – Dr. Gerberding

"This is very big thinking, and it's good thinking. And it's the way the world ought to work. But it is going to require, I think, that we flesh the plan in with the critical path and a timeline. It will require buy-in from Congress…I would like to suggest that we receive this report with both optimism and gratitude, and that we need to revisit it with additional work that can now be done in terms of budget execution and some idea of what it's going to take to actually implement it." – Secretary Leavitt

"From our standpoint, as a large employer, and obviously as a large retailer, directionally we believe this is on target. We do agree that this is the vision that we should all have. And that we should move faster rather than slower. It doesn't have to be perfect to get something started…specifically, we're interested also in the funding issues and how this stuff is going to be paid for. We're interested in the timeline." – Mr. Lampkin

"This is the kind of thing that on the Defense side, we would want to have a component failure analysis to go through a checklist, if this piece is not delivered in a timely way, what will the backup strategy be?" – Dr. Casscells

"In terms of getting people's attention and sense of urgency in this, I think it would be good to state, in plain English, the deliverable…The cost will be a big number, in response to what Secretary Leavitt has correctly mentioned. So I think it's important to know that there's some very big deliverables at the end, and that if you get part way there, there is some deliverables, and that there is no single component that is going to unhorse this thing, and that there are strategies for getting it done." – Dr. Casscells

"This is probably more on target to the end goal of the AHIC mission than most anything we've heard before. And it needs to be done right or not at all. And I do believe that need for a fleshing out, before it's presented to AHIC for a final vote, in terms of where the money is going to come from, what's going to be done first." – Mr. Green

"I'd like to invite this topic as part of our agenda in November, and if not November, in January, depending on how long it takes. I am prepared to initiate some discussions at HHS among the various operating divisions of HHS. There are many implicated here to help, and suggest that rather than accept it today, I'd like to suggest it be on our agenda, with the items that have already been articulated." – Secretary Leavitt

"This clearly has to be integrated with what we're working on with electronic medical record standards. It clearly has to use the same protocol standards, platforms. But this is a project almost as big in parallel." – Secretary Leavitt

Following these discussions, Secretary Leavitt received the recommendations from the PH/CCC Workgroup, which will be further developed and presented at a future AHIC meeting.

Progress of the State Alliance for e-Health

Secretary Leavitt introduced Governor Phil Bredesen of the State of Tennessee and Governor Jim Douglas of the State of Vermont, Co-Chairs of the National Governors Association's State Alliance for e-Health. Governor Bredesen explained that the State Alliance for e-Health was charged with analyzing major issues that states should consider as they evaluate at electronic information interchange. The Alliance has met three times in 2007; another meeting will be held in October of this year. Three task forces have been formed:

- The Health Information Protection (HIP) Task Force deals with issues of privacy and security of health data.

- The Health Care Practice (HCP) Task Force is addressing primarily issues of health professional regulation related to information exchange.

- The Health Information Communication and Data Exchange Task Force is addressing the ways that publicly funded programs contribute to and interact with HIEs.

Governor Bredesen explained that two of the three task forces have provided the Alliance with preliminary recommendations for state action; the Alliance accepted these recommendations at its August meeting (these recommendations were distributed to Community members for their review). As additional recommendations are accepted, they will be consolidated with existing recommendations, as appropriate, and prioritized in terms of critical state actions. He emphasized that the applications of information technology to health care can be overwhelmingly positive. The health care system desperately needs the application of those technologies; the challenge lies in determining how best to accomplish this. Governor Bredesen commented that it is time to move beyond grants for state support and move towards actual utilization of these technologies in the health care setting. Some measure of central direction, from those involved in AHIC, is needed to facilitate moving this work from laboratories and committees out into the real world.

Governor Bredesen outlined three actions that can be taken to move these efforts forward: (1) simplifying (e.g., simpler and more stable protocols for standardization), (2) reducing the size of the landscape and concentrate on a specific area, and (3) determine how best to integrate information technology into the mainstream day-to-day practice of medicine, moving beyond the early adoption phase.

Governor Douglas noted that there are many technological possibilities in the health care field that are there for the grasping, but provider, political, and public acceptance needs to be ensured to make them a reality. The Alliance's task forces are addressing some of those issues in more detail. For example, the HIP Task Force is addressing the fact that respecting the health information of the American people is paramount, but even among public institutions (and between states), there are variations of privacy standards. In addition to the Health Insurance Portability and Accountability Act (HIPAA), there are specific standards for HIV/AIDS information, management for mental health information, and so on. Some level of consistency is needed so that progress can be made. The HCP Task Force is tackling issues related to the increasingly mobile U.S. society. Although there is greater uniformity among states in terms of licensure of professional personnel, licensure in an electronic world needs to be better developed. For example, if a consulting physician is providing information from a distant point, is he or she required to be licensed in the jurisdiction where the patient is or not? The Alliance's Health Information Communication and Data Exchange Task Force currently is addressing the interaction of HIEs—because the federal government is such a major payer of health services in America, any system that is put in place must interact successfully with those efforts.

Governor Douglas noted that the State Alliance for e-Health is involved in a variety of other activities as well. In the area of e-prescribing, launched a pilot program has been launched in two hospitals in Vermont where prescription data are available in the emergency department so that residents of those communities, even if they have never come into that hospital in the past, will have their prescription information available for the emergency room attendants to have and understand when treating an emergent case.

Governor Douglas also reminded the Community that e-health is a way of achieving higher quality care, greater patient safety, and more affordable coverage. He noted that some recent international studies have shown that American people are satisfied in many cases with their health care and its quality. However, the United States is not doing well in many comparative statistical comparisons (e.g., cancer rates, infant mortality, obesity, cost, etc.). The increased percentage of America's gross domestic product that goes to health care is going to be a major impediment to economic progress over time, unless this is controlled. e-health can help to contain these costs while improving quality and patient safety.

Discussion Highlights

"There is a lot of work within this organization at the state level, a lot of Workgroups that are focused on coming with approaches to security and privacy. Where do you see commonality between federal and states so we can get to a common approach across the country on security and privacy?"
– Mr. Hutchinson

"We have to have some commonality. We have to have public acceptance…most Americans, in this 21st century high-tech, interactive world, are beginning to understand that if you buy financial service products over the Internet now and feel comfortable with that, then it's probably okay to have your prescription history online in a secure system. So I think public acceptance continues to be the key to our success. But again, we need some consistency among states, among programs of the federal government, in order to ensure that this is truly effective." – Governor Douglas

"There are a number of experiments out there where when people had the opportunity to opt out, almost universally they opted in. So I think you probably can provide for that one or two percent who have got deep concerns in this in a way that does not undermine the basic structure of what it is you're trying to do. And I think it's also important to remind people that it's hard to imagine something less secure than the paper record, which is in your doctor's office right now." – Governor Bredesen

"There are currently I think 30 some odd states who have adopted privacy regulations that are more stringent than the far from simple federal standard. One of the dilemmas that we face is how to simplify that process. Do you have any thoughts about how best to go about it? Do you have any sense of the willingness of the states to begin to either subordinate their role to the national government or to begin to work with interstate compacts, or uniform laws, or any thoughts about how to solve that?"
– Secretary Leavitt

"I think you get these things done when you've got something to offer. If you just try to change the privacy laws by mandate from the Congress or something, you will get enormous resistance.…It's going to take some leadership. There has got to be some central direction. It's not going to happen by osmosis." – Governor Bredesen

"There are some recommendations from our Health Information Privacy Task Force that are in your packet that address that issue. One recommendation is that the President might direct you, sir, to designate a single national certification body such as CCHIT, to certify electronic record and network

system components, and that the state association or the National Association of State CIOs work with that body to establish uniform standards." – Governor Douglas

"Many of our Blue plans are working within their communities and with their providers to put e-prescribing out into the field to educate physicians, to help them through subscription fees and tools to do this. And we're beginning now to see the results back from the return on the investment…some of the providers have reported back they have reduced time on the phone with pharmacies by up to 92 percent, because of these tools…So we're certainly beginning to see the return on the investment and are very supportive of that, and I know CMS is also moving forward in that area." – Ms. Handelman

"Another huge challenge can be in e-prescribing, as well as we try and advance more telehealth and electronic health records, is the practice of medicine across state lines. And I know you have a Workgroup that's looking at this. It's been an issue that's been talked about for quite some time with many models and different ideas put out there. Do you see some commonalities or areas of resolution coming forward to address some of those challenges, in addition with privacy and security, the practice of medicine varies by state, and how we might be able to overcome some of those barriers as well?" – Ms. Handelman

"What we were hoping to have ultimately [is] some model legislation that states could look at, that would correspond, enable them to either have bilateral agreements or have some approach in which you could have, in essence, a national license. That still leaves a lot of unsolved problems in the area of professional liability, where states have got different policies and standards, and standards there, but I think it's something that they're trying to work through." – Governor Bredesen

"Professional licensure is, of course, historically a state responsibility…The National Federation of Medical Boards has adopted a common application form. Not every state, I think, has adopted it, but we need that kind of uniformity. We need online applications for professionals to get licenses if they need them fairly quickly in other jurisdictions. But we need to engage all of those officials to provide for greater commonality of forms and practice." – Governor Douglas

"What can we do, or what do you recommend we can do to really get after this licensure issue? We heard previous testimony here at AHIC where some of the licensure issues are wrapped up in the business models and the revenue stream of some of the boards. And I greatly appreciate that. But this would seem to be a greater public good issue than a business model issue." – Ms. Gelinas

"One thing that motivates state officials to work together is the threat of federal preemption, and that's occurred in some financial services in terms of licensure of securities dealers over the recent past, and I don't recommend that at all. I believe that states can work this out. But they need to understand the importance in a mobile society of developing more common forms and procedures in order to accommodate the practice that's so mobile these days." – Governor Douglas

"One of the worries I have is that the energy you're developing and the energy we're developing will dissipate, either through the change of governments, and we've got to get this into a unified system. So one of the things I'd like to urge would be that as you continue your effort, that somehow we harness up the efforts of the states and begin to integrate it into this one place where we can simplify through the creation of standards." – Secretary Leavitt

"I believe that a set of reasonably simple and stable standards is what it will take to allow this thing to move forward. The private sector, whether it be the nonprofit sector in universities or whatever, have got to have that stable environment to work and to be innovative and to put these kinds of things together." – Governor Bredesen

"We have now said in the future, 'if you want to get paid, at some point in the future you're going to have to be using an AHIC certified or a CCHIT standard.' The point I want to make is that we're in agreement…and our effort here is to devise a series of simple standards that there is agreement on. Right now, we operate in a world where people are free to set their own standards up, to create a client or to solve a need, and it proliferates their comparative advantage, but it complicates the world every time they do it." – Secretary Leavitt

"On this concept or topic of the simplification and simplifying, I think a perfect example of where coordination across federal and states is, in fact, electronic prescribing. Now, the timeline we're not so excited about because of the time it's taken to get to where we are, but now we're at a tipping point, where you're looking at adoption…I'm happy to report now…in all 50 states, in fact, it is legal for electronic prescribing, including the District of Columbia as well. Alaska was the final state that just passed its new regulations. So all laws and all regulations have now been cleared across all states." – Mr. Hutchinson

AHIC Successor Update

Dr. Kolodner displayed a timeline to highlight the transition between AHIC 1.0 and AHIC 2.0, noting that AHIC 2.0 is expected to come into being in March/April of 2008. He reviewed a brief list of activities that have occurred since the last AHIC meeting, including:

- Publishing the AHIC successor white paper
- Holding a comment period on the white paper through September 10, 2007
- Publishing the grant Notice of Funding Availability
- Requesting letters of intent by September 15, 2007
- Conducting a public meeting
- Presenting the succession strategy and introducing the grant
- Holding a technical assistance session
- Presenting alternatives for key successor design aspects
- Presenting details regarding the grant process.

In terms of next steps, the Planning Group will be funded, and then within four to five months, the Planning Group will incorporate AHIC 2.0, with bylaws, recruited staff and leadership, an initial membership, and Board of Directors. In terms of the grants involved, Dr. Kolodner reported that HHS plans to invest $5 million in the first year for AHIC 2.0, with the intent of committing up to $13 million over the first two years. It is planned to have the entity or entities that will carry this work forward selected by the next AHIC meeting. An announcement is expected to be made at that meeting, which will take place in Chicago on November 13, 2007.

Following these comments, Secretary Leavitt excused himself from the meeting. Mr. Weems served as Chair in the Secretary's absence.

Findings From the *Enhancing Data Quality in EHRs* Report

Dr. Kolodner explained that the focus of this session would be on findings from a report on enhancing data quality in EHRs that was commissioned by the ONC. This report is a followup to a series of 2005 reports that focused on improving the quality of data, including activities to discourage, prevent, and detect fraud. Dr. Kolodner noted that the *Enhancing Data Quality in EHRs* Report will be reviewed, discussed, and assessed by AHIC's Electronic Health Record Workgroup and Confidentiality, Privacy and Security Workgroup. These Workgroups will report back to the AHIC at the January meeting.

Jodi Daniel, Director, Office of Policy and Research, ONC, noted that the recommendations found in the report focus on important issues such as how records are created and maintained (which is fundamental to the success of EHRs), and limiting and detecting potential fraud. None of the recommendations in the report provide new rights to access the data, but rather are setting parameters for how data is accessed, and how to ensure that there are protections in place so that there is only authorized access to the data. The project was led by a Model Requirements Executive Team comprising industry experts in private and public sectors.

Rebecca Busch, of Medical Business Associates, Inc., noted that one of the driving factors behind this effort is the increase in health care fraud activity. She cited the following excerpt from the Executive Summary of the *Report on the Use of Health Information Technology To Enhance and Expand Health Care Anti-Fraud Activities*: "Fraud has a significant impact on the U.S. health economy. The National Health Care Anti-Fraud Association (NHCAA) estimates that "of the nation's annual healthcare outlay at least 3% or $51 billion in a calendar year 2003 was lost to outright fraud." Other estimates by government and law enforcement agencies place the loss as high as 10% of our annual expenditure, or $170 billion." This project is intended to help enhance data quality in the entire EHR environment, including taking steps towards antifraud components that would help in an EHR environment. RTI International served as the project contractor. Ms. Busch noted that project staff within the Health Information Technology Standards Panel to identify existing and new standards needed to meet model functionalities and requirements. The group also worked with the Certification Commission for Health Information Technology (CCHIT) to map model functionalities and requirements for health care anti-fraud to CCHIT certification criteria. She added that many of the recommendations in the report are consistent with other standards that have been evolving in the marketplace.

Reed Gelzer, of Advocates for Documentation Integrity and Compliance, noted that prior fraud studies formed part of the basis for this work, particularly a law enforcement sub-study that had specific recommendations related to antifraud. The working group that generated the *Enhancing Data Quality in EHRs* Report held an all-day meeting to reconcile public comments with the recommendations that have been developed thus far. The recommendations were distributed to Community members and focus on the following 14 areas:

- Audit functions and features
- Provider identification
- User access authorization

- Documentation process issues
- Evaluation and management coding
- Proxy authorship
- Record modification after signature
- Auditor access to patient records
- EHR traceability
- Patient involvement in anti-fraud
- Patient identity-proofing
- Structured and coded data
- Integrity of EHR transmission
- Accurate linkage of claims to clinical records.

Dr. Susan Turney of the Wisconsin Medical Society emphasized that the workgroup felt that it was extremely important that access be controlled for different user types and align with the principles that already exist for minimal necessary, or a need or right to know information. She explained that going forward, everyone will have to take into consideration the rules and regulations that exist at the state and federal level, as well as policies and procedures that occur within each individual organization. Another priority is the creation of a roadmap between the antifraud requirements and the certification criteria (some of the recommendations from the project are already considered criteria in HIT). Dr. Turney also noted that creating awareness and supporting accountability are important issues.

Dr. Gelzer explained that during the workgroup's deliberations, it was noted that as of that time, both the charters for CCHIT and HITSP did not include elements attending to areas of data validity, accuracy, and trustworthiness, which is essentially the larger environment that fraud works within. The workgroup strived to emphasize two important issues in terms of physicians using EHR systems: (1) use of EHRs forms a business system, data can be altered irrecoverably or falsified, and (2) in the health care field, no one is served by systems that can be exploited to execute documentation activities that would not be accepted in the paper world or in the business world in general. Therefore, the workgroup tried to be as specific and practical with regard to risk mitigation for clinician users and patients who are dependent on these systems. It takes time to translate certification requirements into standards. In the meantime, the marketplace is being trusted to address the question of how best to evaluate a system for basic validity issues and alert buyers that it is a criteria that they can take into account in their due diligence.

The recommendations found in the *Enhancing Data Quality in EHRs* Report protect clinicians and patients by providing supportive functions to validate that correct procedures were used and identifying or highlighting outliers before they become serious issues. The recommendations also raise the visibility of basic electronic documentation validity issues in the marketplace for buyers and sellers to take into account in evaluating currently available functions and capabilities.

Dr. Gelzer, Dr. Turney, and Ms. Busch each provided examples from their professional and personal experiences related to these issues.

Dr. Gelzer noted that one of the most important aspects of the *Enhancing Data Quality in EHRs* Report is that it offered an opportunity for the ONC to carry on its very important work and highlighted data quality and integrity issues in these systems in both a formal and informal way. He noted that if the marketplace understands that not only is due diligence necessary, but due diligence can be executed, there are tools for evaluating these systems in the field, and the marketplace will help speed along some of these data quality and integrity issues in parallel with the standards and certification process. A market preference will then become a technical and certified necessity.

Dr. Turney explained that this report and its recommendations represent a first step. If the time is spent to provide this information and educate the work force, both physicians and other providers that are involved in day-to-day patient care, they will better understand that this is not about just seeing patients and tracking information across the different sites of care. It encompasses a much broader perspective; physicians and providers need to be engaged in the discussion.

Ms. Busch highlighted the fact that the natural progression of the process is making it difficult to fabricate a medical record. In the past, ethically challenged organizations could set up a system to submit false claims, whereby they only needed basic components of a record such as a surgical history, history and physical, discharge report, etc. In the evolving environment envisioned by the workgroup, these organizations will have to work much harder to fabricate a medical record. There is fraudulent behavior going on to some degree, but when legitimate players in the market create an interoperable environment and communicate, a host of activities open up avenues for preventing this behavior.

Discussion Highlights

"For consumers and for patients, they probably would not have any disagreement that there is a need for a process to determine if there is fraud going on around medical records. That being said, I think on behalf of patients and consumers, they're going to want the security and protection of doing that across a body of de-identified patient information so that there is not any process through which, during a fraud investigation, the name of the patient and the patient information is going to be made accessible, even to the auditor. That rather, you will be auditing against a case number that can bring some form of security to that patient." – Ms. Davenport-Ennis

"This is an area, Dr. Kolodner, that the Consumer Empowerment Working Group would certainly enjoy the opportunity to work with other of the Workgroups here on AHIC, to look at the recommendations that have been proffered here, and to come back with the body of general consensus from our CE Working Group on perhaps next steps." – Ms. Davenport-Ennis

"I find all the recommendations on target…I just have the concern that the first sentence of [Recommendation] 5.2 would indicate or direct a vendor or another entity from developing software that could be helpful to the clinician in the context of better documentation of a patient encounter."
– Dr. Henley

"If a Medicare patient comes in the office with a wound on their leg, and that was the intent of the visit, but it's a patient who also has diabetes…the injury to the leg is going to get well documented, because that was the intent of the visit. But likely, an astute clinician, because the patient is diabetic, and has other problems, and is on other medications, is going to be asking about those in the context of that visit…they should code for that properly and, therefore, bill for that properly. And I think it's perfectly reasonable and appropriate for software to prompt for that, or at least to ask the question about that…While I may be

over-interpreting [Recommendation] 5.2, the first sentence of 5.2 would lend me to believe that such software should not be developed and should not be either embedded in EHRs, or should not be a separate standalone that would plug and play with an EHR." – Dr. Henley

"We actually discussed this at some length as a side bar…we knew that as recommendations, these would then go through a number of stipulated processes before they were converted into something more rigid, like a certification requirement or a standard. That being said…the marketplace has, to a great degree, already taken care of some of the more onerous early versions of prompting documentation." – Dr. Gelzer

"My approach to some of these guidelines is trying to bring transparency. If we're going to have guidelines, whatever they are, it has to be the same. Because you have providers who are trying to aggregate, encode and what have you, and then you've got payers doing their adjudication system. Then you have rejections or conflicts of information, and people are trying to figure out, well, why is this happening. But just a slightly side note on the whole concept of software systems." – Ms. Busch

"The more input we can get on this from various different groups of folks or various individuals, the better the recommendations can be, and the better we can work with the recommendations that this group has come up with. What I would recommend is that since the plan is to try to turn these over to Workgroups right away, this is a public process, and that if folks can try to get comments in to the Workgroups, they can make public comment during the Workgroup meetings and that sort of thing. Then they can be part of that dialogue that will be starting in the next month." – Ms. Daniel

"Providers clearly should be delivering the highest quality care and finding the most appropriate coding for that care. But I think it's perfectly appropriate for them to add additional data that might or might not change the billing code, depending on the quality of care they're delivering." – Mr. Isenstein

"All of the auditing recommendations that you have in the report seem very strong, and it would catch [cases] of an intent of fraud, it would in a time stamp or all these other mechanisms, create a pattern of, 'oh, this person did this thing in a systemic way, a thousand times in that year, let's look into it.' And that you would have this sort of auditing function that would sort of preclude this intent of fraud on this part." – Mr. Isenstein

"There is a very small number who were actually out to commit fraud, and yes, those are the ones where this was meant to make it much more difficult for them to do so. But the focus here was really, as with quality, while we want to do reporting of quality and be able to report that out, the most important thing is to provide doctors with the tools so that they can, in fact, practice the highest quality of care." – Dr. Kolodner

"To what extent do you think that the personal health record, or the consumer's ability to actually see into the physician's records, is going to, in and of itself, be an additional and important check and balance on the system…If I'm going home to look at my encounter bill, and I see things on there documented that weren't provided, I become a participant in the check and balance system. Have you thought about the patient as being a very important part of not only the quality, but also the integrity of the process?" – Dr. Gerberding

"The individual consumers that I've helped out that get stuck, they have no clue what an IC9 or CPT code is. And I think that's a fundamental aspect from the front-line protection that they even understand what that is, because those IC9 codes and CPTs are being aggregated in all sorts of places, not just in the provider setting, but in the payer setting. And it impacts their ability to figure out if someone has stolen the information. I mean the fraud may not be perpetuated at the provider setting, but somehow people who have gotten access to some of their information are submitting false claims due to these diagnoses

pertaining to them. So in order for a consumer to really fully evaluate or protect themselves, there also needs to be some type of education or screening, that once they get that information, they know what to do with that." – Ms. Busch

"There are multiple layers of access that patients may desire to have, whether they have access to their entire or complete medical record where they can actually go in and comment on it, or whether they have access to information about testing results, or simply a listing of their diagnoses as described by their physician. So I think the consumer engagement piece is huge, and it needs to be discussed as we move along this process, because we can have the best designed system, but not be giving information that's going to be helpful to anybody." – Dr. Turney

"The EHR Workgroup really will get very excited about diving into this report. I see your role in getting us all coordinated, because I think all of us that are Co-Chairs of the Workgroups will be anxious to get this in front of our groups for their specific piece. The one piece that it would be helpful in another iteration is the section on proxy authorship…I think about how many times a nurse makes an assessment that goes on a form that a physician has to sign off on in order for the physician to get paid, or for the hospital to get paid." – Ms. Gelinas

"The level of functionality variation that's out there means that the data quality variability is infinite, and to me, the caveat emptor is about if you're buying these systems for a small practice, or for a hospital, or for an integrated health system, or for the Department of Defense, you really need to do your due diligence—there are well defined rules for how medical records function." – Dr. Gelzer

"Data quality and integrity are really just critical for trust in electronic health records. If you don't have that, we're going have to a hard time promoting adoption of electronic health records, if the doctors don't trust the systems, if the patients don't trust the systems. And that's just the critical message here." – Ms. Daniel

Public Input Session

Speaker Number 1 – Carol Bickford of the American Nurses Association noted that she fully supports the immediate posting of the *Enhancing Data Quality in EHRs* Report for public comment. She explained that industry needs to understand the issues that are in place and the consumer population needs to be able to offer input. She also expressed hope that the *Enhancing Data Quality in EHRs* Report includes a patient-centric focus in terms of the EHR and the documentation associated with it. Dr. Bickford also noted her concern that in relation to the public health initiatives, all of the stakeholders are not included in the information communication structure. For example, the Department of Justice, Department of Agriculture, Department of Homeland Security, and others have not been included. She suggested that there be consideration given to expanding the stakeholder population.

Closing Remarks

Before adjourning the 16th meeting of the AHIC, Dr. Kolodner thanked the Community members, speakers, and participants for their attendance and participation.

Department of Health & Human Services
Office of the National Coordinator for
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American Health Information Community

Health IT Certification Update from CCHIT

Mark Leavitt

Chair

Certification Commission for Healthcare Information Technology

November 13, 2007

Updates

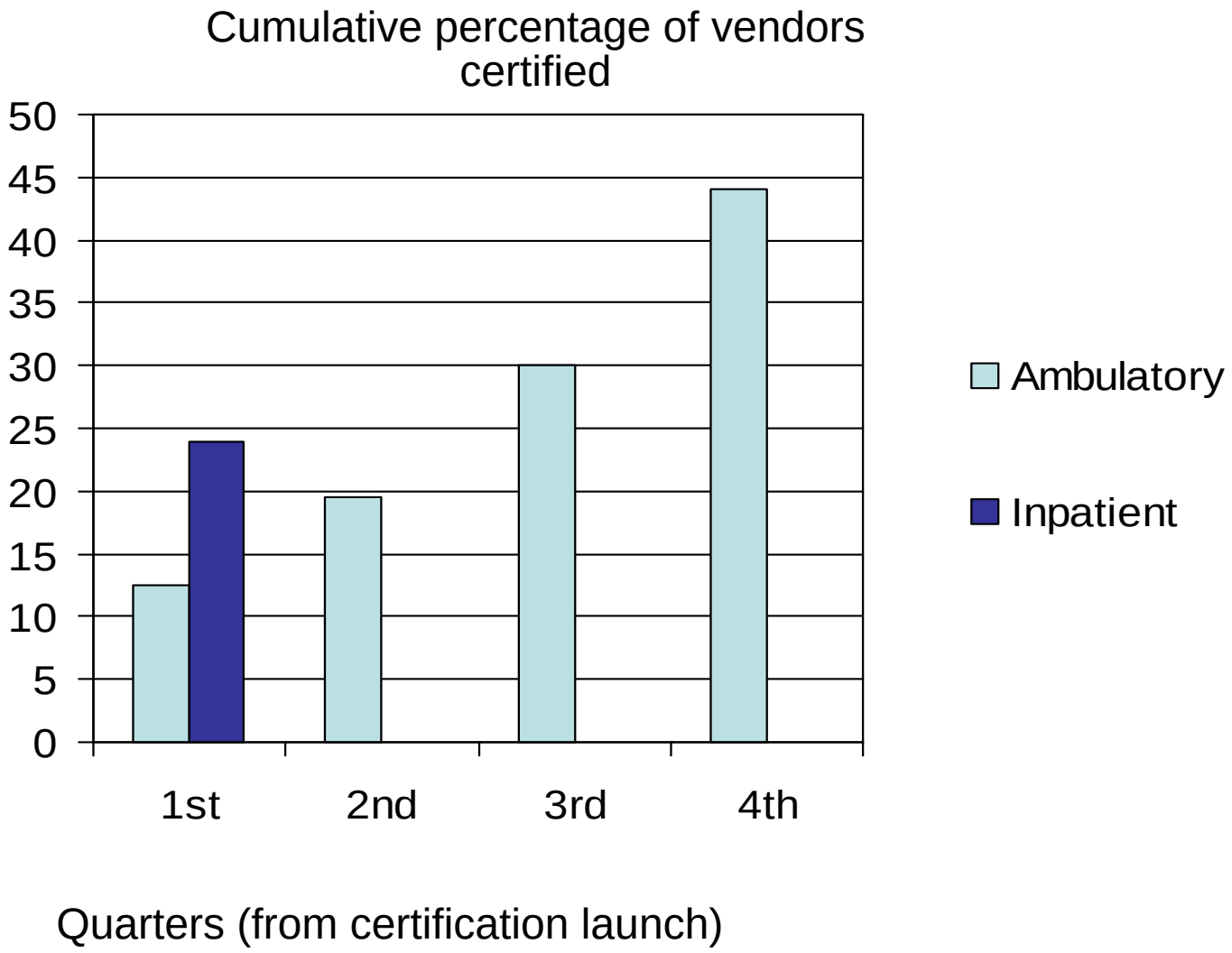
- Certification of inpatient EHRs
- Market acceptance of certification
- Update on development of 2008 certification
- Progress in accelerating health IT adoption

First Certified Inpatient EHR Products Announced

Product	Company	Certification
ChartAccess	Prognosis Health Information Systems	Pre-market
CPSI System	CPSI (Computer Programs and Systems), Inc.	Full
EpicCare Inpatient	Epic Systems Corporation	Full
Healthcare Management Systems	Healthcare Management Systems, Inc.	Full
Soarian Clinicals (with Siemens Pharmacy and Medication Administration Check)	Siemens Medical Solutions USA, Inc	Pre-market
Sunrise Acute Care	Eclipsys Corporation	Full

Products with 2007 Inpatient EHR Certification as of Nov 5, 2007

Market Acceptance of Certification



Update on Development of 2008 Certification

- Update to Ambulatory and Inpatient criteria
- New domains for 2008: Networks, Emergency Depts., Child Health, Cardiovascular Medicine
- Environmental Scans published Sept 12
  - ~1000 public comments received during 30-day period
- First Draft Criteria to be published in November
- Resources for testing standards-based interoperability
  - Collaborative project with MITRE Corp. announced Sept 10
  - Open source development model – testing tools will be free and publicly available
  - High level of interest from public and private entities
  - Technical kick-off teleconference Nov 15

Progress in Accelerating Health IT Adoption

- Financial incentives from payers – public and private
- Regulatory relief for donation of interoperable EHRs
- State-wide health IT adoption initiatives
- Malpractice premium discounts for practices using certified EHRs

Thank you!
Q & A

For more information, please visit:

www.cchit.org

Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

American Health Information Community

Nationwide Health Information Network

Trial Implementations – Demonstrating the Value of Health Information Exchange

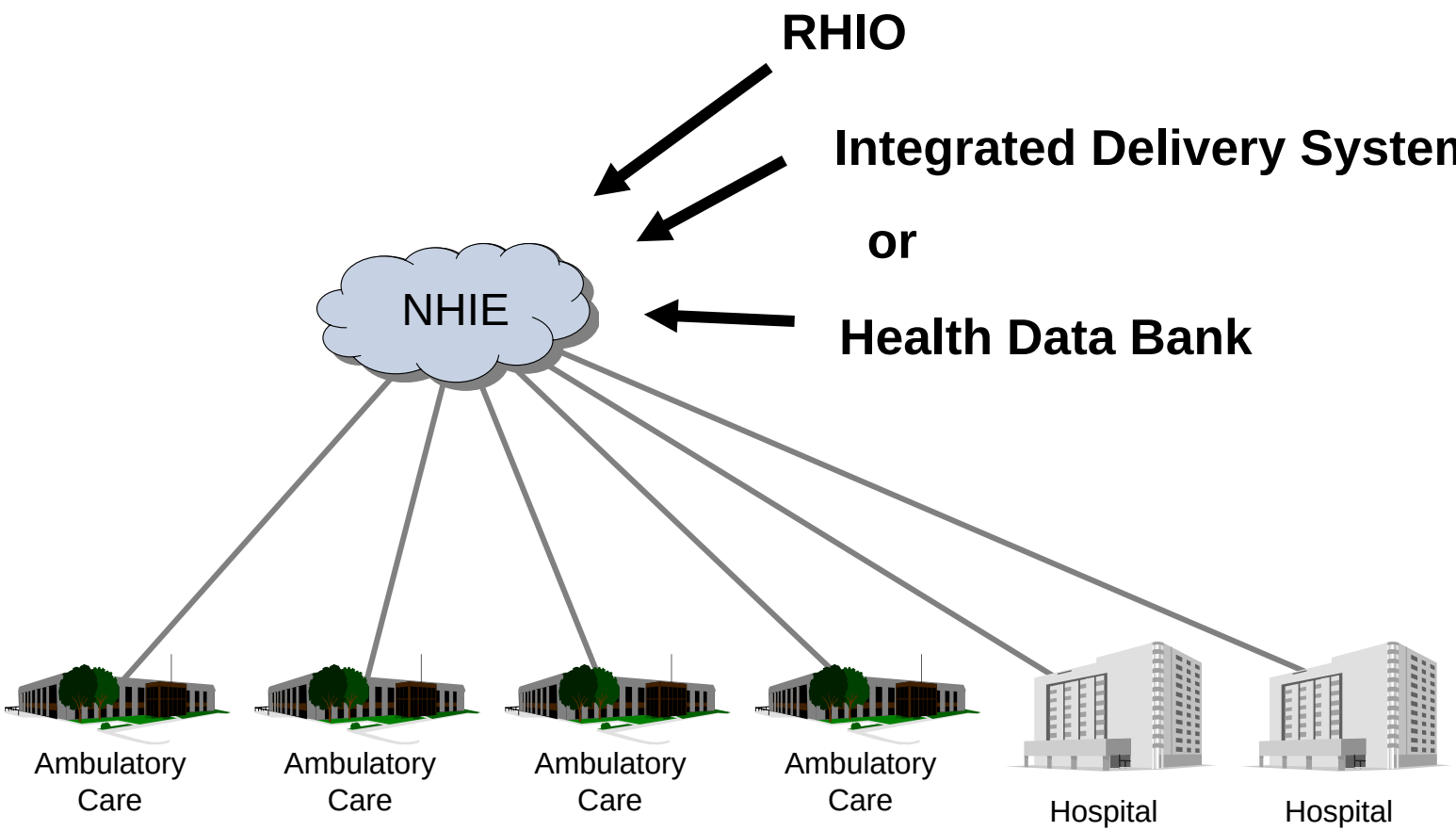
John W. Loonsk
Office of the National Coordinator for Health Information Technology

Liesa Jo Jenkins
CareSpark

Margaret Gunter
Lovelace Clinic Foundation

November 13, 2007

Nationwide Health Information Network



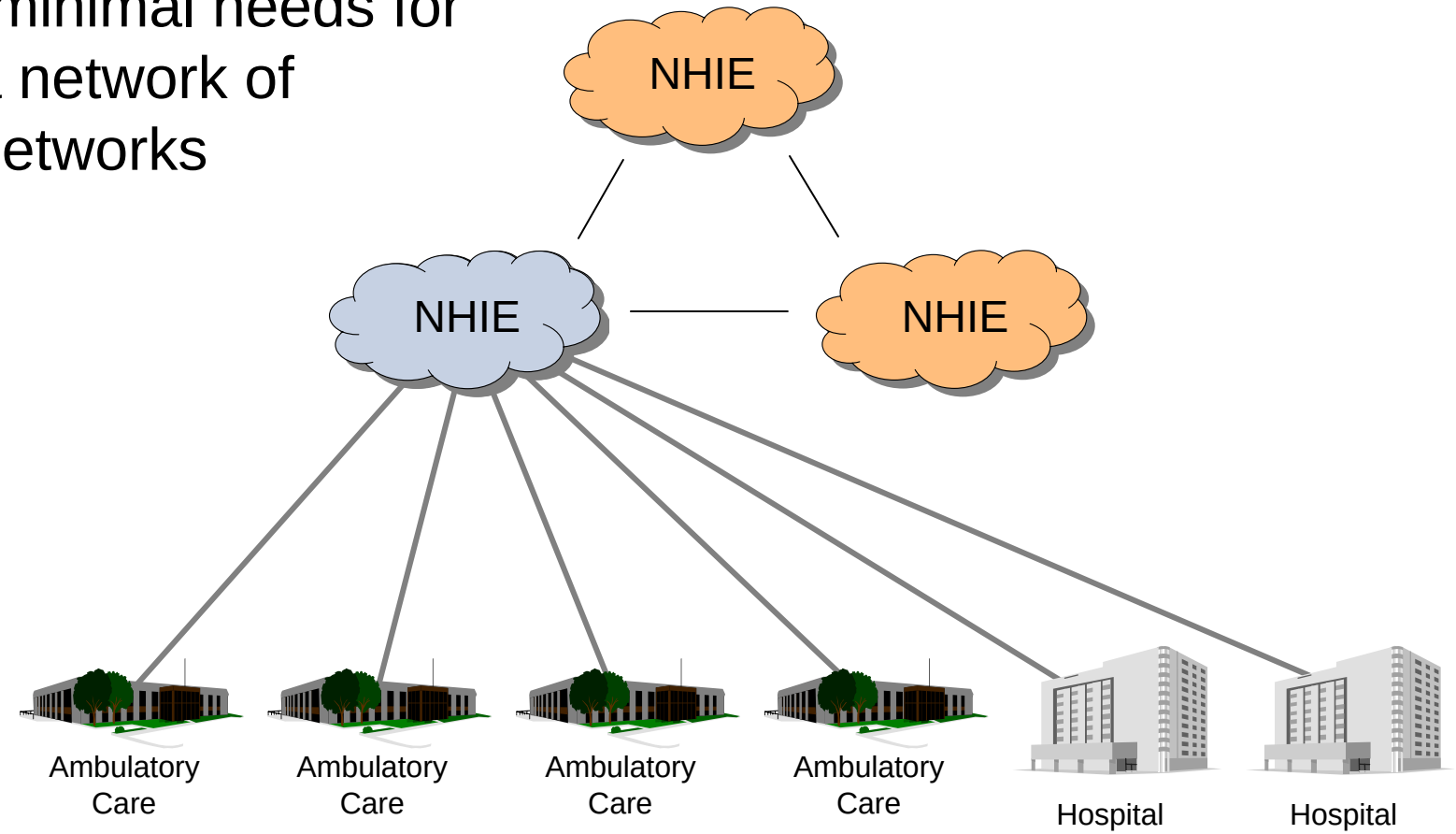
Providers

- Electronic health records

NHIN "Network of Networks"

NHIN Core Services

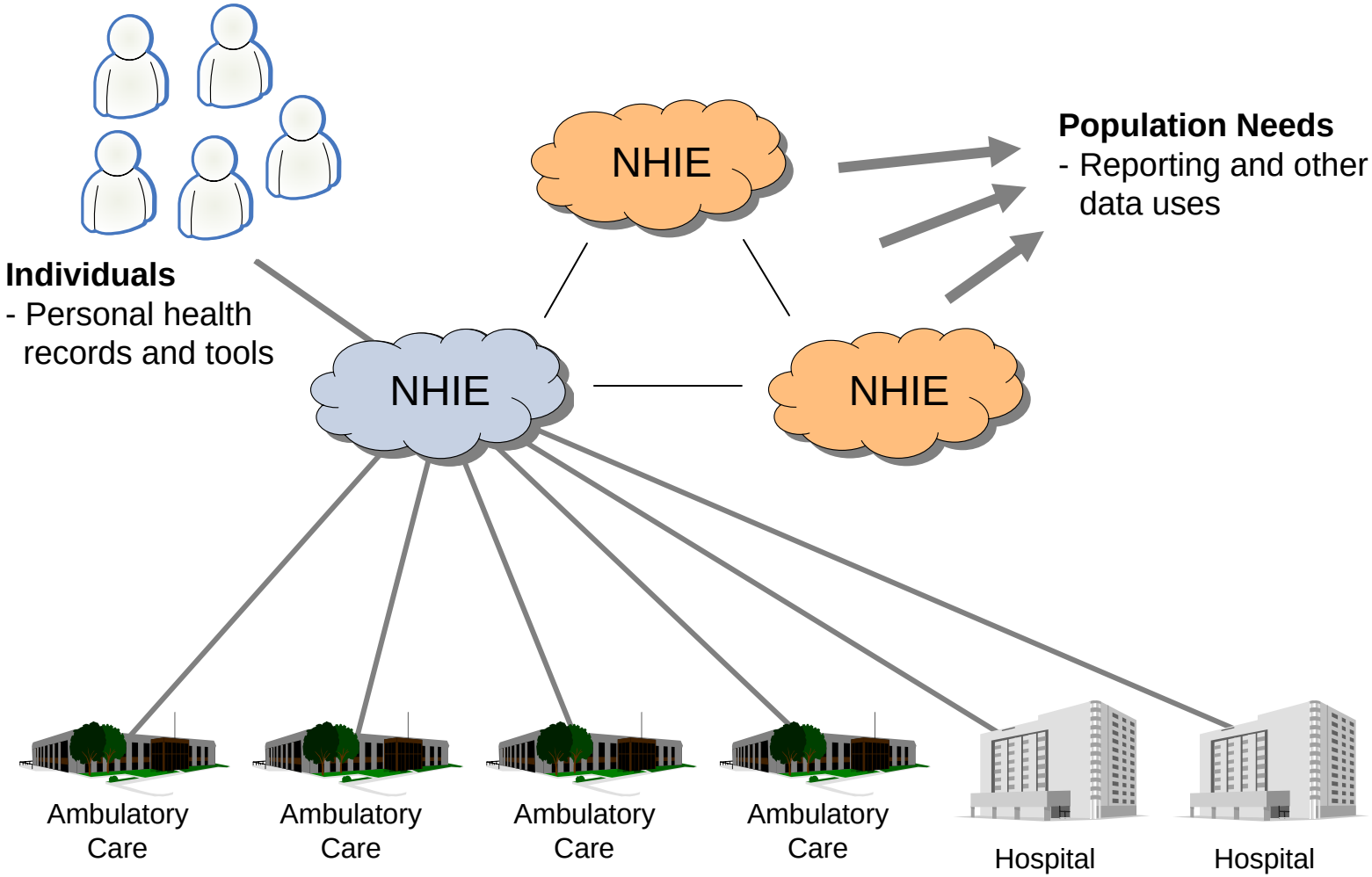
- minimal needs for a network of networks



Providers

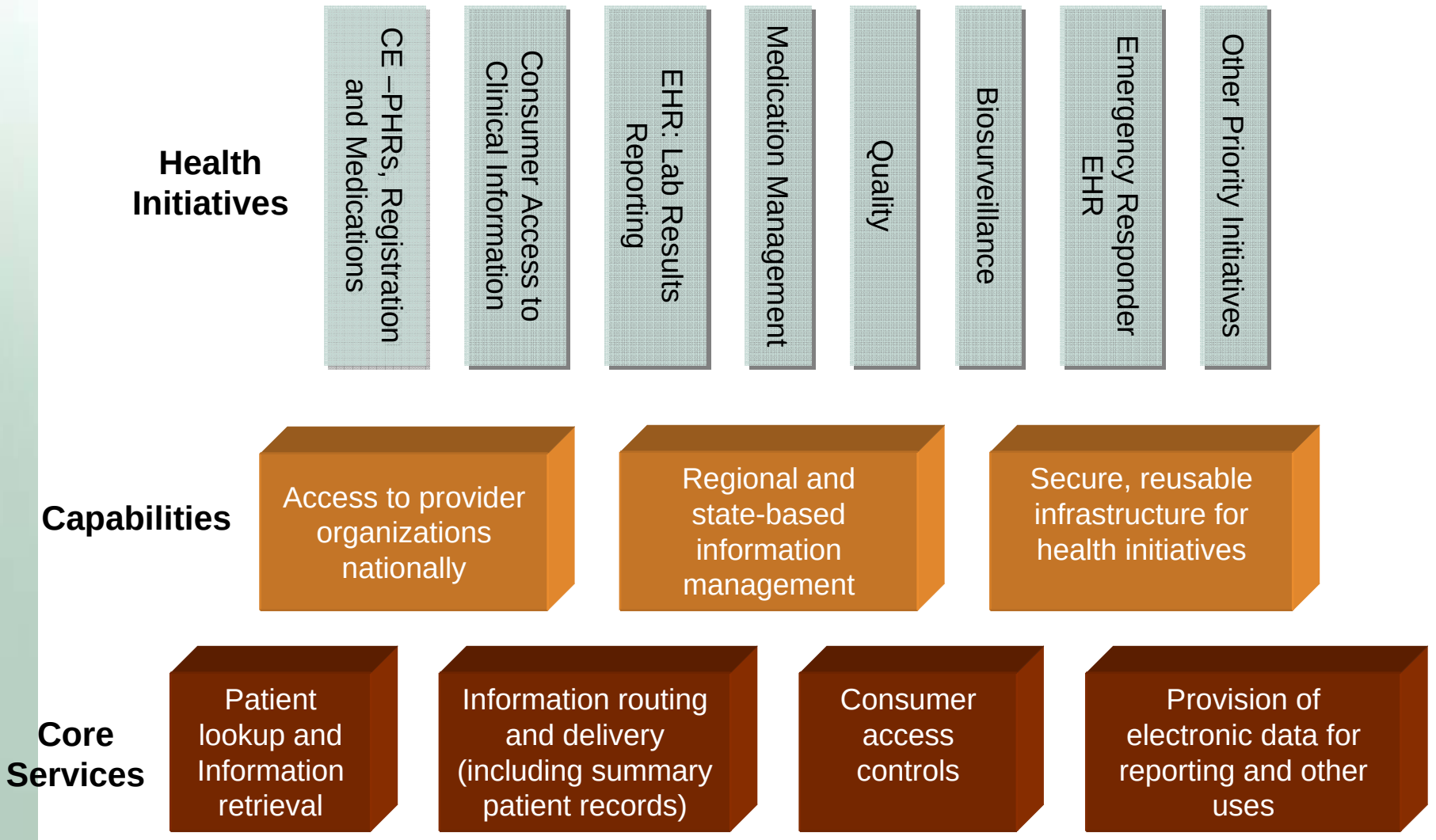
- Electronic health records

NHIN Shared Value for Connecting



Providers
- Electronic health records

NHIN Core Services - Building Blocks for Priority Initiatives



NHIN Cooperative Co-Chairs

- **Core Content Working Group**
  - Lovelace Clinic Foundation (New Mexico)
  - New York eHealth Collaborative (New York State)
- **Core Technical and Security Working Group**
  - West Virginia Health Information Network (West Virginia)
  - Federal NHIE (DoD, VA, HHS, others)
- **Data Use and Reciprocal Support Working Group**
  - North Carolina Healthcare Information and Communications Alliance (North Carolina)
  - MedVirginia (Central Virginia)

NHIN Cooperative Leadership

- **Testing Working Group**
  - National Institute for Standards and Technology
  - Indiana University (Indianapolis metropolitan area)
- **Other Health Information Exchanges**
  - CareSpark (Tricities region of Eastern Tennessee and Southwestern Virginia)
  - Delaware Health Information Network (Delaware)
  - Long Beach Network for Health (Long Beach and Los Angeles, California)
- **Other Participants**
  - Centers for Disease Control and Prevention
  - Healthcare Information Technology Standards Panel
  - Certification Commission for Healthcare Information Technology

Department of Health & Human Services
Office of the National Coordinator for
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American Health Information Community

Tracking Use of Electronic Medical Records

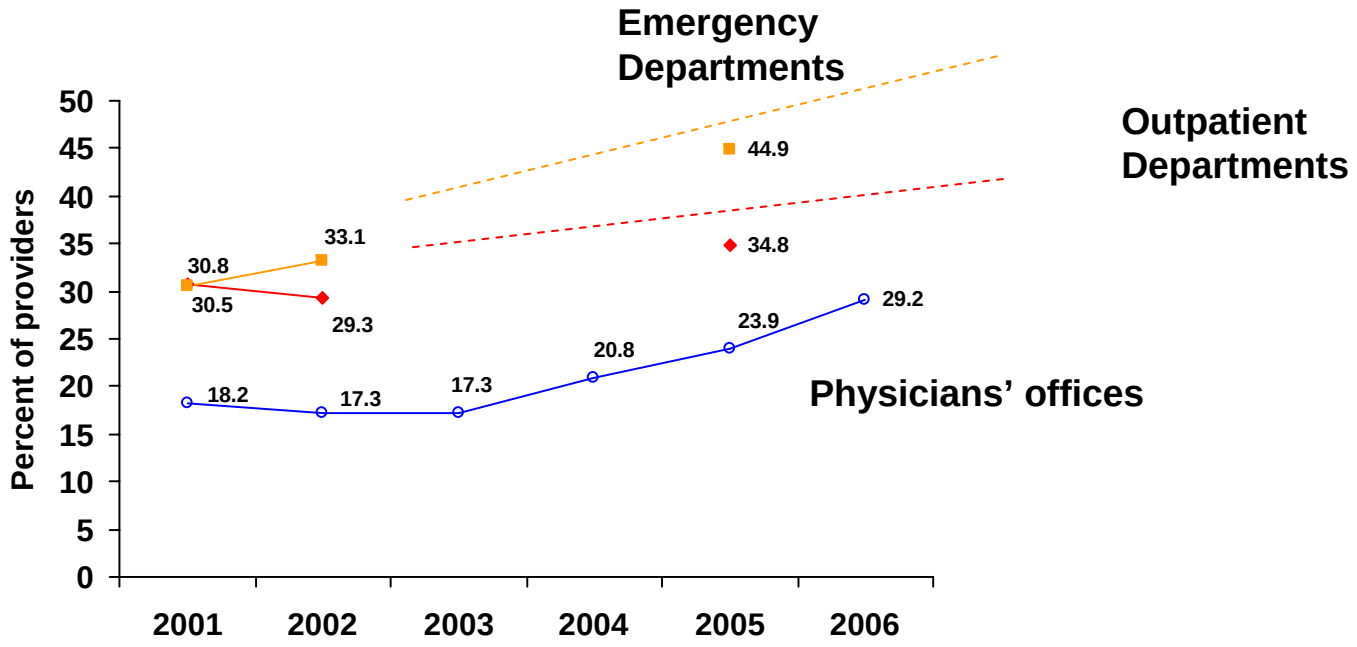
Jane E. Sisk
National Center for Health Statistics
Centers for Disease Control and Prevention

November 13, 2007

National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS)

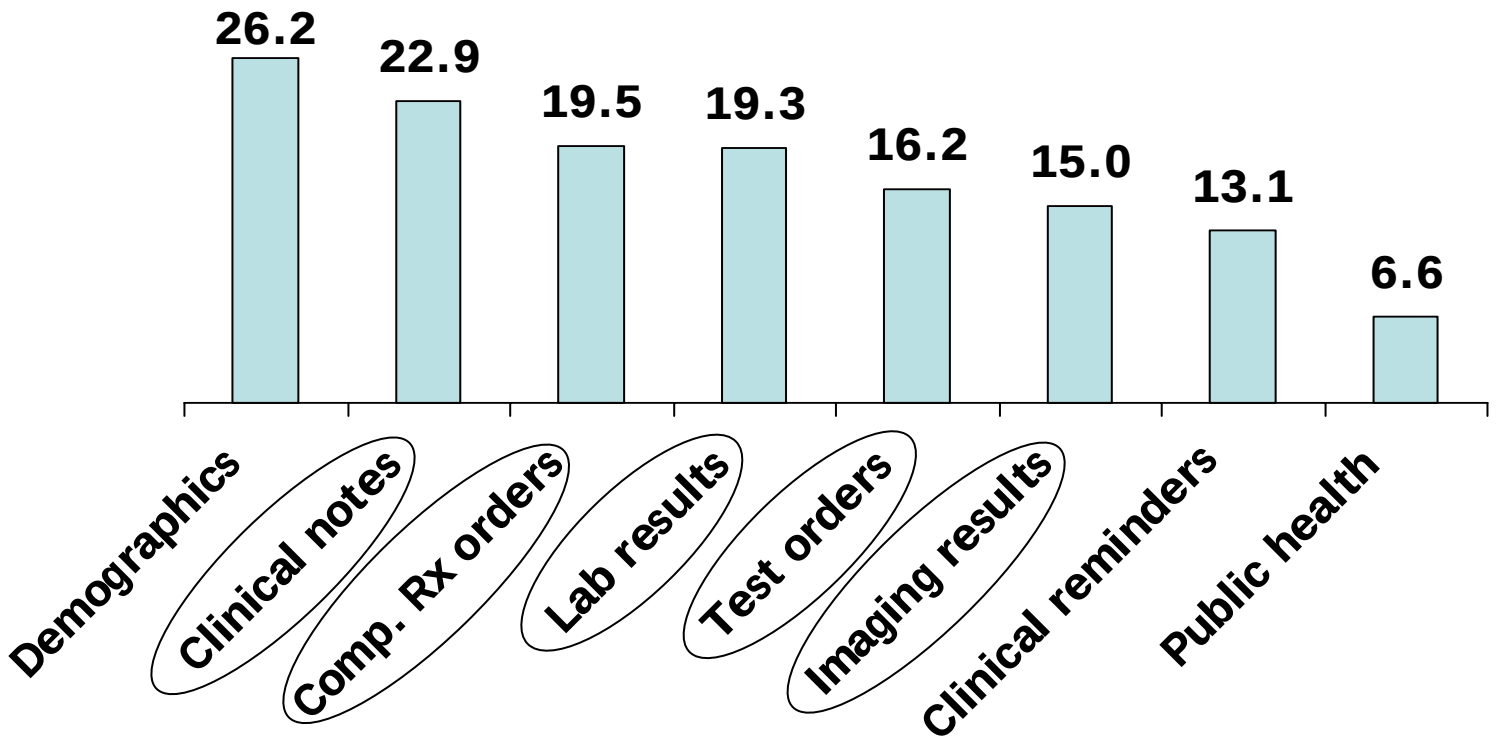
- Annual nationally-representative surveys
  - 3,350 office-based physicians
  - 2,000 additional physicians, 2008 mail survey
  - 500 hospitals
- Scope
  - Nonfederal office-based physicians excluding radiologists, anesthesiologists, and pathologists
  - Nonfederal, general and short-stay hospitals with emergency depts. (EDs) or outpatient depts. (OPDs)
- Face-to-face induction interview followed by medical record abstraction:
  - ~30 office visits, 63% response rate
  - ~100 ED visits, ~150 OPD visits, 92% response rate
- NAMCS, 2006: Advance Data Report Number 393

EMR Use in Ambulatory Care



NOTES: Office-based physician and hospital emergency department trends are significant ($p<.05$).
Office-based physicians include nonfederal, office-based physicians who see patients in an office setting. Excludes radiologists, anesthesiologists, and pathologists.
Sources: National Ambulatory Medical Care Survey, 2001-6; National Hospital Ambulatory Care Survey, 2001-5.

Percent of Office-Based Physicians Using Selected EMR Features

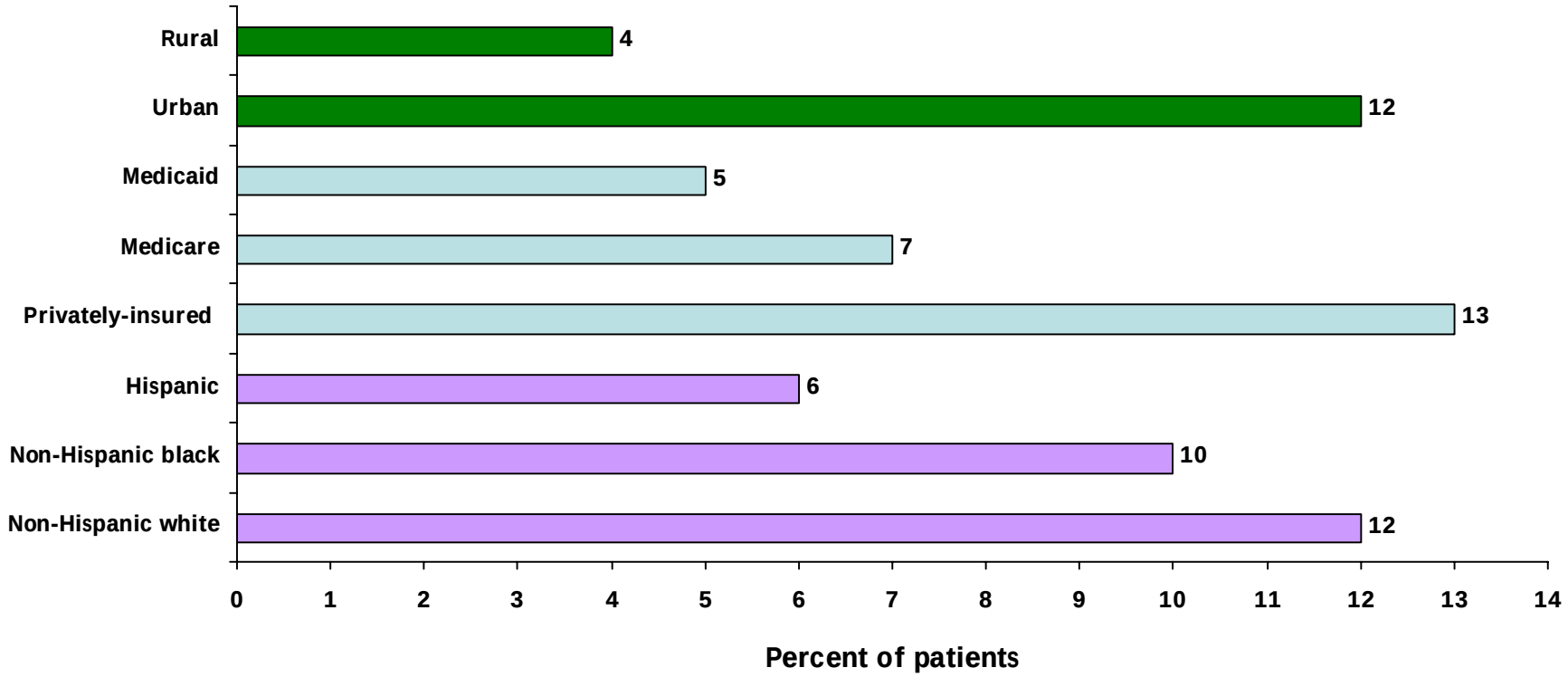


Source: National Ambulatory Medical Care Survey, 2006

EMR Use, NAMCS, 2006

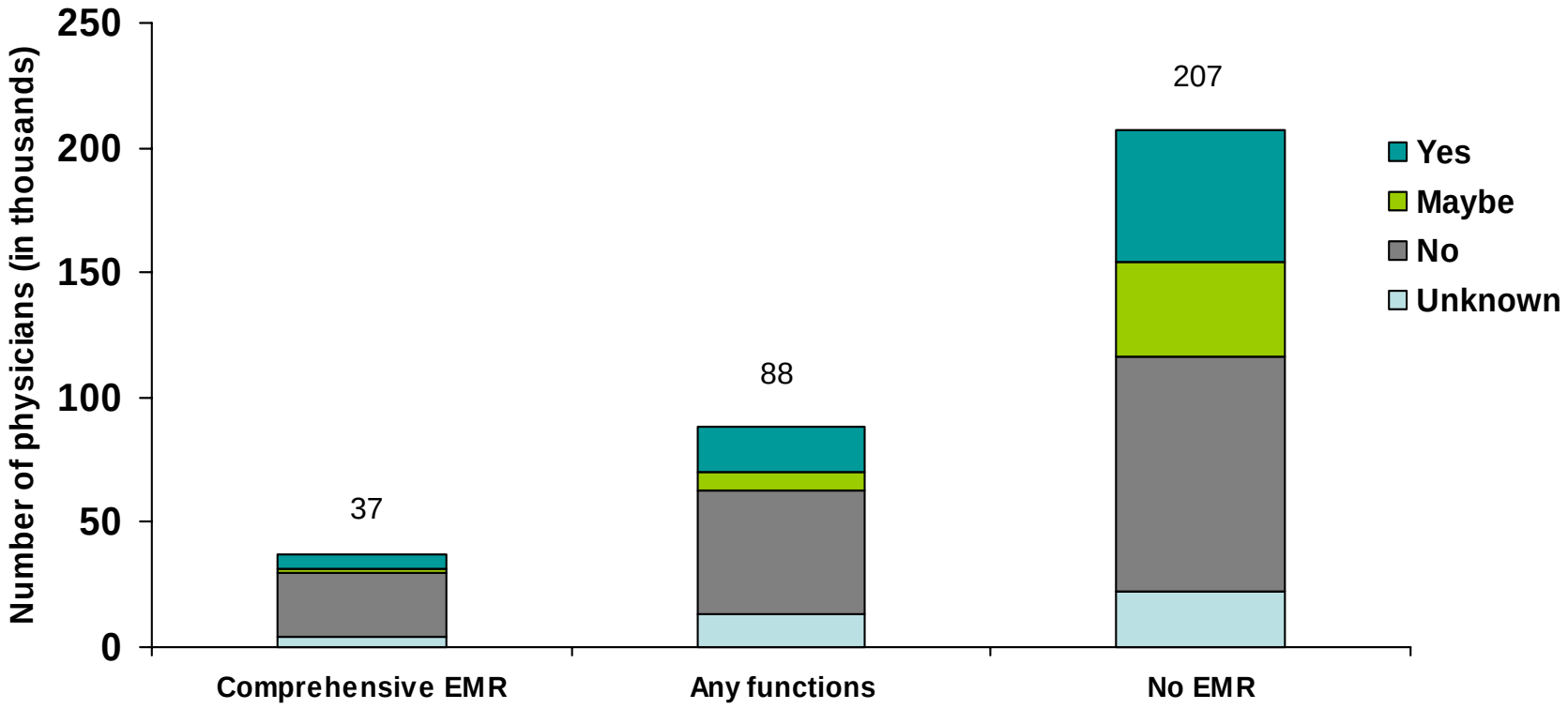
Practice Characteristic	% of all Physicians	% Reporting Full/ Partial EMRs	% Reporting Comprehensive EMRs
All physicians	100	29	12
Size (# of physicians)			
Solo	34	24	7
Partner	12	28	10
3-5	30	30	13
6-10	15	31	17
11 or more	8	47	27
Ownership			
Physician/physician group	82	27	10
HMO	3	76	60
Other	16	34	17
Region			
Northeast	21	24	8
Midwest	20.0	29	14
South	37	24	9
West	23	42	12

Adjusted Percent of Patients Whose Primary Care Providers Used Comprehensive EMRs



Source: National Ambulatory Medical Care Survey, 2005; National Hospital Ambulatory Medical Care Survey, 2005.

Physicians Planning New or Replacement Electronic Medical Record Systems Within Next 3 Years



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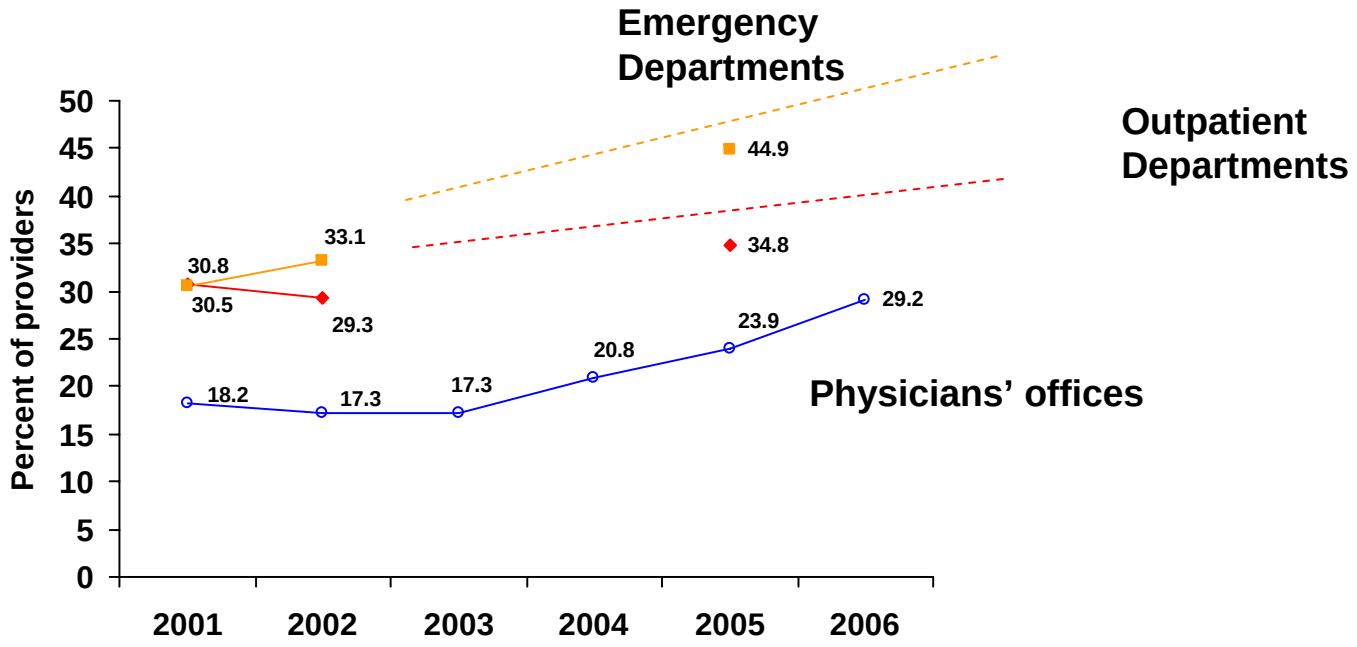

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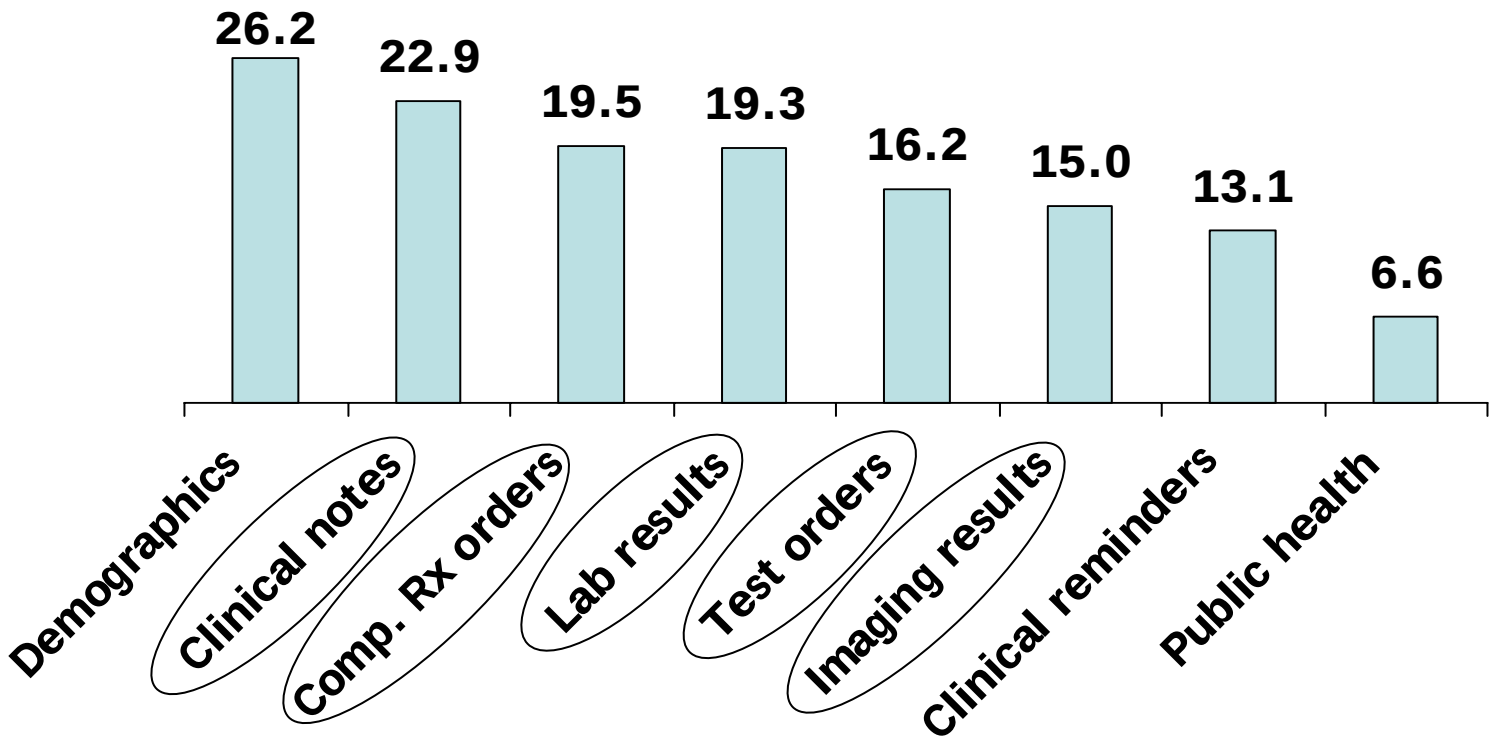

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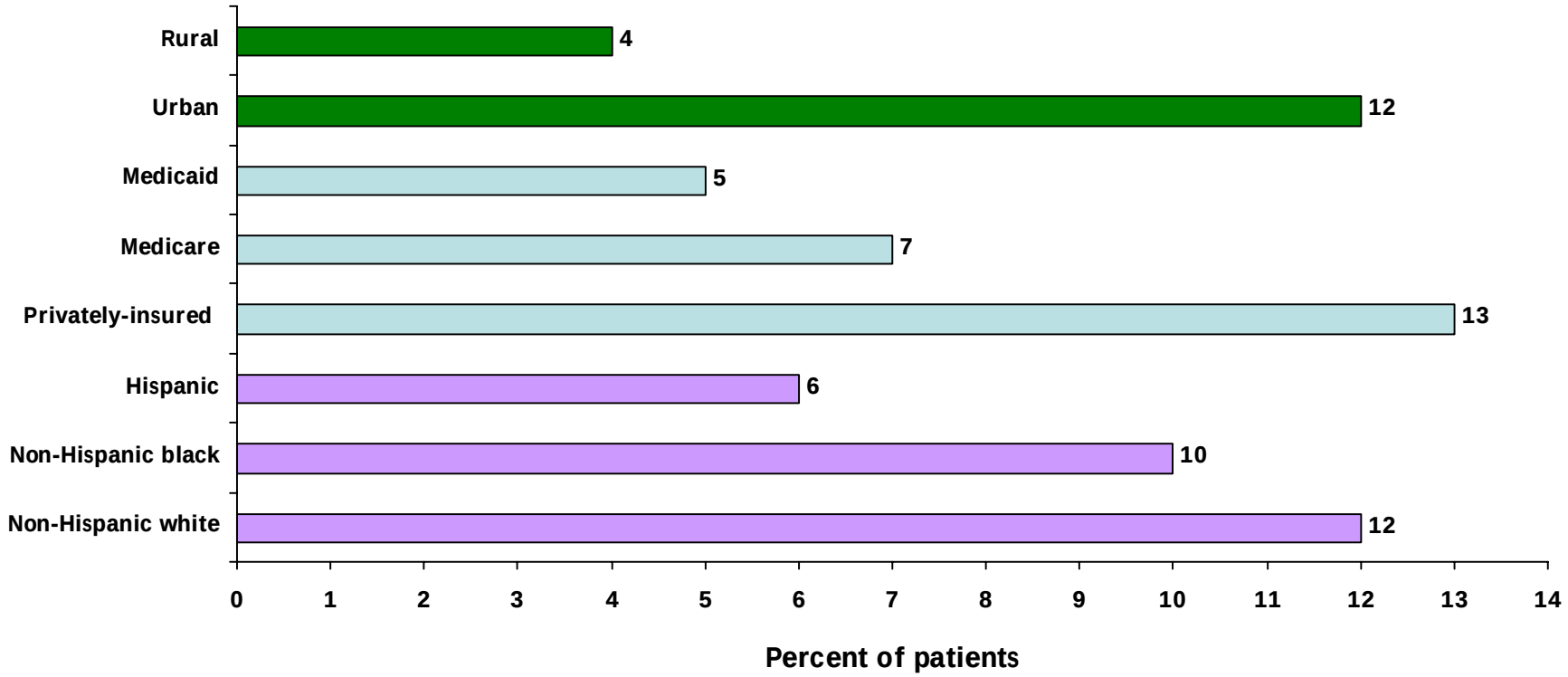

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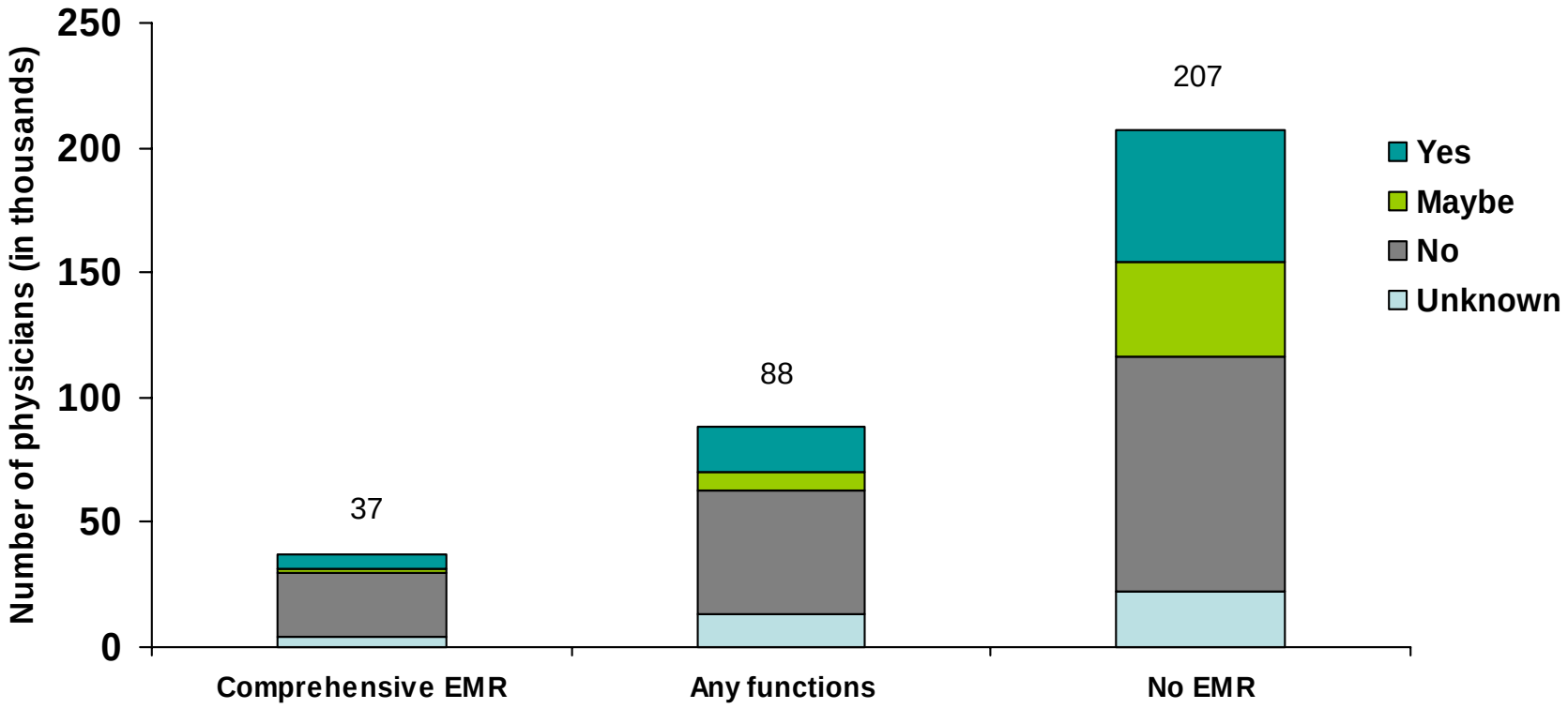

Source: National Ambulatory Medical Care Survey, 2006.

Department of Health & Human Services
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A National Survey of Electronic Health Record Adoption in the United States

David Blumenthal

Massachusetts General Hospital Institute for Health Policy

November 13, 2007

Methodology

- **Mail survey**
- **Sample frame: 5,000 currently practicing physicians randomly selected from the AMA Masterfile**
- **Proposed sample size: 3,000 physicians**
- **Field period: Began in July 2007, currently in the field**
- **Physicians were sent two questionnaires. They were directed to fill out the "physician" instrument and to give the second questionnaire to the person most knowledgeable about the practice characteristics and HIT use.**
- **Current analysis: N approximately equal to 400**
- **Target response rate: 60%**

Definitions of an EHR

- **Historical NAMCS Definition**: Allows providers to define an EHR (excluding billing records).
- **Minimally Functional EHR for National Adoption Rate**: Encompasses a minimum set of functionalities within those defined by the Institute of Medicine framework.
- **Functional EHR**: Definition developed by our Expert Consensus Panel based on the Institute of Medicine framework to maximize the potential for improving quality of care.

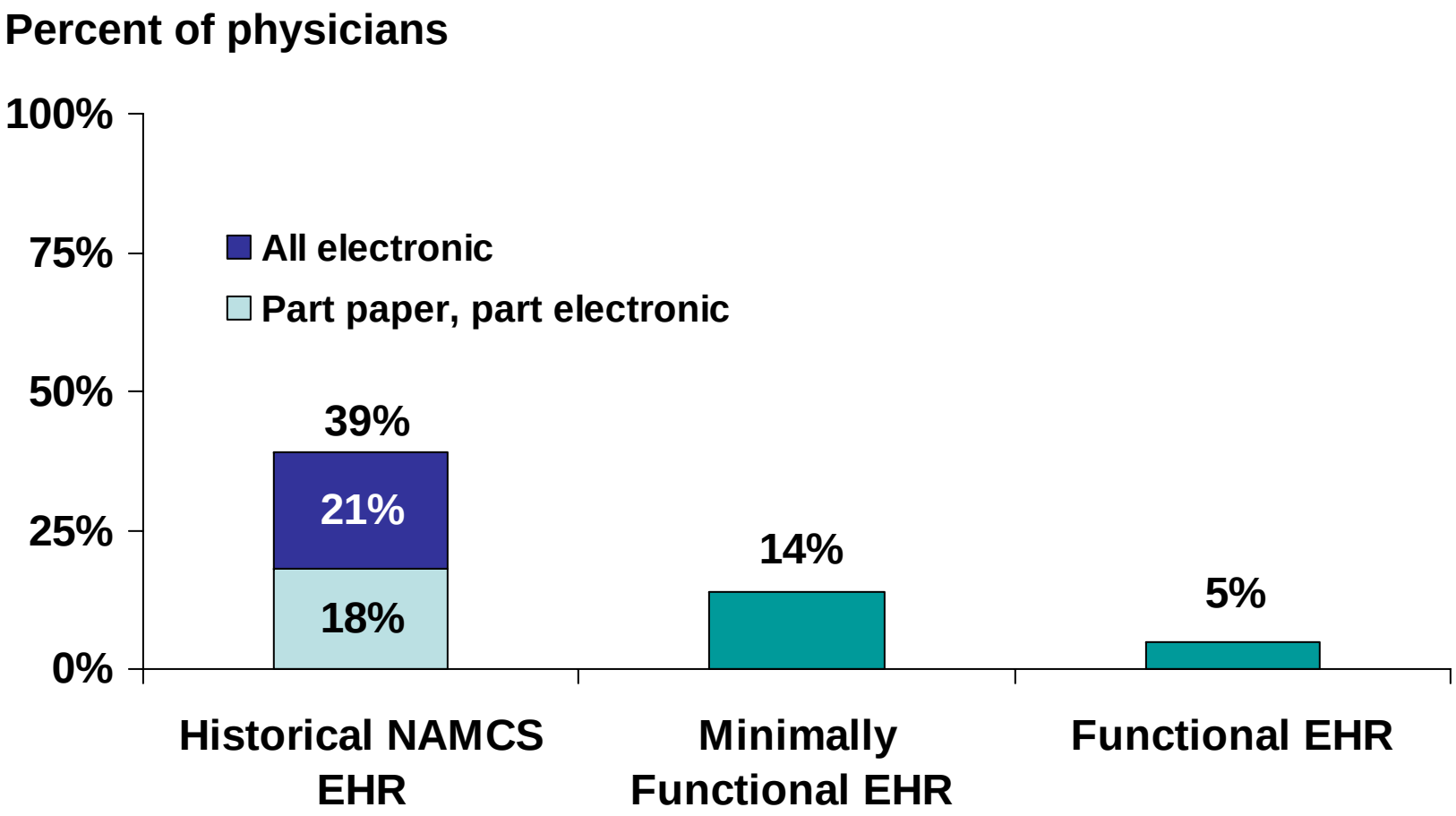
Definition of an EHR – Minimally Functional and Functional

	Minimally Functional EHR	Functional EHR
Health Information and Data		
Patient demographic information		x
Patient problem lists		x
Patient medication lists		x
Clinical notes	x	x
Notes include medical history, follow-up notes		x
Order Entry Management		
Computerized orders for prescription	x	x
Computerized orders for labs	x	x
Computerized orders for radiology	x	x
Orders sent electronically for prescriptions		x
Orders sent electronically for labs		x
Orders sent electronically for radiology		x

Definition of a EHR – Minimally Functional and Functional (con't)

	Minimally Functional EHR	Functional EHR
Results management		
Viewing lab results	x	x
Viewing imaging results	x	x
Electronic images are returned		x
Decision Support		
Warnings of drug interactions or contraindications are returned		x
Out of range lab levels are highlighted		x
Reminders for guideline-based interventions and screenings		x

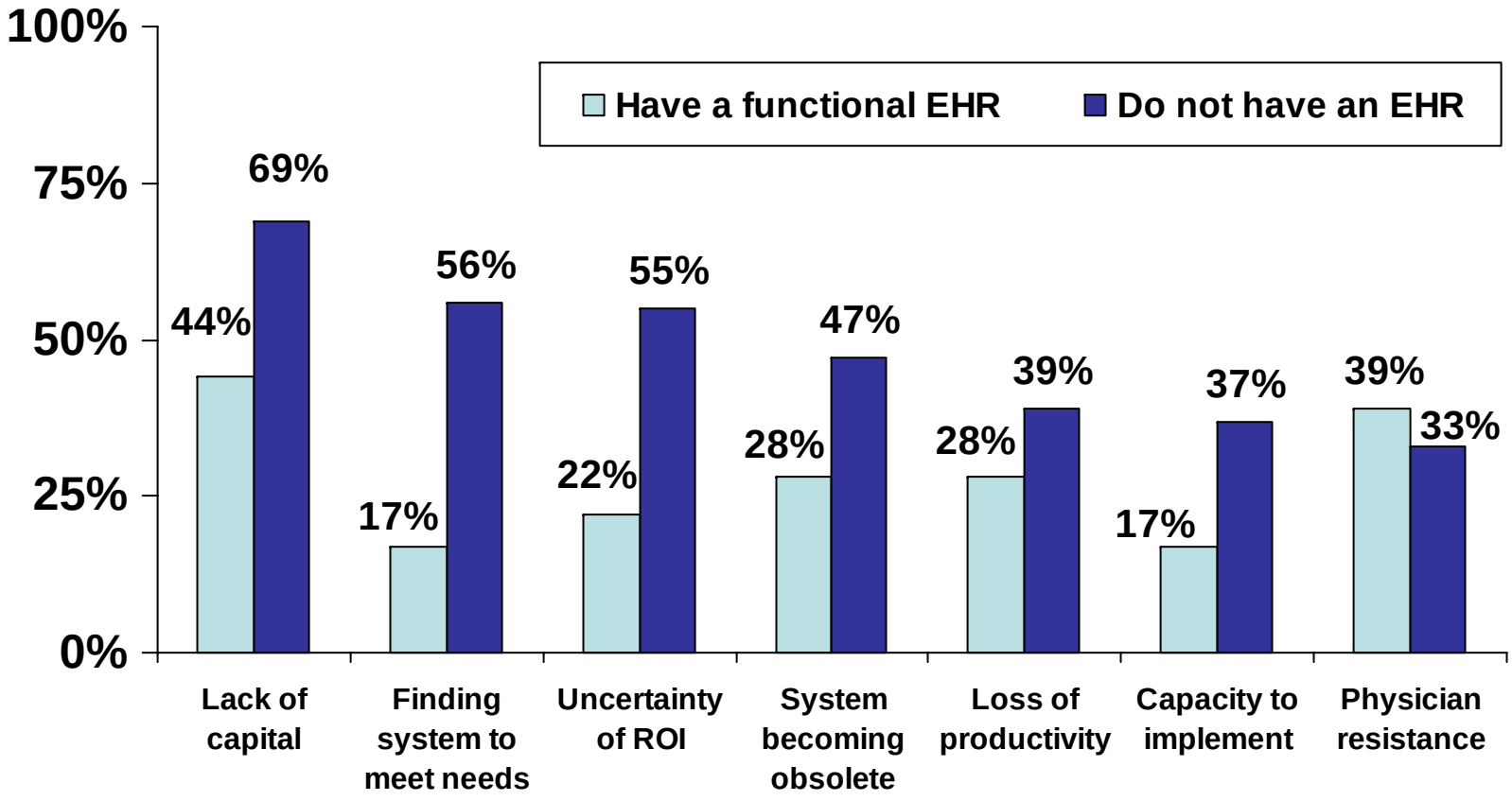
Availability of an EHR Varies By Definition



Source: MGH Institute for Health Policy, George Washington University and RTI, A National Survey of Health Record Keeping among Physicians & Group Practices in the United States, Preliminary Data

Major Barriers to EHR Adoption

Percent of physicians reporting a "major barrier"



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Research Team

Mass General Hospital's Institute for Health Policy	George Washington University
Harvard School of Public Health	RTI

Advancing the National Framework for Uses of Health Data

Presentation to the American Health Information Community

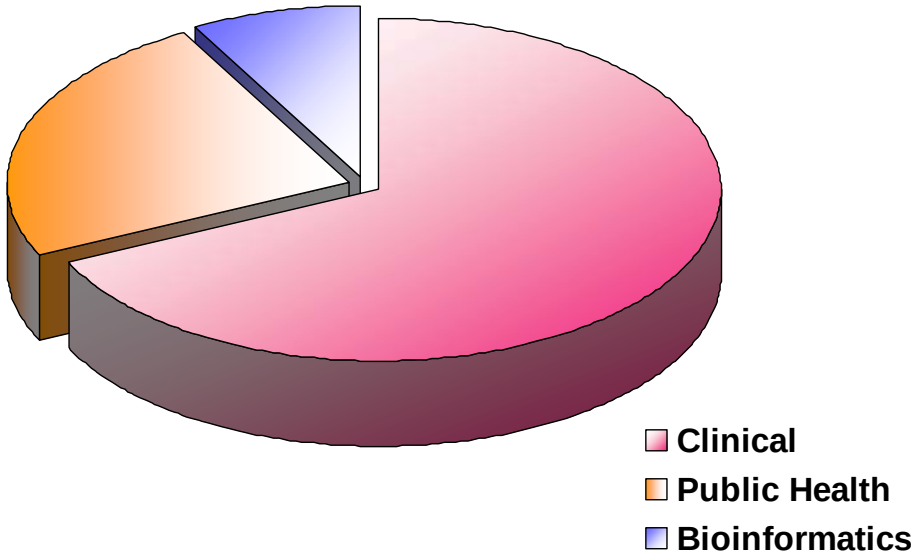
November 13, 2007

Charles Safran, MD, MS
Associate Clinical Professor of Medicine, Harvard Medical School
Chief, Division of Clinical Computing, Beth Israel Deaconess Medical Center
Senior Scientist, National Center for Public Health Informatics, CDC

Don E. Detmer, MD, MA
President and CEO, American Medical Informatics Association
Professor of Medical Education, University of Virginia

American Medical Informatics Association

- 4000+ members in 53 nations
- Of those indicating an area of interest
  - 68% clinical or health care (including personal health management)
  - 24% public health/population
  - 8% bioinformatics



Today's Discussion Topics

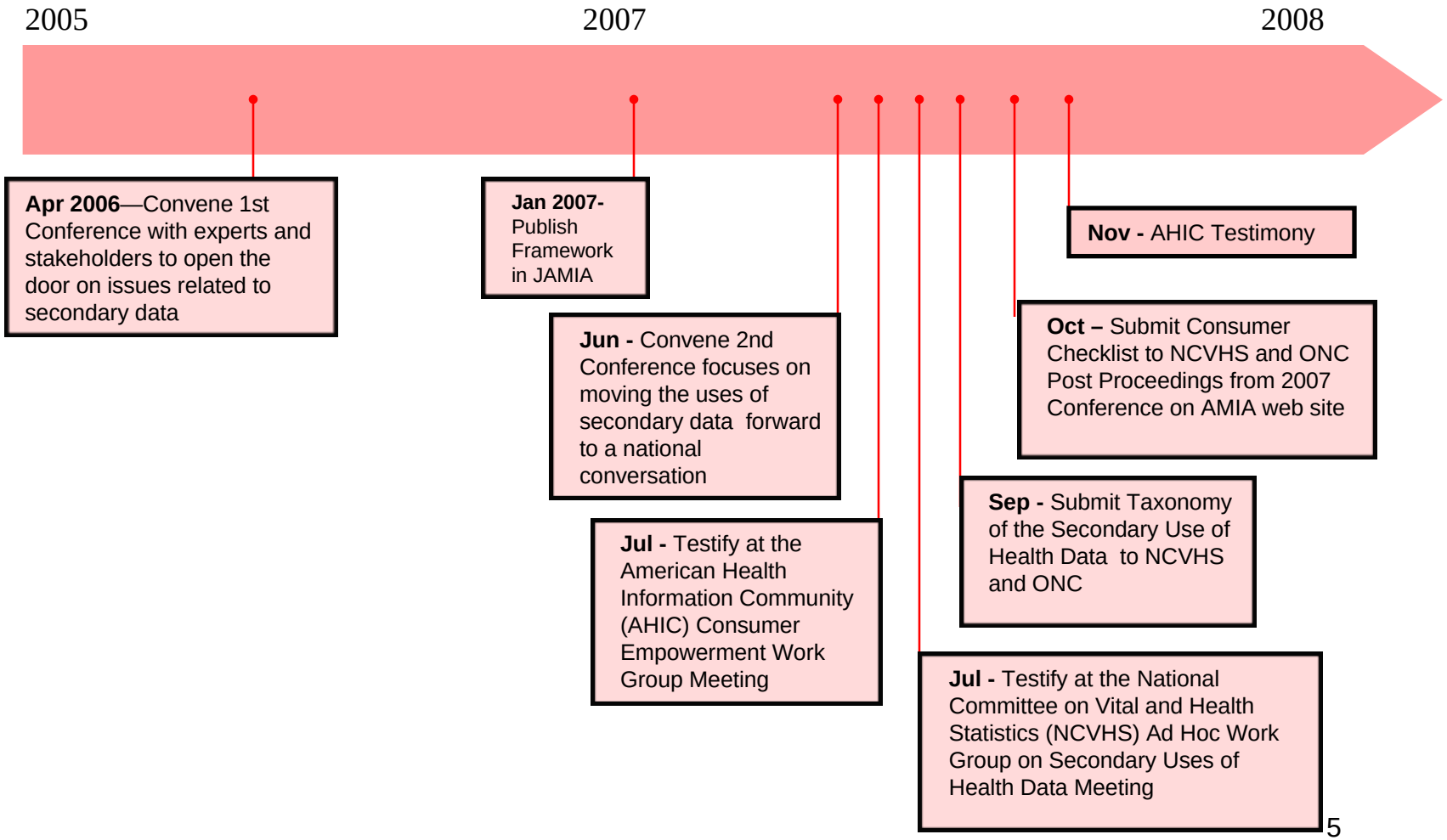
- Clinical Data & Why Important
- Milestones & Framework
- Overview of 2007 Conference Findings
  - Consumer Awareness
  - Taxonomy of Use
  - Principles of Data Stewardship
- Next Steps

Value of Health Data

Data can be used to

- **Enhance experiences** for individuals
- **Expand knowledge** about disease & treatment
- **Strengthen understanding** of effectiveness & efficiency
- **Support public health** & homeland security
- **Help businesses** meet needs of their customers

Milestones and Accomplishments in Data Reuse Discussion



Major Findings from 2006 AMIA Meeting

- Secondary uses of health care data are widespread
- Patient privacy issues dominate public policy debate
- Technology & business development outpace policy & practice
- Stewardship not ownership should drive policy
- Leadership needed at national & state levels

Journal of the American Medical Informatics Association Volume 14 Number 1 Jan / Feb 2007

White Paper

Perspectives on Informatics

Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper

CHARLES SAFRAN, MD, MS, MERYL BLOOMROSEN, MBA, W. EDWARD HAMMOND, PHD, STEVEN LABKOFF, MD, SUZANNE MARKEL-FOX, PHD, PAUL C. TANG, MD, DON E. DETMER, MD, MA, WITH INPUT FROM THE EXPERT PANEL (SEE APPENDIX A)

Abstract Secondary use of health data applies personal health information (PHI) for uses outside of direct health care delivery. It includes such activities as analysis, research, quality and safety measurement, public health, payment, provider certification or accreditation, marketing, and other business applications, including strictly commercial activities. Secondary use of health data can enhance health care experiences for individuals, expand knowledge about disease and appropriate treatments, strengthen understanding about effectiveness and efficiency of health care systems, support public health and security goals, and aid businesses in meeting customers' needs. Yet, complex ethical, political, technical, and social issues surround the secondary use of health data. While not new, these issues play *increasingly critical* and complex roles given current public and private sector activities not only expanding health data volume, but also improving access to data. Lack of coherent policies and standard "good practices" for secondary use of health data impedes efforts to strengthen the U.S. health care system. The nation requires a framework for the secondary use of health data with a robust infrastructure of policies, standards, and best practices. Such a framework can guide and facilitate widespread collection, storage, aggregation, linkage, and transmission of health data. The framework will provide appropriate protections for legitimate secondary use.

J Am Med Inform Assoc. 2007;14:1–9. DOI 10.1197/jamia.M2273.

Introduction

The American Medical Informatics Association (AMIA) convened a panel of diverse stakeholders and experts to discuss a full range of issues related to secondary use of health data. Specifically, AMIA has sought, in an open and neutral environment, to encourage a national discourse on this topic and attendant issues that will guide creation of a national framework. This report highlights the urgency and complexity of issues surrounding secondary use of health data by presenting the panel's key findings and recommendations. The report seeks to encourage public and private sector organizations engaged in health information policy formulation to emphasize the importance of secondary use of health data, and to recruit well-informed colleagues to develop the national framework. As important first steps, the panel recommends continuing dialogue, raising awareness, building collaboration, and clarifying issues. (See Table 1.) Secondary use of health data must become a priority for policymakers in the U.S. The panel's recommendations provide guidance on the composite resulting paper. Douglas Barton, W. Ed Hammond, Steve Labkoff, and Suzanne Markel-Fox served as members of the Steering Committee. They were actively involved in and provided valuable input to all aspects of the planning processes. Remarks by David Brailer (as the National Coordinator for Health Information Technology) and presentations from Doug Barton (Lockheed Martin), Blake Caldwell (Centers for Disease Control and Prevention (CDC), Nancy Davenport-Ennis (National Patient Advocate Foundation), Stan N. Finkelstein (Harvard-MIT), Melissa Goldstein (Markle Foundation, Connecting for Health), Michael I. Lieberman (GE Healthcare), Eleanor Perfetto (Pfizer), and Kevin Tabb (Stanford Hospital and Clinics) helped to shape the discussions and findings. Dasha Cohen from AMIA helped organize and coordinate logistics for the meeting; Lisa Piazza helped prepare for and facilitate the onsite discussions; Elaine Steen helped edit the report; and Freda Temple provided onsite meeting support as well as helped with production of this document.

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Reuse of Health Data

- Reuse (secondary use) of health data occurs when data are used for purposes other than those for which they were originally collected

- Valuable
  - quality/safety, public health, payment & business operations, research, provider certification and/or accreditation, post marketing surveillance & related business uses

- Questionable and/or Inappropriate

Dimensions of Use Framework

- **Accountability** – level of sanctions or penalties for disclosures or inappropriate use of patients' health data
- **Transparency** – the extent to which the practices governing the use of patients' health data are known & understood by those who disclose or use data and to the patients whose data are subject to use
- **Patient consent/notification** – the opportunity offered to patients to allow/permit the use of their health data. Notification refers to the mechanism by which patients are informed of their right to consent
- **Cost (resources required for) of re-identification** – is a proxy for the nature, complexity, & extent to which patients can be re-identified in a database(s)
- **Oversight** – the extent to which the entity is subject to governance or supervision; includes the ability to impose remedies for breaches
- **Regulatory/Law** – framework of regulations & laws that govern uses of health data, including penalties & enforcement guidelines

Consumer Awareness

about Personal Health Information for non-HIPAA Covered Entities

- A **Data Reuse Policy** should:
  - Be prominently posted, with an effective date
    - Written in clear understandable language
    - Identify contact to resolve privacy issues
    - Describe any & all uses of health data & any sharing of data with other organizations, whether you can be identified or not
    - Describe how personal data are protected
    - Describe how to receive a free report of who has accessed your data, & when
  - Describe how your permission is obtained to share data with others
    - Decisions to opt-out of data sharing should not result in denial of services
    - Provide advance notification of any changes
    - Allow termination, without penalty, if you do not agree with the changes
  - Describe whether, upon termination of the agreement, you can remove your data & prevent further disclosure, whether identifiable as yours or as part of a group
  - Describe how your data are handled if the organization is sold, merges with another organization, or files for bankruptcy

http://www.amia.org/inside/initiatives/healthdata/2007/draftconsumerchecklist.pdf

Taxonomy

- The taxonomy identifies possible uses of personal health information to clarify societal, public policy, legal, & technical dimensions.
- The taxonomy supports more focused, productive discussions regarding health data & their use.
- **Axes of the taxonomy**
  - What are the categories or classes of reuse?
  - How are the data used?
  - What are the existing or potential sources of health data?
  - Who are the users?

- **Future steps**:
  - Taxonomies are dynamic & must be maintained
  - Provide additional granularity for the commercial use category

www.amia.org/inside/iniatiatives/healthdata/2007/index.asp

Data Stewardship
Building & Maintaining a Chain of Trust

- ***Data stewardship*** encompasses the responsibilities & accountabilities associated with managing, collecting, viewing, storing, sharing, disclosing, or otherwise making use of personal health information.

- ***Principles*** of data stewardship apply to all the personnel, systems & processes engaging in health information storage & exchange within & across organizations.

Benefits of Data Stewardship Principles

- Provides rationale & safeguards for the legitimate uses of health data
- Describes enforcement mechanisms that provide reassurance of appropriate usage
- Describes benefit to the field of having “trusted data stewards” who adhere to these principles
  - These stewards should be able to share data without having to create ad hoc data handling guidelines for each transaction

Need for Data Analytic Principles

- A statistically sound approach is necessary for analysis of large clinical practice data sets
- Random analysis or unstructured data mining could yield associative conclusions & potentially introduce false positive associations
- Standard data analysis principles provide a framework for sound studies with credible and reproducible results, & for minimizing errors possibly introduced during analysis
- Data analysis principles mitigate the risk of false positives that could cause misidentification of a safety problem
- Provides a grounding for multiple parties such that analyses can be more readily compared

Next Step: Refine Data Stewardship Principles

- **Accountability** (including governance, oversight, & extent & level of applicable regulations)
- **Openness & transparency** (including structure, processing & delivery of data, plus business processes & practices)
- **Notification** to patients
- **Privacy & security** (including data quality, de-identification, & costs of re-identification)
- **Granularity of consent**
- **Permitted uses & disclosures** (including data aggregation & analyses)
- **Data analysis principles**
- **Enforcement & remedies**

AMIA Next Steps

- Differentiate appropriate & inappropriate use
  - Provide additional granularity for the commercial use category
- Develop recommendations to assure maintenance of Use Taxonomy
- Refine Stewardship Principles included Data Analysis principles
- Publish white papers
- Participate with AHIC, NCVHS, IOM & others, particularly with respect to negative impact on biomedical & health-related research

THANK YOU

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SECONDARY USES AND RE-USES OF HEALTHCARE DATA: TAXONOMY FOR POLICY FORMULATION AND PLANNING

This taxonomy is to be used as a resource in developing plans and policies related to secondary uses of healthcare data. The first section is meant to be inclusive of all categories or classes of secondary uses of healthcare data (in **bold**), but not exhaustive in enumerating the entire set of detailed uses in any given category. In contemplating a plan or policy relative to secondary uses of data, one should be able to refer to the taxonomy and consider how the plan or policy might apply to each class or category of use listed in the taxonomy.

The second section of the document lists factors that may be considered in formulating plans or policies for the secondary uses and re-uses listed in section one. For example, policies for re-use of data might be more restrictive for identifiable data or for data obtained from a vulnerable population.

The third section of the document lists the requirements and restrictions that might be imposed on the secondary use of data on the basis of the uses and factors for consideration. One would then be able to relate policy statements to a particular secondary use of data. For example, if a policy stated that "All secondary use of data to identify markets and promote sales requires prior patient consent" one would know that consent should be obtained from all patients contributing to the database before their data could be shared with manufacturing and sales firms that would target them as potential customers.

The final section of the document lists existing or potential sources of secondary data.

1) **Secondary uses and re-uses of data**
   - a) **Protect and enhance public health**
     - i) Enable and support biosurveillance
       - (1) Monitor and report vital statistics
       - (2) Monitor and report biometric demographics (e.g. weight, height, blood pressure, normal lab values)
       - (3) Identify, monitor, and report health and illness trends
       - (4) Identify, monitor, and report infectious diseases (e.g. culture, serology, DNA/RNA probe results)
     - ii) Export data to health registries
       - (1) Cancer or rare disease registries
       - (2) Drug and device registries
     - iii) Report toxic exposures (e.g. smoking, Agent Orange)
   - b) **Develop security and confidentiality algorithms and test de-identification routines**

- **c) Conduct research**
- **d) Create and maintain terminology and representation formalisms**
- **e) Develop and apply decision support for health care providers**
  - (i) Develop and test the efficacy of decision support algorithms
  - (ii) Develop order sets, rules, and alerts
- **f) Support quality of patient care**
  - (i) Manage quality and outcomes
  - (ii) Manage staffing and resources
  - (iii) Develop and assess quality indicators
  - (iv)Support quality reporting (e.g. HEDIS)
- **g) Improve patient safety**
  - (i) Conduct pharmacovigilance (post market drug and device surveillance)
    - (1) Detect and analyze adverse and sentinel events
    - (2) Support risk profiling
  - (ii) Monitor and survey to prevent patient adverse events
- **h) Manage personal health**
  - (i) Provide patient-specific feedback and assessments of progress toward health goals
  - (ii) Maintain personal health records
  - (iii) Provide links to knowledge resources based on personal health information
- **i) Educate and credential healthcare providers and assess training activities** (e.g. types and outcomes of procedures)
- **j) Analyze and Manage Finances**
  - (i) Conduct automated billing, claims processing
  - (ii) Analyze activity-based charge capture, cost accounting
  - (iii) Develop predictive models of costs and accounting
- **k) Detect fraud and illicit activity**
  - (i) Detect illegal and inappropriate activity (e.g., Medicare upcoding)
  - (ii) Report drug screen results to detect illegal drug use
- **l) Identify markets and promote sales**
  - (i) Conduct market research
  - (ii) Target marketing to physicians
  - (iii) Target marketing to patients and families

2) <u>Factors influencing authorization for secondary use of healthcare data</u>

- **a) Identification Status**
  - i) Patient-identifiable data
  - ii) De-identified data (HIPAA definition)
  - iii) Anonymized data
    - (1) No linkage possible (alteration of PHI, precluding linkage)
    - (2) Relinkable data
    - (3) Linked with protected key (trusted third party)
- **b) Consent provided at the time of data collection**
  - i) No consent by the individual
  - ii) Consent by the individual
    - (1) Broad and unspecified

(2) Time-limited consent
(3) Consented for partial, source specific use (e.g., no psychiatric data)
(4) Consented for the particular type of secondary use

c) Demographic representation
i) Age
ii) Race
iii) Gender
iv) SES
v) Insurance status

d) Focus on a vulnerable population (e.g. prisoners, pregnant women, undocumented immigrants)

e) Original collector and aggregator of the data
i) Government
ii) Health Plan
iii) Other private entity

f) Proposed secondary user of the data
i) Government agency
ii) Academic institution
iii) Private, not-for-profit entity
iv) Private, for-profit entity

g) Funding source for secondary use
i) Government agency
ii) Academic institution
iii) Private, not-for-profit entity
iv) Private, for-profit entity

h) Financial compensation to data collector or data steward for providing data to a second party
i) No compensation
ii) Compensation

i) Beneficiary of secondary use
i) Society
ii) Researcher
iii) Academic institution/medical center
iv) Private, for-profit entity (e.g., financial gain)

j) Disclosure of secondary use
i) Not disclosed publicly
ii) Publicly disclosed
(1) Disclosure of results only
(2) Disclosure of research methods utilized
(3) Disclosure of analytic principles that guided the use of the data

3) <u>Requirements imposed on secondary use of healthcare data</u>

a) Required level of consent and authorization
i) IRB evaluation not required
ii) IRB evaluation required

(1) No consent by the individual required
(2) Consent by the individual required

b) Compensation of patients

i) No compensation required
ii) Compensation of individual patients required

4) <u>Existing and potential sources of data for secondary use</u>

a) Public Use Datasets

i) Medicare
ii) Medicaid
iii) CDC surveys (some Primary data use, e.g. NHANES)

b) Private Datasets

i) Open-source data
ii) Commercial use datasets (at patient level)
(1) Pharmacy benefit/claims manager
(2) Provider databases
(a) Individual providers
(b) Aggregated data from provider consortia
iii) Consortium databases
(1) caBIG
(2) CTSA recipients
(3) University Health Systems Consortium
iv) Aggregated clinical repositories hosted by HIT vendors
v) Personal health records, including patient-entered data
vi) Health Information Exchanges (RHIOs, etc)

Perspectives on JAMIA Informatics

White Paper ■

Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper

Charles Safran, MD, MS, Meryl Bloomrosen, MBA, W. Edward Hammond, PHD, Steven Labkoff, MD, Suzanne Markel-Fox, PHD, Paul C. Tang, MD, Don E. Detmer, MD, MA, with input from the expert panel (see Appendix A)

Abstract Secondary use of health data applies personal health information (PHI) for uses outside of direct health care delivery. It includes such activities as analysis, research, quality and safety measurement, public health, payment, provider certification or accreditation, marketing, and other business applications, including strictly commercial activities. Secondary use of health data can enhance health care experiences for individuals, expand knowledge about disease and appropriate treatments, strengthen understanding about effectiveness and efficiency of health care systems, support public health and security goals, and aid businesses in meeting customers' needs. Yet, complex ethical, political, technical, and social issues surround the secondary use of health data. While not new, these issues play *increasingly critical* and complex roles given current public and private sector activities not only expanding health data volume, but also improving access to data. Lack of coherent policies and standard "good practices" for secondary use of health data impedes efforts to strengthen the U.S. health care system. The nation requires a framework for the secondary use of health data with a robust infrastructure of policies, standards, and best practices. Such a framework can guide and facilitate widespread collection, storage, aggregation, linkage, and transmission of health data. The framework will provide appropriate protections for legitimate secondary use.

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Introduction

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Table 1 ■ Panel Recommendations

Recommendation	Discussion
Increase transparency of data use and promote public awareness	Ongoing public policy discussions must explicitly and directly address the secondary use of health data. Conducting and managing these activities must enlist diverse stakeholders and fully disclose uses and safeguards through open and readily accessible processes.
Focus ongoing discussions on data access, use, and control—not on ownership	Consensus-building meetings encompassing a broad constituency must focus on data access and control policies and practices for secondary use of data. Focus should emphasize access and control, not ownership. Discussants should consider best approaches to risk management and mitigation.
Discuss privacy policies and security for secondary use of health data	To develop consensus on pivotal issues, public and private sector organizations advancing the use of health information should promote discussions that include a wider range of stakeholders than were engaged in this conference. Ongoing discussions must address complex issues related to private and secure secondary use of health data.
Increase public awareness of benefits and challenges associated with secondary use of health data	A wide range of interested parties, especially consumer-oriented patient and caregiver groups, should promote public education regarding benefits of EHRs and about secondary use of health data. A first step is to identify appropriate organizations and agencies that have a role to play in this effort. The aim of the education is to build public awareness and trust in secondary use of health data.
Create a taxonomy for secondary uses of health data	A taxonomy identifying possible non-clinical uses of personal health information is needed to clarify societal, public policy, legal, and technical issues. The taxonomy will support more focused, productive discussions regarding health data and their use.
Address comprehensively the difficult, evolving questions related to secondary use of health data	Questions to address encompass data transparency, consumer awareness and understanding, technical issues and challenges of identity management and user authentication, commercialization and sale of data, and oversight. The de-identification and anonymization of data merit additional attention by technical experts in authentication, de-duplication, and identity management.
Focus national and state attention on the secondary use of health data	The Panel encourages AMIA to share the findings of this meeting with all interested stakeholders, including, but not limited to, the Department of Health and Human Services (DHHS) National Committee on Vital and Health Statistics (NCVHS) and the American Health Information Community (AHIC). Additional efforts should be undertaken to formulate a roadmap that depicts multi-tiered use and re-use of health data; the roadmap should take into account all foreseeable applications and the full complexity of issues.

nents of the envisioned national framework. (See Table 2). Public and private sector stakeholders can elaborate upon these components through discussions that will produce, over time, appropriate technical safeguards and supportive public policies that further the public good. Strengthening and maintaining public trust requires ongoing transparent dialogue with our citizens concerning use of their health data.

Background

In today's data-intensive health care environment, providers generate terabytes of patient data. Laboratory auto-analyzers, pharmacy systems, and clinical imaging systems produce increasingly complex and voluminous data, augmented by data from systems supporting health administrative functions such as patient demographics, insurance coverage, financial data, etc. Clinical narrative information, captured electronically as structured data or transcribed "free text," can also be captured as digital voice dictations or scanned hand-written records. As clinicians adopt electronic health records (EHRs) as the standard for clinical practice, as a byproduct, new sources of detailed clinical information will be created. Those data, combined with existing data, will dramatically increase the breadth and depth of information available for non-clinical applications. Recent advances make it increasingly likely that human genomic data will be routinely available in the future.

While individual patients' rapid, secure electronic access to their own health information can lead to better, more efficient, and more personalized care, demands proliferate for access to, and analysis of, health data outside of clinical settings. Aggregated health data provide value to a broad range of research, quality, public health, and commercial applications. For example, carefully controlled clinical data analysis underpins the measurement of quality and safety in health care delivery. Future pay-for-performance models will likely strengthen linkages between physicians' and hospitals' performance data and reimbursement. Evidence suggests that the public health community can analyze aggregated data to facilitate early detection of emerging epidemics or bioterrorist threats. Commercial enterprises collect health care data to derive products and services that they sell to customers, including third party payers, researchers, and marketing entities.

Secondary uses of health data[1] can enhance individuals' health care experiences, expand knowledge about diseases and treatments, strengthen understanding of health care systems' effectiveness and efficiency, support public health and security goals, and aid businesses in meeting customers' needs. Yet, access to and use of health data pose complex ethical, political, technical, and economic challenges. For

[1]For purposes of this meeting, secondary use of data was defined as non-direct care use of personal health information (PHI) including but not limited to analysis, research, quality/safety measurement, public health, payment, provider certification or accreditation, and marketing and other business including strictly commercial activities.

example, to meet public health, emergency preparedness, and homeland security imperatives the federal government has initiated real-time collection of data from emergency rooms and other sources—without public dialogue, based on authority from existing public health law. Further, there are reports of the buying and selling of non-anonymized patient and provider data by the medical industry—carried out without explicit consent from patients or physicians. Such activities include pressuring or coercing patients to consent to data disclosure for use not covered by regulation, and abuses of commercially available, identifiable patient information. Although the Health Insurance Portability and Accountability Act of 1996 (HIPAA) applies to health information created or maintained by health plans, health care clearinghouses, and health care providers who engage in certain electronic transactions, there is a potential lack of protection of personal health information (PHI) when used by entities not explicitly covered by HIPAA legislation or regulations. Individuals and organizations may mistakenly perceive HIPAA to assure protection of all secondary use of PHI by users, beyond those covered entities specifically noted in HIPAA.

These issues are not new. Fresh consideration of secondary uses of health data is, however, critical. Both public and private sector organizations continue to design systems enabling secondary use of health data for applications in clinical, public health, biomedical, policy, health services research areas, as well as for other evolving public concerns, including emergency preparedness, global epidemiology, and homeland security.

Renewed public and private sector efforts promote adoption of EHRs. Related efforts focus on developing a nationwide, secure health information network that can support safe, equitable, efficient, effective, and patient-centered health care. Such initiatives include establishment of the American Health Information Community (AHIC) and contracts awarded to develop prototypic architectures for a Nationwide Health Information Network (NHIN). Recent National Institutes of Health (NIH) initiatives promote population-based studies to identify genetic and environmental causes of common illnesses. These portend potential low-cost sequencing of personal genomes in the not too distant future. The NIH Roadmap for Medical Research promotes clinical research networks and data sharing. The foregoing activities emphasize the need to re-examine implications of secondary uses of person-specific data. In July 2006, the Robert Wood Johnson Foundation (RWJF) announced *Project HealthDesign: Rethinking the Power and Potential of Personal Health Records*, a national program designed to stimulate innovation in the development of personal health record (PHR) systems. Further, the *Roadmap for Clinical Decision Support*, developed by AMIA under contract to the Office of the National Coordinator for Health Information Technology (ONC), presents a vision for an ongoing cycle of data collection, research, and new knowledge generation to strengthen clinical decision support. In addition to national initiatives such as those listed, there are myriad activities related to the secondary use of health data at state, regional, and organizational levels.

Catalyzing the Discussion of Secondary Use of Health Data

While pivotal to strategic improvements in the U.S. health system, secondary use of health data poses technical, strategic, policy, process, and economic concerns related to the ability to collect, store, aggregate, link, and transmit health data broadly and repeatedly for legitimate purposes. Thus, lack of coherent policies and standard "good practices" for secondary use of health data impedes efforts to transform the U.S. health care system. Further, growing availability of technologies supporting secondary uses, combined with data expansion, per se, heightens urgency to engage the public in a transparent dialogue. Addressing these myriad challenges ultimately requires a national framework for secondary use of health data, including a robust infrastructure of policies, standards, and best practices.

AMIA has sought, in an open and neutral environment, to further national discourse on secondary uses of health data and attendant issues in a manner that will guide creation of a national framework. AMIA convened a meeting of diverse stakeholders (i.e., the panel) to discuss the full range of such issues, including, but not limited to:

- What are the potential benefits and risks regarding the secondary use of health data?
- Who owns health data and who has the right to access the data and for what purposes?
- What are the evolving public trust issues with respect to patient consent for secondary use of health data? Do patients have the right to audit or put other constraints on the use of their data, even after anonymization?
- In light of serious public health threats such as avian flu, how does society reconcile the public good with the rights of the individuals while weighing health versus privacy considerations?
- What problems may develop as innovative technologies enhance the ability and ease of widespread data sharing and additional commercial uses?
- What can be done to address issues arising from inappropriate use and/or exploitation of data sharing?
- What regulations, legislation, and/or policies and procedures are needed to address these issues?

All stakeholders must develop sufficient understanding of the inherent benefits and risks of secondary uses of health data in order to develop effective policies and practices. This, in turn, will require ongoing discussion, education, communication, and collaboration among consumers, ethicists, health care practitioners, industry specialists, informaticians, policy makers, researchers, and others. The work of this panel, as reflected in this report, is a first step in promoting dialogue among stakeholders about the opportunities and challenges related to the secondary use of health data.

Methodology

An expert panel convened April 27–28, 2006, in the metropolitan Washington, D.C., area. A steering committee composed of a small group of experts and representatives of the major sponsors of the meeting set goals and an agenda for the meeting. The steering committee suggested potential discussants and panel participants. The 36 panel members

Table 2 ■ Components of a National Framework for Secondary Use of Health Data

Transparent policies and practices for the secondary use of health data
Focus on data control, rather than data ownership per se
Consensus on privacy, policy, and security
Public awareness
Comprehensive scope (beginning with a taxonomy)
National leadership

included representatives from health care providers, technology vendors, pharmaceutical companies, consulting firms, practitioners, researchers, government agencies, and citizen stakeholders. Appendix A (available as a JAMIA online supplement at www.jamia.org) comprises a complete list of sponsors and participants. To inform discussions, participants received background information and discussion questions before the meeting.

The panel focused on secondary uses of person-specific health data. The panel designated certain topics as outside its scope, including both truly de-identified data that cannot be re-identified to specific persons, and technical processes and procedures for achieving data de-identification. These were nevertheless considered important to the overall topic.

The meeting agenda viewed secondary use of health data from four main perspectives: the consumer; patient safety, quality, and research; public health; and industry (see Appendix B, available as a JAMIA online supplement at www.jamia.org, for complete agenda). AMIA staff and consultants served as facilitators and recorders to support the deliberations. Divided into four sessions, the first day focused on these perspectives. Each session began with two background presentations that provided an overview of the topic and identified the salient issues. Next, the entire group shared observations on the topic through plenary discussions moderated by a facilitator. Following open discussions, each of the four round tables considered previously prepared common scenarios, with associated questions intended to guide discussion. (See Appendix C for the scenarios.) Each group selected a presenter who summarized the small group's discussions, including areas of agreement and ideas for future efforts. During his address to the group at a dinner meeting that closed the first day's work, David Brailer, MD, PhD, shared insights from his experience as the National Health Information Technology Coordinator and as CEO of Care Science.

The second day began with a presentation of a synthesis of Day One discussions. This was followed by additional small group discussions and reports on the common themes of Day One, and a final round of group discussions and reports focusing on recommendations and future steps.

Definition of Terms and Abbreviations

The panel quickly recognized a need to clarify terminology in common use for the context of the meeting. For effective communication, all participants in the dialogue had to use the same vocabulary in the same way. The panel offered the following working definitions for terms used during the meeting, and agreed that further refinement of the terminology is needed (see Recommendations).

anonymized data—alteration of PHI that makes it impossible to link individuals with their data.

commercialization—the sale or resale of health data.

covered entities—The Administrative Simplification standards adopted by the U.S. Department of Health and Human Services (DHHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) apply to any entity that is a health care provider that conducts certain transactions in electronic form (called here a "covered health care provider"); a health care clearinghouse; a health plan. An entity that is one or more of these types of entities is referred to as a "covered entity" in the Administrative Simplification regulations.

de-identified data—the elimination of all identifiers as enumerated under HIPAA under the safe-harbor method (i.e., a patient's name, medical record number, social security number, and other data fields that directly link a patient to their data). There is potentially another approach that involves having a statistician determine that the ability (likelihood) of being able to combine data with other public sources of information and successfully identify an individual is extremely small.

electronic health record (EHR)—personal data created, developed, maintained, and/or provided by clinicians, providers, and allied health providers in direct patient care; an electronic application containing health information about individuals that is used by clinicians, providers, and allied health professionals to provide direct care for the individuals.

health data—data about or from an individual such as a person's age or serum potassium level. In aggregate, an individual's data are called personal health information (PHI).

personal health record (PHR)—an electronic application through which individuals can access, manage, and share their health information, in a private, secure, and confidential environment; personal data created, developed, maintained, and/or provided by individuals about themselves.

primary use of data—the use of PHI by the organization or entity that produced or acquired these data in the process of providing real-time, direct care of an individual.

reversibly anonymized data—the alteration of PHI in such a way that re-identification may be accomplished through access to a protected key that makes it possible to link individuals with their data only through a trusted intermediary.

secondary use of data—non-direct care use of PHI including but not limited to analysis, research, quality/safety measurement, public health, payment, provider certification or accreditation, and marketing and other business including strictly commercial activities.

Meeting Highlights

The meeting style and format, including thought-provoking scenarios and questions, prompted lively discussion of the complex issues. These ranged beyond specific situations presented in the scenarios. Meeting highlights follow below, organized by the four perspectives of the conference.

Consumer Perspective

The first session focused on the issues of privacy and security of personal health information from the consumer's point of view. Background presentations highlighted policy challenges associated with electronic health information exchange, and EHR-related consumer benefits as well as pitfalls related to privacy breaches. During the discussion period, panelists reviewed the scenario of an imaginary "Mrs. Powter" whose employer is switching employees to a new health plan to cut costs (see Appendix C). The questions raised during this discussion reverberated throughout the meeting:

Who owns the data in Mrs. Powter's personal health record?

When Mrs. Powter leaves Health Plan #1 what happens to her data?

What are the issues (e.g., data exchange standards, cost) that arise when transferring data among health plans?

What additional, secondary uses of the data should be permitted?

Should Mrs. Powter be asked for permission for each instance of usage or should she give global permission?

Small group discussions covered a variety of issues related to personal data: participants drew a distinction between data ownership and access to data; differentiated between the PHR and the EHR; raised concerns about data misuse, consent under duress, and gaps in HIPAA protections; debated relevant intellectual property issues; and considered the rights of patients versus their obligations with respect to the patient's own data.

Patient Safety, Quality, and Research Perspective

Launched by presentations about secondary uses of health data for research purposes, the second session considered challenges related to conducting research with data originally collected for another purpose (i.e., insurance claims). Panel members turned to consideration of a scenario in which, as part of a cost cutting effort, a health plan queries the company's data repository to link outcomes of therapy for hypertension to medicines prescribed as evidenced by claims data, in an attempt to determine which drugs lower blood pressure most effectively. The group discussed the limitations of the study approach and the potential shortcomings of the data as well as whether the conclusion reached by this method was valid. The panel concluded that standards were lacking for establishing levels of evidence. It further determined the need to establish explicit rules or conventions to define evidence, and to validate secondary datasets. The discussion covered complex issues related to de-identification of data, including increasingly available technical approaches for re-identification of data through dataset interlinkages.

Public Health Perspective

The panel discussed the growing use of health data for purposes of emergency preparedness, public health, epidemiology, and homeland security. The first presentation described BioSense, a CDC program to improve the nation's capabilities for real-time biosurveillance and situational awareness. The second presentation offered lessons learned by a systems integration company in developing projects involving data subject to privacy constraints. Panel members discussed a scenario in which university-based researchers attempted to gain access to a scrubbed copy of BioSense data to study quality and disparity in emergency treatment across the United States. The group considered the now-familiar issues of obtaining patient consent for downstream use of data, concerns about potential data re-identification, and the need for clear rules and safeguards for release of data. There was strong agreement on the need to inform and educate patients about all downstream uses of their data. However, there was diverse opinion regarding the most effective and practical approaches to accomplish this. Participants agreed that these topics warrant further discussion.

Industry Perspective

Major topics discussed during the session on industry perspectives included growing commercialization of health data and use of health data for business and proprietary purposes. Two industry viewpoints promoted dialogue, one from a consortium of clinicians who made their pooled data available to consortium members for quality-related research and sold the data to non-consortium researchers, and a second from the pharmaceutical industry, describing the variety of uses that it makes of aggregated data, and limitations and advantages of various data sources. The group scenario addressed collection and sale of patient data by a fictional Regional Health Information Organization's (RHIO) Chief Executive Officer (CEO), who was tasked with developing a business plan identifying a revenue stream not reliant upon federal or state funds. Panel members once again grappled with the issues of patient consent for the sale of data used for non-direct patient care purposes. They considered whether the sale of data for a specific use (medical research versus proprietary or targeted marketing) should have a bearing on the issue, and whether the situation would be different if the RHIO was funded by private sector dollars rather than by the federal government.

Major Findings and Recommendations

By design, the meeting enumerated major issues associated with secondary uses of health data as the starting point for an all-encompassing, nationwide dialogue. The panel's findings and recommendations, presented below, form topics to guide AMIA's further collaborative efforts and activities.

Finding 1: Secondary use of health data is widespread. The presentations and discussions, as well as the literature (see Appendix D for a selected bibliography), document widespread, growing secondary use and re-use of health data. Such uses occur in both public and private sectors for proprietary, research, and monitoring purposes with less than comprehensive regulation. Participants agreed that, in most instances, providers, physicians, and their patients are generally unaware of this development, despite the growth and success of a multimillion-dollar industry based on the sale of health and heath-related data. Further, while HIPAA requires many health care providers and health insurers to obtain additional documentation before disclosing person-specific health information, and to closely scrutinize requests for access to health information for secondary purposes, such as for research, HIPAA rules only address the use and disclosure of health information by "covered enti-

ties" (i.e., health care providers, health plans, and clearinghouses).

Recommendation 1: Increase transparency of data use and promote public awareness. Ongoing public policy discussions must explicitly and directly address the secondary use of health data. Conducting and managing these activities must enlist diverse stakeholders and fully disclose uses and safeguards through open and readily accessible processes.

Finding 2: The focus needs to be data access and control, not data ownership. Group consensus was that focusing on "ownership" diverts attention from needed development of sound policies and practices. Participants acknowledged that responsibility for ensuring privacy and safeguarding patient data applies across the diverse continuum of data users. Technical advances enable creation of many databases that are now maintained, updated, used, and re-used for multiple purposes, including those outside direct patient care. Technology has also enabled easy transmission of such data. Despite HIPAA requirements regarding the de-identification of data and adherence to data use agreements, there is the potential for the re-identification of patients and providers through the linkage of disparate databases. A need exists to further explore and explicitly address issues of health data access and control throughout data life cycles. Extensive discussions covered the need to develop policies for secondary uses of health data, recognizing that such policies will be complex.

Recommendation 2: Focus ongoing discussions on data access, use, and control—not on ownership. Consensus-building meetings encompassing a broad constituency must focus on data access and control policies and practices for secondary use of data. Focus should emphasize access and control, not ownership. Discussants should consider best approaches to risk management and mitigation.

Finding 3: Critical issues include patient privacy and public trust. Use of person-specific patient data for purposes other than direct patient care and public health is not well understood and is poorly monitored. This raises numerous ethical, technical, economic, and procedural concerns. The sense of the meeting participants was that too few safeguards exist that adequately address secondary uses of health data. Further discussions about informed consent must clarify how data uses for specific purposes can remain in compliance with federal, state, and local laws. Health data uses not covered by privacy regulations, including uses of data obtained via coerced or compelled consent, can erode public trust and might potentially hinder the public good. Some panel members asserted that development and execution of patient choice options involving explicit authorization for use of their own data (opting in/opting out) provides the only adequate means to mitigate patient privacy issues. Participants acknowledged that no "single unified patient (consumer) perspective" exists. Consumers will view the issue in many possible ways—assuming they are informed about it. Thus, substantial variation in consumer viewpoints will make issues related to patient (consumer) consent and choice complex.

Recommendation 3a: Discuss privacy policies and security for secondary use of health data. To develop consensus on pivotal issues, public and private sector organizations advancing the use of health information should promote discussions that include a wider range of stakeholders than were engaged in this conference. Ongoing discussions must address complex issues related to private and secure secondary use of health data.

Recommendation 3b: Increase public awareness of benefits and challenges associated with secondary use of health data. A wide range of interested parties, especially consumer-oriented patient and caregiver groups, should promote public education regarding benefits of EHRs and about secondary use of health data. A first step is to identify appropriate organizations and agencies that have a role to play in this effort. The aim of the education is to build public awareness and trust in secondary use of health data.

Finding 4: Technological capabilities to merge, link, re-use, and exchange data outpace establishment of policies, procedures, and processes to do so ethically and legally. Increasingly complex issues arise from advancing technical capabilities. Meeting participants did not agree on technical issues such as whether data can be truly anonymized, or what are the preferred methodologies for "identity management." There is a need to build consensus around working definitions of secondary health data uses, and to develop clearer understanding of strengths and limitations of using specific types of health data. Defining secondary uses for health data must also envision the potential impact of future EHR evolution, as well as advances in communications capabilities and forthcoming biomedical research, such as large scale, population-based genomic studies that generate vast amounts of personal genetic information.

Recommendation 4a: Create a taxonomy for secondary uses of health data. A taxonomy identifying possible non-clinical uses of personal health information is needed to clarify societal, public policy, legal, and technical issues. The taxonomy will support more focused, productive discussions regarding health data and their use.

Recommendation 4b: Address comprehensively the difficult, evolving questions related to secondary use of health data. Questions to address encompass data transparency, consumer awareness and understanding, technical issues and challenges of identity management and user authentication, commercialization and sale of data, and oversight. The de-identification and anonymization of data merit additional attention by technical experts in authentication, de-duplication, and identity management.

Finding 5: Progress requires additional attention and leadership at state and national levels. Existing efforts to develop and implement a nationwide interconnected and interoperable network infrastructure do not adequately address issues of secondary health data use. National-level leadership must obtain input from a broad range of public and private sector stakeholders in order to develop adequate policies, standards, and legal/regulatory remedies regarding the secondary use, abuse, and misuse of health data. Stakeholders include those who collect the data for primary use; those who use the data for non-clinical purposes; patients and the public; those who create policy about health data; those who inform and educate health care professionals, industry, patients, and the public; and philanthropic organizations

that support development of policy on critical health and technology issues.

Recommendation 5: Focus national and state attention on the secondary use of health data. The Panel encourages AMIA to share the findings of this meeting with all interested stakeholders, including, but not limited to, the Department of Health and Human Services (DHHS) National Committee on Vital and Health Statistics (NCVHS) and the American Health Information Community (AHIC). Additional efforts should be undertaken to formulate a roadmap that depicts multi-tiered use and re-use of health data; the roadmap should take into account all foreseeable applications and the full complexity of issues.

Conclusion

A natural byproduct of existing clinical and administrative activity is an increasing array of rich data sources and datasets. Many such resources contain personally identifiable or potentially identifiable data—i.e., the data can be re-identified after being de-identified. The increasing volume, complexity, and diversity of health care data and information systems, as well as approaches to identifying and linking datasets, pose significant problems for the future.

Panel participants estimated that a well-established multi-million-dollar business exists that utilizes secondary health data as its primary resource. However, the panel conducted no research to establish this estimate. For several decades, various organizations such as hospitals, health plans, and payers have "mined" mostly administrative claims and prescription data. In the current health care environment, an expanding, diverse array of users in the commercial research, public health, policy, and clinical and biomedical research communities seeks access to secondary health data. Widespread use of personal health data outside of the primary care setting often occurs with commercial intent as employers, payers, and insurers attempt to fulfill business and proprietary-oriented goals and objectives. Furthermore, as EHRs continue to evolve and the adoption of health information technology increases, more health data will become readily available, with predictable increased efforts to access and use these data for various non-patient care purposes.

Unfortunately, some data usages, such as by the Medical Information Bureau, are neither well regulated nor subject to citizen oversight. Many recent regional efforts to establish health information exchanges face a business challenge to provide information utilities to the community at the lowest possible cost. Although not often in public, stewards of these data exchanges and their business partners are exploring non-subscription models for revenue generation which frequently include selling clinically rich datasets to industries that already purchase surrogates for such data. In addition, the imperatives from public health and homeland security have initiated the collection of real-time data (such as emergency room data) from hospitals and other providers across the country without public dialogue. At a minimum, a public dialogue is needed.

Meeting participants agreed that the rapidly evolving nationwide efforts for more widespread health information exchange must include work to address pressing issues of secondary health data usage, as outlined in this report. The panel report lays a foundation for new dialogue about these uses, and emphasizes important roles to be played by the public and private sectors. In addition to stimulating future action, the panel's recommendations provide guidance regarding the components that should shape a national framework for secondary use of health data:

- Transparent policies and practices for the secondary use of health data;
- Focus on data control ownership rather than data ownership per se;
- Consensus on privacy, policy, and security;
- Public awareness and trust;
- Comprehensive scope (beginning with a taxonomy); and,
- National leadership.

Public and private sector stakeholders, in future discussions on the secondary use of health data, can explore these components more fully. Through creation of appropriate technical safeguards and supportive public policy, the panel believes that the secondary use of health data can further the public good. A more transparent dialogue with our citizens concerning the use of their health data is key to maintaining and strengthening the public trust, while enhancing the public's informed actions.

AMIA Board of Directors (BOD) Response and Action

By convening this expert panel and disseminating this report, AMIA has identified the topic of the secondary use of personal health information as a critical issue for the continued widespread adoption of health information technology. The AMIA BOD reviewed the paper and endorsed the panel's recommendations. The BOD anticipates that it will commit additional organizational resources to advance the work of the panel. AMIA will encourage other organizations to collaboratively pursue the recommendations and to continue this important public discourse.

Appendix C: Discussion Scenarios

A) Mrs. Powter is a 44-year-old mother of two who works for a small business and obtains health insurance for her family through her employer. Health Plan #1 provides an online personal health record (PHR) linked to a pharmacy benefits management (PBM) company. The PHR is automatically updated with claims data and medications from the PBM. She can add problems to the problem list and add medications to her medication list. A wellness program provided by Health Plan #1 asks her questions and records answers in the PHR.

Since health premiums will rise by 15%, her employer decides to switch all 15 employees to Health Plan #2.

Who owns the data in the PHR?

Is there a difference between the data that Mrs. Powter entered vs. the plan's encounter data or data from the PBM?

When Mrs. Powter leaves Health Plan #1 what happens to her data?

Who pays the cost to transfer the data between systems, presuming that is allowable: the sending health plan, the receiving health plan, or Mrs. Powter (because it's a PHR)?

From a logical viewpoint, what would be necessary (what kind of standards) in order for no additional effort to be required to transfer the data from #1 to #2?

Where should the PHR data be stored—at the PBM, at the person's computer, both, or neither?

If the sending and/or receiving systems do not conform to clinical data exchange standards, who bears the cost of transfer change? Who determines the relevant standards?

What kind of "pressures" (and by whom) should be used to encourage or enforce the required clinical data exchange standard?

What additional, secondary use of the data should be permitted? Should Mrs. Powter be asked for permission for each instance of usage, or should she give global permission?

Would the answers to these questions differ if the health plans were federally or state funded plans (under Medicare or Medicaid)?

B) A large insurance company is facing what it perceives as a very difficult period in claims expenses coming in the next few years. Its Chief Executive Officer (CEO) directs his staff to trim costs. An eager analyst in his group wants to deliver on cost savings and decides to look to the company's spending on chronic care medicines. He decides to run a series of queries from his own company's data repository attempting to link outcomes of therapy to medicines prescribed (as evidenced by claims data). As his health plan pays for both laboratory tests and prescriptions, he can link laboratory results and hospitalization data to prescribing information. He decides to look at hypertension as a diagnosis and then tries to find out which drugs lower blood pressure most effectively. His analysis complete, he reports back to his superiors about his findings, which suggest that generic medications are the only medicines that should be covered by the plan going forward.

What defines a standard of evidence from health data?

Who decides what studies demonstrate valid conclusions (i.e., is there a peer review process for making such claims)?

Should data as described above be considered "evidence"—should its use in clinical care be considered Evidence Based Medicine (EBM)?

Should there be standards of how information from studies such as this one is reported to the public? Should the data behind these findings be made available for external verification?

C) University-based researchers wanting to study quality and disparity in emergency treatment across the United States develop a sound study methodology. They receive approval from their institutional review board (IRB) and funding from a private foundation. With support from their influential senators and representatives, they approach the Centers for Disease Control and Prevention (CDC) and request a scrubbed copy of the agency's BioSense data.

Is this a legitimate tertiary use of data?—Tertiary in the sense that the original owner of the data has not been involved in making a determination of how the data should be used.

Does the patient or provider of data to CDC need to be informed or is consent required?

Can the patient/provider opt out?

What assurance is required, if any, that the tertiary use of data in the emergency treatment study conforms to the terms of the study design and any data use agreements executed between the CDC and the researchers? Who is responsible for auditing the use of data or making this determination?

Does the patient/provider have the right to inspect/review the use of the data?

D) State RHIO has been funded by AHRQ to design, build, and implement a health information exchange. The stakeholders are convened and form a governance board and appropriate working groups to use these funds wisely and well. A CEO is hired to run the RHIO and develop a business plan that does not require federal or state funding. One idea that surfaces is collecting and selling patient data.

Who owns the data? Who can use the data and for what purposes?

Who gets compensated when the data are used for non-patient care purposes?

Should patients be informed each time their data are used for non-patient care purposes and would they have the right to opt in or out?

Under what circumstances is specific patient consent required? Would the need for consent differ if the data are de-identified?

Is physicians' consent required for use of data from patients under their care?

Does the use of the data (e.g., medical research vs. identification of patients for targeted marketing of pharmaceuticals) have a bearing on the issue?

How does use of these clinical data for payment or reimbursement fit into the privacy issues? Should payers be permitted to use the data for other purposes?

To what extent can patient data be used to evaluate provider performance?

Should these data be used without patient permission for health surveillance? Should drug companies be able to use these data for drug trials? Could these data be used to help identify patients for eligibility in clinical trials or other research protocols?

Would the answers to these questions differ if the RHIO were funded by private sector dollars?

Appendix D: Selected Bibliography

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The National Committee on Vital and Health Statistics
A Public Advisory Body to the Secretary of Health and Human Services

Enhanced Protections for Uses of Health Data:

Recommendations to HHS on A Data Stewardship Framework

American Health Information Community
November 13, 2007

– Ad Hoc Work Group on Uses of Health Data –

Simon Cohn, MD, MPH, NCVHS and WG Chair
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Discussion Outline

- Scope of Work and Process
- Terminology
- Why Now?
- Data Stewardship Framework
- Observations, Recommendations, and Next Steps

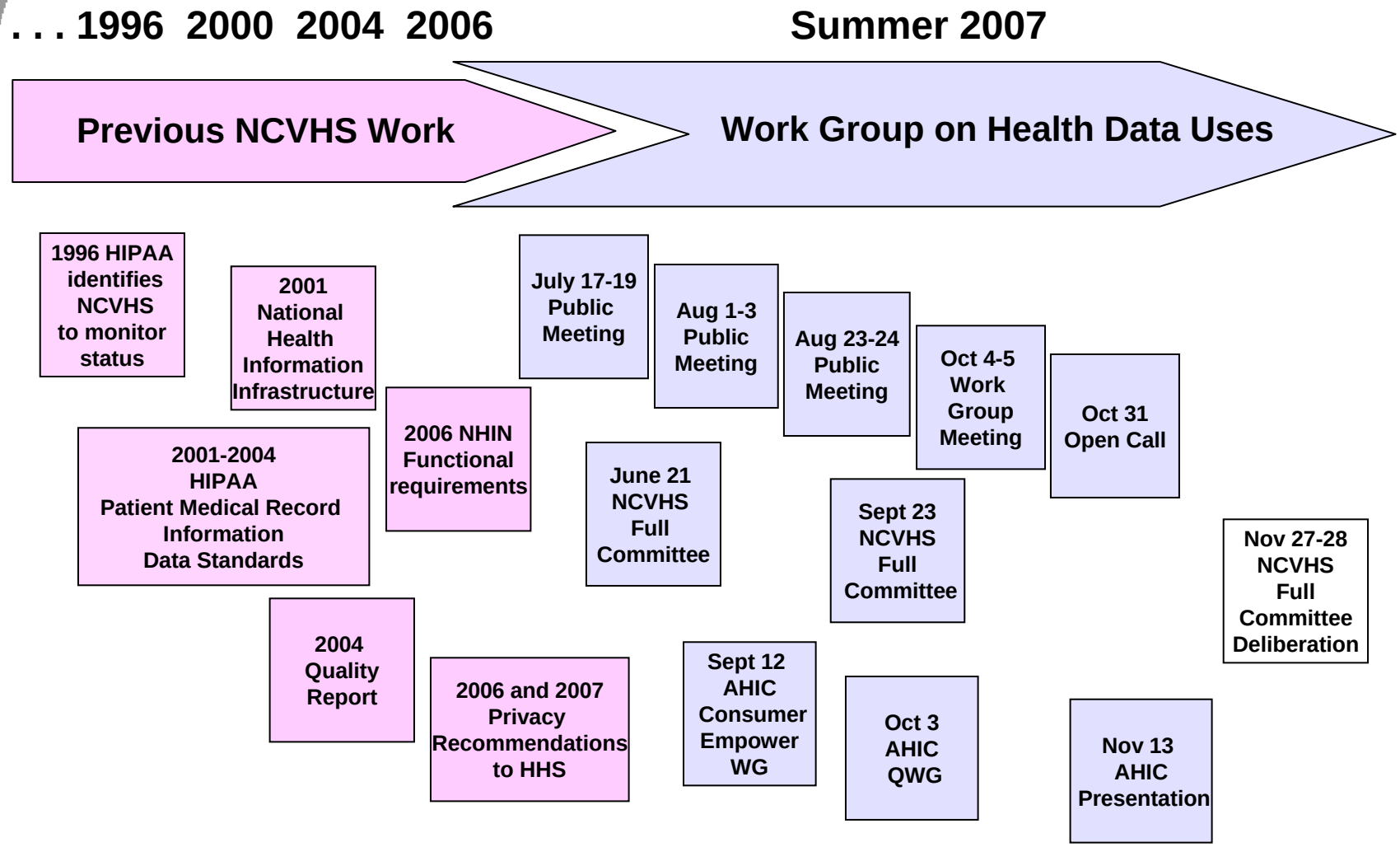
NCVHS

NCVHS Scope of Work

- Develop a conceptual and policy framework that provides guiding principles to balance risk, sensitivity, benefits, obligations, and protections of various uses of health data
- Develop recommendations for HHS on data stewardship principles and other measures to enable optimal uses of health data, while respecting privacy of the individuals who are the sources of those data

Emphasis on appropriate protections surrounding uses of health data for quality measurement, reporting, and improvement

NCVHS Timeline



NCVHS Process

- Public Meetings in Washington, DC
- 58 Expert Testifiers from:
  - Provider and consumer representatives
  - Quality organizations
  - Health information exchanges
  - Vendors who process and use health data
  - Research and public health communities
- Interim findings discussed with AHIC Consumer Empowerment and Quality Workgroups
- Release of draft document that will be modified based on public comment

NCVHS

Related Work and Collateral Documents

- **AHIC QWG Vision Summary and Quality Use Cases**
- **AHRQ National Health Data Stewardship RFI**
- **AMIA – Toward a National Framework for Secondary Use of Health Data**
- **NCVHS selected reports, including:**
  - Recommendations on Initial Functional Requirements for a NHIN, October 30, 2006
  - Recommendations to the Secretary of HHS Regarding Privacy and Confidentiality in the NHIN, June 22, 2006
  - Report to the Secretary of HHS on Personal Health Record (PHR) Systems, September 9, 2005
  - Report on Measuring Health Care Quality, May 2004

NCVHS

Terminology

- Terms such as “secondary use”
  - Are difficult to define, with no standard reference
  - Connote lesser importance than other uses
- Grouping all uses under a single rubric may result in all being treated the same

NCVHS is avoiding the use of “secondary” or other such terms, and encourages explicit and unique description of each use of health data

NCVHS

Why Address Uses of Health Data Now?

- **Electronically available health data are no longer just claims data, but include more clinically rich data**
- **Electronic data can be linked more readily with other databases**
- **Sources of electronic health information are expanding beyond HIPAA protections of covered entities and their business associates**
- **Electronic solutions to protect and secure data continue to evolve, including approaches to allow individual consent to follow data**

NCVHS

Recurring Themes

- **Enhanced use of health information technology:**
  - Increases ability to use health data to benefit health care
  - Enhances quality measurement and reporting
  - Enables a more real time quality improvement cycle
  - Supports public health surveillance and responsiveness
  - Expedites accrual of cases for timely identification of complications from drugs and devices and clinical research
- **But, raises concerns about the potential for harm**
  - Erosion of trust in the health care system with potential compromise to health care may occur when there is divergence between expected and actual use of health data
  - Discrimination or confidentiality concerns may be amplified with increased ability to collect longitudinal data, coupled with sophisticated means to re-identify data

HIPAA

- **Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification provisions promote electronic exchange of financial and administrative transactions**
- **HIPAA legislation's requirements for health information privacy resulting in issuance of Privacy Rule**
- **HIPAA only regulates:**
  - Covered entities (CE) that electronically transmit health information in connection with transactions for which HHS has standards
    - Health care payers
    - Health care providers
    - Health care clearinghouses
  - Covered entity use of business associates and their agents
    - Person or entity acting on behalf of CE to perform a function regulated by HIPAA via a business associate contract

HIPAA Privacy Rule and Challenges

- **Covers only individually identifiable health information (in any form – paper, electronic, or oral) held or transmitted by a covered entity**
  - This is called "protected health information" (PHI)
  - Does not cover "personal health information" held by organizations not covered by HIPAA
- **Requires authorization for disclosure of PHI, except for:**
  - Uses for treatment, payment, or health care operations (TPO)
  - When required by law, public health, health oversight, research (when covered by Common Rule or waived by a privacy board), and certain other uses
- **Includes an array of activities in health care operations**
  - E.g. quality assessment, competency review, payment processes, compliance activities, business planning, and general administration
- **Does not protect de-identified data [defined as 17+ designated identifiers (safe harbor) or statistical process]**
  - NCVHS heard concerns related to the sale of de-identified data

NCVHS

Health Data Stewardship Conceptual Framework

Health Data User and Use Profile						
User: *Provider, Payer, Clearinghouse, Business Associate or Agent, Researcher, Public Health, PHR Vendor, Other*						
Regulatory Status: *HIPAA, State Data Statutes, IRB, FDA, VA, Privacy Board, Other State Laws, FTC, Other*						
Identity Status: *Identifiable, HIPAA De-identified (Safe Harbor), HIPAA De-identified (Statistical), Limited Data Set, Anonymization, Pseudonymization, Other*						
Analysis of Benefits and Potential Risks						
Intended use of data *Treatment, Payment, Healthcare Operations, Research, Public Health, Other*						
Impact: *Benefits to Individual & Society, Potential Risk for Harms*						
Data Stewardship Considerations						
Accountability Chain of Trust	*Transparency*	*Individual Participation & Control*	*HIPAA De-identification*	*Security Safeguards & Controls*	*Data Integrity/ Quality*	*Oversight of Data Uses*

Guiding Principles for Making Recommendations on Enhanced Protections for Uses of Health Data

- **Protections should . . .**
  - **maintain or strengthen individual's health information privacy**
  - **enable improvements in the health of Americans and the healthcare delivery system of the Nation**
  - **facilitate uses of electronic health information**
  - **not place an undue administrative burden on the healthcare industry**
  - **increase the clarity and uniform understanding of laws and regulations pertaining to privacy and security of health information**
  - **build upon existing legislation and regulations whenever possible**

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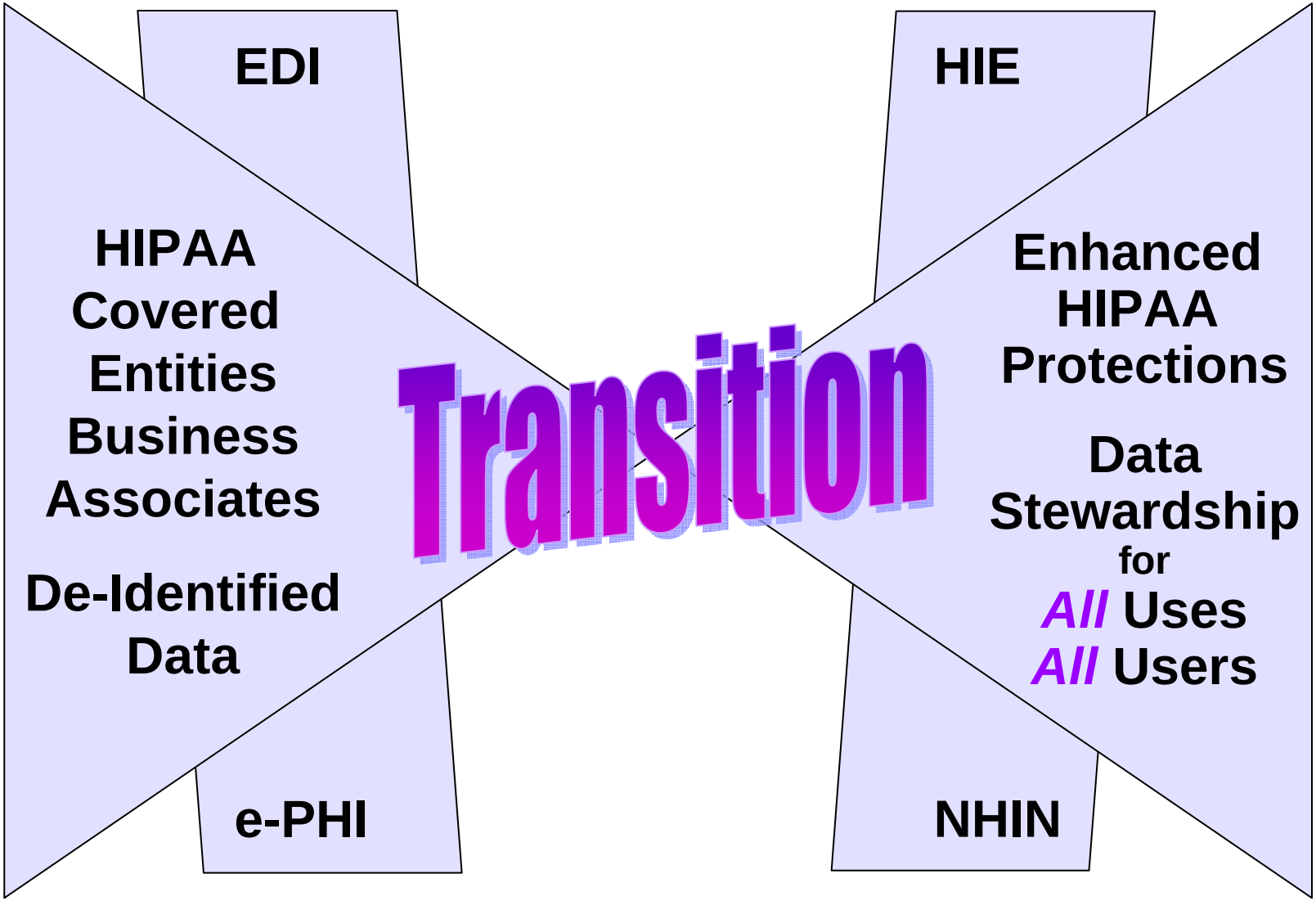
Observations and Recommendations



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Categories of Recommendations

- Principles of Data Stewardship
- Oversight for Specific Uses of Health Data
- Transitioning to a NHIN
- Additional Privacy Protections for Health Data

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Draft Recommendations on Principles of Data Stewardship

- **Accountability and chain of trust within HIPAA**
  - Covered entities specify in business associate contracts terms that:
    - Clearly describe uses of:
      - identifiable health data
      - de-identified health data
    - Require contract between business associates and agents, and identification of all agents to covered entity
    - Include a yearly confirmation of compliance with contract
  - Business associates include all companies requiring access to protected health information during transmission
- **Transparency**
  - Enhancements to notice of privacy practices
  - Make information available, upon request, about specific uses and users
  - Make information available, upon request, about specific information disclosed to other organizations, such as public health
  - FTC uses its authority to ensure that privacy policies fully inform and do not mislead the public

Draft Recommendations on Principles of Data Stewardship, *continued*

- **Individual Participation and Control over Personal Health Data**
  - Assure authorization for personal health information uses not protected under HIPAA
  - Evaluate technologies to manage individuals' authorization
- **De-identification**
  - HIPAA definition (safe harbor or statistical process) is the only currently recognized means to de-identify protected health information
  - NCVHS will further investigate uses of de-identified data, and potentially offer recommendations for guidance.
- **Security Safeguards and Controls**
  - Promote technical security measures and compliance with HIPAA Security Rule by all business associates and their agents
- **Data Integrity and Quality**
  - Data for quality measurement, reporting, and improvement follow rules and guidelines to ensure precision and reliability of quality measures

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Draft Recommendations on Oversight for Specific Uses of Health Data

- **Quality Measurement, Reporting, and Improvement**
  - Uses of health data for quality measurement, reporting, and improvement are within scope of HIPAA health care operations
  - Use a proactive oversight process accountable to senior management and governance to ensure compliance with HIPAA
  - Assess risk and apply further protections as appropriate when quality activities are conducted across different covered entities within an organized health care arrangement
- **Research**
  - Harmonize research regulations
  - Clarify definition of research and provide methodologies that help differentiate research from quality
  - Widely disseminate quality/research guidance
  - Identify approaches to ensure that when a quality study becomes generalizable and evolves into research, that HIPAA Privacy and IRB requirements are respected

Draft Recommendations on Transitioning to a NHIN

- **Adopt data stewardship principles in NHIN activities**
- **Use NHIN trial implementations to evaluate**:
  - Individual choice applications
  - Data stewardship principles in comprehensive databases
  - Potential new de-identification techniques
  - Chain of trust enhancements
  - Educational modalities to improve understanding

Draft Recommendations on
Additional Privacy Protections for Health Data

- **Address need for:**
  - More inclusive, federal privacy legislation for health data
  - In absence of comprehensive federal privacy legislation, expanded definition of covered entity under HIPAA
- **Promote legislative or regulatory measures on anti-discrimination**
- **Use findings from HISPC to encourage states to map their data restriction laws to one another in order to promote interoperability**

Next Steps

- **Address additional public comment to finalize recommendations**
- **NCVHS full committee review and consideration November 27-28, 2007**
- **Ongoing analysis and subsequent recommendations anticipated**

Thank You

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About NCVHS

- **Statutory public advisory body to the Secretary of Health and Human Services**
  - 58 year history of advising HHS in the areas of health data, health statistics, privacy and national health information policy
  - Congressionally mandated role in HIPAA
- **18 members**
  - 16 appointed by the Secretary, 2 by Congress
  - Leaders and experts in their fields
- **Reputation for open, collaborative processes and the ability to deliver timely, thoughtful, and practical recommendations**

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