

The Community

American Health Information Community

**October 31, 2006
8:30 a.m. - 3:30 p.m.**



**Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 800
Washington, DC 20201**

TABLE OF CONTENTS

Agenda	1
September 12th Meeting Minutes	2
Overview of Personalized Health Care	3
Population Health and HIT	4
Clinical Research and HIT	
Health Information Technology Standards Panel (HITSP) Standards and Interoperability Specifications	5
Biosurveillance Minimum Data Set	6
Visioning & 2007 Priority Areas	7

A G E N D A

American Health Information Community

October 31, 2006

8:30 a.m. – 3:30 p.m. (EST)

Hubert H. Humphrey Building, Room 800

8:30 a.m. **CALL TO ORDER** – *Secretary Leavitt*

8:35 a.m. **Introductory Comments** – *Secretary Leavitt*

8:45 a.m. **Comments** – *Robert Kolodner*

8:50 a.m. **Comments** – *David Brailer*

9:00 a.m. **Overview of Personalized Health Care**

Moderator – *Gregory Downing, National Institutes of Health*

Panelists:

- *Alfred Berg, Family Medicine, University of Washington School of Medicine*
- *John Glaser, Harvard Partners*
- *Joel Kupersmith, Veterans Health Administration*
- *Janet Warrington, Affymetrix*
- *Kathy Hudson, Berman Bioethics Institute, Johns Hopkins University*

10:15 a.m. **Break**

10:30 a.m. **Overview of Population Health and HIT**

- *Terry Cullen, Indian Health Service*

Overview of Clinical Research and HIT

- *Anthony Hayward, National Institutes of Health*

10:45 a.m. **Health Information Technology Standards Panel (HITSP) –
Standards and Interoperability Specifications**

- *John Loonsk, Office of the National Coordinator*
- *John Halamka, Chair, HITSP*

11:30 a.m. **Biosurveillance Minimum Data Set**

- *Art Davidson, Denver Public Health Department*

12:15 p.m. **Lunch Break**

1:15 p.m. **Visioning & 2007 Priority Areas – Workgroup Perspectives**

- *Electronic Health Record Workgroup – Lillie S. Gelinis, Jonathan Perlin*
- *Chronic Care Workgroup – Colin Evans, Tony Trenkle*
- *Consumer Empowerment Workgroup – Nancy Davenport-Ennis, Paul Tang*
- *Biosurveillance Workgroup – Charles Kahn, John Lumpkin*
- *Quality Workgroup – Carolyn Clancy*
- *Considerations Across Priority Areas – John Loonsk, Kelly Cronin*

3:15 p.m. **Public Input**

3:30 p.m. **ADJOURN**

Meeting Report

American Health Information Committee September 12, 2006

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

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

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

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

Call to Order

Joining Secretary Leavitt counterclockwise around the table were:

David Brailer, MD, PhD, Vice Chair, AHIC

Colin Evans, Director, System Software Lab, Intel (Mr. Evans represented Craig Barrett, PhD, Chairman of the Board, Intel)

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

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

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

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

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

Robert Cresanti, Under Secretary for Technology, Department of Commerce

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

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

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

Kevin Hutchinson, CEO, SureScripts

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

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

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

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

Introductory Comments

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

- Adopt health information technology standards that will be at the level of interoperability that exists.
- Work with common quality measures that will be adopted to engage the quality of the care that is being purchased with tax dollars.
- Begin making price and quality information about the care that they purchase and provide transparent to their consumers.
- Create positive incentives to reward those who offer and those who purchase high-quality, competitively priced care.

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

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

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

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

- *Broad Charge:* Make recommendations to the Community regarding the protection of personal health information in order to secure trust, and support appropriate interoperable electronic health information exchange.
- *Specific Charge:* Make actionable confidentiality, privacy, and security recommendations to the Community on specific policies that best balance the needs between appropriate information protection and access to support and accelerate the implementation of the consumer empowerment, chronic care, and EHR-related breakthroughs.

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

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

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

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

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

Approval of August 1, 2006, Meeting Minutes

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

State Health Information Exchange (HIE) Panel

State-Level Health Information Exchange Initiatives

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

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

Ms. Kloss reviewed the following key project findings:

- Important innovation and learning are underway in many states.
- There is no single model for state-level HIE initiatives, nor should there be.
- States are uniquely positioned to engage stakeholders for coordination of HIE efforts.
- States play a critical role in the Nationwide Health Information Network (NHIN) and must be more fully engaged in partnering with the federal government in its development.
- Even the most experienced organizations face significant barriers.

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

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

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

- Build mechanisms to promote strategic synergy among states and between state and federal efforts. This includes establishing a coordinating body for active, ongoing collaboration, and developing a roadmap to make that linkage explicit.
- Create salient financial models for sustainable HIE.
- Engage and leverage public and private payers.
- Advance the understanding of how state policymakers and government agencies should be involved.
- Develop vehicles for support and knowledge-sharing among state-level HIE initiatives.

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

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

- Identify barriers with federal solutions.
- Recommend HIE cost models that have generated revenue.
- Determine the involvement of state Medicaid programs.
- Examine the flexibility of state Medicaid programs to facilitate HIE.
- Explore how and when to engage CMS and other public payers.
- Examine the role of the VA, Department of Defense (DoD), and other federal employee health benefit programs.
- Create explicit links and coordination mechanisms between the work of AHIC and ONCHIT and state-level HIEs.

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

Health Information Exchange in Rhode Island

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

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

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

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

- Advance the work of the NHIN prototypes and cost estimates to determine how HIE will be sustainable.
- Ensure federal HIT initiatives support state and regional initiatives, and, with dialogue, create a more actionable federal agenda.
- Assist states in aggregating their market power—employers, Medicaid payers, and regulators should work together.
- Answer the question of “who benefits?” based on real-world experience.
- Rapidly advance a national prescription drug history.

Health Information Exchange in Massachusetts

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

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

- Massachusetts Health Data Consortium – This group is the “convener” and is involved in education, facilitation, and incubation of HIE-related projects. It also is responsible for policy development activities related to HIE and HIT.
- New England Healthcare Electronic Data Interchange Network – This group carries out administrative HIE between provider and payer organizations. As a free-standing, self-supporting corporation owned by its members, the Network processes approximately 50 million administrative transactions per year.
- MA-SHARE – A subsidiary of the MHDC, this organization is charged with creating community utility for clinical data exchange (common technologies and tools that can be used by any organization in Massachusetts).
- Massachusetts eHealth Collaborative – This effort, funded by Blue Cross/Blue Shield of Massachusetts, is examining the effects of provider use of electronic medical records (EMRs). The project includes 450 providers and 200 practice sites across three communities.
- MassPRO – This serves as the quality improvement organization for the Doctor’s Office Quality Information Technology Pilot Program.

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

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

- Provide thought leadership.
- Use the “bully pulpit” to drive change and get buy-in.
- Remove federal barriers to HIE.
- Help align incentives to foster a market for HIE.
- Avoid proscriptive mandates—providers and payers need flexibility to adapt to local circumstances.

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

Health Information Exchange in Colorado

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

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

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

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

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

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

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

- Leadership, to bring Medicaid and other health plans to the table, and to increase the synergy among national-level initiatives/federal programs.
- Communication, to send a clear message about the importance of state-level HIE.
- Build more effective working partnerships with states, to obtain ongoing input and guidance from states and find creative ways to help states and channel resources at all stages.
- Strive to put the federal house in (more) order, to expand the timeframes for action and support from the federal level and coordinate/streamline efforts among multiple federal agencies/programs impacting states “on the ground.”

State Health Information Exchange

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

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

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

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

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

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

- Significant interdependencies exist between states and federal government to realize policy, political, and market environments for HIE.
- There is a need for states to understand federal HIT initiatives to align efforts.
- Partnerships can be synergistic if agendas are coordinated and information is shared.
- States are instrumental to developing a nationwide interoperable infrastructure for HIE.
- AHIC and ONCHIT need to consider state implications in all recommendations.

Discussion Highlights

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HIT Adoption Survey Presentation

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

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

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

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

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

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

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

- The definition of the EHR needs to be clarified and established. The expert consensus panel has agreed that the Institute of Medicine's definition, which lays out eight key functionalities, is probably the most desirable definition. For survey and data collection purposes, the panel modified this definition to include four key functionalities that constitute the core of an EHR.
- It is essential to define what is meant by the term "adoption," because adoption has three components: (1) the acquisition of HIT or EHR, (2) its installation, and (3) its use.
- Reliable, objective, and reproducible data collection methods need to be designed. Some such data collection methods are in place through activities undertaken by the federal government through the National Ambulatory Medical Care Survey (NAMCS) as well as through the American Hospital Association and others. These efforts could be complimented by additional data collection activities to yield an even more complete picture.

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

Tracking Use of Electronic Medical Records

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

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

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

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

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

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

Sustainable High Value Care for All: Searching for Solutions

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

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

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

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

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

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

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

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

Discussion Highlights

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

– Dr. Blumenthal

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

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

– Dr. Blumenthal

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

– Ms. Davenport-Ennis

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

Personalized Health Care – Considerations for the American Health Information Community

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

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

Emerging opportunities for personalized health care include the following:

- Many health care systems and public resources are now beginning to incorporate genetic tests into their framework.
- Some practical applications of genetic tests are already emerging, such as identifying risk for disease, confirmatory diagnostic tests, and selection of appropriate therapies (pharmacogenomics).
- The technology platform costs for genomic tests are decreasing and becoming feasible for medical use. Some of these technologies are already in place at the bedside or in the clinic.

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

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

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

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

Discussion Highlights

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

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

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

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

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

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

Public Input Session

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

Closing Remarks

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



Using Genetic Information at Ground Level The Perspective of Primary Care

Alfred O. Berg, MD, MPH
Professor and Chair
Department of Family Medicine
University of Washington, Seattle

October 31, 2006

Primary Care: The Front Line for Medical Care

FAMILY MEDICINE
GENERAL INTERNAL MEDICINE
GENERAL PEDIATRICS
(OBSTETRICS AND GYNECOLOGY)

- Account for more than half of all office visits to physicians in the US — 471,000,000 in 2004
- Personal medical home
- First contact for most patients
- Comprehensive
- Continuous
- Community and Population focused

Primary Care Physicians See Common Problems

- Specialize in breadth of knowledge and expertise
- Recognize patterns that suggest the unusual
 - Need information systems and decision support
- Typically high volume of patient visits means that support systems must work in time all the time
- Medical tests and interventions must be appropriate for populations in which rare conditions are rare
 - Tests with even small errors have magnified effects
 - Often most positives are false positives, requiring unproductive and expensive further testing

3

Primary Care Physicians are Relentlessly Practical

- **A new test or intervention must**
 - Be available, feasible, and acceptable to the patient
 - Do what it says it does
 - Be accurate
 - Be reproducible
 - Improve clinical outcomes that patients would notice and care about compared to current practice
 - Not increase adverse effects
 - Be worth it (cost-effective)

4

What About Genetic Tests?

- **Primary care physicians are skeptical of "genetic exceptionalism"**
 - Many non-genetic tests in current use produce the same kinds of information promised for genetic tests:
 - Risk
 - Prognosis
 - Response to drugs and other therapies
 - Have ethical, legal, and social consequences
 - Many current electronic health records can already accommodate test results (genetic or otherwise), and intelligently link them to other parts of the record

5

What About Genetic Tests?

- Thousands already available
- Little regulation — buyer beware
- Direct-to-consumer and direct-to-physician marketing
- Clinicians and consumers need reliable advice
- Precedent of the United States Preventive Services Task Force that evaluates preventive interventions — AHRQ
- **EGAPP** — new model project sponsored by CDC
 - Evaluation of
 - **G**enomic
 - **A**pplications in
 - **P**ractice and
 - **P**revention

6

EGAPP

- CDC principal sponsor, partner with AHRQ evidence centers
- Non regulatory
- Independent, non-federal, multidisciplinary
- Minimize conflicts of interest
- Evidence-based, transparent, and publicly accountable
- Reviews underway:
 - Testing for early detection of ovarian cancer
 - Testing before placing a patient on an antidepressant drug
 - Testing for family-related colon cancer
 - Testing for response to treatment for colon cancer
 - Genetic profiling for cardiac risk
 - Breast cancer gene expression profiling

7

EGAPP Experience So Far

- **Quantity and quality of evidence supporting testing in typical practice settings is disappointing**
 - Weak research designs in published articles
 - Some potentially important data are proprietary
 - Scant evidence on potential benefits and harms
 - No head-to-head comparisons with current practice
 - Not tested in typical patient populations
 - Little information about cost and cost-effectiveness compared with current practice
 - No information about ethical, legal, and social implications, especially for family members

8

Conclusions

- Genetic testing to assess risk or guide therapy holds great promise
- Recognize importance of appropriateness in primary care settings
- New tests and technologies must improve on what we have
- There will likely be few examples of genetic tests that meet standards for common use in typical practices in the next 3-5 years
- Many current electronic health records can already link test information to other parts of the record
- Enormous need for more and better quality research on effects of testing on clinical outcomes (good and bad), with results publicly available



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

Support for Structured Genetic Results in the EMR and Clinical Research Infrastructure at Partners HealthCare

John Glaser, PhD

Vice President and CIO, Partners HealthCare

Senior Advisor, Deloitte Center for Health Solutions

October 31, 2006

Copyright 2006 Partners HealthCare System, Inc. All Rights Reserved

Partners HealthCare

- Ten hospitals, 7000 physicians
- \$6B in revenues
- Delivers patient care – 4M outpatient visits and 160,000 admissions/year
- Conducts \$1B in biomedical research annually
- Teaching affiliate of the Harvard Medical School
- Founded by the Brigham and Women's Hospital and the Massachusetts General Hospital

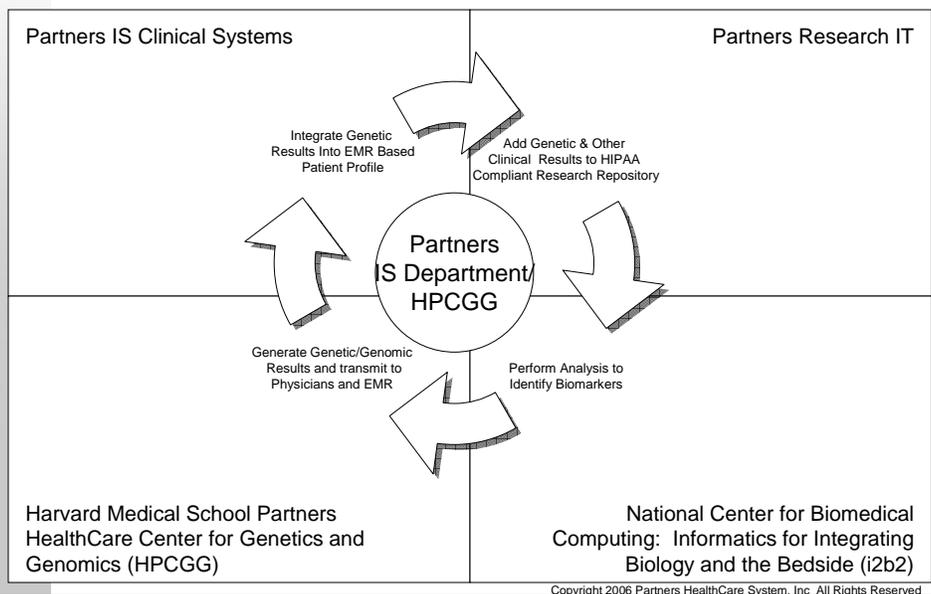
Copyright 2006 Partners HealthCare System, Inc. All Rights Reserved

Clinical and Research Questions

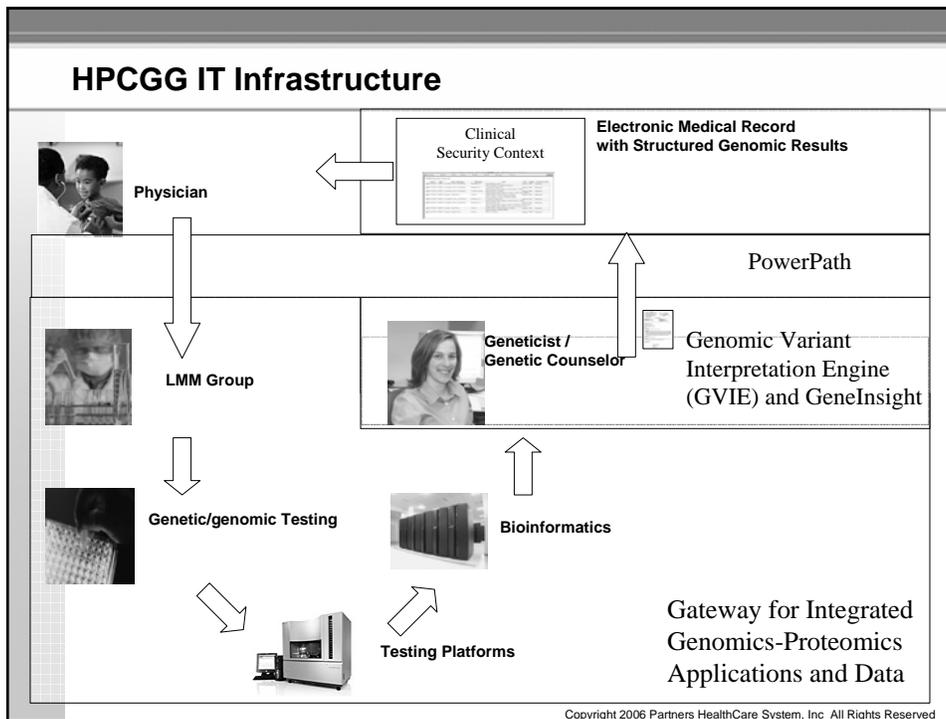
- Research
 - Why do some patients with asthma respond to steroid treatment while others do not?
 - Why do some patients with diabetes have few complications even with “poor” control whereas others with good control have severe complications?
- Clinical
 - Can I lower my cholesterol by diet alone or should I start on an anti-cholesterol drug now?
 - An infant has persistent hypoglycemia in the NICU. Will this resolve with time or is it caused by high insulin production due to a gene mutation? Do we need to remove her pancreas surgically or wait?
 - Should this 40 year old with mild heart failure be put on the transplant list right away (because he has a genetic cardiomyopathy that will worsen rapidly)?

Copyright 2006 Partners HealthCare System, Inc. All Rights Reserved

Partners Groups Supporting Personalized Medicine



Copyright 2006 Partners HealthCare System, Inc. All Rights Reserved



Patient Genetic Profile Module in the EMR

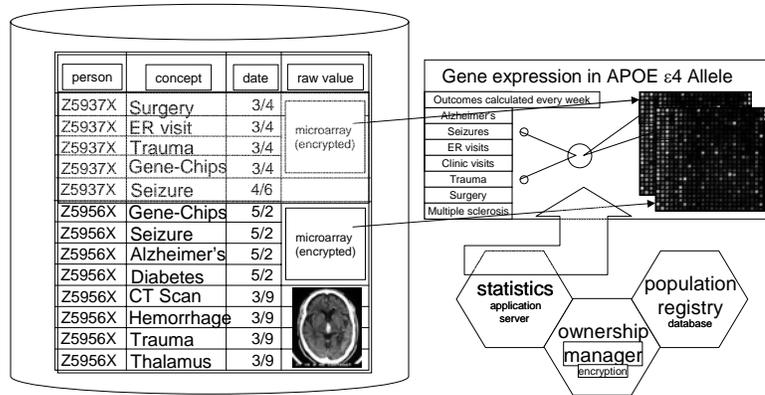
Date	Site	Primary Specimen	Indication	Test	Status
06/07/2006	MGH	Long - Fecal Tissue	Pharmacogenomics	GGT5B	Archived/Aborted
06/07/2006	MGH	Blood - Peripheral	Family History	GGT5B, LCT2p65, SCMP65	Final
06/07/2006	MGH	Blood - Peripheral	Family History	GGT5B, LCT2p65, Exam 5, MYBPC3	Final
06/07/2006	MGH	Blood - Peripheral	Pharmacogenomics	GGT5B, LCT2p65, SCMP65, CYP2A, F207M, CYP2A, MDR1A, MDR1B	Final
06/07/2006	MGH	Blood - Peripheral	Pharmacogenomics	GGT5B, LCT2p65	Final
06/07/2006	MGH	Frost Tissue/Block - Lung for EGFR	Pharmacogenomics	29920-1, GPT13M, Exam 19, EGFR	Final
06/07/2006	MGH	Frost Tissue/Block - Lung for EGFR	Pharmacogenomics	GGT5B	Final
06/07/2006	MGH	Frost Tissue/Block - Lung for EGFR	Pharmacogenomics	22K_2343del, B746_R748del, Exam 19, EGFR	Final

- Identified variants are represented in the CDR in structured form
- Reference information related to the test performed is also retained
- We are currently working on establishing clinical decision support rules targeting this information

Copyright 2006 Partners HealthCare System, Inc. All Rights Reserved

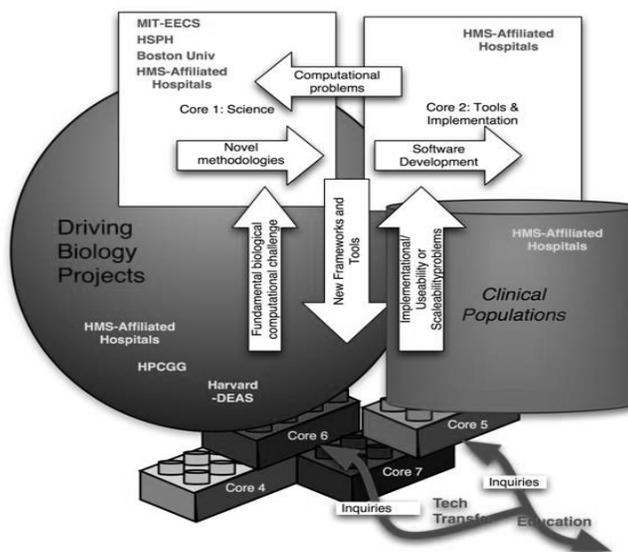
Clinical Trials Performed In-Silico

Clinical trial performed exclusively in computer memory finds APOE epsilon 4 allele determines risk of seizures after trauma



Copyright 2006 Partners HealthCare System, Inc. All Rights Reserved

i2b2 is Creating Infrastructure for a Merged Genomic and Phenotypic Data Repository and Analyses Tools



Copyright 2006 Partners HealthCare System, Inc. All Rights Reserved

Challenges of IT Support Personalized Medicine

- **Infrastructure and applications**
 - To what degree can we leverage patient care data to support research on the genomic basis of disease?
 - How do you structure, store and “operate” genomic and proteomic data and transactions?
 - What are the methods needed for processing this data?
 - How different will our clinical systems be in ten years?
- **Implementation and care improvement**
 - What is the impact on the safety, quality and efficiency of care?
 - Will we significantly accelerate the discovery process?
 - What steps are needed to manage privacy?
 - How should we educate our medical staff?
 - What are the new issues in our approaches to practice?
 - How should we work with the payers on reimbursement strategies?



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

Department of Veterans Affairs Genomic Medicine Database

First Steps in Implementation of Major New Initiative

Joel Kupersmith, M.D.
Chief Research and Development Officer
Department of Veterans Affairs

October 31, 2006

VA Healthcare System

Large system

- \$34.7 billion budget
- 5.3 million patients, 7.6 million enrollees
- 1400 Sites of Care
 - 172 Medical Centers
 - 876 Clinics
 - 207 Readjustment Counseling Centers
 - 134 Nursing Homes
- Academic affiliations are the underpinning (107 AHCs)
 - Clinician-scientists are the backbone of VA clinical care, research and culture

VA Healthcare System

Patient Population

- Older
 - 49 % > age 65 (increasing population > age 85)
- Sicker
 - Compared to Age-Matched Americans
 - 3 Additional Non-Mental Health Diagnoses
 - 1 Additional Mental Health Diagnosis
- Poorer
 - ~ 70% with annual incomes < \$26,000
 - ~ 40% with annual incomes < \$16,000
- Loyal
 - Little turnover
- Changing Demographics
 - 4.5% female overall - 22.5% of outpatients <50 years of age

3

Need for Genomic Population Cohort Project

Genomic Population Cohort

- It has generally been considered that the implementation of a large genetic population cohort will considerably advance the field of genomic medicine
- Move from striking familial diseases and scattered tests to use in everyday practice
- The VA has the capacity to create such a cohort for the benefit of veterans and the nation
- VA intends to collect genetic information from all consenting veterans and link it to its Electronic Health Record

4

Need for Genomic Population Cohort Project

nature International weekly journal of science

insight commentary

Nature 429, 475-477 (27 May 2004) |

The case for a US prospective cohort study of genes and environment

Francis S. Collins¹

Abstract

Information from the Human Genome Project will be vital for defining the genetic and environmental factors that contribute to health and disease. Well-designed case-control studies of people with and without a particular disease are essential for this, but rigorous and unbiased conclusions about the causes of diseases and their population-wide impact will require a representative population to be monitored over time (a prospective cohort study). The time is right for the United States to consider such a project.

5

Genomics Cohort – Why VA?

VA Attributes for Genomics Cohort

- VA has healthcare system with large population (7.6 million records) treated in a variety of settings
 - More stable population than in other sectors
- VA has an *research network* integrated in the healthcare system
- VA has unrivaled Electronic Health Record
- VA has vehicles for and considerable success in translation of research findings directly to clinical care
- Provide veterans with state-of-the-art care
 - Veteran-centric initiative

6

Implementation of VA Genomic Cohort

Implementation steps

- Establish governance of program
 - Genomic Medicine Program Advisory Committee
 - Genomic Medicine Management Committee
 - Office of Research and Development
- Pilot project underway
 - Via Cooperative Studies Program
 - Collect genetic specimens as part of clinical trials
 - Address many questions regarding collection, cost, consensus, etc.
 - Make estimate of future financial needs
 - Over 30,000 specimens collected with capacity for banking 100,000
 - Now ready to broaden pilot project beyond CSP
- Project funding

7

Implementation of VA Genomic Cohort

Implementation steps (cont)

- Enlarge capacity in genomics
 - Pharmacogenomics RFA
 - Methodology RFAs
 - Other research funding steps
- Establish Central IRB
- Develop computer capability to incorporate genomic data into EHR
 - Assure security
- Provide for educational needs
 - CME versus EHR/Point of Contact
- Open discussions with potential collaborators and with broader community moving in the same direction

8

Implementation of VA Genomic Cohort

Implementation steps (cont)

- Address privacy/ethical issues
 - Maintaining high ethical standards and beneficence is critical
 - Discussion with stakeholders is essential
 - *Communication with Veterans and Veteran Service Organizations*
 - *Meeting with leadership of VSOs*
 - *Focus groups, etc.*
 - Also will address issues in Genomic Medicine Advisory Committee and with a variety of experts inside and outside the VA
 - Practical need for answers in this initiative may serve as precedent-setting construct



Integration of Genomic Technologies in Clinical Practice

Development of Standard Controls and Best Practice Guidelines

Janet A. Warrington, Ph.D.

Chairholder, External RNA Controls Consortium

Chairholder, CLSI MM16 Subcommittee

Leader, Clinical and Laboratory Genomic and Genetic Standards

Vice President, Emerging Markets and Molecular Diagnostics R&D

Affymetrix Inc.

October 31, 2006

Personalized Health Care Today

	Save Lives	Save Dollars
Whole Blood Glucose – Diabetic Control	✓	✓
Near Patient Coagulation – Coumadin Mgmt	✓	✓
PSA – Prostate Cancer Detection	✓	✓
T4/TU/TSH – Thyroid Management	✓	✓
Lipid Analysis – Coronary Disease Prevention	✓	✓
Troponin Assays – M.I. Triage	✓	✓
Strep Tests – Antibiotic Use	✓	✓
* HercepTest – Breast Cancer – Therapy Selection	✓	✓
*Gleevec – Chronic Myelogenous Leukemia	✓	✓
Iressa – Non-Small Lung Cell Carcinoma	✓	✓

*Used genomic technology in development and/or clinical trials

Personalized Health Care Today

First FDA cleared microarray-based diagnostic test

December 2004



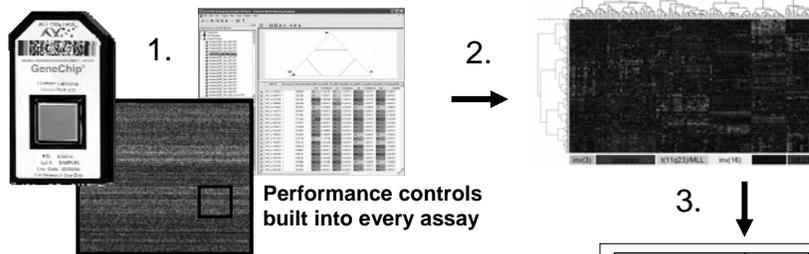
Roche AmpliChip™ CYP450 Array



Roche AmpliChip™ CYP450 Test (IVD)

3

Clinically Useful Information Output from Genomic Assay



1. Automated analysis includes quality check with standard controls
2. Automated interpretation by signature comparison to controlled reference database
3. XML output, categorical with probability information to end-user

Disease type	
subclass 1	0%
subclass 2	98%
subclass 3	1%
subclass 4	0%
Related disorders	
type 1	0%
type 2	0%
Infection status	
CMV	100%

4

Evidence of the Need to Act Now

- >20 microarray-based diagnostic products in pipeline
- Increased awareness of value of harmonization of terminology, controls, protocols, best practice guidelines, electronic information management systems
 - Increasing amount of clinically relevant genomic information
 - Increasing cost of development
 - Increasing cost of care

5

The External RNA Controls Consortium

- 175 members, 92 organizations, 14 countries
 - Government, regulatory, academic laboratories and biotechnology, pharmaceutical and diagnostic companies
- Ways of working
 - Volunteer organization
 - Open to anyone with an interest in working together
 - Consensus based decision making
 - Publish final results as a group by the group
- Goals
 - Develop well-characterized standard controls for multiple genomic technology platforms e.g. microarray, RT-PCR
 - Develop protocols for multiple applications, research and clinical laboratory
- First Deliverable, August 2006
 - (MM16) Use of External RNA Controls published by CLSI

6

Clinical and Laboratory Genomic and Genetic Standards

- Volunteer organization, 70 participants, 50 organizations, 19 countries
 - Public and private sectors; government, industry, academic
- Goals
 - Recommendations for qualification of performance controls for microarray-based DNA genetic tests
 - Develop forum for driving consensus on characteristics and output of algorithms for microarray DNA-based genomic tests
- Ways of working
 - Volunteer organization, consensus based
 - Open to anyone interested in working together
 - Publish recommendations, all information made public

7

Widespread Adoption of Integrated E-Medical Records Requires Consensus on Standard Controls and Best Practices

New Genomic Dx & Rx

- Disease status
- Disease class
- Molecular profile
- Treatment choice
- Response to care
- Infection status
- Pathogen response

E-Medical Records

- XML, Categorical
- Probability info
- Demographic ref info
- Data quality info x Standard ref materials



Access

- Patient, Rx, Dx, Clin Lab
- Domestic vs. Int'l
- Privacy protection
- Reimbursement

Impact

- Raise standard of care
- Improved efficiency
- Improved communication
- Fewer mistakes
- Epidemic outbreak mgmt
- Outcome data access
 - x R&D targeting
- Cost

Summary

- This is the right time to establish standardized electronic medical record infrastructure, standard controls and guidelines for genomic based assays
- Harmonization benefits patients, physicians, test and drug developers, regulatory bodies, trade and commerce
- Standards accelerate development
- Development dollars are more efficiently spent when standards are in place

9

Standard Controls and Best Practice Initiatives

- External RNA Controls Consortium
- Clinical and Laboratory Standards Institute MM16
- Clinical and Laboratory Genomic and Genetic Standards Group
- Organization for Economic Cooperation and Development (OECD) Biotechnology Industry Advisory Committee, Working Party on Biotechnology
- FDA MicroArray Quality Control Project
- Others...

10

The External RNA Controls Consortium: a progress report

The External RNA Controls Consortium*

Standard controls and best practice guidelines advance acceptance of data from research, preclinical and clinical laboratories by providing a means for evaluating data quality. The External RNA Controls Consortium (ERCC) is developing commonly agreed-upon and tested controls for use in expression assays, a true industry-wide standard control.



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

Policy Priorities for Personalized Medicine

Kathy Hudson, Ph.D.
Director, Genetics & Public Policy Center
Johns Hopkins University
Funded by the Pew Charitable Trusts & NIH

October 31, 2006

Prerequisites for Personalized Medicine

- Public confidence
- Robust Research Pipeline
- Quality assurance for genetic tests and paired treatments.
- Providers equipped with tools
- Quality linked to payment
- Outcomes tracked overtime
- Strong privacy protections



Public Confidence

- Large majorities approve of genetic testing and technology for health-related purposes.
- Low level of genetic literacy
 - but there is little data on how much the public really needs to know about the “science” to make informed “health” decisions and on the correlation between literacy and support.
- Americans expect that the government ensures safety and accuracy of genetic tests.
- Large majorities feel insurers and employers should not have access to genetic information.
- We have a problem with trust.

3

Public Confidence

- **Public Views of Scientists**

“Yes, but you know what? You are a reasonable person. We are responsible people here, but some of those scientists, because of the science and because of their warped minds, they will do something stupid like that, and you know they can, and they will.”

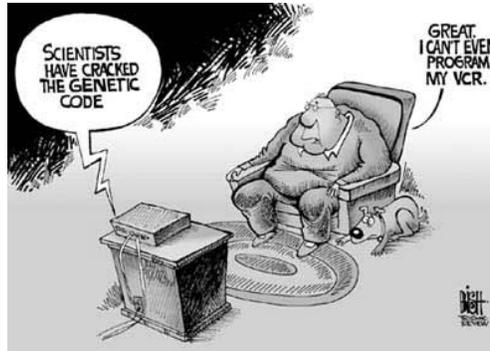


4

Public Confidence

- **Scientists' Views of the Public**

"I don't think that the general uninformed public should have a say, because I think there's a danger. There tends to be a huge amount of information you need in order to understand. It sounds really paternalistic, but I think this process should not be influenced too much by just the plain general uninformed public..."



5

Genetic Testing Quality

Status Report



- FDA has reviewed and approved only a handful of genetic test "kits"
- FDA has recently asserted authority over a subset of laboratory-developed tests ("homebrews")
- CMS is responsible for the quality of genetic testing laboratories and the analytic validity of home-brew tests.
- CMS oversight of genetic testing laboratories is insufficient

6

Genetic Testing Quality

Survey says.....

- Most genetic testing labs are CLIA certified
- 16% overall, and more than a third of high volume labs have no specialty certification
- 35% do not do PT at all for some tests
- More PT produces fewer PT deficiencies
- More PT reduces proportion of analytic errors
- Large majority of labs support CMS genetic testing specialty

7

Genetic Testing Quality

Creation of a CLIA Genetic Testing Specialty supported by:

- The Personalized Medicine Coalition
- The American Society of Human Genetics
- Three expert advisory groups to HHS
- More than 100 companies, patient groups, and provider organizations.

For nearly a decade CMS has reiterated its commitment to create a genetic testing specialty. In July 2006, the agency decided not to pursue a genetic testing specialty.

8

Tools for Health Care Providers

Over 1000 genetic tests available and that number is growing steeply.

Despite their utility in aiding clinical decision-making, relatively few guidelines for genetic testing have been developed by health care provider organizations.

Need to increase the evidence base for many many tests.

Need a sustainable system of supporting health professional organizations to developed evidence-based guidelines (e.g. for tests reviewed by EGAPP).

9

Strong Privacy Protections

Access and Use

- Clinical Genetic Information
 - Privacy protected by HIPAA privacy regulations
 - Equal protections for all health information—genetics not “special”
 - “De-identified” information and samples can be used in research
- Research Information
 - Rapid growth of large Biobanks.
 - Questions about whether genetic information can ever be de-identified given that DNA is the ultimate identifier
 - De-identification severs links between participant/donor and researchers.
 - Subsequent research without consent may undermine participant’s interests and contribute to public mistrust of research.
- Misuse of Genetic Information
 - Strong statutory protections needed: insurance, employment, education, law enforcement

10

Next Steps

- Public Confidence:
 - ✓ Earn it by demanding transparency and encouraging engagement
- Genetic Testing Quality:
 - ✓ Create CLIA genetic testing specialty
 - ✓ Rationalize FDA role in genetic testing
- Healthcare Provider Tools:
 - ✓ Create funding mechanism for organizations to develop evidence-based practice guidelines
- Privacy and Misuse
 - ✓ Enact statutory protections against discrimination
 - ✓ Carefully re-review policies governing use of de-identified samples

11



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

American Health Information Community

Interagency Health IT Policy Council
Population Health Workgroup - Priority Areas

Terry Cullen
Indian Health Service

October 31, 2006

1

Overview

HIT-enabled population health activities will permit more complete, efficient, and timely:

- Improvements in population health status through clinical performance measurement using longitudinal health data linked with external data sources
- Measurement and reduction of healthcare disparities
- Identification and management of emerging health conditions
- Assessment, intervention, and evaluation of the impact of appropriate interventions for populations at increased risk for certain disorders
- Clinical performance improvement
- Population health research
- Dissemination of population health information

2

Current State

- Current HIT use for population health management is typically limited to information obtained from registries
- Improving the health status of American populations requires a robust HIT solution that supports population health management

3

Benefits of Using HIT

- Facilitate identification of at risk patients/populations
- Facilitate monitoring of population health status and population health prevention and improvement
- Enable information exchange between appropriate partners
- Identify HIT requirements needed for population health management
- Increase effectiveness and efficiencies of population health management in federal and private sectors

4

Near Term Opportunities

- Patient / Population identification
- Identify critical data elements
- Privacy & security
- Store and/or retrieve longitudinal patient data
- De-identify and reuse data
- Data Mapping
- Integration of other data
- Multi-directional reporting

5



American Health Information Community

Overview of Clinical Research and Health IT

Anthony Hayward

National Center for Research Resources, NIH

October 31, 2006

1

Clinical Research in Healthcare Informatics

Overview: What is Clinical Research?

- Clinical research improves healthcare
- Study of drug, biologic or device in human subjects with the intent to discover potential beneficial effects and/or determine its safety and efficacy
- Research is the basis of all improvements in treatments – preventive and symptomatic
 - Antihypertensives reduce stroke risk
 - Taxol for breast cancer
 - Gleevec for chronic myeloid leukemia

2

Current State: The Scale of Clinical Research

2004/5 biomedical research expenditures:

• NIH	\$28.5B
• Pharma	\$30.6B
• Biotech	\$19.8B
• Devices	\$10.8B
• Other	\$ 6.5B
Total:	\$96.2B

Costs from Moses et al JAMA 294:1333-1342

3

Benefits HIT Brings to Clinical Research

- Provides standards that allow for structured data flow across both the research and care processes (e.g., caBIG, NLM, CDISC, HL7)
- Provides communications among providers, patients and researchers that partially support outcome and adverse event reporting (but much is still paper based)
- Existing databases serve as data warehouses for:
 - Clinical findings and laboratory results
 - Patient histories and family histories
 - Medication histories... but, the data need to be standardized to be comparable across clinical sites and across the research community

4

Opportunities for HIT in Clinical Research

- Facilitate patient access to clinical trials
- Support better baseline data for comparisons
- Speed adverse event identification and reporting
- Tracking of human subject consents
- Common vocabularies, anonymization of human subject information

5

Population Health Workgroup Priority Areas

October 31, 2006

Population health management requires the integration of longitudinal individual patient health information, functional and behavioral data and external non-patient data (such as occupational and environment information.) Integrating patient, environmental, occupational, and other data enables a variety of population health management activities including: recognizing and managing emerging health conditions, identifying patient populations at increased risk for specific disorders, improving clinician performance with respect to particular populations, measuring and reducing healthcare disparities, providing snapshots of population health status at particular times, facilitating translational research, and making available population health management information to clinicians and consumers at the point of care. Federal programs use population health information to: identify the health status of populations; recognize past, present and future health care trends; permit health care organizations to monitor and improve the health of certain populations, prevent the onset or worsening of medical conditions; enable the delivery of needed information to patients with certain health conditions, their family members, and treating health care professionals; and support essential health services research needed to transform and improve health care quality and outcomes.

Efficient and effective population health management is currently limited by the: lack of widespread granular and interoperable electronic patient and population data; gaps in and limited understanding of the requirements needed to integrate patient data over time, across providers, as parts of defined populations, and with other critical data; and limits on the ability to generate information and make available pertinent reports to consumers, clinicians, communities, insurers and policy makers to assist with improving the health and functioning of populations.

The Population Health Workgroup has identified 10 priority requirements needed to enable electronic population health management. The use of EHRs at the point of care has enabled the electronic collection of critical data elements that support numerous population health management activities. Further, multi-directional health information exchange between patients, clinicians, public health programs, payers, and other health care organizations is essential for effective and efficient population health management. Given the increasing use of EHRs and the growing need for health information exchange, the Population Health Workgroup has identified the following priorities:

Near Term -- The need to:

1. identify patients and populations with certain health conditions and/or characteristics
2. identify critical data elements and measures that are essential in tracking population health status, including prevalence, incidence, and aggregate health status measures
3. protect and maintain the privacy and security of patient and population data (including how data access is controlled by different roles and functions) consistent with federal and other standards. Compliance with HIPAA will support needed privacy and security protections. State and local privacy and security requirements must be considered.
4. store and/or retrieve (e.g., at the provider, health care facility, local, community, regional, state, or national level) longitudinal patient data (e.g., diagnoses, demographics, medications, mortality, claims, etc.) across multiple providers. Patient data would include the date (point in time) of the health care encounter. Data would be retrieved using tools developed to query data by authorized persons.
5. de-identify and reuse longitudinal patient -level data and aggregate de-identified patient data to support analyses of trends and issues for the selected population(s)
6. map very granular data to more aggregated data or classification data and harmonizing (if necessary) data collected from multiple EHR systems;
7. integrate other data available from local, state, and federal data systems (e.g., public health networks, registries (e.g., immunizations), etc);

8. define, support and implement multi-directional reporting capacity (e.g., through electronic portals or other mechanisms) to patients, clinicians, and/or appropriate health programs for population health management including prevention and treatment.

Mid - Longer Term Priorities – The need to:

1. implement a standard data element for provider identification. The implementation of the NPI standard will facilitate the identification of providers and clinical specialties for population health management. The NPI will enable provider-level quality improvement activities such as the delivery of needed population health information to clinicians for treatment and education of clinical specialties.
2. integrate patient data with other data sources including: environmental data, occupational data, school attendance data, geographic data, etc. Linking patient health data with these external data sources provides information that is essential for identifying persons at risk of certain health events for both prevention and treatment. Some external data sources important for population health management may be available but to date have not been integrated into electronic health information systems (e.g., school attendance records). A barrier is that some needed external data is not available or is not available in an electronic format.

Examining the ability of health programs to engage in electronic population health management activities for a few selected health conditions will permit a comprehensive assessment of these near and mid to long-term priorities. The following is an illustrative example, for one condition – asthma - of the different types of data that would be needed to assess the 8 priority areas described above using a snapshot of an integrated, longitudinal EHR patient data linked with other data sources:

- identify patients with asthma electronically within an electronic health record
- populate a patient ‘list’ or populations registry with these patients electronically from the EHR
- specify explicit definitions for population health measures (including prevalence and incidence) and aggregate health status measures related to asthma (including baseline as well as prior time period measures). This should incorporate certain pre-defined clinical quality measures, and additional measures (e.g., reduction in the number of deaths, hospitalizations, physician visits, emergency department visits, school or work days missed, symptom free days, limitations in activities, asthma action/care plan in place and updated regularly, depression screening, family impact, etc.). Measures would define the population of interest (e.g., asthmatic children diagnosed with depression);
- specify a minimum data set for the specified population health measures related to asthma. These could include: disease specific data (e.g., health (respiration status), medications, appropriate diagnosis stratification (e.g., mild intermittent asthma) functioning, mental health status, quality of life, mortality, cost, prevalence and incidence, trends), demographic data, claims data, geographic data, environmental data (e.g., ambient air quality), occupational data, school attendance data, and other data available from local, state, and federal data systems; and
- specify the various data sources that are expected to provide the needed data (e.g., electronic health records, and data from other federal, state, and local sources, etc.). Data would be retrieved by those persons who are authorized to access data.

Targeting at least 3 conditions/populations of interest (e.g., asthma, cancer, substance abuse, frail elderly, persons with disabilities, and/or other populations of interest) and specifying the population health measures to be assessed, and the data and data sources needed, will allow a more comprehensive assessment of the enumerated priorities to support population health management needs.



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

First Round of Standards Harmonization: HITSP Interoperability Specifications

John D. Halamka, MD

Chair, Health Information Technology Standards Panel

John W. Loonsk, MD

Office of the National Coordinator for Health
Information Technology

October 31, 2006

First Round of Standards Harmonization Results

- Context for the Health Information Technology Standards Panel (HITSP) Work
 - AHIC recommendations
 - HITSP Process
- Initial Interoperability Specifications
 - What standards were chosen?
 - What were the controversial issues?
- What are the next steps?

First Round of Standards Harmonization Results

- AHIC breakthroughs
- Use cases
 - Context
 - Processes
 - Data
- HITSP
 - Harmonization of standards
 - Gaps and needs
 - Specificity as to how to use the standard in implementation level guidance – “Interoperability Specifications”

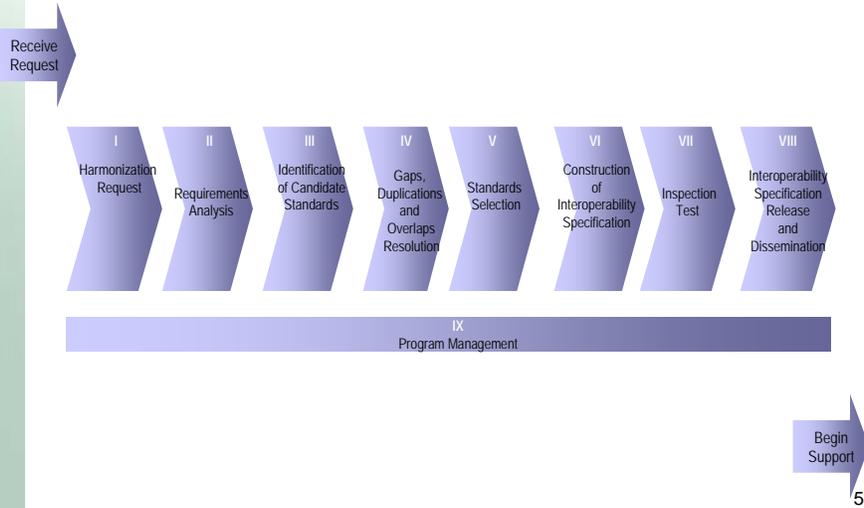
3

Standards Harmonization

- Process
 - Partnership of public and private stakeholders operating through a neutral and inclusive governance model
 - Board of Directors, HITSP Panel, Technical Committees, and Coordination Committees
 - Bylaw-based, consensus based process
 - Consensus process is used to success for majority of TC decisions
 - Voting process is used only when consensus process failed
 - When voting is used, a Quorum is 50% of voting TC members e.g. regularly participating institutional representatives
 - 66% of those casting a vote must agree for a vote to pass
 - One vote is allowed per institutional member “representative on record” or regular participant
 - 261 registered HITSP organizations
 - Estimated 12,000 volunteer hours through September

4

Harmonization Process Steps



Tier 1 Standards Readiness Criteria



- The standards required to support each major Use Case event were organized within an agreed upon standards taxonomy
- The standards selected for inclusion in the pool were examined using 'HITSP approved' Tier 1 Harmonization Readiness Criteria
- Standards in the pool were then considered for inclusion in the Interoperability Specifications by application of the Tier 2 Harmonization Readiness Criteria

6

Tier 2 Standards Readiness Criteria

- Suitability
 - The standard is named at a proper level of specificity and meets technical and business criteria of use case
- Compatibility
 - The standard shares common context, information exchange structures, content or data elements, security and processes with other HITSP harmonized standards or adopted frameworks as appropriate
- Preferred Standards Characteristics
 - Approved standards, widely used, readily available, technology neutral, supporting uniformity, demonstrating flexibility and international usage are preferred
- Standards Development Organization and Process
 - Meet selected criteria including balance, transparency, developer due process, stewardship and others.
- Total Costs and Ease of Implementation
 - Deferred to future work

7

Consumer Empowerment - Registration and Medication History

- Scope
 - As part of a personal health record, this Interoperability Specification addresses two key areas: the patient's registration data and their medication history
- Standards
 - 13 "named standards" were identified to support this Interoperability Specification (See Appendix 1a)
 - 5 separate constructs were developed (See Appendix 1b)
 - Approximately 170 pages of implementation level guidance were developed to support the specific use of these standards to achieve interoperability (See [Consumer Empowerment HITSP/IS-03](#))
- Issues and Remedies
 - Need for patient summary record within the technical environment of care providers, pharmacies, and health plans
 - Support and leverage the existing HL7-ASTM (the Continuity of Care Document – "CCD") harmonization initiative
 - Introduce new electronic links without replacing the existing links
 - Promote architectural independence

8

Electronic Health Records (EHR)

- Laboratory Results Reporting

- **Scope**
 - This Interoperability Specification is relevant to clinical care providers who wish to have laboratory test results and laboratory interpretations electronically available for patients for whom they are providing care
- **Standards**
 - 10 “named standards” were identified to support this Interoperability Specification (See Appendix 2a)
 - 12 separate constructs were developed (See Appendix 2b)
 - Approximately 250 pages of implementation level guidance were developed to support the specific use of these standards to achieve interoperability (See [Electronic Health Record Laboratory Results Reporting HITSP/IS-01](#))
- **Issues and Remedies**
 - Lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards
 - Accommodate both laboratory message transaction and document sharing approaches
 - Select standards with wide coverage to address gaps and provide mapping between standards to address overlaps

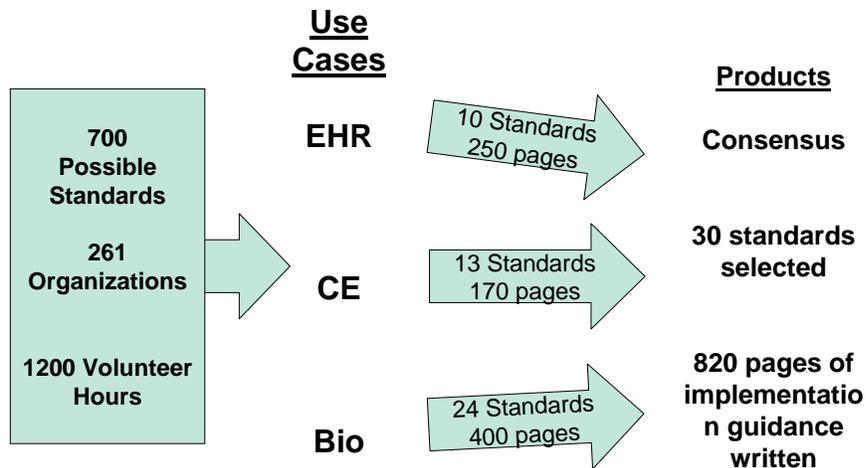
9

Biosurveillance

- **Scope**
 - This Interoperability Specification includes the transmission of essential data from ambulatory care and emergency department visits, utilization, and lab result data from electronically enabled healthcare delivery and public health systems in a standardized and anonymized format, to authorized Public Health Agencies with less than one day lag time
- **Standards**
 - 24 “named standards” were identified to support this Interoperability Specification (See Appendix 3a)
 - 16 separate constructs were developed (See Appendix 3b)
 - Approximately 400 pages of implementation level guidance were developed to support the specific use of these standards to achieve interoperability (See [Biosurveillance HITSP/IS-02](#))
- **Issues and Remedies**
 - Need to maximize data sources and provides stringent data management to ensure proper routing, security, privacy, and timely reporting
 - Support any variant of architectural environments
 - Select full options of standards to maximize data and information exchange

10

Summary



11

Next Steps

- HITSP has approved three Version 1 sets of standards and implementation guidance ("Interoperability Specifications")
- HITSP calls on industry to begin the implementation process for these Interoperability Specifications, during which HITSP will work with implementers to test the specifics of the implementation guidance
- HITSP asks that the AHIC recommend these standards and implementation guidance to the Secretary
- HITSP will return to the AHIC at least yearly with updates to Interoperability Specifications
 - Because these are the Version 1 Interoperability Specifications, HITSP will return to the AHIC no later than April, 2007 with version 2 updates for recommendation to the Secretary
- In the coming months, HITSP will seek to include a harmonized summary record (CCD) standard into Interoperability Specifications
- HITSP will work with CCHIT to establish Interoperability Specifications in the CCHIT criteria via the joint CCHIT/HITSP working group

12

Appendices

- Consumer Empowerment Registration and Medication History
- EHR Laboratory Results Reporting
- Biosurveillance

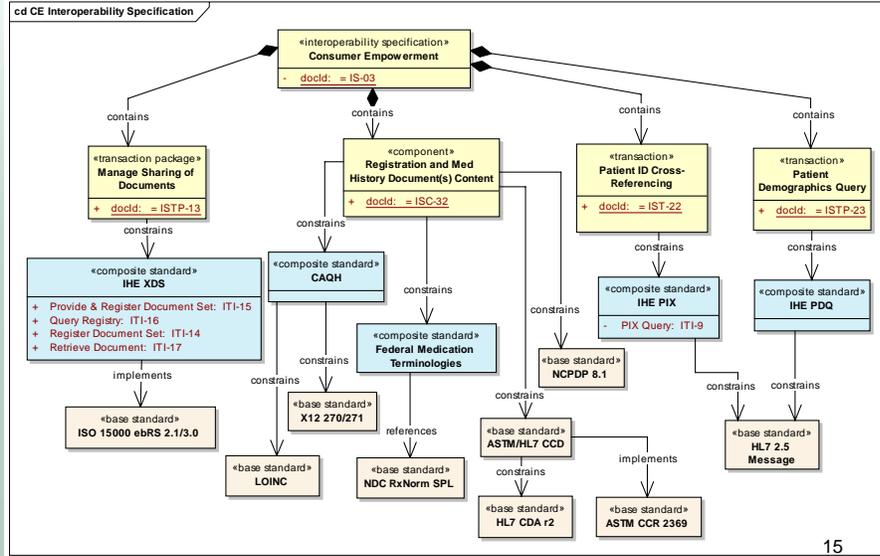
13

1a. Consumer Empowerment Registration and Medication History: Recommended Standards

Recommended Standards
Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1
Accredited Standards Committee (ASC) X12 Standards Release 004010
American Society for Testing and Materials (ASTM) Standard Specification for Continuity of Care Record (CCR): # E2369-05
Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules
Federal Medication Terminologies
Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)
Health Level Seven (HL7) Version 2.5
Health Level Seven (HL7) EHR System Functional Model Draft Standard for Trial Use (DSTU)
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0
Logical Observation Identifiers Names and Codes (LOINC®)
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 8.1

14

1b. Consumer Empowerment Registration and Medication History



1b. Consumer Empowerment Registration and Medication History: HITSP Constructs

Document	Title
HITSP/IS/CE-03	Consumer Empowerment
HITSP/ISC-32	Registration and Medication History Document Content Component
HITSP/ISTP-13	Manage Sharing of Documents Transaction Package
HITSP/IST-22	Patient ID Cross-Referencing Transaction
HITSP/IST-23	Patient Demographics Query Transaction

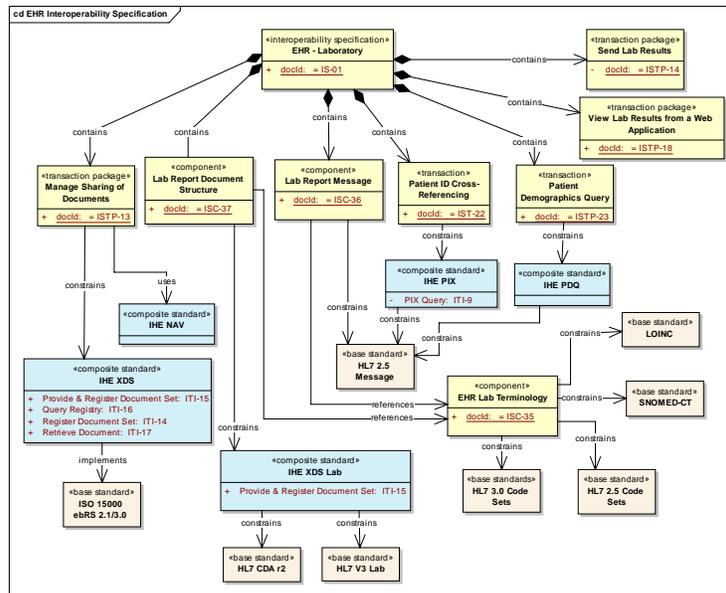
2a. Electronic Health Record Laboratory Results Reporting: Recommended Standards

Recommended Standards

Clinical Laboratory Improvement Amendments (CLIA) of 1988
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification
Health Level Seven (HL7) Version 2.5
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 2.0
International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000 -- Part 4: Registry services specification (ebRS), May, 2004
Logical Observation Identifiers Names and Codes (LOINC®)
Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®)
Unified Code for Units of Measure (UCUM)

17

2b. Electronic Health Record Laboratory Results Reporting



18

2b. Electronic Health Record Laboratory Results Reporting: HITSP Constructs

Document	Title
HITSP/IS/EHR-01	Electronic Health Records: Laboratory Results Reporting
HITSP/ISTP-14	Send Laboratory Result Message to Ordering Clinician and Providers of Care Transaction Package
HITSP/IST-18	View Laboratory Results from a Web Application Transaction
HITSP/ISC-44	Secure Web Connection Component
HITSP/ISTP-13	Manage Sharing of Documents Transaction Package
HITSP/IST-22	Patient ID Cross-Referencing Transaction
HITSP/IST-23	Patient Demographics Query Transaction
HITSP/IST-29	Notification of Document Availability Transaction
HITSP/ISC-35	EHR Lab Terminology Component
HITSP/ISC-36	Lab Result Message Component
HITSP/ISC-37	Lab Report Document Component
HITSP/ISC-45	Acknowledgements Component

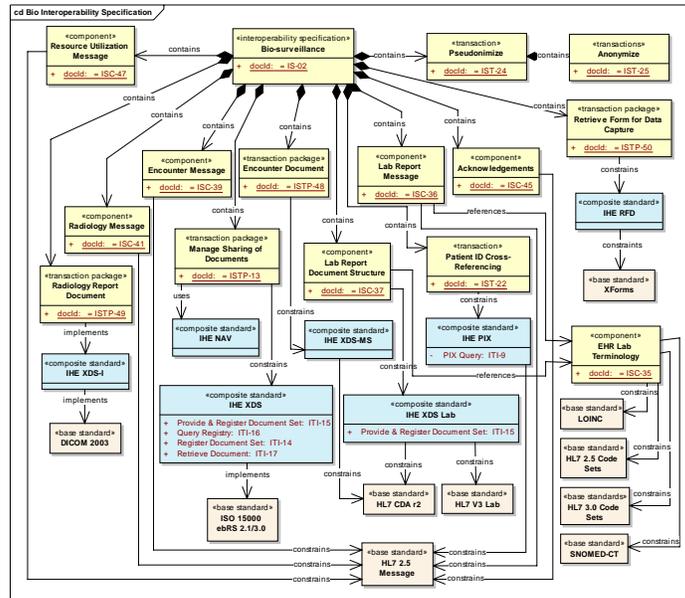
19

3a. Biosurveillance: Recommended Standards

Recommended Standards
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4)
Clinical and Laboratory Standards Institute (CLSI) [formerly the National Committee for Clinical Laboratory Standards (NCCLS)]
Clinical Care Classification (CCC) Version 2.0 [formerly known as the Home Healthcare Classification (HHCC) System]
Clinical Laboratory Improvement Amendments (CLIA) of 1988
College of American Pathologists Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)
Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987
HCPCS Level II Code Set
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification
Health Level Seven (HL7) Version 2.5
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDAW/CDAR2)
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 2.0
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0
Integrating the Healthcare Enterprise (IHE) Radiology Technical Framework Revision 7.0
International Classification of Diseases, Ninth Edition, Clinical Modifications (ICD-9-CM)
International Classification of Diseases, 10 th revision, Related Health Problems (ICD-10 CM)
International Organization for Standardization (ISO) Health Informatics -- Pseudonymization, Unpublished Technical Specification # 25237
Logical Observation Identifiers Names and Codes (LOINC®)
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm
National Uniform Billing Committee (NUBC) Uniform Bill Version 1992 (UB-92)/Current UB Data Specifications Manual
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Hospital Availability Exchange (HAVE)
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE)
Unified Code for Units of Measure (UCUM)

20

3b. Biosurveillance

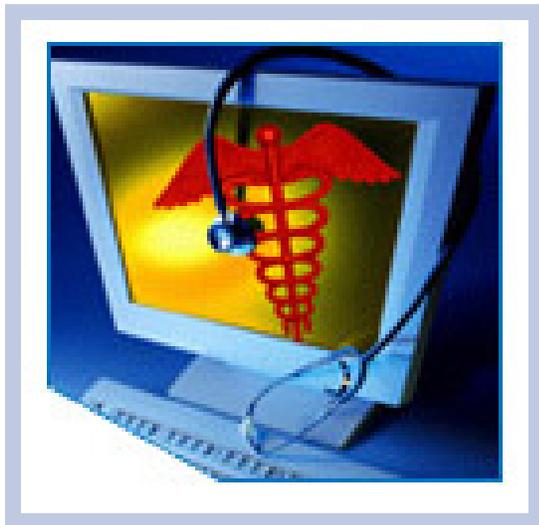


3b. Biosurveillance: HITSP Constructs

Document	Title
HITSP/IS/BIO-02	Biosurveillance
HITSP/IST-24	Biosurveillance Pseudonymize Transaction
HITSP/ISC-25	Anonymize Transaction
HITSP/ISC-39	Encounter Message Component
HITSP/ISC-41	Radiology Results Message Component
HITSP/ISC-47	Resource Utilization Message Component
HITSP/ISC -48	Encounter Document Component
HITSP/ISTP-49	Radiology Report Document Transaction Package
HITSP/ISTP-50	Retrieve Form for Data Capture Transaction Package
HITSP/ISTP-13	Manage Sharing of Documents Transaction Package
HITSP/IST-22	Patient ID Cross-Referencing Transaction
HITSP/IST-29	Notification of Document Availability Transaction
HITSP/ISC-35	EHR Lab Terminology Component
HITSP/ISC-36	Lab Result Message Component
HITSP/ISC-37	Lab Report Document Component
HITSP/ISC-45	Acknowledgements Component

HITSP Interoperability Specifications:
Electronic Health Records Laboratory Results Reporting HITSP/IS-01
Biosurveillance HITSP/IS-02
Consumer Empowerment HITSP/IS-03

Executive Overview



Submitted to:

American Healthcare Information Community

Submitted by:

Healthcare Information Technology Standards Panel



DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final Draft	HITSP Project Team	October 20, 2006



TABLE OF CONTENTS

FOREWORD	4
EXECUTIVE OVERVIEW	7
Electronic Health Record (EHR) Laboratory Results Reporting	7
Biosurveillance	9
Consumer Empowerment	11



FOREWORD

This document introduces the first set of Interoperability Specifications developed as an artifact of the Healthcare Information Technology Standards Panel (HITSP) standards harmonization process. An Interoperability Specification is a suite of documents that provides implementation level guidance that will:

- Identify standards and specific implementation context for those standards
- Describe specific value sets for unambiguous data exchange and system to system interaction
- Provide the necessary instruction to implement the specific standards in commercial and self-developed systems.

The American Healthcare Information Community charged the HITSP with harmonizing health interoperability standards for three specific situations:

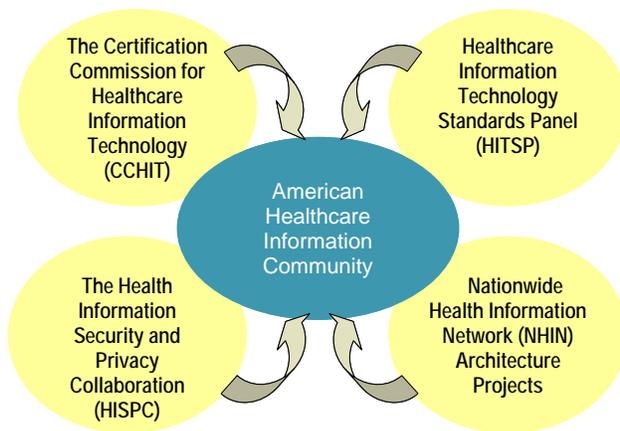
- **Electronic Health Records:** Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.
- **Biosurveillance:** Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
- **Consumer Empowerment:** Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. It also describes the HITSP process for health standards harmonization. If you are familiar with HITSP, please proceed to the next major section titled – Executive Overview.

U.S. Nationwide Health Information Interoperability

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. health IT can be used to enable better integration of clinical information. However, as of 2006, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized interoperability standards.





The American Health Information Community¹ (AHIC), a 2005 federally-chartered commission made up of leaders from public and private health sectors, was formed to provide recommendations 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. At the same time, the Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) identify interoperability standards to facilitate the

exchange of patient data (HITSP), 2) define a process for certifying that health IT products comply with appropriate standards The Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a Nationwide Health Information Network (NHIN). These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration.

HITSP's Role within Nationwide Interoperability Efforts

The HITSP² is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term "standard" refers, but is not limited to:

- Specifications
- Implementation Guides
- Codes Sets
- Terminologies
- Integration Profiles

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications (IS) and information policies, including Standards Development Organization (SDO) work products (e.g. standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare informatics to ensure that the resulting standards are globally relevant
- Be Use Case driven, using information from stakeholders and basing decisions on industry needs

¹ <http://www.hhs.gov/healthit/ahic.html>

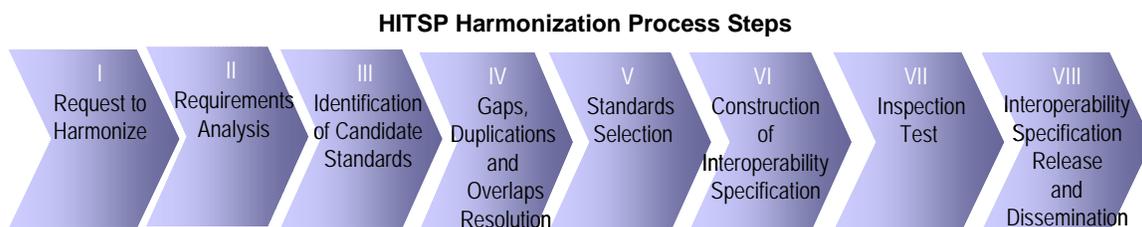
² www.hitsp.org



The work of HITSP is conducted through formally chartered Technical Committees of volunteer members. The artifact of the Technical Committee activities is an Interoperability Specification (IS) and related documents referred to as IS Transaction Packages, IS Transactions, or IS Components.

How Use Cases and HITSP Interoperability Specifications are Developed

The American Health Information Community (AHIC), as the representative of public and private health sector stakeholders, identified the three Use Cases (available at www.hitsp.org) that drove the initial efforts of the HITSP. Nationwide public and private health sector priorities continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee follow an 8 step process, depicted in the figure below.



The current version of each Interoperability Specification has been approved by the HITSP as *Ready for Implementation Testing*, which is the first action in Step VIII, Interoperability Specification Release and Dissemination. Upon successful completion on the Implementation Testing, the Interoperability Specifications will be considered *Ready for Implementation*.



EXECUTIVE OVERVIEW

Each Interoperability Specification (IS) is actually a suite of documents that, taken as a whole, provide a detailed map to existing standards and specifications that will satisfy the requirements imposed by a given Use Case. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the Interoperability Specification provides recommendations and a roadmap for corrections to be made. Each Interoperability Specification includes IS Transaction Packages, IS Transactions, and IS Components relevant to a specific Use Case. In all there are 23 documents that make up the three Interoperability Specifications. Of the 23 documents, eight are referenced by multiple Interoperability Specifications. This modular approach will support future re-use of HITSP artifacts.

The Interoperability Specifications summarized in this document can be retrieved from the HITSP website using the following links:

[Electronic Health Record Laboratory Results Reporting HITSP/IS-01](#)

[Biosurveillance HITSP/IS-02](#)

[Consumer Empowerment HITSP/IS-03](#)

For each Interoperability Specification, this executive overview provides the business problem to be addressed, highlights the prominent challenges encountered and describes how they were resolved, and lists the HITSP recommended standards selected to meet the requirements of each Use Case.

ELECTRONIC HEALTH RECORD (EHR) LABORATORY RESULTS REPORTING

This Interoperability Specification is designed to meet the specific requirements of sending laboratory results to clinicians for patient care. Lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards, contributes to duplicate and unnecessary laboratory testing. Both of which impact the quality and cost of healthcare.

The HITSP EHR Interoperability Specification is relevant to clinical care providers who wish to have laboratory test results and laboratory interpretations electronically available for patients for whom they are providing care. Laboratory test results and interpretations are available for integration into an electronic health record (EHR), local or remote, or another clinical system. The Use Case includes two scenarios that cover typical interfaces involving an EHR system (or equivalent) and laboratory results.

The HITSP EHR Interoperability Specification describes both a laboratory message transaction and a document sharing paradigm. Ordering providers of care always receive results as a laboratory message, non-ordering providers of care access historical laboratory results as documents, and "copy-to" providers



of care may receive either messages or document availability notifications. The dual path of message and document provides a greater degree of implementation flexibility.

Challenges

The EHR Technical Committee has identified gaps in terminology standards for reporting laboratory results. These gaps are minimized by the selection of standards that give the widest coverage, but vocabulary domains with clinical content are very large and encompass many specialties. The innovation in healthcare informatics is fast-paced, resulting in gaps as the standards attempt to catch up. In addition to gaps, there is a significant overlap. This overlap is well understood and monitored by the sponsoring SDO. A mapping from the Health Level Seven (HL7) Version 2.5 ORU^R01 message to the Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework XD*-LAB constrained HL7Clinical Document Architecture (CDA) document is a necessary accessory to this specification. This mapping will be the basis for interoperability between messages and documents.

Transactions

The core transactions that comprise this Interoperability Specification include the following:

- **Send Laboratory Result:** This includes all the data definitions and interactions for the HL7 V2.5 Laboratory Result Message. It relies on two components:
 - × The Laboratory Result Message Component (HITSP/ISC-36) specifies constraints on the HL7 V2.5 message and
 - × The Laboratory Result Terminology Component (HITSP/ISC-35) describes the vocabulary constraints
- **Manage Sharing of Documents:** This is a generic document-sharing paradigm that can be used for any electronic document. For this specification, the specific document of interest is the HL7 CDA specification based on the Integrating the IHE Laboratory Technical Framework XD*-LAB. The HITSP Laboratory Report Document Structure Component Specification (HITSP/ISC-37) describes the Laboratory CDA document and the Laboratory Result Terminology Component (HITSP/ISC-35) describes the vocabulary constraints

Ancillary transactions address Web Services, Notification of Document Availability, Patient Demographics Query (PDQ) and Patient ID Cross-Referencing (PIX).

Recommended Standards

The Interoperability Specification is the result of an assessment of the current practices in electronic laboratory results reporting and the requirements of the EHR Use Case. The EHR Technical Committee (EHR TC) chose this combination of standards because they meet the requirements of the Use Case and reflect both current practice and future directions for healthcare information sharing.



The following table lists the standards selected to implement the entire ONC harmonized Use Case for EHR LAB. It is important to note that the industry use of HL7 v3.0 and HL7 2.5 standards is evolving, and the expectation is that these standards will become more broadly used. The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange. The CDA Release 2.0 distribution includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. The HL7 CDA Release 2.0 is a limited subset of HL7 V3. It builds upon other HL7 standards, including the HL7 Reference Information Model (RIM), Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and V3 Structures. This Implementation Specification does not imply a full adoption of HL7V3, but just refers to HL7 CDA R2 and the limited subset of HL7V3 artifacts used by HL7 CDA R2.

<i>Recommended Standards</i>
Clinical Laboratory Improvement Amendments (CLIA) of 1988
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification
Health Level Seven (HL7) Version 2.5
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 2.0
International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (eXML), Technical Specification # 15000 -- Part 4: Registry services specification (eRS), May, 2004
Logical Observation Identifiers Names and Codes (LOINC®)
Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®)
Unified Code for Units of Measure (UCUM)

BIOSURVEILLANCE

This Interoperability Specification is designed to meet the specific requirements of the Biosurveillance Use Case, defined as implementation of near real-time, nationwide public health event monitoring to support early detection, situational awareness, and rapid response management across care delivery, public health, and other authorized Government agencies.

The scope addressed in the Interoperability Specification is the transmission of essential data from ambulatory care and emergency department visits, utilization, and lab result data from electronically enabled healthcare delivery and public health systems in a standardized and anonymized format, to authorized Public Health Agencies with less than one day lag time. While the system and processes ultimately must also support the ability for authorized public health personnel to go back to the data source to seek to re-link the anonymized biosurveillance data to the data source as part of an appropriate public health investigation, such re-linking has been deferred for future effort.

The management of data to ensure proper routing, security, privacy, and timely reporting is critical to enabling biosurveillance activities. Potential architectural solutions to data flow issues include using



individual facility data sources (e.g., single hospitals or ambulatory care sites) or networked system such as a multi-facility system or supporting organization that uses data in the course of providing other services and sends data to all appropriate public health agencies. Other permutations of these two models can also be considered. The role of the data or network system can be accomplished by several different stakeholders, including hospital systems, health plans, independent laboratories, and other possibilities. However, this IS was defined to be independent of architecture choice and is intended to support any variant of the architectural choices identified above.

Challenges

The Biosurveillance Technical Committee has focused its work around an analysis of the Biosurveillance Use Case provided by the American Health Information Community (AHIC). This work has also been informed by the proceedings of the AHIC Biosurveillance Data Steering Group (BDSG). Even so, an implementer of this Interoperability Specification must provide the technical infrastructure and security framework necessary to support operations in accordance with law, regulation, best practices and business agreements.

The Technical Committee worked with the United States Health Information Knowledgebase to evaluate the metadata and repository for use in standards selection using demographic and encounter data as a test case. The results and the resource will be used to extend this Interoperability Specification to additional domains and clinical data information exchange standards.

The BIO Technical Committee has selected standards with more options than might otherwise be defined between communication partners. As Biosurveillance is based upon secondary use of clinical data, the processes and data capture options are somewhat opportunistic, and associated data mining processes have more latitude in translation and data preparation processes. Since it is important to maximize the data sources to contribute data to the biosurveillance information system, information exchange selections include options for data capture from both legacy environments and emerging environments. Vocabulary, message, and content standards have been selected in consideration of providing the most comprehensive, machine process able fulfillment of the data requirements provided by the AHIC BDSG.

Transactions

The core transactions that comprise this Interoperability Specification include the following:

- **Pseudonymize Data:** Apply a common standard to Codify Document Content, Anonymize or Pseudonymize patient data to protect patient identity from undesired disclosure when communicating care data to/from external parties.
- **Anonymize Data:** Apply a common standard to Codify Document Content, Anonymize or Pseudonymize patient data to protect patient identity from undesired disclosure when communicating care data to/from external parties.

Ancillary transactions address Manage Sharing of Documents, Retrieve Form from Data Capture,



Notification of Document Availability, Acknowledgements, and Patent ID Cross-Referencing (PIX).

Recommended Standards
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4)
Clinical and Laboratory Standards Institute (CLSI) [formerly the National Committee for Clinical Laboratory Standards (NCCLS)]
Clinical Care Classification (CCC) Version 2.0 [formerly known as the Home Healthcare Classification (HHCC) System]
Clinical Laboratory Improvement Amendments (CLIA) of 1988
College of American Pathologists Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)
Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987
HCPCS Level II Code Set
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification
Health Level Seven (HL7) Version 2.5
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 2.0
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0
Integrating the Healthcare Enterprise (IHE) Radiology Technical Framework Revision 7.0
International Classification of Diseases, Ninth Edition, Clinical Modifications (ICD-9-CM)
International Classification of Diseases, 10 th revision, Related Health Problems (ICD-10 CM)
International Organization for Standardization (ISO) Health Informatics -- Pseudonymization, Unpublished Technical Specification # 25237
Logical Observation Identifiers Names and Codes (LOINC®)
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm
National Uniform Billing Committee (NUBC) Uniform Bill Version 1992 (UB-92)/Current UB Data Specifications Manual
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Hospital Availability Exchange (HAVE)
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE)
Unified Code for Units of Measure (UCUM)

CONSUMER EMPOWERMENT

Consumer Empowerment is the active involvement of consumers (i.e., individuals) in managing their healthcare and gaining the benefits of having their health information in a format easily accessible to them. This includes having a personal health record (PHR) to track patient information, insurance, family history, medications, and other special conditions.



As part of a personal health record, this Interoperability Specification addresses two key areas: the patient's registration data and medication history.

A vital part of a personal health record is registration information. Going to the doctor or hospital frequently requires filling out multiple forms. These forms collect information such as name, address, insurance, medications, allergies, etc. Then, when an individual requires laboratory work or other testing, the same information has to be collected again. A single electronic registration will make it easier for individuals to give their information and for clinicians to use it. Additionally, the consumer could update the information once and share it with all healthcare providers.

An electronic medication history provides the consumer with an updated list of all pertinent medications and allergies in an easily accessible format. Most individuals do not know the specific medications and exact dosages that have been prescribed to them, and often do not know their allergies. In addition, clinicians do not always have consistent prescription information about the same individual nor do they have easy access to medication information directly from the patient. Too often, this results in errors or unnecessary treatments. An electronic medication history would have all the current data available to the individual and to each authorized healthcare provider. The need for an electronic medication history was highlighted by the high interest in the KatrinaHealth.org web tool. Having a complete electronic medication list would also prevent drug-to-drug or allergic reactions when subsequent prescriptions are written.

Based on the charge from the American Health Information Community, the Consumer Empowerment Use Case presumes some level of linkage between consumer's registration summary and their medication history. This linkage is an important consideration for identifying and locating individual consumers and their available medication information across network systems. For the purposes of this Use Case, the linking of a consumer's registration summary to the medication history includes: (1) identity matching, (2) linkages between the data, (3) and the ability to incorporate both types of data simultaneously into a system (although they may come from different systems themselves).

The Consumer Empowerment Interoperability Specification addresses three scenarios to satisfy the harmonized Use Cases defined by ONC. They are:

- Consumer creates account to host registration summary & medication history
- Consumer visits Healthcare Provider and provides registration summary information
- Authorized Healthcare Provider reviews medication history

This Interoperability Specification defines an interoperable registration and medication history document; one means of which to share this type of document is by registering them in a record locator and retrieving them from the referenced document repository. Some of the other HITSP Use Cases define other types of documents (e.g. a laboratory report in the EHR Use Case) which may also be used as part of information exchange to and from a consumer PHR). Other types of interoperable documents may be



defined by HITSP in the future for radiology reports, images, electrocardiogram (ECG) reports, etc. These other types of documents are out of scope of the current Use Case.

Challenges

The CE Technical Committee has been charged with introducing the consumer, and the PHR, as an integral partner of the healthcare information flow representing a new paradigm in healthcare interoperability. This paradigm establishes the consumer as the active participant in health information exchange that touches all segments of the industry; providers/care facilities, health plans, pharmacies/prescription benefit managers, and others. This challenge is exacerbated by the current information technology situation wherein providers, health plans, pharmacies, and pharmacy benefit manager industry segments each have created different standards based on differing business needs and timing, with shared and overlapping data elements via three different standards developers: HL7, ASC X12, and NCPDP SCRIPT.

In addition to these aforementioned standards, a fourth standard initiative from ASTM targeting the provider-provider and provider-consumer interoperability space, entitled the Continuity of Care (CCR), passed favorable ballot in October 2005. In the latter phase of the successful CCR balloting process, ASTM and HL7 initiated a formal harmonization effort regarding their respective efforts addressing the same interoperability space. This harmonization initiative resulted in the joint development of the Continuity of Care Document (CCD) which was issued as an HL7 ballot in August 2006.

The CE Technical Committee has determined that it is in the best interest of HITSP harmonization efforts to wholeheartedly support this HL7-ASTM harmonization initiative and leverage its deliverables to the highest degree possible. To this end, in the absence of having a balloted CCD standard to reference, the approach taken by the CE TC is to align its Interoperability Specification to the expected technical design characteristics of the CCD. This CE Interoperability Specification artifact is therefore intended to facilitate the transition from the current disparate standards environment to a harmonized state through use of a preliminary specification that is on the convergence path of the promised HL7-ASTM harmonization. HITSP is committed to migrate this preliminary specification to the final balloted result of this HL7-ASTM harmonization work as soon as it's officially available. The HITSP has set a target date of six months (i.e. March-April 2007) for the release of the final approved HL7 CCD. At this time the situation will be revisited and a determination will be made as to whether the publication of an interim HITSP Interoperability Specification is appropriate.

Transactions

The Consumer Empowerment Use Case includes:

- Enabling consumers to establish permissions and access rights for viewing their data
- Authenticating consumers, designated caregivers, and health professionals
- Querying other organizations for data and matching to the consumer
- Accepting "batch" data from other organizations and matching to the appropriate consumers



- Accessing, viewing, and sharing registration summaries and medication histories
- Recording of interactions to enable access and viewing tracking and generation of system logs.

Recommended Standards
Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1
Accredited Standards Committee (ASC) X12 Standards Release 004010
American Society for Testing and Materials (ASTM) Standard Specification for Continuity of Care Record (CCR): # E2369-05
Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules
Federal Medication Terminologies
Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)
Health Level Seven (HL7) Version 2.5
Health Level Seven (HL7) EHR System Functional Model Draft Standard for Trial Use (DSTU)
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0
Logical Observation Identifiers Names and Codes (LOINC®)
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 8.1

* * *

HITSP refers you to hitsp.org for additional information about the HITSP, its charter, membership, and work products. You can contact the Panel Secretariat, Ms. Michelle Maas Deane, by phone at (212) 642-4884, or by email using mmaasdeane@ansi.org.



APPENDIX – COMPLETE LISTS OF STANDARDS



EHR LABORATORY RESULTS REPORTING LIST OF STANDARDS

Standard	Description
Clinical Laboratory Improvement Amendments (CLIA) of 1988	Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. Visit www.fda.gov/cdrh/cliia and www.cms.hhs.gov/cliia for more information.
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification ³	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information.
Health Level Seven (HL7) Version 2.5	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the US and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. Visit http://www.hl7.org for more information.
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit http://www.hl7.org for more information. Visit www.hl7.org for more information.
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0	The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (XD*-LAB) that describes a clinical laboratory report as a human-readable electronic document. This document, which may also contain data in a machine-readable format and contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. This document is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document, and is not intended to address ordering or return of laboratory results to the ordering provider.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 2.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common

³ Using the full Interoperability Specification, please refer to section 2.1 Overview for discussion of Standard Transactions and Codesets and to section 2.2.5 for information relating to HIPAA Security and Privacy



Standard	Description
	language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 2.0 for Final Text, specifies the IHE transactions defined and implemented as of August 2005. Of particular focus for HITSP Interoperability Specifications are Patient Identifier Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), Cross Enterprise Document Sharing (XDS), and Notification of Document Availability (NAV) Integration Profiles. The latest version of the IHE Technical Framework is available at http://www.ihe.net/Technical_Framework .
International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000 -- Part 4: Registry services specification (ebRS), May, 2004	Describes eXtensible Markup Language (XML) and its usage characteristics. Consists of 4 parts: ebCPP, ebMS, ebRIM, and ebRS. Part 4 ebRS defines the interface between the registry and the registry clients, as well as the interaction protocols, message definitions and XML schema. Visit http://www.iso.org for more information.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of Universal identifiers for laboratory and other clinical observations maintained by Regenstrief Institute. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology; etc. Contact the Regenstrief Institute at e-mail: loinc@regenstrief.org or visit www.regenstrief.org/loinc for more information.
Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®)	A validated clinical healthcare terminology and infrastructure that makes healthcare knowledge more usable and accessible. The SNOMED CT Core terminology provides a common language that enables a consistent way of capturing, sharing and aggregating health data across specialties and sites of care. Among the applications for SNOMED CT are electronic medical records, ICU monitoring, clinical decision support, medical research studies, clinical trials, computerized physician order entry, disease surveillance, image indexing and consumer health information services. Maintained by the College of American Pathologists (CAP), information is available at www.snomed.org/snomedct/index.html .
Unified Code for Units of Measure (UCUM)	The Unified Code for Units of Measure is a code system intended to include all units of measure used in science, engineering, and business with the goal of facilitating unambiguous electronic communication of quantities together with their units.



BIOSURVEILLANCE LIST OF STANDARDS

Standard	Description
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4)	A uniform coding system used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. Visit www.ama-assn.org/ama/pub/category/3113.html for more information.
Clinical and Laboratory Standards Institute (CLSI) [formerly the National Committee for Clinical Laboratory Standards (NCCLS)]	A global, nonprofit, standards-developing organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. Visit www.nccls.org for more information.
Clinical Care Classification (CCC) Version 2.0 [formerly known as the Home Healthcare Classification (HHCC) System]	Provides a standardized framework and a unique coding structure for assessing, documenting, and classifying home health and ambulatory care. This system consists of two interrelated taxonomies: CCC of Nursing Diagnoses and CCC of Nursing Interventions classified by 21 Care Components that represent the Functional, Health Behavioral, Physiological, and Psychological Patterns of patient care. The 21 Care Components serve as a standardized framework for mapping and linking the two interrelated CCC taxonomies to each other and to other health-related classifications. Visit www.sabacare.com for more information.
Clinical Laboratory Improvement Amendments (CLIA) of 1988	Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. Visit www.fda.gov/cdrh/clia and www.cms.hhs.gov/clia for more information.
College of American Pathologists Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. Visit www.snomed.org/snomedct/index.html for more information.
Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55	Adds a mechanism for selective protection of individual attributes within arbitrary DICOM service-object pair (SOP) instances. It may be used to achieve protection of identifying information, e.g. a reversible anonymization or pseudonymization of DICOM SOP instances while continuing to use unmodified lower level message and protocol services for network transfer, storage, and media exchange of composite image information objects. Visit http://medical.nema.org/ for more information.
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	A set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the United States, and associated areas. The standard covers all land areas under the sovereignty of the United States, the freely associated states of Federated States of Micronesia and Marshall Islands, and the trust territory of Palau. Visit http://www.itl.nist.gov/fipspubs/ for more information. NOTE: ASC X12 transactions and ASC X12N Implementation Guides do not allow use of this standard; instead they require use of the U.S. Postal Service's National Zip Code and Post Office Directory -- which provides similar alphabetic code values.
HCPCS Level II Code Set	Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes (Level I of HCPCS) for billing purposes. In some cases a HCPCS code may be used to identify a unusual ordered service mapped to the AHIC data set. CMS maintains HCPCS codes. www.cms.hhs.gov/MedHCPCSGenInfo/ .
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and



Standard	Description
	protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information.
Health Level Seven (HL7) Version 2.5	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It has widespread use in the US and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 for Patient Identifier Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), Laboratory Results Reporting, and Acknowledgements. Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit www.hl7.org for more information.
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0	The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (XD*-LAB) that describes a clinical laboratory report as a human-readable electronic document. This document, which may also contain data in a machine-readable format and contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. This document is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document, and is not intended to address ordering or return of laboratory results to the ordering provider.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 2.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 2.0 for Final Text, specifies the IHE transactions defined and implemented as of August 2005. Of particular focus for this HITSP Interoperability Specification is Patient Identifier Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), Cross Enterprise Document Sharing (XDS), and Notification of Document Availability (NAV) Integration Profiles. The latest version of the IHE Technical Framework is available at http://www.ihe.net/Technical_Framework .
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Exchange of Personal Health Record Content (XPHR) Integration Profile describes the content and format of summary information extracted from a PHR system for import into an EHR system, and vice versa. The purpose of this Integration Profile is to support interoperability between PHR systems used by patients and EHR systems used by healthcare providers. The Cross Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network. In the registry, healthcare providers publish pointers to



Standard	Description
	documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents.
Integrating the Healthcare Enterprise (IHE) Radiology Technical Framework Revision 7.0	The IHE Radiology Technical Framework specifies the Cross Enterprise Document Sharing for Imaging (XDS-I) Integration Profile which enables sharing of imaging documents such as radiology images and reports across healthcare enterprises. XDS-I extends XDS by sharing, locating and accessing DICOM instances from its original local sources, e.g. for radiologists or oncologists.
International Classification of Diseases, Ninth Edition, Clinical Modifications (ICD-9-CM)	A two part, three volume, coding system used to identify diseases and treatments. ICD-9-CM Volumes 1 and 2 describe codes for diseases, injuries, impairments, and other health problems; along with their causes. ICD-9-CM Volume 3 describes codes for procedures and actions taken for prevention, diagnosis, treatment, and management. Visit http://www.cdc.gov/nchs/ for more information.
International Classification of Diseases, 10 th revision, Related Health Problems (ICD-10 CM)	The International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) is used for mortality statistics reporting. It is owned and published by the World Health Organization (WHO). The National Center for Health Statistics (NCHS) is responsible for use of the (ICD-10) in the United States and has developed a clinical modification of the classification for morbidity purposes. ICD-10-CM, has more codes and classifications and expanded ambulatory coverage compared to ICD-9-CM. ICD-10-CM is not yet approved for implementation in the US.
International Organization for Standardization (ISO) Health Informatics -- Pseudonymization, Unpublished Technical Specification # 25237	Health Informatics – Pseudonymisation. Still under development as of October, 2006. Scheduled for ballot December 2006. The HITSP Biosurveillance TC recognizes that ISO/DTS 25237 is a draft standard. An informal Liaison relationship is established to harmonize the ongoing work of this TC and assure consistency with this draft standard that we expect will continue to inform the work of this TC. Visit www.iso.org for more information.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. Visit www.loinc.org for more information.
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	Provides standard names for (1) clinical drugs and (2) drug dose forms as administered to a patient. Also provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. Food and Drug Administration (FDA) National Drug Codes (NDCs) for specific drug products and many of the drug vocabularies commonly used in pharmacy management and drug interaction software are additionally linked to RxNorm. Visit http://www.nlm.nih.gov/research/umls/rxnorm/index.html for more information.
National Uniform Billing Committee (NUBC) Uniform Bill Version 1992 (UB-92)/Current UB Data Specifications Manual	A code set identifying status of patient discharge on an institutional claim (e.g., inpatient, outpatient, hospice, home care). Visit www.nubc.org for more information.
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Hospital AVailability Exchange (HAVE)	<p>Specifies an XML-formatted document that allows healthcare provider organizations to communicate specific utilization information and status of a facility (e.g., hospital, trauma center, nursing home) and its resources; including bed capacity and availability, emergency department status, the available service coverage, and the status of a hospital's facility and operations. HAVE is initially intended for use in disaster or emergency situations. Visit www.Oasis-open.org for more information.</p> <p>Reasoning: The BIO TC has identified the Hospital Availability Exchange (HAVE) dataset as being closely aligned with the data elements identified by the Biosurveillance</p>



Standard	Description
	<p>Data Steering Committee. The HAVE specification is being proposed as an Organization for the Advancement of Structure Information Standards (OASIS) standard, but has not yet been fully reviewed and adopted. HAVE was derived from the results of the HAVBed project sponsored by the Agency for Health Resources and Quality. While it is anticipated that the HAVE specification will soon be approved by Oasis, and is likely to meet the requirements for reporting the data elements for hospitals and health resource availability identified by the BDSG, pending this formal approval the choice of a specific standard to represent these data elements remains a gap as defined in the HITSP policies. HAVE specification contains terminology specific to utilization information and allows communication of the status of a hospital and its resources to other emergency agencies, including bed capacity and availability, emergency department status, the available service coverage, and the status of a hospital's facility and operations.</p> <p>Qualifier: The needs of biosurveillance would be better suited if this terminology were instantiated as a coded vocabulary</p>
<p>Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE)</p>	<p>Describes a standard message distribution framework for data sharing among emergency information systems using the XML-based EDXL. This format may be used over any data transmission system. DE is initially intended for use in disaster or emergency situations. Visit www.oasis-open.org for more information.</p> <p>Reasoning:</p> <p>The Emergency Data Exchange Language (EDXL) is a suite of specific XML based standards intended as a suite of emergency data message types including resource queries and requests, situation status, message routing instructions and the like, needed in the context of cross-disciplinary, cross-jurisdictional communications related to emergency response. It is the result of a project of the Disaster Management eGov Initiative of the Department of Homeland Security (DHS) as a means to enhance XML based inter-agency emergency data communications. DHS partnered with industry members of the Emergency Interoperability Consortium (EIC) to bring the work to OASIS for advancement and standardization.</p>
<p>Unified Code for Units of Measure (UCUM)</p>	<p>A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. Visit http://aurora.regenstrief.org/UCUM/ for more information.</p>



CONSUMER EMPOWERMENT LIST OF STANDARDS

Standard	Description
Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1	Detailed Implementation Guides keyed to release 004010 of the X12 standards. These Implementation Guides provide details on the use of X12 standards to accomplish specific transaction functions. Some of the version 004010 Implementation Guides, but not all, have been adopted as Implementation Specifications under HIPAA. Many of the version 004010 Implementation Guides, including all of those adopted under HIPAA, have Addenda that contain updates -- only -- to the original Implementation Guides. These Addenda are identified as version 004010A1. Implementation Guides 004010X092 and 004010X092A1 describe transactions for Eligibility Inquiry and Response. Implementation Guides are published by Washington Publishing Company. Visit www.x12.org for more information.
Accredited Standards Committee (ASC) X12 Standards Release 004010	Release (version) 004010 of the Accredited Standards Committee (ASC) X12 standards including the X12.5 Interchange Control, X12.6 Application Control Structure, 270 Eligibility, Coverage or Benefit Inquiry, 271 Eligibility, Coverage or Benefit Information and other control standards for the uniform electronic interchange of business transactions. Published by the Data Interchange Standards Association (DISA). Visit www.x12.org for more information.
American Society for Testing and Materials (ASTM) Standard Specification for Continuity of Care Record (CCR): # E2369-05	A core data set of the most relevant and timely facts about a patient's healthcare. It is to be prepared by a practitioner at the conclusion of a healthcare encounter in order to enable the next practitioner to readily access such information. It includes a summary of the patient's health status (e.g., problems, medications, allergies) and basic information about insurance, advance directives, care documentation, and care plan recommendations. An XML version of the CCR, known as the Continuity of Care Document (CCD), prepared by Health Level Seven (HL7) in collaboration with ASTM, also exists and described under Health Level Seven standards. Visit www.astm.org for more information.
Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules	Provide agreed-upon business rules and guidelines for using and processing eligibility inquiry and response transactions between providers and health plans; in particular those that have been adopted under HIPAA. Visit www.caqh.org for more information.
Federal Medication Terminologies	<p>A set of federal terminologies related to medications, including the Food and Drug Administration's names and codes for ingredients, manufactured dosage forms, drug products and medication packages, the National Library of Medicine's RxNORM for describing clinical drugs, and the Veterans Administration's National Drug File Reference Terminology (NDF-RT) for specific drug classifications.</p> <p>This leverages the controlled terminology from three medication models that are maintained by the federal government:</p> <p>National Drug File Reference Terminology (NDF-RT)</p> <ul style="list-style-type: none"> - Veterans Health Administration <p>Structured Product Labeling (SPL)</p> <ul style="list-style-type: none"> - Food and Drug Administration <p>RxNorm</p> <ul style="list-style-type: none"> - National Library of Medicine
Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)	The Continuity of Care Document (CCD) constrains the HL7 Clinical Document Architecture Release 2 (CDA R2) in accordance with requirements specified in American Society for Testing and Materials (ASTM) standard E 2369-05, "Standard Specification for Continuity of Care Record (CCR)." The resulting CCD specification is developed as a collaborative effort between ASTM and HL7, and is intended as an alternate implementation to the one specified in ASTM E2369-05 for those organizations preferring to use HL7 Clinical Document Architecture (CDA) to communicate this information. Visit www.hl7.org for more information.



Standard	Description
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 2.5	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identifier Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. Visit www.hl7.org for more information.
Health Level Seven (HL7) EHR System Functional Model Draft Standard for Trial Use (DSTU)	The HL7 EHR System Functional Model and Standard documents key functions of Electronic Health Record Systems (EHR-S) to enable consistent expression of system functionality. The functions are organized in two ways: as a hierarchy within the broad headings of care delivery and infrastructure functions; and as a list of functions that are deemed essential or desirable within four common care settings. Visit www.hl7.org for more information.
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0	The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (XD*-LAB) that describes a clinical laboratory report as a human-readable electronic document. This document, which may also contain data in a machine-readable format and contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. This document is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document, and is not intended to address ordering or return of laboratory results to the ordering provider. Visit www.ihe.net for more information.
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Exchange of Personal Health Record Content (XPHR) Integration Profile describes the content and format of summary information extracted from a PHR system for import into an EHR system, and vice versa. The purpose of this Integration Profile is to support interoperability between PHR systems used by patients and EHR systems used by healthcare providers. The Cross Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. Visit www.ihe.net for more information.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. Visit www.loinc.org for more information.



Standard	Description
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 8.1	Provides for the real-time electronic transfer of prescription data between pharmacies and providers. Functions supported include communication of new prescriptions, prescription changes, refill requests, prescription fill status notifications, and prescription cancellations. Visit www.ncdp.org for more information.





American Health Information Community

Biosurveillance Data Steering Group

Final Report
October 31, 2006

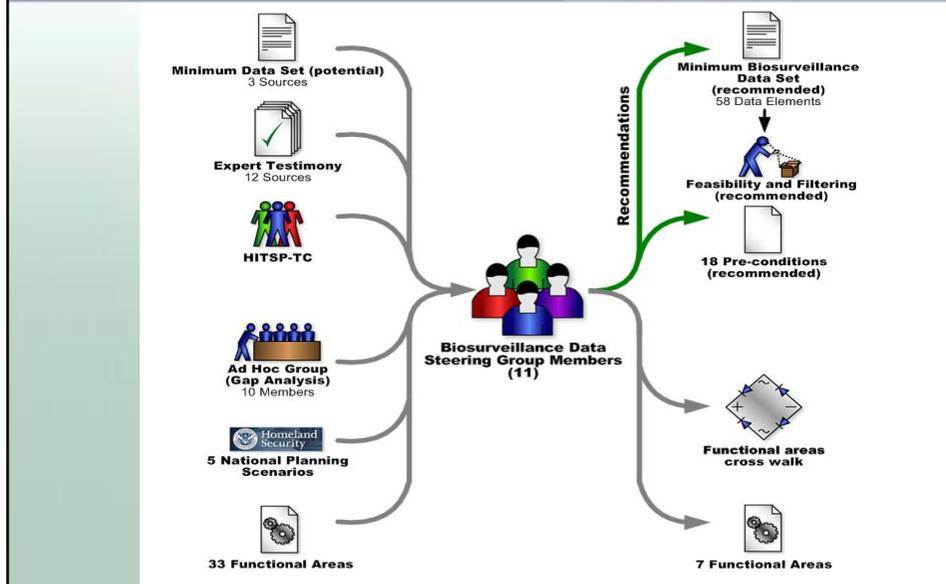
Biosurveillance Data Steering Group Charges

- **Broad Charge:**
 - Make recommendations to the Community so that within one year, essential ambulatory care and emergency department visits, 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.
- **Specific Charge:**
 - The specific charge of the BDSG will be to identify the requirements for data from ambulatory care, emergency departments, and laboratories necessary for multi-jurisdictional biosurveillance programs. These requirements will build upon previous work completed by the AHIC Biosurveillance Work Group and the Health Information Technology Standards Panel Biosurveillance Technical Committee (HITSP-TC). Recommendations that specify these requirements will also refine and supplement the work of the HITSP-TC.

Biosurveillance Data Steering Group (BDSG) Inputs, Process, and Outputs

Source/ Driver	Inputs	Process	Outputs
BSV	Scope of work Data elements	Matrix, Target, Validation	Initial Minimum Data Set (MBDS)
Ad hoc Group	Initial MDS National Planning Scenarios	Gap Analysis Review	Refined MBDS Category Validation
BDSG	Need to clarify functional area scope CDC definitions	Balloting and Analysis	In (short vs. long term) vs. excluded Functional area - Crosswalk
BDSG	Need for context	Steering group discussions	Preconditions - Scope of Work
HITSP - TC	Harmonization of Standards	Identify standards	AHIC - MBDS Cross Reference
Experts	Testimony	Comment and discussion	MBDS feasibility MBDS filtering criteria

Minimum Biosurveillance Data Set Recommendations Process: from inputs to deliverables



Adoption of the Minimum Biosurveillance Data Set

Recommendation 1.0:

The Secretary of the U.S. Department of Health and Human Services should adopt the Minimum Biosurveillance Data Set to guide data collection in biosurveillance programs that involve the simultaneous sharing of clinical data from health care providers to authorized local, state and federal public health agencies.

(Details of the Minimum Biosurveillance Data Set are provided in Appendix B)

Minimum Biosurveillance Data Set – Categories (Appendix B)

MBDS Category	No.	Examples:
Base Facility Elements	5	Facility: Identifier, Name, Location, No. of beds, and No. of Licensed beds
Daily Facility Summary Report	18	Admissions, Discharges, and Deaths in last 24 hours, Facility Status, Staffing
Patient Data Elements	10	DOB, Age, Gender, Zip Code, State, and Event Date/Time
Clinical Data Elements	10	Diagnosis/injury code, Chief Complaint, Temperature,
Laboratory & Infectious Disease Test Orders	3	Order Number, Test/Procedure Name and Test/Procedure Code
Laboratory & Infectious Disease Results	12	Performing Lab, Specimen Source, Results and Test Interpretation

Total data elements: 58

Working Towards Implementation

Recommendation 1.1:

By September 2007, the U.S. Department of Health and Human Services, in collaboration with state and local governmental public health agencies, should work with clinical care partners to implement the short term Minimum Biosurveillance Data Set and enable simultaneous data access to local, state and federal public health entities for biosurveillance purposes.

Evaluation of Implementation Models

Recommendation 1.2:

By March 2007, the U.S. Department of Health and Human Services, in collaboration with state and local governmental public health agencies, and clinical care partners, should evaluate implementation models, costs, and determine availability of resources and establish a plan to effect a short term Minimum Biosurveillance Data Set implementation.

Filtering of the Minimum Biosurveillance Data Set

Recommendation 2.0:

Public health agencies and partners who implement the short term Minimum Biosurveillance Data Set should filter out some components of the following data elements as appropriate: date of birth, age, zip code, and diagnosis/injury code.

(Details of Minimum Biosurveillance Data Set filtering are provided in Appendix B).

Monitoring the Minimum Biosurveillance Data Set

Recommendations 3.0:

CDC should, no less than annually, involve local, state and federal public health agencies and clinical care partners, in an MBDS monitoring process for biosurveillance usefulness, and make appropriate modifications as evidence develops to support such modifications.

Preconditions for deciding on MBDS elements (Appendix A)

- Use and collection of secondary clinical data will help support the following preparedness functional areas (Appendix D)
 - Early event detection
 - Situational awareness
 - Outbreak management
 - Countermeasure and response administration
- A multi-jurisdictional approach includes collaborative decision-making and coordinated efforts to assure maximal benefits to all partners. All authorized jurisdictions (i.e., federal, state and local), capable of receiving data, should have simultaneous access to timely data.
- Data will be shared to support initial public health investigations while preserving traditional comprehensive public health investigatory roles and responsibilities. Biosurveillance systems should support public health practice at all jurisdictional levels.

Functional Areas¹ for short term focus (Appendix D)

- **Early Event Detection (EED)**
 - Secondary use of clinical data
 - Reportable disease case reporting
 - Situational awareness
- **Outbreak Management (OM)**
 - Case investigation and management
 - Integration with early detection and countermeasure administration
 - Linking laboratory test results with clinical case data
- **Countermeasure & Response Administration (CRA)**
 - Support apportionment and allocation for limited supplies

¹The Public Health Information Network (PHIN) Preparedness Initiative
Loonsk JW, et al. *JAMIA* 13:1-4, 2006.

October 31, 2006

The Honorable Michael O. Leavitt
Chairman
American Health Information Community
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Chairman:

In May 2006, the American Health Information Community approved a recommendation from the Biosurveillance Workgroup to form a Biosurveillance Data Steering Group to address specific issues described within the recommendations. In June 2006, the Biosurveillance Data Steering Group (BDSG) was formed and was given the following specific charge:

Specific Charge for the Data Steering Group: The specific charge of the BDSG will be to identify the requirements for data from ambulatory care, emergency departments, and laboratories necessary for multi-jurisdictional biosurveillance programs. These requirements will build upon previous work completed by the AHIC Biosurveillance Workgroup and the Health Information Technology Standards Panel Biosurveillance Technical Committee (HITSP-TC). Recommendations that specify these requirements will also refine and supplement the work of the HITSP-TC.

The BDSG foremost recognized that the charge did not include identifying requirements for a comprehensive public health surveillance system but rather an adjunct system for traditional disease reporting. Our deliberations highlighted several key areas to be addressed to achieve the group's specific charge:

- Define a Minimum Biosurveillance Data Set needed to support crucial public health functions within and among local, state and federal jurisdictions for biosurveillance.
- Determine feasibility and filtering requirements for each element of the recommended Minimum Biosurveillance Data Set.

This letter provides both context and recommendations for how these issues can be addressed to enable the transmission of ambulatory, emergency department, and lab data from electronically enabled health care systems to public health systems.

BACKGROUND AND DISCUSSION

The American Health Information Community (AHIC) Biosurveillance Workgroup identified a Minimum Biosurveillance Data Set (MBDS) to be used in data collection for biosurveillance and public health reporting. The MBDS is needed to meet the key biosurveillance and public health functions, including initial event detection, situational awareness, outbreak management, and response management.

The BDSG membership represents experts from local, state and federal public health agencies and clinical care partners. The BDSG coordinated their efforts to coincide with those of the Health Information Technology Standards Panel Technical Committee on Biosurveillance (HITSP-TC). To guide the steering group's deliberations and process, the BDSG identified a nomenclature and glossary of terms that provides a working language that can be used throughout the public health community regarding biosurveillance. Data requirements for multi-jurisdictional biosurveillance were determined based on an iterative process that was validated by case studies and expert opinion.

Through analysis of biosurveillance use cases, public health scenarios, and identification and analysis of the MBDS, the BDSG established a set of Preconditions (see Appendix A) that are considered guiding principles or assumptions. These helped clarify our scope, anticipated outcomes and relationships for the data providers and consumers of MBDS elements supportive of public health preparedness (see Appendix B). The BDSG identified several needed data elements that had not previously been identified by HITSP-TC or the Biosurveillance Workgroup.

The BDSG selected five (5) representative scenarios from the comprehensive list of 15 Homeland Security National Planning Scenarios (see Appendix C). The chosen scenarios, encompassing a wide range of situations, permitted an expert public health panel to perform a gap analysis and test the utility and validity of a proposed biosurveillance MBDS. The BDSG identified several key functional areas and reached consensus on which were in scope and should be carried forward during MBDS analysis (see Appendix D). Key functional areas, identified as within scope for multi-jurisdictional biosurveillance, were then cross-referenced with the MBDS to assure utility of each data element.

Following MBDS identification based on the selected National Preparedness Scenarios, the BDSG solicited expert testimony from across the nation to determine the feasibility (i.e., electronic availability and prevalence of standard vocabularies) of the proposed Minimum Biosurveillance Data Set. With this input, the BDSG refined the MBDS by determining a specific level of feasibility for each element: "Could the data element be transmitted electronically by 25% of reporting facilities with currently available resources in the: short term (< 1 year), longer term (1-2 years) or not feasible (>2 years)?"

Expert opinion, implementation guidelines, and current practices guided the BDSG to identify elements (or their components) with a "filtering" requirement based on criteria set forth by the group. An element (or a component thereof) might be filtered because it is too sensitive to share for biosurveillance purposes or is not essential for public health functions. The BDSG, while making these recommendations to the Biosurveillance Workgroup, was careful to consider the balance between the needs of these multi-jurisdictional biosurveillance programs and the highly sensitive areas surrounding public health. To be clear, filtering applies only to this proposed biosurveillance effort and does not impact traditional public health reporting activities. Collectively, the feasibility and filtering determination process helped refine and guide the MBDS to its present state.

RECOMMENDATIONS

I. Adoptions and Minimum Biosurveillance Data Set Implementation

A minimum data set is necessary to meet the specific charge to obtain data in a biosurveillance program to enable key public health functions, including initial event detection, situational awareness, outbreak management, and response management.

Recommendation 1.0: The Secretary of the U.S. Department of Health and Human Services should adopt the Minimum Biosurveillance Data Set to guide data collection in biosurveillance programs that involve the simultaneous sharing of clinical data from health care providers to authorized local, state and federal public health agencies. (Details of the Minimum Biosurveillance Data Set are provided in Appendix B)

Recommendation 1.1: By September 2007, the U.S. Department of Health and Human Services, in collaboration with state and local governmental public health agencies, should work with clinical care partners to implement the short term Minimum Biosurveillance Data Set and enable simultaneous data access to local, state and federal public health entities for biosurveillance purposes.

Recommendation 1.2: By March 2007, the U.S. Department of Health and Human Services, in collaboration with state and local governmental public health agencies, and clinical care partners, should evaluate implementation models, costs, and determine availability of resources and establish a plan to effect a short term Minimum Biosurveillance Data Set implementation.

II. Filtering of the Minimum Biosurveillance Data Set

The BDSG considered the issues of filtering data coming from clinical care to public health along two axes – the first to ensure confidentiality and privacy protections for consumers of healthcare and the second to share only clinically relevant information that enables the public health functions of biosurveillance. For the purposes of biosurveillance, filtering was defined as “patterns (masks) used to either select or deselect data. Within the reporting facility, where all data are compared to the filter, only those data matching the filter criteria will either be transmitted or withheld, respectively.”

Recommendation 2.0: Public health agencies and partners who implement the short term Minimum Biosurveillance Data Set should filter out some components of the following data elements as appropriate: date of birth, age, zip code, and diagnosis/injury code. (Details of filtering are included in Appendix B.)

III. Program Evaluation

The Biosurveillance Data Steering Group recommendations include strategies that build on existing programs and local, state, and federal health department capacity to implement a biosurveillance program that simultaneously transmits data from electronically enabled clinical care settings to local, state, and federal public health agencies, as feasible. Clear, measurable metrics are needed to guide the implementation, monitoring, and evaluation of this effort in the short and long term. Program evaluation should be designed and implemented by public health officials experienced in biosurveillance programs.

Recommendations 3.0: CDC should, no less than annually, involve local, state and federal public health agencies and clinical care partners, in an MBDS monitoring process for biosurveillance usefulness, and make appropriate modifications as evidence develops to support such modifications.

These recommendations are supported by information obtained through research by and testimony to the Biosurveillance Data Steering Group, which is contained in the supporting documents available at <http://www.hhs.gov/healthinformationtechnology/>.

Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing these recommendations with you and the members of the American Health Information Community.

Sincerely yours,



Arthur Davidson
Co-chair, BDSG



Martin LaVenture
Co-chair, BDSG

Appendix A
Biosurveillance Data Steering Group (BDSG)
Preconditions for Deciding on Minimum Biosurveillance Data Set Elements

Purpose: The BDSG considered these guiding principles and assumptions when determining which Minimum Biosurveillance Data Set (MBDS) elements would support public health preparedness.

1. The BDSG will utilize the ASTHO Biosurveillance definition¹ as a working definition for the group.
2. MBDS elements will not meet all current public health data stream needs (i.e., our charge is to develop the minimum data set). State and local jurisdictions will continue to receive fully identifiable data based on current regulations for notifiable diseases/conditions.
3. The BDSG will focus on readily available electronic data entry with essentially no new clinician and/or facility effort from ambulatory care settings (i.e., emergency department and outpatient), inpatient settings (i.e., hospital and nursing home), and laboratories. We recognize there may be some effort to mobilize and implement an action plan to acquire some data elements. While the Health Information Technology Standards Panel (HITSP) may suggest an implementation plan, we recognize that there may be some near term barriers in acquiring some of these data.
4. Use and collection of secondary clinical data will help support the following preparedness functional areas (see Appendix D, Preparedness Functional Area Matrix):
 - a. Early event detection
 - b. Situational awareness
 - c. Outbreak management
 - d. Countermeasure and response administration
5. Optimally, data will be available in real-time, but will not exceed 24 hours before reporting. Additional data requests or expansion of the MBDS may potentially delay data transmission. Automated systems should not be equated with instantaneous delivery. System derived date/time stamps will be associated with all data messages.
6. Patient-specific information will only be accessed by registered, authorized health care professionals and public health officials and only be used for biosurveillance and other public health purposes.
7. All non-essential Protected Health Information (PHI) will be filtered out and retained by the submitting facility before sending to public health authorities.
8. Information transmission from data sources will require some filtering. Precisely how filtering occurs (e.g., receive everything except *x*, vs. a specific listing of everything desired) should be determined. The purpose and principles of filtering (e.g., limited to specific conditions, avoidance of confidential information disclosure or the public health evidence to support filtering) should be explicitly developed. Imposing specific approaches to data filtering may affect the timeliness of reporting.

Appendix A
Biosurveillance Data Steering Group (BDSG)
Preconditions for Deciding on Minimum Biosurveillance Data Set Elements

9. A linking process (e.g., randomly-generated, encoded number) will assure that patient-level information (i.e., name and address), removed prior to submission, is retrievable if required. Only authorized public health officials should have access to facility and patient-level information during a public health investigation.
10. A multi-jurisdictional approach includes collaborative decision-making and coordinated efforts to assure maximal benefits to all partners. All authorized jurisdictions (i.e., federal, state and local), capable of receiving data, should have simultaneous access to timely data
11. Specific data elements for multi-jurisdictional sharing will be based on the level of jurisdictional accountability and responsibility. Although simultaneous data sharing is expected, the scope of shared data elements (e.g., PHI) should differ by jurisdiction and legislative rule.
12. Data will be shared to support initial public health investigations while preserving traditional comprehensive public health investigatory roles and responsibilities. Biosurveillance systems should support public health practice at all jurisdictional levels.
13. In addition to extensive federal and state public health agency participation, local health departments (LHDs) will be involved in biosurveillance systems development and implementation. Any widespread MBDS capture should leverage and complement existing relationships between LHDs and local hospitals/providers.²
14. Information gathered by public health agencies should enable (wherever possible) near real-time sharing with clinical providers (e.g., emergency departments and infection control practitioners) to improve their ability to respond to rapidly evolving events.
15. The BDSG will not prescribe the method by which MBDS elements will be transferred. The architecture for transmission should synergize with and leverage local, regional and state health information exchange investments that adhere to and support emerging national standards.
16. Ongoing efforts will be made to evaluate what is available, feasible, useful and valuable for multi-jurisdictional data sharing. While this MBDS is a good first approximation, new elements should be added as they are proven to have utility.
17. The BDSG considered the feasibility of transmitting each MBDS element. Given very practical implications, feasibility encompasses defining requirements and mandatory lead time for MBDS transmission. The BDSG took into account what reasonable, real-world timeframes for compliance would be. For example, HIPAA was a phased, non-trivial process over multiple years. The spectrum and range of HIT capacities and variation in adoption and successful HIT implementations will significantly impact on reporting burden, acceptance and compliance with anticipated MBDS requirements. Lead time for modifying a main-frame system generally requires a minimum of 1 to 2

Appendix A
Biosurveillance Data Steering Group (BDSG)
Preconditions for Deciding on Minimum Biosurveillance Data Set Elements

years given budget cycles and competing demands. Given that background, feasibility was defined as “Could each data element be transmitted electronically by 25% of reporting facilities with currently available resources in the: short term (< 1 year), longer term (1 to 2 years) or not feasible (>2 years)?”

18. The process of MBDS transmission will require some piloting prior to widespread implementation. Pilot efforts should be undertaken to determine what are potential pitfalls and methods to enhance adoption through reuse of knowledge and methods that promote technical assistance for health care organizations. Piloting should also address BDSG suggested tools that are based on proposed standards yet to be universally adopted. For example, the Hospital Availability Exchange (HAVE)³ is a proposed standard the BDSG suggests to gather many of the daily facility summary report elements. Such piloting will help assess feasibility but may delay early widespread MBDS implementation.

¹ ASTHO: Biosurveillance is often referred to as syndromic surveillance; however the ability to detect events early requires a broader set of information than that of syndromes. While there is no single agreed upon definition, there is agreement that such “biosurveillance” systems need to take advantage of integrated data from multiple sources including public health information as well as electronic health information not traditionally monitored by public health. Biosurveillance systems must leverage two major surveillance methods:

- 1) Well established public health surveillance methods and sources used for the tracking, monitoring, and reporting of health-related information, such as epidemiologic investigations of infectious disease outbreaks or environmental conditions, are needed to ensure a broad coverage of data sources, to use as baselines comparisons, and to support the accuracy and reliability of the biosurveillance findings.
- 2) Early event detection and situational awareness, the use of an automated system to evaluate case and suspect case reporting along with statistical surveillance and data visualization of pre-diagnostic and diagnostic data to support the earliest possible detection of events that may signal a public health emergency, is an essential component for near real-time detection of natural or man-made health events.

² National Association of County and City Health Officials, Statement of Policy: Biosurveillance. No. 06-02, confirmed July 25, 2006

³ Hospital AVailability Exchange (HAVE) is a draft XML specification that allows the communication of the status of a hospital and its resources to other emergency agencies, including bed capacity and availability, emergency department status, the available service coverage, and the status of a hospital’s facility and operations. <http://www.comcare.org/HAVE.html>

Appendix B

TABLE 1: MINIMUM BIOSURVEILLANCE DATA SET SPECIFICATIONS (MBDS)¹ (Total number of data elements: 58)

1. BASE FACILITY DATA ELEMENTS (5)

General:

- These data elements are generally static and should be submitted at baseline and updated as necessary.

Feasibility:

- Many data elements will need web form collection as HL7 messages have limited structures to address these concepts.

BASE FACILITY DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
1.1	Facility Identifier	Y	N	Unique facility identifier	<u>General:</u> <ul style="list-style-type: none"> ▪ Facility identifier is routinely transmitted; facility name and location are derived.
1.2	Facility Name	Y	N	Name of facility	
1.3	Facility Location	Y	N	City, (county) and State	<u>General:</u> <ul style="list-style-type: none"> ▪ May use FIPS county codes.
1.4	Number of Facility Beds	Y	N	Total number of physically available facility beds including those in non-participating or non-licensed areas; regardless of licensing or staffing status.	<u>General:</u> <ul style="list-style-type: none"> ▪ Potentially active or usable beds at full capacity in a disaster.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

BASE FACILITY DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
1.5	Number of Licensed Beds	Y	N	Total number of Medicare and/or Medicaid certified and licensed beds within a facility).	

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

2. DAILY FACILITY SUMMARY REPORT DATA ELEMENTS (18)

General:

- Daily aggregate reports will likely need preparation by reporting facility; alternative, (may be costly) is calculation by data recipient.
- May require additional fields to assess hospital burden. Patients may overload facilities at multiple points (e.g., emergency department). Uncertain if hospital census is prepared routinely (e.g., at midnight) by each facility for daily reports.
- Not currently transmitted electronically, would require - Standard definitions, and new resources (personnel, technology, workflow re-engineering).

Feasibility:

- May require manual review of registration system for a daily aggregate report.
- May not be directly calculable from aggregation of record level data.
- May require significant data entry (e.g., web form), since daily facility report for these categories are not available and are not easily transferable.
- May require significant programming by sending facilities to achieve automation.

Filtering:

- Situational filtering would “turn on” daily reporting for many of these elements in response to an event (e.g., a disaster or major public gathering) which otherwise would not be expected of each facility.
- Need periodic testing to confirm capacity and accuracy.

DAILY FACILITY SUMMARY REPORT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
2.1	Admissions last 24 hours	Y	N	Number of admissions to facility in last 24 hours	
2.2	Discharges last 24 hours	Y	N	Number of discharges from facility in last 24 hours	

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: “Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= ‘Y’), **Longer term** (1-2 years= ‘Y*’) or **not feasible** (>2 years= ‘N’)?”

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

DAILY FACILITY SUMMARY REPORT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
2.3	Deaths last 24 hours	Y	N	Number of deaths recorded at facility in last 24 hours.	<u>General:</u> (Health Level 7 [HL7]) <ul style="list-style-type: none"> ▪ Table 0136: Patient Death Indicator ▪ Values: Yes/No ▪ Where used: PID ▪ Additional: Patient Death date/time ▪ Values: Time Stamp ▪ Where used: PID
2.4	Clinical Status	Y*	N	Facilities clinical resources are operating <ul style="list-style-type: none"> ▪ Within normal conditions. ▪ At Level-1 surge conditions. ▪ At Level-2 surge conditions. ▪ Exceeded; acceptable care cannot be provided to additional patients. Diversion or community surge response is required. 	<u>General:</u> <ul style="list-style-type: none"> ▪ Description and values are based on proposed Hospital Availability Exchange (HAVE) specification. http://www.comcare.org/HAVE.html

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

DAILY FACILITY SUMMARY REPORT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
2.5	Facility Status	Y*	N	Facility resources are operating under: <ul style="list-style-type: none"> ▪ No limitation adversely affects routine/general facility operations. ▪ Limited conditions due to damage, operating on emergency backup systems, or facility contamination. ▪ Severe conditions with active process of partial or full evacuation. ▪ Closure; facility no longer capable of providing services and only emergency services/restoration personnel may remain in the facility. 	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ CDC currently receives automatically but there has been no evaluation. <u>Feasibility:</u> <ul style="list-style-type: none"> ▪ May be possible to retrieve from current systems (e.g., EMS systems used in 35% of EDs; over 50% use some system).
2.6	Facility Operations	Y*	N	Status of supplies necessary for facility operations: <ul style="list-style-type: none"> ▪ Meets the current needs. ▪ Current needs not being met 	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ Pharmacy stock data (especially antibiotics) should be gathered.
2.7	Staffing	Y*	N	Available personnel to support facility operations <ul style="list-style-type: none"> ▪ Meets the current needs. ▪ Current needs not being met. 	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ Staffing capacities should be broken down by specialty (i.e., nurse, physician, respiratory therapy, and pharmacist).

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

DAILY FACILITY SUMMARY REPORT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
2.8	Decontamination Capacity	Y*	N	Capacity for chemical/biological/radiological patient decontamination. <ul style="list-style-type: none"> ▪ Not being used, but available if needed. ▪ In use and able to accept additional patients. ▪ In use at maximum capacity. ▪ Needs exceed available capacity. 	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ Might quantify to determine throughput capability and threshold for rerouting to other facilities. <u>Feasibility:</u> <ul style="list-style-type: none"> ▪ No electronic form of decontamination capacity data exist.
2.9	EMS Traffic Status	Y*	N	Facility capable of: <ul style="list-style-type: none"> ▪ Accepting all EMS traffic. ▪ Some limited EMS traffic due to specific resource limitation. ▪ Receiving no EMS traffic and requesting re-route of traffic to other facilities. ▪ Not Applicable. This facility does not have an emergency department. 	<u>General:</u> (HAVE)

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

DAILY FACILITY SUMMARY REPORT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
2.10	EMS Capacity	Y*	N	Number of each triage patient type the hospital can accept. <ul style="list-style-type: none"> ▪ Number of victims with immediate needs. ▪ Number of victims with delayed needs. ▪ Number of victims with minor needs. ▪ Number of deceased victims. ▪ One or more comments. 	<u>General:</u> (HAVE)
2.11	EMS Census	Y*	N	Number of each triage patient type the overall hospital currently has. <ul style="list-style-type: none"> ▪ Number of victims with immediate needs. ▪ Number of victims with delayed needs. ▪ Number of victims with minor needs. ▪ Number of deceased victims. ▪ One or more comments. 	<u>General:</u> (HAVE)
2.12	Adult ICU Beds	Y*	N	Capacity status for adult ICU beds	<u>General:</u> (HAVE) Beds supporting critically ill or injured patients; includes ventilator support and all major subtypes of ICU beds (e.g., neuro, cardiac, trauma, or medical) except burn ICU beds.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

DAILY FACILITY SUMMARY REPORT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
2.13	Medical Surgical Beds	Y*	N	Capacity status for medical-surgical beds.	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ Ward beds; may or may not include cardiac telemetry capability.
2.14	Burn Beds	Y*	N	Capacity status for burn beds.	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ Burn ICU beds; either approved by the American Burn Association or self-designated; NOT included in other ICU bed counts.
2.15	Pediatric ICU Beds	Y*	N	Capacity status for pediatric ICU beds.	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ Similar to adult ICU beds, but for patients 17-years-old and younger.
2.16	Pediatrics Beds	Y*	N	Capacity status for pediatrics beds.	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ Ward medical/surgical beds for patients 17-years-old and younger.
2.17	Negative Flow Isolation Beds	Y*	N	Capacity status for negative airflow isolation beds.	<u>General:</u> (HAVE) <ul style="list-style-type: none"> ▪ Respiratory isolation. <i>NOTE:</i> Value may include beds counted above.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

DAILY FACILITY SUMMARY REPORT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
2.18	Available Ventilators	Y*	N	Functional ventilators not in current use.	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ Ventilator category: Should include Bi-Pap machines and several other machines that can assist ventilation. <p><u>Feasibility:</u></p> <ul style="list-style-type: none"> ▪ Not routinely collected nor collected by BioSense ▪ No identified specification

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

3. PATIENT DATA ELEMENTS (10)

General:

- Laboratories do not see the patient and have no unique patient identifier. Laboratories receive a specimen sample with limited patient demographic information. Should limit the number of data elements to those the laboratories receive.
- For inpatient and outpatient facilities, transmitted information should be limited to patient status changes (e.g., Admission/Discharge/Transfer [ADT]) available through HL7 transactions, not for every inpatient event.

Filtering:

- Concerns regarding privacy: month and year of birth, gender, and 5 digit zip code may be sufficient to identify many persons, especially older ones.

PATIENT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
3.1	Pseudonymized Data Linker	Y*/N	N	A health care organization-specific longitudinal number that links to patient-level information (i.e., medical record number, name and address) retained at the reporting facility.	<u>General:</u> <ul style="list-style-type: none"> ▪ The MBDS data sent to local, state and national public health agencies will not be fully identifiable.
3.2	Event Date/Time	Y	N	Date /time of the patient admission/discharge/transfer (ADT).	<u>General:</u> (HL7) <ul style="list-style-type: none"> ▪ Values: Time Stamp ▪ Where used: EVN for ADT ▪ Concerns about duplicate (ADTs) out of the multiple sending systems.
3.3	Event Type	Y	N	Designation of event type: admission, discharge, or transfer.	<u>General:</u> (HL7) <ul style="list-style-type: none"> ▪ Table 0003: Event Type Code ▪ Values: HL7 defined ▪ Where used: EVN for ADT ▪ Additional: MSH – 9

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: “Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= ‘Y’), **Longer term** (1-2 years= ‘Y*’) or **not feasible** (>2 years= ‘N’)?”

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

PATIENT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
3.4	Date of Birth (DOB)	Y	Y	Limited to month and year	<p><u>General:</u> (HL7)</p> <ul style="list-style-type: none"> ▪ Where used: PID ▪ Full DOB not needed, and introduces confidentiality concerns (w/ zip/gender). <p><u>Filtering:</u></p> <ul style="list-style-type: none"> ▪ Requires an action or manipulation to remove the day.
3.5	Age	Y*	Y	Numeric value for age	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ Requires calculation for some ADT systems. <p><u>Filtering:</u></p> <ul style="list-style-type: none"> ▪ For sparsely populated areas will need to limit actual age and categorize into less specific groups.
3.6	Age units	Y*	N	Days, Month or Years	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ Requires calculation for some ADT systems. ▪ BioSense: Unified Code for Units of Measure (UCUM) ▪ Where used: OBX-6

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

PATIENT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
3.7	Gender	Y	N	HL7 Administrative Sex <ul style="list-style-type: none"> ▪ F – Female ▪ M – Male ▪ O - Other ▪ U - Unknown 	General : (HL7) <ul style="list-style-type: none"> ▪ Table 0001: Administrative Sex ▪ Values: User defined ▪ Where used: PV-1, PID-8, NK1-15, GT1-9, IN1-43, STF-5
3.8	Zip Code	Y	Y	Home address [minimum 5 Digit Zip]	<u>General:</u> <ul style="list-style-type: none"> ▪ 5-digit zip may not be needed, depending on use/purpose. ▪ Refer to HIPAA guideline. <u>Filtering:</u> <ul style="list-style-type: none"> ▪ Sparsely populated geographic locations will need filtering of 5 digit zip code.
3.9	State	Y	N	Home address [2 character abbreviation]	<u>General:</u> (HL7) <ul style="list-style-type: none"> ▪ Where used: PID-11 Patient Address
3.10	Transaction date/time update	Y	N	System Time stamp for when the message was sent (all registration (ADT) system transactions).	<u>General:</u> Required for de-duplication and/or data manipulation at receiving site based on temporal order.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

4. CLINICAL DATA ELEMENTS (10)

General:

- Presumes 1) data are obtained by monitoring HL7 messages and 2) facility identifier and pseudonymized linker have been associated with the clinical data element record
- For inpatient and outpatient facilities, transmitted information should be limited to patient status changes (e.g., Admission/Discharge/Transfer [ADT]) available through HL7 transactions, not for every inpatient event.
- Need to determine what messages for hospitalized patients, through the course of care, should be included in these clinical data elements.
- Real time ICD-9 CM coding is not routine; often not done until almost 72 hours after patient discharge.
- Most clinical data elements come from registration system with diagnosis assigned after discharge.

Feasibility:

- Collecting nursing data (temperature, pulse oximetry, and notes) would require installing a nursing documentation system.

Filtering:

- Concern about confidentiality and identification of individuals as well as their specific (and sensitive) diagnoses may make filtering a greater priority or even inhibit transmission until filters are established and implemented.

CLINICAL DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
4.1	Diagnosis/Injury Code	Y	Y	<ul style="list-style-type: none"> ▪ ICD-9 Clinical Modification diagnosis codes. ▪ Supplementary Classification of External Causes of Injury and Poisoning. ▪ Supplementary Classification of Factors Influencing Health Status and Contact with Health Services. 	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ Likely not available in real time ▪ May vary as more information is acquired. <p><u>Feasibility:</u></p> <ul style="list-style-type: none"> ▪ Available but incomplete due to reporting delay. <p><u>Filtering:</u></p> <ul style="list-style-type: none"> ▪ Mental/behavioral health and STD/HIV conditions or diagnoses

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

CLINICAL DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
					should be filtered.
4.2	Diagnosis Type	Y	N	Qualifier for Diagnosis/Injury Code specifying type of diagnosis. <ul style="list-style-type: none"> ▪ Preliminary ▪ Interim ▪ Final ▪ Admitting 	<u>General:</u> <ul style="list-style-type: none"> ▪ Correct for billing but not necessarily during an encounter or within 24 hours of event.
4.3	Diagnosis Date/Time	Y	N	Date of onset of diagnosis	<u>General:</u> <ul style="list-style-type: none"> ▪ Not readily available, surrogate would be system time stamp of diagnosis data entry.
4.4	Discharge Disposition	Y	N	If discharged, place to where patient was released. (e.g. Discharged to home or self care (routine discharge), Admitted as an inpatient to this hospital, Left against medical advice or discontinued care).	<u>General:</u> (HL7) <ul style="list-style-type: none"> ▪ Table 0112: Discharged Disposition ▪ Values: User defined ▪ Where used: PV1-36, PV2-27
4.5	Patient Class	Y	N	Patient classification within facility: <ul style="list-style-type: none"> ▪ E: Emergency ▪ I: Inpatient ▪ O: Outpatient ▪ P: Pre-admit ▪ R: Recurring patient ▪ B: Obstetrics 	<u>General:</u> (HL7) <ul style="list-style-type: none"> ▪ Table 0004: Patient Class ▪ Values: User defined ▪ Where used: PV1-2

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

CLINICAL DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
4.6	Symptom/Illness Onset Date/Time	N	N	Documented date/time of symptom/illness onset by triage or clinician.	<u>General:</u> <ul style="list-style-type: none"> ▪ Symptom onset typically recorded in free text without any coded value. ▪ Paper dominated process at present, but evolving electronic applications make data capture more feasible in the future. ▪ May require significant reformatting of onset date/time (e.g., 2 weeks ago to actual date).
4.7	Chief Complaint	Y	N	Short description of reason for seeking care, recorded during initial registration.	<u>General:</u> <ul style="list-style-type: none"> ▪ Most often text string in current registration systems. Coded complaint recorded by clinicians likely to become available in next 2-3 years as emergency department electronic triage systems are installed.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

CLINICAL DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
4.8	Temperature	N	N	Recorded temperature during triage	<p><u>General:</u> (HL7 & LOINC)</p> <ul style="list-style-type: none"> ▪ LOINC Code for 'Body temperature' ▪ Where Used: OBX-3 <p><u>Feasibility:</u></p> <ul style="list-style-type: none"> ▪ Not currently captured electronically in most departments, for example in one state's surveillance system only 1 in 67 hospitals capture this data electronically. Electronic capture of this data element will likely become available in next 2-3 years as emergency department electronic triage systems are installed.
4.9	Pulse Oximetry	N	N	Record pulse oximetry value during triage.	<p><u>General:</u> (HL7 & LOINC)</p> <ul style="list-style-type: none"> ▪ LOINC Code for 'Pulse Oximetry' ▪ Where Used: OBX-3 <p><u>Feasibility:</u></p> <ul style="list-style-type: none"> ▪ Not currently captured electronically in most departments, for example in one state's surveillance system only 1 in 67 hospitals capture this data electronically. Electronic capture of this data element will likely become available in next 2-3 years as

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

CLINICAL DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
					emergency department electronic triage systems are installed.
4.10	Nursing/Triage Notes	N	Y	Text string written by nurse or health care partner	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ May have serious implications for privacy and security ▪ May be source for travel history ▪ No current travel history menu boxes ▪ Usually stored as data string ▪ May be source to search for recent (e.g., in the past 24, 48, and 72 hours) patient location (e.g., mall, concert, stadium). <p><u>Filtering:</u></p> <ul style="list-style-type: none"> ▪ Filtering will not solve significant privacy issues and concerns.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

5. LABORATORY/INFECTIOUS DISEASE-RELATED TEST ORDER DATA ELEMENTS (3)

General:

- Presumes 1) data are obtained by monitoring HL7 messages and 2) facility identifier and pseudonymized linker have been associated with the laboratory/radiology test order element record.
- Messages will include all transactions or tests ordered for hospitalized patients, throughout the course of care, as well as those seen in outpatient settings.
- The BDSG has presumed a desired subset of all laboratory tests focused primarily on infectious diseases. Additional laboratory and/or radiologic tests may be transmitted, but a defined set has not been determined.
- Infectious diseases-related describes a broad category of laboratory tests used to identify microorganisms including: gram stain, routine culture, susceptibility testing, serology, polymerase chain reaction (PCR), genotype/phenotype, DNA, RNA, direct florescent antibody (DFA), antigen testing, and any testing for influenza.

Feasibility:

- Sending laboratory/radiology test orders without vocabulary standardization will make information aggregation impossible and difficult at best. Prior vocabulary standardization efforts have been costly and generally met with resistance from data providers.

Filtering:

- Methods to filter for specific test based on unique (idiosyncratic) data provider laboratory or radiology service codes will be required in the absence of comprehensive use of LOINC/SNOMED and/or DICOM standard vocabulary.

LABORATORY/INFECTIOUS DISEASES TEST ORDER DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
5.1	Order Number	Y	N	Accession number as defined by reporting laboratory <ul style="list-style-type: none"> ▪ HITSP may use the term "specimen ID". 	<u>General:</u> <ul style="list-style-type: none"> ▪ Laboratories receive one source specimen that yields multiple specimens for various tests. The accession number is not unique to a specific test but rather the specimen source.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

LABORATORY/INFECTIOUS DISEASES TEST ORDER DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
5.2	Test/Procedure Name	Y	N	Procedure name from reporting laboratory.	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ Laboratory name will be used to interpret test as non-LOINC codes will be meaningless to receiver. <p><u>Filtering:</u></p> <ul style="list-style-type: none"> ▪ Tests and procedures associated with legally protected status conditions or diagnoses (e.g., HIV) should be filtered.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

LABORATORY/INFECTIOUS DISEASES TEST ORDER DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
5.3	Test/Procedure Code	Y*	Y	A code (e.g., LOINC/DICOM) and/or text description name should be sent; Idiosyncratic codes are the norm, thus a text description is required at a minimum.	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ Assuring accurate LOINC test code values for each test requires a submission and communication with Regenstrief Institute to add new tests and corresponding codes. <p><u>Feasibility:</u></p> <ul style="list-style-type: none"> ▪ Standardizing to LOINC mapping and implementation is difficult in smaller labs. ▪ Limited current market penetration of LOINC code mapping makes natural language processing of test/procedure name (description) a necessity. ▪ Will become easier as LOINC coding progresses in dealing with panels and institutions convert to utilize LOINC in the Laboratory Information Systems (LIS). <p><u>Filtering:</u></p> <ul style="list-style-type: none"> ▪ Tests and procedures associated with legally protected status conditions or diagnoses (e.g., HIV) should be filtered.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

6. LABORATORY/INFECTIOUS DISEASES-RELATED RESULT DATA ELEMENTS (12)

General:

- Presumes: 1) data are obtained by monitoring HL7 messages 2) order/accession number, facility identifier, and pseudonymized linker have been associated with the clinical data element record.
- Need to coordinate with national electronic laboratory reporting initiative.
- Infectious diseases-related describes a broad category of laboratory tests used to identify microorganisms, including: gram stain, routine culture, susceptibility testing, serology, polymerase chain reaction (PCR), genotype/phenotype, DNA, RNA, direct florescent antibody (DFA), antigen testing, and any testing for influenza.

Feasibility:

- Collecting laboratory results should synergize with ongoing work of the EHR-Lab Interoperability and Connectivity Standards (ELINCS) project to establish laboratory test result standardization. ELINCS can serve as the foundation towards achieving standardized laboratory test result reporting.
- ELINCS, with ACLA member laboratory support, provides a rational, consensus implementation guide for standardizing test result information.
- ELINCS is based on a more widely used HL-7 version, within health care and public health. Much work remains to be accomplished (including laboratory test orders).

Filtering:

- Defining and testing the laboratory and/or radiologic test subset for transmission will be critical but has yet to be determined.

LABORATORY/INFECTIOUS DISEASES RESULT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
6.1	Reporting Laboratory Identifier	Y	N	Standard national identifier value	<u>General:</u> <ul style="list-style-type: none"> ▪ CLIA or CAP laboratory number

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

LABORATORY/INFECTIOUS DISEASES RESULT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
6.2	Performing Laboratory	Y	N	Standard national identifier value	<u>General:</u> <ul style="list-style-type: none"> ▪ CLIA or CAP laboratory number. <u>Feasibility:</u> <ul style="list-style-type: none"> ▪ When sending specimen from referring laboratory to performing lab – CLIA # is not carried on request.
6.3	Report Date/Time	Y	N	Date and time of report transmission	<u>General:</u> <ul style="list-style-type: none"> ▪ Electronic time stamp
6.4	Result Status	Y	N	Is the result: <ul style="list-style-type: none"> ▪ Preliminary ▪ Partial ▪ Final ▪ Corrected ▪ Amended 	<u>General:</u> (HL7) <ul style="list-style-type: none"> ▪ Where Used: OBR-25
6.5	Collection Date/Time	Y	N	Date (and time, when appropriate) of the specimen collected.	<u>General:</u> <ul style="list-style-type: none"> ▪ Generally no Collection Date/Time indicated on paper requisitions; may use default (accession) date/time for specimen receipt.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: “Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= ‘Y’), **Longer term** (1-2 years= ‘Y*’) or **not feasible** (>2 years= ‘N’)?”

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

LABORATORY/INFECTIOUS DISEASES RESULT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
6.6	Specimen Source	Y*	N	The Identification of the Specimen Material (e.g. CSF – Cerebral Spinal Fluid, SER – Serum, FLU – Body Fluid Unspecified, BLDV – Blood Venous).	<p><u>General:</u> (HL7)</p> <ul style="list-style-type: none"> ▪ Table 0070: Specimen Source Codes ▪ Values: HL7 defined ▪ Where used: OBR-15 <p><u>Feasibility:</u></p> <ul style="list-style-type: none"> ▪ Some data sources may only have free-text field stored in message.
6.7	Ordered test code	Y	N	A code (e.g., LOINC) and/or text description name should be sent; Idiosyncratic codes are the norm, thus a text description is required at a minimum.	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ Need method to convert to a standard code set, e.g., LOINC <p><u>Feasibility:</u></p> <ul style="list-style-type: none"> ▪ Must at least have the data source ordered test description name ▪ Will become easier as LOINC coding progresses in dealing with panels and institutions convert to utilize LOINC in the LIS.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: “Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= ‘Y’), **Longer term** (1-2 years= ‘Y*’) or **not feasible** (>2 years= ‘N’)?”

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

LABORATORY/INFECTIOUS DISEASES RESULT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
6.8	Resulted test	Y*	Y	Standard codes or LOINC have greatest coverage for resulted test.	<p><u>General:</u></p> <ul style="list-style-type: none"> ▪ Many institutions may have limited LOINC implementations ▪ Association of Public Health Laboratories (APHL) has built a filter to select appropriate tests for communicable disease reporting. <p><u>Feasibility:</u></p> <ul style="list-style-type: none"> ▪ Limited implementation of LOINC codes will delay capacity to filter; would need to key off institution's idiosyncratic code. <p><u>Filtering:</u></p> <ul style="list-style-type: none"> ▪ For large organizations (e.g., national laboratories) operating at a very large scale (e.g., 10 million results/day) daily processing may delay reporting/transmission. ▪ Would require mapping of idiosyncratic codes to defined lists (e.g., APHL, <i>see above</i>) to effectively filter by test codes. ▪ BioSense looks at the diagnostics section field to determine if is microbiologic test; ideally would filter on diagnostics, but uncertain if

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the available BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

LABORATORY/INFECTIOUS DISEASES RESULT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
6.9	Result	N	N	Includes all test results including susceptibilities, serology's, non-organisms; coded value.	<u>General:</u> <ul style="list-style-type: none"> ▪ Currently, test results are generally report in the test interpretation field (see 6.11). ▪ Need method to convert to a standard code set, e.g., SNOMED.
6.10	Result unit	N	N	May be in various formats: <ul style="list-style-type: none"> ▪ Coded value (e.g., SNOMED) for organism without a unit. ▪ Susceptibility would have a unit ▪ Viral copies 	<u>General:</u> <ul style="list-style-type: none"> ▪ Need method to convert to a standard code set, e.g., SNOMED. <u>Feasibility:</u> <ul style="list-style-type: none"> ▪ Likely available only as free text; if end-user processes free text this would be feasible (Y).

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

LABORATORY/INFECTIOUS DISEASES RESULT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
6.11	Test interpretation	Y	N	May be in various formats: <ul style="list-style-type: none"> ▪ Organism may be SNOMED coded ▪ Modifiers may describe growth (e.g., colony count or “heavy”). ▪ Susceptibility for each antibiotic with accompanying minimal inhibitory concentration (MIC) value. ▪ Qualitative susceptibility measures (e.g., resistant, susceptible, intermediate). ▪ Viral copies ▪ Categorical (positive/negative) 	<u>General:</u> <ul style="list-style-type: none"> ▪ Variable use of SNOMED by facilities ▪ Where Used: OBX-8 <u>Feasibility:</u> <ul style="list-style-type: none"> ▪ Free text interpretations. ▪ May need to convert into 3 or 4 fields since transmitted field blends multiple concepts. <u>Filtering:</u> <ul style="list-style-type: none"> ▪ Group was unable to define specific rules and methods to implement a filtering process on test interpretation field. ▪ Filtering should occur at the resulted test level (see 6.8) since the absence of a result (e.g., faulty transmission) does not uniformly indicate test was negative. ▪ Abnormal flags would only be available for tests done on-site. ▪ BioSense does not filter at level of positive test, they receive all tests. ▪ APHL is developing a method (i.e., natural language processing) to find appropriate test results by reading the free text interpretation field.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG interpretation field. Guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: “Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= ‘Y’), **Longer term** (1-2 years= ‘Y*’) or **not feasible** (>2 years= ‘N’)?”

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

LABORATORY/INFECTIOUS DISEASES RESULT DATA ELEMENTS					
NO.	Data Element	Feasible ² (Y/Y*/N)	Filter ³ (Y/N)	Description (values)	Notes/Comments
6.12	Test status	Y	N	Coded value: <ul style="list-style-type: none"> ▪ O: Order received; specimen not yet received ▪ I: No results available; specimen received, procedure incomplete ▪ S: No results available; procedure scheduled, but not done ▪ A: Some, but not all, results available ▪ P: Preliminary: A verified early result is available, final results not yet obtained ▪ C: Correction to results ▪ R: Results stored; not yet verified ▪ F: Final results; results stored and verified. Can only be changed with a corrected result. ▪ X: No results available; Order canceled. ▪ Y: No order on record for this test. (Used only on queries) ▪ Z: No record of this patient. (Used only on queries) 	<u>General Comments:</u> (HL7) <ul style="list-style-type: none"> ▪ Table 0123: Results Status ▪ Values: HL7 defined ▪ Where used: OBR-25

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

TABLE 2: Additional Data Elements considered but not selected for Minimum Biosurveillance Data Set (14)

NO.	Data Element	Description	User
1.	Mode of conveyance	Method by which patients are transported to hospital	Public health investigator
2.	Triage travel history	Any travel information such as malls, concerts, etc.	Public health & Hospital safety officer
3.	Subjective fever, cough, sore throat, shortness of breath,	May not be indicated in the CC section but could be captured in an electronic clinical encounter section	Health authority
4.	Decontamination loading	Percent of decontamination facilities currently utilized	Hospital safety officer
5.	Patient air source	Room air, face mask, intubated etc.	Health authority
6.	Heart Rate	Date/time of heart rate measurement (beats/minute).	Health authority
7.	Blood Pressure	Blood pressure - indication of shock and other clues	Health authority
8.	Patient treatment history	Previous facility and what patient received for treatment	Health authority
9.	Clinical evaluation notes	Free text data on pre-diagnostic findings (HL7)	Health authority
10.	Number waiting for triage	Patients massed and waiting for triage at an ER Facility	Health authority
11.	Number waiting for beds available	Triaged patients waiting	Health authority
12.	Number admitted but not in licensed bed	Patients who may be in halls, cafeterias, conference rooms etc	Health authority
13.	Ventilator category	Normal, Bi-Pap, other ventilator-substitute	Health authority
14.	Staffing capacities by specialty	Nurse, physician, pharmacist, respiratory therapist	Hospital safety officer, health authority

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
 ▪ **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

Feasibility Testimony Questions:

1. To what extent are the listed minimum data set (MBDS) elements available electronically now within your organization, membership, entity or jurisdiction? What future plans or steps would be necessary to make those data elements available? What standard vocabularies are in place to enable machine interpretable health exchange (e.g., Level 4 interoperability) with other systems? Please describe the status of those standards in your organization both currently and for the future (including implementation timelines).
2. What changes would be required in your organization, membership, entity or jurisdiction in order to collect the proposed MBDS elements in electronic format? What are anticipated costs (both human/workflow and infrastructure) associated with those changes toward MBDS element collection? Please include reference to the following in your response:
 - o end user workflow
 - o interfaces
 - o mapping and filtering of elements
 - o commercial-off-the-shelf (COTS) products
 - o daily reports
 - o please add additional items _____

References:

1. Farzad Mostashari, M.D., MSPH, Assistant Commissioner for the Bureau of Epidemiology Services, New York City Department of Health and Mental Hygiene
2. Shaun Grannis, M.D., M.S. Research Scientist, Regenstrief Institute, Inc.; Assistant Professor of Family Medicine, Indiana University School of Medicine.
3. Jason DuBois, Vice President, Government Relations, American Clinical Laboratory Association (ACLA)
4. Elvin Adams, M.D., Health Authority/Medical Director, Tarrant County Public Health
5. George Hripcsak, M.D., M.S., Professor and Vice Chair of Biomedical Informatics at Columbia University, Associate Director of Medical Informatics Services New York-Presbyterian, Senior Informatics Advisor for the New York City Department of Health and Mental Hygiene
6. Janet Glowicz, R.N., Chief Epidemiologist, Collin County Health Care Services
7. John C. White, C.N.M.T., Assistant Director, Environmental Health and Safety, Radiation Safety Officer-Radioactive Materials, The University of Texas Southwestern Medical Center at Dallas
8. John T. Carlo, M.D., M.S.E., Medical Director/Health Authority, Dallas County Department of Health & Human Services
9. Michael Sternberg, R.N., Infection Control, Plaza Medical Center of Fort Worth
10. Ron Kasowski, Facility Director of Environmental Safety and Emergency Management, Baylor Health Care System
11. Terry Stagg, Director of Emergency & Risk Management, Kellwest Hospital, Wichita Falls, TX
12. David Buckeridge, Aman Verma, and David Siegrist, Tarrant County Evaluation Study {FINAL REPORT} (APC)

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

13. Health Level Seven Specifications for Electronic Laboratory-Based Reporting of Public Health Information

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: “Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
▪ **Short term** (< 1 year= ‘**Y**’), **Longer term** (1-2 years= ‘**Y***’) or **not feasible** (>2 years= ‘**N**’)?”

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Resource and Costs Estimation of the BDSG Minimum Biosurveillance Data Set:

The BDSG considered the relative cost for implementation of reporting/transmission systems for the MBDS. These estimates are very preliminary and based on a limited survey of experts. The estimates are imprecise due to the large variation in capacities of health care organizations which would be requested to transmit data on a daily basis. Some would easily adapt to these transmission requests given their sophistication and skill with prior HIT implementations. If central technical resources promoted and supported capacity building, the individual health care organization estimates may be lower but would require greater technical assistance investment. We anticipate a broad range of capacities, thus these cost estimates may significantly underestimate resources required for the less initiated. Attempting to leverage this effort with the Nationwide Health Information Network could substantially increase the cost given the need to invest heavily in infrastructure to achieve level-4 interoperability. Changes in structure of existing clinical systems creates significant burden in clinical settings; cost implications extend beyond simple physical implementations but may involve drastic business process analysis efforts and modification of work flow to accommodate transition to standardized vocabularies throughout the enterprise.

A factor which we were unable to estimate was the cost of disk storage. If facilities (e.g., large laboratories) are required to create and store pseudonymized data linkers, massive storage may be required to track what was sent. Disk storage for some institutions may be necessary as staging areas where free text may be converted to coded values (e.g., LOINC/SNOMED). If there were need to audit processes and verify conversion procedures, disk space may again be significant. On-line data storage for many health care organizations is typically purged every 6-18 months. It is uncertain whether this process of building MBDS would require data to be stored for longer periods.

The BDSG recognized that costs vary based on the data type. Base facility data elements may be relatively easy to acquire; ICD-9 coded values, used for diagnoses, have a long tradition in health care organizations making implementation easier and less expensive. Similarly, patient data elements are relatively standard and much less costly than laboratory data. Laboratory/microbiology data standardization will require much effort in mapping and data transformation. As described in the table above, many laboratories continue to practice with information systems where free text fields are more prevalent incurring greater standardization costs.

Preliminary resources and scale for costs were estimated by experts and from national experience (i.e., BioSense) for startup and maintenance based on health care organization. Specific resources are needed in each of the following categories: interfaces, mappings, training, submitting reports, and assigning responsibility to staff. A more extensive review of prior studies (e.g., Gartner or HIMSS) should be undertaken to confirm these estimates.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

1. Resources for startup and a minimum of 3 years maintenance should be considered for each health care organization setting

Clinical setting site:

- Approximately \$ 250,000-\$300,000 for startup and \$50,000-\$75,000 for ongoing costs without the nursing data items.
- Includes startup and maintenance including laboratory.
- Building an interface to the registration system is \$50,000-\$100,000 for startup and three years of maintenance, not including adding the random number generator. An estimate of \$100,000 total. Preliminary cost estimates
- An interface to the laboratory system could also be in the \$50,000-\$100,000 range, but additional costs might be incurred to cover the filtering.
- Integration with infection control work processes will incur additional costs. Efforts to synergize and link Biosurveillance with general public health surveillance should be a goal of this effort. Infection control is a continuum from hospital to the community. Method for reconciliation of confirmed case reports and avoiding double counting requires careful human review. We have not estimated the cost of this linkage and effort.

CDC BioSense site

- Estimated resources for starting a new CDC BioSense sites is approximately \$115,000- \$155,000 for the clinical site.

City/County/State Health Department

- Resources for state or city/county health department to invest in capacity to receive/sent new HI7 messages, analysis, data management, local analysis, is approximately \$175,000 startup and \$100,000 ongoing.
- Feedback, follow-up and response initiation would require additional personnel costs.
- Resources for integration with traditional disease surveillance and communicable disease control would ultimately be necessary for these systems to have true value at a local level. No estimates are available for those efforts.

2. Cost of a web-based resource for summary facility data entry (e.g., HAVE specification elements)

- About \$15 -18 million for the nation's 4,500 hospitals per year.
- On average, \$3,300-\$4,000 per hospital per year, based on a typical, standard ASP costs.
- Cost is estimated based on the population of the region served at \$.04 - \$.05 cents per person (300 million population) plus additional funding for integration of regions and states into a unified national system.

3. Costs for evaluation and testing:

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: "Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:

- **Short term** (< 1 year= 'Y'), **Longer term** (1-2 years='Y*') or **not feasible** (>2 years= 'N')?"

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix B

- Periodic (annual) program review, auditing, testing, and improvement resources are essential. Multiple efforts should be funded to support ongoing evaluation. No estimates are available for those efforts.

¹ Preconditions for Deciding on Minimum Biosurveillance Data Set (MBDS) Elements: to full understand the scope of BDSG assumptions and guiding principles, the reader should consult the accompanying Preconditions document.

² Feasibility values: “Could data element be transmitted electronically by 25% of reporting facilities with currently available resources in the:
▪ **Short term** (< 1 year= ‘**Y**’), **Longer term** (1-2 years= ‘**Y***’) or **not feasible** (>2 years= ‘**N**’)?”

³ Filters: patterns (masks) used to either select or deselect data; within the reporting facility, all data are compared to the filter. Only those data matching the filter criteria will either be transmitted or withheld, respectively.

Appendix C
Biosurveillance Data Steering Group (BDSG)
DHS National Planning Scenarios for deciding on
Minimum Biosurveillance Data Set (MBDS)

- Scenario 1: Nuclear Detonation – 10-Kiloton Improvised Nuclear Device
- Scenario 2: Biological Attack – Aerosol Anthrax
- Scenario 3: Biological Disease Outbreak – Pandemic Influenza*
- Scenario 4: Biological Attack – Plague
- Scenario 5: Chemical Attack – Blister Agent
- Scenario 6: Chemical Attack – Toxic Industrial Chemicals
- Scenario 7: Chemical Attack – Nerve Agent*
- Scenario 8: Chemical Attack – Chlorine Tank Explosion
- Scenario 9: Natural Disaster – Major Earthquake
- Scenario 10: Natural Disaster – Major Hurricane*
- Scenario 11: Radiological Attack – Radiological Dispersal Devices*
- Scenario 12: Explosives Attack – Bombing Using Improvised Explosive Devices
- Scenario 13: Biological Attack – Food Contamination*
- Scenario 14: Biological Attack – Foreign Animal Disease
- Scenario 15: Cyber Attack

* Indicates those scenario selected as representative for testing the validity of the MBDS during the gap analysis phase.

Appendix D
 Biosurveillance Data Steering Group (BDSG)
 Preparedness Functional Area Matrix
 10/31/2006

Short Term (1 year)	Longer Term (2-3 years)	Not in BDSG Scope
------------------------	----------------------------	-------------------------

Early Event Detection (EED)	NOTES
1. Secondary use of clinical care and other health-related data for early identification of public health events	Primary source for entire Minimum Biosurveillance Data Set (MBDS) will be re-purposed, previously collected clinical data. More likely to be used in the early phases of an event to intensify surveillance but unlikely to detect an event.
2. Reportable disease case reporting from clinical care via the Web and 24/7 call reporting systems with triage of disease urgency	Reportable disease (case) reporting will follow usual procedures to inform the local and state public health officials in accordance with current regulations. This MBDS-based process may accelerate automated diagnostic or laboratory reporting but not replace traditional disease investigation and control measures.
3. Situational awareness of the size, location, and spread of a health event using secondary use data and case reporting	Requires fair amount of calculation by public health officials if data sources are dependent on raw existing messages being diverted, filtered, and pseudonymized. Alternative would be data entry mechanism (e.g., HAVE System) that provides summary values in specific categories of resource availability. This has implications for resources to support this effort.
4. Disease data exchange using HL7-specific implementation guides	The exact implementation mechanism and standard of how data are transmitted is the purview of the Standards Panel (HITSP)
5. Detection algorithms to determine and visualize deviation from normal disease patterns	Knowledge of the algorithm would be helpful to the group as it would drive what data are considered minimal.

Appendix D
 Biosurveillance Data Steering Group (BDSG)
 Preparedness Functional Area Matrix
 10/31/2006

Short Term (1 year)	Longer Term (2-3 years)	Not in BDSG Scope
------------------------	----------------------------	-------------------------

Outbreak Management (OM)	NOTES
1. Case investigation and management	Will support this activity but will not be sufficient to complete entire task. Some of the data will be obtained by tracing back through the pseudonymized identifier.
2. Exposure contact tracing	Does not presume there is exposure information but rather may be a key to particular geographic area(s) where an investigation may be triggered; may inform traditional investigations.
3. Exposure source investigation and linking of cases and contacts to exposure sources	(see above). Need to determine the value of these systems or reporting to address this functional component .
4. Data collection, packaging, and shipment of clinical and environmental specimens	
5. Integration with early detection and countermeasure administration capabilities	Data source may help integrate vaccination and early detection information and make determination for targeted counter measure. May help determine population needing intervention and see whether resources exist to help them and the feasibility of an intervention.
6. Linking laboratory test results with clinical case data	Will require careful attention to implementation and how the unique pseudonymized identifier is identically reproduced across the continuum of care so aggregation can effectively link patient with multiple laboratory tests or diagnoses.
7. Flexibility to support agent-specific and emerging requirements while adhering to standard terminology and data relationships	This is a system function that should be addressed. How can we "turn on" a surveillance measure or target new data capture? An important feature but beyond the immediate scope.

Appendix D
Biosurveillance Data Steering Group (BDSG)
Preparedness Functional Area Matrix
10/31/2006

Short Term (1 year)	Longer Term (2-3 years)	Not in BDSG Scope
------------------------	----------------------------	-------------------------

Connecting Laboratory Systems (CLS)	NOTES
1. Standard HL7 message formats and terminology standards for specimen receipt and laboratory result reporting	
2. Receipt and management of specimen and sample data	
3. Monitoring of testing activity to project load distribution during a large-scale event	Capacity measures and the HAVE specification do not accurately predict staffing volume and needs. Would the current capacity of the laboratory indicate capacity during an emergency situation. How do we differentiate between capacity for staff, reagents, and energy (e.g., fuel)? Not currently available in electronic form.

Appendix D
 Biosurveillance Data Steering Group (BDSG)
 Preparedness Functional Area Matrix
 10/31/2006

Short Term (1 year)	Longer Term (2-3 years)	Not in BDSG Scope
------------------------	----------------------------	-------------------------

Countermeasure and Response Administration (CRA)	NOTES
1. Support and track administration of vaccinations and prophylaxes	These data are not readily available from routine system, thus have been excluded from the MBDS. Likely retrievable from parallel systems (e.g., immunization registries or specific tools for CRA).
2. Support apportionment and allocation for limited supplies	Might be helpful to see the needs of where the supplies need to go during an event
3. Traceability to drug lot, vaccinator, or clinic	Linked with #5 below. (Not collecting Vaccine data)
4. Adverse events monitoring	Consistency of Coding- Issues and consistency of coding
5. Follow-up of patients (e.g., vaccine "take" response evaluation)	
6. Isolation and quarantine monitoring and tracking	
7. Links to distribution vehicles (such as commercial distribution channels and the Strategic National Stockpile to provide traceability between distributed and administered products	
8. Integration with immunization and disease registries	

Appendix D
Biosurveillance Data Steering Group (BDSG)
Preparedness Functional Area Matrix
10/31/2006

Short Term (1 year)	Longer Term (2-3 years)	Not in BDSG Scope
------------------------	----------------------------	-------------------------

Partner Communications and Alerting	NOTES
1. Rapid distribution of health alerts and communications to public health workers, primary care physicians, public health laboratory workers, the public, etc.	CDC Health alert Network and Epi X-change function to achieve these goals.
2. Multiple channels of distribution: e-mail, pagers, voicemail, and/or automated faxing	
3. Selective distribution based on the urgency and sensitivity of the message	
4. Collaborative communications (Web boards, threaded discussions, and Web conferencing) among a defined set of involved public health professionals	

Appendix D
 Biosurveillance Data Steering Group (BDSG)
 Preparedness Functional Area Matrix
 10/31/2006

Short Term (1 year)	Longer Term (2-3 years)	Not in BDSG Scope
------------------------	----------------------------	-------------------------

Cross-Functional Components (CFC)	NOTES
<p>1. Secure message transport: ensuring messages are received and read only by intended audiences</p> <p>2. Public health directory for consistent, uniform management of people, roles, organizations, organization types, and jurisdictions when exchanging information</p> <p>3. Recipient addressing: identifying appropriate recipient lists for information exchange</p> <p>4. Terminology standards: adhering to standard vocabulary lists and structures</p> <p>5. System security and availability: protecting systems from sabotage or failure, and protecting data from corruption or unauthorized access</p> <p>6. Privacy: protecting patients and organizations from fraudulent or unauthorized use of their information</p>	<div style="border: 1px solid black; padding: 10px; width: fit-content; margin: auto;"> <p>NOTE: For the purposes of BDSG we will not consider these cross-functional components within our scope. These are however acknowledged as essential infrastructure and should continue to be considered elsewhere (i.e., CDC and Health Information Technology Standards Panel). At some future point BDSG may consider and want to include a listing and status of these areas for reference.</p> </div>



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

American Health Information Community

AHIC Workgroups
Priority & Visioning Presentation

October 31, 2006



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

American Health Information Community

Electronic Health Records Workgroup
Vision and Priority Areas
– **Lillie S. Gelinas, Jonathan Perlin**

October 31, 2006

Broad Charge: What are we trying to accomplish?

To make recommendations to the Community on ways to achieve widespread adoption of certified electronic health records (EHRs), minimizing gaps in adoption among providers.

Vision for the Future

- Person-centric healthcare system
- Extensive provider use of and access to electronic health information
- Widespread use of interoperable HIT
- New reimbursement systems that support improved outcomes achieved through virtual care
- New reimbursement systems

Where are we today?

- Provider-centric healthcare system
- Low levels of adoption of EHRs
- Minimal interoperability
- Low demand for HIT
- Employer based/public fee-for-services reimbursement

Interim State: Where can we be in 2014?

- Provider-centric healthcare system
- Widespread adoption of EHRs with incremental availability of interoperable health information
- Strong demand for HIT functions
- Incentives or new models of reimbursement

EHR Priorities

- Patient Identification
- Medication List/ Allergy
- Laboratory Results
- Problem List
- Clinical / Encounter Notes
- Anatomic Pathology Results
- Vital Signs
- Family History/ Health Factors
- Radiology Reports: Not including images
- Immunizations

Selected Key Barriers to Implementing These Priorities

- Patient Identification
- CLIA
- Textual Clinical/Encounter Notes, Radiology Reports, Anatomic Pathology Results
- Includes Familial Health Information
- Concern re Secondary Uses of Data (e.g., Immunization Registries)

Critical Components for reaching the Interim State

- Financial/business model
- Incremental technological progress
- Mitigation of medico-legal liability
- Confidentiality, privacy, and security guidelines
- Organizational/culture change



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

American Health Information Community

Chronic Care Workgroup

Vision and Priority Areas

– Colin Evans, Tony Trenkle

October 31, 2006

Broad Charge: What are we trying to accomplish?

Make recommendations to the Community to deploy widely available, secure technologies solutions for remote monitoring and assessment of patients, as well as patient related communication between clinicians.

Vision for the Future

Person Focused Healthcare

- Care available in home, work, school – anywhere, anytime
- New reimbursement systems that support improved outcomes achieved through virtual care
- Care coordinated across multiple providers and provider types
- Patient engagement integral to the care process

Vision for the Future

Person Focused Healthcare

- Usable by anyone/Accommodate persons with disabilities
- Affordable
- Portable
- Compatible with provider IT systems and other devices
- Bi-directional communicate with pharmacies, labs, healthcare advocates and other providers
- Enhance provider/patient relationship
- Provide real-time, continuous physiologic information
- Remote monitoring of symptoms before they become chronic

Where are we today?

Provider-centric fragmented healthcare system

- Care sought in the office, clinic, lab, hospital,
- Care across multiple providers not coordinated
- Lack of reliable, secure and affordable health information technologies available in the home, school and office setting that can communicate with care providers
- Unit reimbursement for most ambulatory services
- Employer based/public fee-for-service reimbursement in healthcare setting

Interim State: Where can we be in 2014?

Less fragmented provider-centric healthcare

- Wide-spread adoption of limited number of interoperable remote services
- Remote services reimbursable under specific circumstances
- Bi-directional electronic communication between providers and patients

Critical components for reaching the Interim state

- A sustainable financial/business model for provider and patient use of interoperable monitoring devices and communications between the clinician and the patient
- Interoperable, user friendly, secure and affordable technologies
- Assurances that confidentiality, privacy and security can be preserved
- Mitigation of medico-legal liability that may be associated with virtual/remote care
- Organizational/workforce changes to accommodate virtual care

Identified Key Enablers

- Financial
- Technological
- Confidentiality, Privacy and Security
- Medico-legal
- Cultural

Near Term Priorities

- **Communications between the clinician and the patient**
 - Critical for assuring accurate and timely guidance
- **Vital sign monitoring**
 - Weight: guides immediate treatment in CHF patients
- **Lab monitoring**
 - Blood Glucose: for patients with diabetes
- **Device monitoring**
 - Spirometry: asthma can be managed at home, in school, and at work

Longer-Term Priorities

- **Vital sign monitoring**
 - Blood pressure
 - Cardiac rate and rhythm
 - Pulse oximetry
- **Lab monitoring**
 - Anticoagulation levels
- **Other device monitoring**
 - Motion (falls, bed motion, etc)
 - Medication adherence



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

American Health Information Community

Consumer Empowerment Workgroup
Vision and Priority Areas

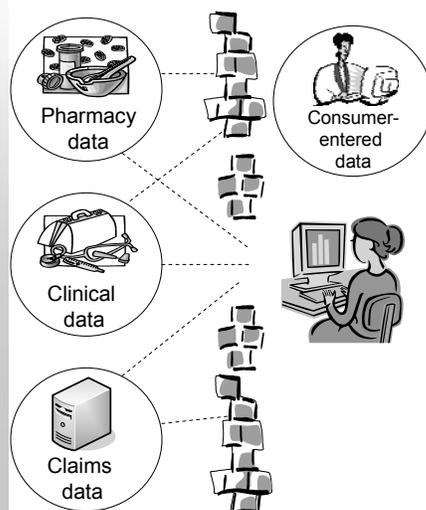
– **Nancy Davenport-Ennis, Paul Tang**

October 31, 2006

Broad Charge: What are we trying to accomplish?

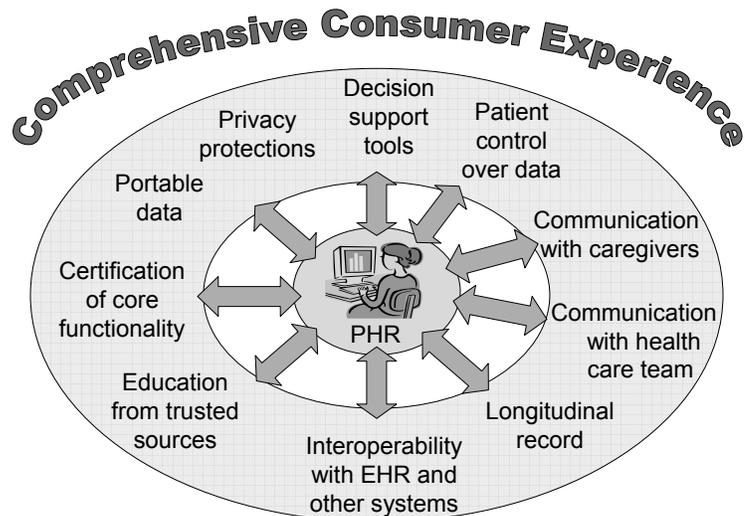
- Make recommendations to the Community to gain widespread adoption of a personal health record (PHR) that is easy to use, portable, longitudinal, affordable, and consumer centered.
- The critical components that support widespread adoption are:
 - Functionality
 - Interoperability
 - Consumer awareness
 - Business models

Where are we today?



- **Lack of consumer awareness and engagement**
 - **Standalone PHRs available, but uptake poor**
 - Manual entry of data
 - Lack of interface with clinical data sources
 - Lack of communication tools
 - **Good experience with integrated PHR/EHR**
 - Primarily available in integrated delivery systems
 - Relatively rich functionality, but tethered to single provider organization
 - Lack of portability
 - **Lack of a sustainable business model for PHR sponsors**
-
- **Overall small fraction of population using PHR**

End-State Vision Where do we want to end up?



End-State Vision Where do we want to end up?

- Widespread adoption of PHRs supporting health and wellness
 - Comprehensive, longitudinal, "record" about an individual's health acquired from all relevant sources [data]
 - Timely, understandable, context-sensitive health information from trusted sources [knowledge]
 - Tools that support an empowered consumer taking an active role in managing his/her health
 - Tools to facilitate communication with health care team and caregivers
- Uniform privacy protections for personal health information that follow the data and give patients control of their PHI

End-State Vision Components Needed

- Interoperability technical standards
 - Terminology
 - Health information exchange and data portability (among PHRs and EHRs)
 - Security (including authentication, authorization, data access control)
- Interoperable policies
 - Uniform privacy protection that transcends local and state boundaries
 - Authorizations
 - Licensure
- Widespread adoption of interoperable EHRs
- Nationwide Health Information Network that facilitates sharing of personal health information to authorized users under the control of consumers

Key Enablers for Accelerating Adoption of PHRs

- Public education about PHRs from trusted sources
- Comprehensive privacy protection for portable personal health information
- Certification for core PHR functions, interoperability, security and access control
- Greater adoption of EHRs and electronic prescribing systems among providers
- Automated population of PHRs with clinical data from multiple sources employing interoperability standards
- Development of standards for consumer-focused, evidence-based educational information and decision support tools

Priorities to Drive PHR Adoption

Near Term

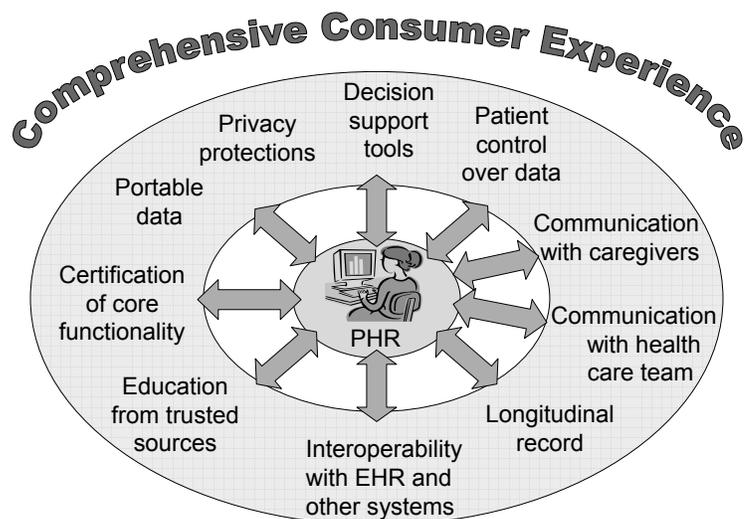
- Lab results
- List of conditions and allergies
- Prescription refills and renewals
- Administrative features
- Reminders for patients

Subsequent

- Online consultation
- Summaries of health care encounters
- Endorsed educational information
- Decision support
- Patient health outcomes

End-State Vision

Where do we want to end up?





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

American Health Information Community

Biosurveillance Workgroup
Vision and Priority Areas
– Charles Kahn, John Lumpkin

October 31, 2006

Broad Charge: What are we trying to accomplish?

Make recommendations to the Community to implement the informational tools and business operation to support real-time nationwide public health event monitoring and rapid response management across public health and care delivery communities and other authorized government agencies.

Current state: Where are we today?

- Public health agencies not interconnected
 - Only a small proportion can receive electronic data from clinical care or public health partners
 - “Silos” of data exist in clinical and public health systems
- Poorly articulated business case for data/information exchange between public health and clinical care - despite legal requirements
- Public health programs and information technology support separated in most states
 - Emphasis on information systems is sometimes inadequate

Current state: Where are we today?

Case Reporting

- Reporting is typically manual and passive, but notifiable disease reporting varies across states.

Bi-directional Communications

- Technologies exist, standards and infrastructure are under development but not yet complete.

Response Management

- Variable degrees of application use and integration, includes supporting outbreak investigations, tracking countermeasures, and linking to response registries.

Adverse Events Reporting

- Reporting is typically manual, voluntary and passive, supported by disparate systems.

End-State: Where do we want to end up?

Connectivity between Public Health and Healthcare systems

- Local, state and federal public health agencies can share data seamlessly with clinical care and each other
- Infrastructure and policies are in place to enable data aggregation at appropriate levels of public health to monitor population health trends, disease outbreaks, and medical product safety.

Case Reporting

- Rapid, Standardized case reporting across States
- Case criteria integrated into EHR's Decision Support Algorithms
- EHR prompts clinicians when diagnosis matches reportable disease and sends electronic report approved by clinician

Bi-directional Communications

- Integrated public health and clinical care communications
- Public health communications deliver value to clinicians which incents providers to communicate on a routine basis with public health

End-State: Where do we want to end up?

Response Management

- Integrated applications to support:
 - Outbreak investigation
 - Countermeasure administration and tracking
 - Ongoing visibility of supply and demand for critical resources
- Linkage of point of care EHR and registry data to emergency management systems
- Improved access to and tracking of
 - Isolation/ quarantine cases
 - Patient data for those displaced from usual site of care
 - Disaster case management services

Adverse Events Reporting

- Standardized (and consolidated) Adverse Events reporting
- Automated EHR prompting and report filing for medical products

Key enablers

- Public Health Involvement in Health Information Exchange efforts (NHIN, RHIOs, etc.)
- Leveraging work done by Public Health Information Network (requirements, standards, certification)
- HITSP and CCHIT include requirements for public health surveillance and response
- Open, participatory process for certification of public health information systems

Priorities in the near term

Improve business case for data/information exchange between public health and clinical care

Case Reporting

- Initiate process for standardizing national case definitions
- Harmonize and adopt public health standards for web-based electronic case reporting
- Define requirements and architect strategy for integrating electronic case reporting into EHRs

Bi-directional Communications

- Define requirements for a centralized website for sharing of standards
- Standardize formats for constructing health alerts and have these approved by a national standards body

Response Management

- Design pilot for sharing hospital utilization data with public health
- Continue integration of commercial sector supply chain and distribution

Adverse Events Reporting

- Develop and adopt national standards
- Identify candidate systems to consolidation



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

American Health Information Community

Quality Workgroup
Progress Update and Priority Areas
– **Carolyn Clancy**

October 31, 2006

Broad Charge: What are we trying to accomplish in the long term?

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

Specific Charge: What are we trying to accomplish in the near term?

Make recommendations to the American Health Information Community that specify how certified health information technology should capture, aggregate and report data for a core set of ambulatory and inpatient quality measures.

Workgroup progress to date

- Two workgroup meetings
- Examination of business case
- Common agreement on HQA/AQA starter measures
- Environmental scan
- Review of HIT certification process

Emerging principles for the Quality Workgroup

- Specific solutions for data aggregation and reporting not prescribe
- Apply requirements approach focused on standardization and discrete capture of data elements critical for reporting
- Focus on accountability, transparency and improvability, helping clinicians obtain feedback in real time
- An array of solutions for decreasing the burden of data collection is necessary

Emerging principles for the Quality Workgroup

- Quality reporting is one of several secondary uses for clinical data
- Solution will require the skills of many
- Development/evolution of market competition and collaboration will be a significant enabler

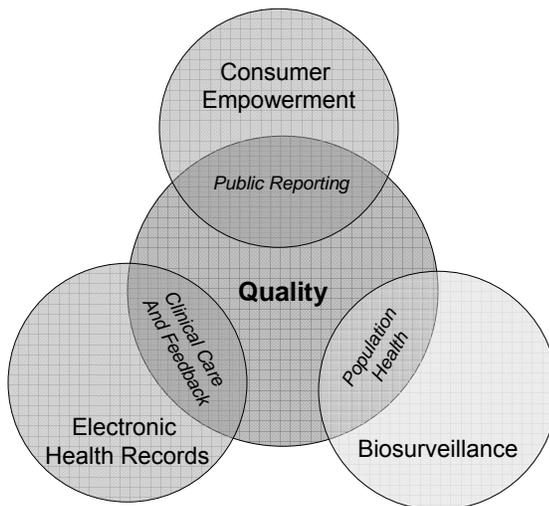
Priorities in the near term

- Automate data capture and reporting to support of a core set of AQA clinician-focused quality measures
- Automate data capture and reporting to support of a core set of Hospital Quality Alliance (HQA) inpatient quality measures
- Provide feedback to providers in real or near-real time
- Enable data aggregation

Next steps

- Continued exploration of the broad and specific charges
- Development of recommendations for the specific charge and priority areas
- Visioning exercise

Quality in context: The Quality Workgroup overlaps materially with other AHIC efforts



AHIC Workgroups' Priority Areas Narratives

Consumer Empowerment Priority Areas

The Consumer Empowerment Workgroup recognizes the critical importance of portability and interoperability of the data contained in a personal health record. While full interoperability and the policies to protect consumers are necessary over the long-term for the widespread adoption and use of personal health records, they are complex issues to solve and are dependent upon a sequence of events taking place. Therefore, the Workgroup believes that work should begin in the near future to achieve portability and interoperability while advancing priority areas to drive incremental adoption of PHRs that deliver value to consumers.

The Consumer Empowerment Workgroup has identified ten priority areas that represent features or functions of PHRs that are all important for consumers to realize the full benefit of PHRs. Five of these can be advanced in the **near term** and drive adoption. They are:

- **Prescription refills** – includes renewing of prescriptions with provider, ordering refills of existing prescriptions with a pharmacy if service is available. When automated, prescription refills can reduce medication errors, offer convenience to consumers and improve workflow in physician’s offices.
- **Lab results** – includes receiving, sharing, and storing numeric and graphical representation of lab test results. Visualizing changes in lab results can be a powerful motivator to patients with diabetes, high cholesterol and other chronic conditions.
- **List of conditions and allergies** – includes a list of health conditions past and present, current allergies especially to drugs or medical supplies. If pre-populated, this information can provide consumers easy access to an abbreviated medical history.
- **Administrative features** – includes appointment scheduling, editing of demographic and account profiles, checking on insurance eligibility and claims, financial recordkeeping and management, privacy and access controls. These can be important triggers for consumers to initially engage and use a PHR.
- **Reminders for patients** – includes reminders for appointments, prescriptions, and preventive measures such as annual check-ups, cancer screening (e.g., mammograms and colonoscopies), risk modification (e.g., cholesterol tests and blood pressure monitoring), and immunizations. Reminders can be helpful to healthy populations for the purposes of disease prevention and wellness, and the sick to improve compliance with treatment or follow up.

The remaining five priority areas are either less feasible in the near term or are important but not critical to initial PHR adoption:

- **Decision support** – includes logic and information to facilitate patient decisions on their health care options. This could also include functions that would facilitate incorporation of patients’ preferences in their clinicians’ decisions about treatments
- **Summaries of health care encounters** – includes dates of service, diagnosis codes and procedure codes from health care encounters
- **Online consultation** – includes email communication and online consultations with a clinician
- **Patient health outcomes** – intended to cover adverse events and other patient reported health outcomes that might not normally be part of a problem list or summary of encounters
- **Educational information** – includes reliable and/or evidence-based health information, links to reliable, consumer-friendly medical information sites, and online medical libraries

These priority areas involve several issues surrounding data flow, work flow, architecture, policy/regulation, and data access and control which are either barriers or enablers to implementation. Some general barriers and enablers to these priority areas include:

- Demonstrating the value of a PHR to patients and providers acts as an enabler
- Legal issues include perceived provider liability associated with sharing information with consumers; enablers include changes in state law such as malpractice caps, and education on liability and HIPAA
- Lack of integration into the workflow of providers and the lack of EHR adoption are barriers; an enabler is the encouragement of integration of PHRs into the workflow, especially in offices using EHRs

In order to implement the **near term priority areas**, the following specific barriers or enablers would be considered:

- Prescription refills – Connectivity between physician offices, PHRs, and pharmacies would enable automated refills. Mechanisms to avoid fraud and abuse of prescription drugs might need to be addressed.
- Lab results – State laws would need to be analyzed and potentially altered to enable timely access to lab results that require clinician interpretation. Interoperability and architecture to enable retrieval of historical lab data of interest would also be needed.
- List of conditions and allergies – Appropriate authentication processes would need to be implemented; translations of medical terminology into layman’s terms would need to be developed; and standards for allergies would need to be developed and adopted.
- Administrative features – No consistent policies exist for consumer-entered or consumer-altered data but mechanisms to record the sources of data or changes could be considered. Many administrative features require interoperability among providers, patients, and payer applications (practice management systems, EHRs, PHRs, and payer portals) as well as secure data exchange.
- Reminders for patients – The data quality of pre-populated or stand-alone PHRs might impact the appropriateness of reminders for patients if these reminders are dependent on an accurate, reliable and up-to-date medical history to alert consumers about appropriate steps to take for disease prevention and/or management. PHRs integrated with EHRs exist but typically with only one provider who might not have access to a patient’s longitudinal health record.

Biosurveillance Priority Areas

The Biosurveillance Workgroup recognizes the critical importance of an integrated and interconnected public health and healthcare delivery system that enables real-time, secure, and appropriate bi-directional exchange of information. A fully integrated solution relies on the assumption that underlying infrastructure, defined outside this workgroup, will be in place to support connectivity between public health and clinical care. Therefore, the priority areas described here do not include connectivity, but instead focus on areas where close interactions between clinical care and public health will have a positive impact on the future of consumer care and population health.

The Biosurveillance Workgroup has identified four priority areas to be supported within the domain of biosurveillance. All are important for consumers and population health to realize the potential benefits that could be derived from interoperable health information technology. In each priority area there are components that can be advanced in the **near term**, providing a strong foundation for future efforts. The priority areas are:

- **Case Reporting** – Case Reporting would integrate case criteria and reporting mechanisms into EHRs. These mechanisms should trigger more rapid recognition of potential cases and prompt clinicians to ensure that reportable cases are automatically sent to public health authorities. Automation could result in significant reductions in the time it takes for a full reporting cycle. Automation would also significantly reduce the work load of health care providers who currently complete legally mandated reporting manually and passively. Reporting now is typically manual and passive (requiring initiation of reports by physicians). Clinical care data combined with electronic laboratory reporting (ELR) can be used as surrogates for initial disease case information. In summary, the case reporting priority area includes:
 - Automated case reporting from clinical care to public health
 - Providing information to clinicians for making diagnoses
 - Integrating electronic laboratory reporting into case reporting and response
 - Reporting in parallel to local, state and national levels of public health (PH)
 - Integrating with disease registries

- **Bi-Directional Communications** – Bi-directional communication refers to the dissemination and interactive exchange of information not only from clinical care entities to public health entities but also the reverse: from public health entities to clinical care entities. Communication modes include:
 - e-mailing alerts
 - collaborative technologies which are used for more discussion-like exchange
 - web pages with community health information
 - electronic exchange based on messaging standards (e.g., HL7 messaging)

Communications may vary from secure exchanges for a limited audience to more publicly available information. Public health may provide a variety of communications such as health alerts, investigation findings, aggregation of clinical data to guide clinical care, updates to case criteria, and guidelines for the general public. Bi-directional communication can make public health data accessible to people in different regions in ways that better support their public health and clinical care activities.

- **Response Management** – The response management area includes multiple aspects of containing and responding to a health event. Managing an outbreak requires knowledge of available prophylaxis and treatment resources, bed and response availability which is critical for making informed decisions and deploying and administering response

countermeasures. Response also includes tracking and managing the administration of countermeasures, including treatments, prophylaxis, isolation and quarantine. During a response, registries must be maintained and this priority area encompasses automated integration with response-related registries, such as: immunization registries for responders, registries of emergency response volunteers, registries of people given countermeasures and those requiring long-term follow-up. In summary, the response priority area includes:

- Outbreak management
 - Automated exchange of resource utilization data
 - Integration of the commercial sector countermeasure supply chain with emergency demand
 - Tracking and managing administration of countermeasures
 - Integration with registries for effected individuals, responders, volunteers, countermeasures, long-term follow-up
- **Adverse Events Reporting** – reporting encompasses the electronic submission of adverse events including nosocomial infections, medication errors, adverse drug events, adverse events related to medical devices, biologics and some medical errors. Traditionally, this has involved a clinician recognizing an adverse event, completing a form, and submitting it to the appropriate public health authorities or entities.

Adverse Events reporting would be improved by standardizing and automating adverse events reporting for medical products. Prevention would be improved by linking EHRs to sources listing drug-to-drug interactions and drug allergies, such as FDA’s Structured Product Labeling (SPL) database.

These priority areas involve several issues surrounding data flow, work flow, architecture, policy/regulation, and/or data access and control which are either barriers and/or enablers to implementation. Some general barriers and enablers to these priority areas include:

- Public health adoption of newly available electronic data to support public health practice. Enablers include involvement of public health in the development of policies, standards and data use agreements. In addition, existing work in related domains such as the Public Health Information Network (PHIN) should be leveraged to ensure interoperability and promote certification of public health information systems.
- Concerns for confidentiality and privacy of personal data. Enablers include implementing a secure infrastructure to protect data during transport; and developing strong state legislation to protect data collected by public health. Data from clinical data sources will be anonymized but linked, and outbreak investigation will support query-back capability to obtain details during an authorized public health investigation.
- Reporting and messaging standards to support public health priority areas need to be defined and enforced by policy. This is enabled by ensuring that the standards are approved by a recognized standards panel (e.g., HITSP), and implementing a central authoritative web repository where these standards (e.g, vocabularies, message formats, reportable disease listings) can be obtained by implementers.

In order to implement the **near term priority areas**, the following specific barriers or enablers would be considered:

- Standardize disease reporting - disease reports vary by State. Enablers would:
 - Develop national standards for disease reporting and support disease reporting based on those standards.

- Automate Disease reporting – disease reporting is currently a passive activity (requiring initiation of reports by physicians) and is often manual. Enablers would:
 - Prompt clinicians when a case meets the criteria for reporting.
 - Issue report in parallel to local, State and national levels of PH.
 - Standardize electronic messaging formats and have these approved by a national standards organization (e.g. HITSP) and implement into EHR functionality.
- Develop a target data set for transmission from clinical care to public health. An enabler would be approval by the AHIC of a common minimum data set (to be proposed by the Biosurveillance Data Steering Group on 10/31/06 AHIC meeting).
- Integrate Electronic Laboratory Reporting into case reporting and response.
- Health alerting is challenged by a lack of underlying communications infrastructure. Enablers include standardizing formats for constructing health alerts and have them approved by a national standards body (e.g. HITSP) and ensuring availability of high speed internet connectivity for clinicians and public health.
- Standardize adverse events reporting – adverse events reports vary by type. Enablers include development and adoption of national standards for adverse events reporting.
- Automate reporting of Adverse Events – Adverse events’ reporting is currently a passive activity (requiring initiation of reports by physicians) and is often manual. An enabler would be to ensure EHR functionality that will prompt clinicians to issue a report when an adverse event occurs, and electronically issue the adverse events report to pertinent PH agencies once approved by the clinician.
- Integrate commercial sector supply chain with demand – During a shortage or emergency, the availability of resources must be ascertained from multiple disparate sources. Automating exchange of hospital utilization data through use of approved standards (e.g., HITSP standards) would act as an enabler.
- Integrate public health activities with EHRs – Barriers include a lack of widespread EHR adoption combined with limited integration of EHRs with public health activities. EHR integration should include:
 - Integrating case criteria into EHR decision support to assist clinicians in diagnosing a case
 - Prompting for adverse event and disease reporting
 - Integration with disease and immunization registries
 - Lists of drug interaction and drug allergy information

Electronic Health Record Priority Areas

The Electronic Health Record Workgroup (EHR WG) recognizes that there are many electronic health records (EHR) available in the marketplace, 22 of which are CCHIT certified. There has been significant publicity regarding the benefits of utilizing health information technology (HIT) in the management and delivery of healthcare. Yet, adoption of this care-enabling technology by physicians has been modest.

The EHR Workgroup has identified ten priorities that represent essential minimum features or functions of EHRs. These features or functions are the utilities identified as the most important clinical data elements by clinicians who are either considering adoption of EHRs, or those who have adopted but desire interoperability in these areas. These utilities are noted in priority order as determined by the EHR Workgroup, and are all considered critical for comprehensive patient care. Priority descriptions are examples of the utility and not intended to encompass the entire scope.

- **Patient Identification:** Ability to accurately identify and maintain a single patient record for each patient. Can contain demographic information including addresses, phone numbers, date of birth, sex and other information needed for the provision of care.
- **Medication List / Allergy:** Managed over time and include entire medication history for any medication, including alternative supplements and herbal medications, medications ordered by providers, dispensed by pharmacy, over the counter medications, and patient self-reported meds. Allergy list can contain the entire allergy history, allergen and reaction. This also can include drug reactions that are not classifiable as true allergy and intolerances to dietary or environmental triggers.
- **Laboratory Results:** May include the result itself; result units if applicable; normal ranges or indicator flags; and any comments associated with the result. The result itself has many forms: Numerical results, including titers; Ordinal results; Results cut-off value which requires interpretative information in the form of normal ranges or indicator flag; Alphanumeric results that now generally take the form of free-text, such as results from anatomical pathology.
- **Problem List:** May contain current and/or chronic conditions, diagnoses, symptoms, and functional limitations. These are managed over time to provide historical information and tracking.
- **Clinical / Encounter Notes:** Narrative and/or based on a structured template. Describes in detail the clinician's assessment, plan, intervention and evaluation during a care episode. An encounter serves as a focal point linking clinical, administrative and financial information.
- **Anatomic Pathology Results:** see Laboratory Results.
- **Vital Signs:** Component of a patient's health status at a specific point in time. Typically includes height, weight, blood pressure, pulse, respiration, oxygen saturation, and pain level.
- **Family History/ Health Factors:** May contain a detailed problem list and health history of a patient's family members. Typically used by providers when assessing familial risk and planning care.
- **Radiology Reports: Not including images:** Textual findings described by provider evaluating radiological media.
- **Immunizations:** May contain immunization encounters, vaccine events, and other immunization-related information. This could enhance immunization registry and surveillance activities; give more robust data with respect to coverage levels, immunization histories, vaccine decision support, record exchange and patient/parent

reminders, standardize communication to/from providers/users of vaccine information such as primary care physicians and schools; and provide an up-to-date standardized method of communication to keep vaccination records current and complete.

Throughout months of testimony and research, the EHR Workgroup has determined there are five types of barriers and enablers for which additional research and strategic actions must be undertaken to achieve the broad charge of “widespread adoption of certified EHRs, minimizing gaps in adoption among providers.” These types of barriers and enablers are:

- Financial/ Business Case
- Technological State
- Legal and Regulatory
- Organizational and Cultural
- Privacy and Security

There are also enablers and barriers specific to the priority areas noted above. These involve issues surrounding data flow, architecture, work flow, policy/ regulation, and/ or data access and control. Please note: data and interoperability standards are needed in all of the above priority areas. In order to implement and adopt EHRs that provide utility in these priority areas, the following specific barriers are some of the issues that will be or have been addressed by the workgroup:

- Patient Identification- Need for an accurate and reliable patient identification absent a national patient identifier.
- Laboratory Results- CLIA and current State laws restrict sharing of laboratory results data.
- Clinical/ Encounter Notes, Radiology Reports, Anatomic Pathology Results- Preservation of the necessary clinical context in these textual documents while structuring data to be machine readable and interoperable.
- Family History/ Health Factors- Policies, guidance and protections related to the inclusion of other family member’s health history in the patient’s record.
- Immunizations: Policies and guidance will be needed for secondary uses of data for public health reporting, quality metrics, registries, etc.

Chronic Care Workgroup Priority Areas

The broad charge to the Chronic Care Workgroup focuses on a specific area important to person-centric healthcare: that of remote monitoring and assessment of patients *and* secure communication between patients and clinicians, as well as among clinicians. Achieving widespread adoption of at least a few remote interoperable monitoring technologies within our current provider-focused, employer-funded system will create a demand for HIT which can support care in any setting -- home, work, school, travel -- and pave the way for a time when “virtual” care is the common expectation.

The CCWG is addressing cross-cutting critical issues for the broad charge, and in the context of several specific opportunities for remote monitoring, they have also identified the following priority areas:

- **Vital Signs: Weight in the near term; BP, cardiac rate and rhythm, pulse oximetry in the longer term.** Weight is the single most actionable piece of information that can be used to guide immediate treatment in patients with Congestive Heart Failure.
- **Lab Monitoring: Glucose readings in the near term (for persons with diabetes); anticoagulation monitoring in the longer term.** Home based, accurate, certified technologies for Internal Normalized Ratio (for monitoring the time it takes for blood to clot) readings are not widely available in the near term.
- **Device Monitoring: Spirometry in the near term; motion (falls, bed motion, etc.) monitoring and medication adherence monitoring in the longer term.** Asthma and other forms of chronic obstructive pulmonary disease, the most common chronic conditions across all age groups, can be managed at home, in school, and at work.

Widespread adoption of remote monitoring and secure communication is dependent on addressing five types of barriers and enablers in five critical areas:

1. Sustainable financial models
 - Current unit based reimbursement focuses on services in the provider setting. At this point, there is no incentive for clinicians to expend their resources on remote non-reimbursable services, when those same services can be reimbursed in the care setting.
2. Interoperable, user friendly, secure, inexpensive technologies
 - Clearly, information must flow freely between patient monitoring systems and the health information technologies within offices of the clinicians responsible for their care. There are currently no interoperable systems that are marketable to consumers.
3. Assurances that confidentiality, privacy, and security can be preserved
 - There must be ways to ensure that the information transmitted is reliable, accurate, secure, representative of the appropriate patient, and is transmitted to the intended recipient.
4. Mitigation of medico-legal liabilities
 - Remote care implies the ability for clinicians to “practice” across state lines and to use information generated by remote assessment (as opposed to in-person examination) without undue administrative burden or fear of legal ramifications.
5. Cultural and work flow changes from the status quo
 - Remote monitoring and care will demand new skill sets and workflows in the provider setting. Patients, too, will need to feel comfortable with the new technologies. The nature of the patient/physician encounter, now so deeply entrenched as a face-to-face event, will need to be further examined.

Quality Workgroup Priority Areas

At its broadest level, the Quality Workgroup is focused on leveraging the use of health information technology to enable the development of useful quality measures that span care settings, standardize the data capture and ease the reporting of comprehensive current and future measures, improve clinical performance by improving access to information at the point of care through clinical decision support, and better align performance measures with both capabilities and limitations of HIT. More specifically, the Quality Workgroup is focused on developing recommendations for the American Health Information Community that specify how certified health information technology should capture, aggregate and report data for a core set of ambulatory and inpatient quality measures. Although the Workgroup has just begun its work, it is clear that tremendous opportunities also exist to align the development of electronic health records with the nation's goal to make quality information transparent to providers and the public.

The Quality Workgroup has identified key preliminary priority areas that will be critical in the **near term** in driving advances in quality measurement and the maturation of interoperable health information technology to support these quality measures. These priority areas include the following:

- **Provide feedback to providers in real or near-real time** – involves leveraging the data capture that supports the development of the denominator for quality measures and translating those patient identification algorithms into clinical decision support functionality to help providers know precisely what they need to do (and for whom) to ensure quality of care.
- **Automate data capture and reporting to support a core set of AQA alliance quality measures** – involves, at a minimum, defining documentation, storage and export guidelines for electronic health records to capture and transmit the data elements required to determine the numerator and denominator of a core set of *clinician* quality measures.
- **Automate data capture and reporting to support a core set of Hospital Quality Alliance (HQA) quality measures** – involves, at a minimum, defining documentation, storage and export guidelines for electronic health records to capture and transmit the data elements required to determine the numerator and denominator of a core set of *hospital* quality measures.
- **Enable data aggregation** to allow public reporting of quality measures based on comprehensive clinical data that is pooled across providers and merged, as appropriate, with other data sources.

Please note that due to the recent formation of the workgroup, the above near term priority areas do not represent a full list of the priority areas that may emerge.

These priority areas involve several issues surrounding data flow, workflow, architecture, policy/regulation, and data access and control which are either barriers or enablers to implementation. Some **general barriers and enablers** to the near term priority areas include:

- Business case for automating quality measurement is needed which is related to the incentives for EHR adoption and the sharing of clinical data
- Storage needs to support data aggregation and public reporting in clinical care, at a regional, state and/or national level
- Business process and workflow considerations that may be required to ensure uniform capture of data (may add clinical documentation burden that isn't always easy to address because of workflow and time it takes)
- Access control consideration to support appropriate access by different roles and functions at different levels

- Decision rights and responsibilities for use of data once it is transmitted from the provider system
- Security and privacy considerations to address issues related to patient identification once the data leaves the provider system

In order to implement the near term priority areas, the following **specific barriers and enablers** would be considered:

- Automating data capture and reporting to support a core set of AQA/HQA quality measures – a barrier to automation is the current inability to collect electronic data and report the measures; enablers would be agreement on a set of data requirements and certification for EHR vendors on common capabilities for quality reporting
- Providing feedback to providers in real or near-real time – barriers to provider feedback are the lack of integration into the current providers' workflow and the lack of EHR adoption; enablers would be 1) the encouragement of integration of quality reporting into the workflow, especially in offices using EHRs, 2) EHRs that accommodate quality measures and clinical decision support, and 3) demonstration of the value of quality reporting to patients and providers
- Enabling data aggregation – a barrier to data aggregation is the lack of a single comprehensive data source that spans the continuum of care; an enabler would be the ability to combine electronic data from a variety of sources: labs, pharmacy, EHRs, web-based tools, claims

HHS Proposal for Consideration Clinical Research Priority Areas

Improvements in health care generally follow clinical trials that compare new preventive measures or treatments to the best currently available. Electronic health records that document observations from clinical care provide a window into the health care process and a baseline from which clinical research can make health care improvements. The integration of clinical care records with the clinical research process therefore has great potential to accelerate the translation of research findings into improved practice at the point of care. However, this will require data and an underlying interoperability framework with sufficient specificity to be comparable across venues of research and care.

This document outlines proposed priority areas for the use of healthcare information technology to facilitate clinical research, a broad activity that includes determination of epidemiology and mechanisms of disease and the development of diagnostic, preventive, and therapeutic markers and interventions, including those related to behavioral health, and their evaluation via clinical studies and post-market surveillance. Consultations with subject matter experts in the clinical research community and in government agencies involved in health care and health-related research have identified ten priority areas representing features or functions of healthcare IT that are important for promoting evidence-based care. Five of these priority areas can be advanced in the **near term**:

- **Participation in clinical research** –includes providing the means to enhance communication between researchers and physicians whose patients are likely to qualify for clinical trials (e.g., psychiatrists, oncologists) and work with other caregivers who can help additional patients, such as those with chronic conditions or rare diseases or those who reside in medically underserved communities, become aware of and participate in appropriate research protocols.
- **Data anonymization, identification and de-identification services**– these are essential services for clinical research; clinical researchers will participate in the development of standards that will make it possible to derive real value from electronic health records while ensuring patient privacy, confidentiality, and the integrity of data used for research activities.
- **Automated protocol management** – helps participants and physicians coordinate appointments and obtain and record results from tests and examinations required to complete the studies, and to track changes in address, marital status, and other information needed for long-term studies.
- **Enhanced lab data analysis** – includes receiving, sharing, and storing lab results with the specificity needed for research in ways that prevent unnecessary repetition of tests received as part of regular clinical care and facilitate data comparison across laboratories and care providers; this could also include secondary analyses as new technologies mature and move into the clinic, e.g., gene expression profiling, proteomics.
- **Documentation of patient and family histories** – provides invaluable data for researchers probing the influences of genetic, environmental, behavioral and social factors on disease.

Five additional priority areas listed below are either less feasible in the near term or less critical for initial efforts to integrate clinical research and health care information systems:

- **Adverse event detection and reporting** – addresses the need for increased public trust in clinical research, an area where healthcare IT can make a critical difference by allowing much more rapid and specific identification of adverse events, thereby

- improving the quality of care for research participants and reducing the administrative burden of tracking and reporting adverse events.
- **Automated Case Report Forms** – includes collection of data from the patient record, using structured vocabularies and appropriate standards, that would allow most of the data required to complete a case report form to be extracted automatically, greatly reducing administrative burden to physicians with patients in clinical trials, permitting rapid detection of adverse events, and improving the quality of the data collected.
 - **Post-intervention tracking** – includes collection of longitudinal data after the conclusion of a clinical study so that the efficacy and long-term effects of an intervention can be assessed, such as quality of life, improvement in symptoms, and adverse events.
 - **Patient Consent Management** – on-line tools for informing patients and physicians about risks and benefits of research participation, and for accessing informed consent documents so that researchers can easily view and manage associated data permissions for enrolled participants and so that patients can provide consent to secondary uses of their information if they so choose.

All of these priority areas involve issues surrounding data flow, workflow, architecture, policy/regulation, and/or data access and control which are either barriers and/or enablers to implementation. Some general barriers and enablers to these priority areas include:

- Harmonizing the standards across electronic health records and clinical research applications, particularly regarding terminologies.
- Developing a strong understanding of the requirements for electronically-enabled clinical research work flows. This work has been done on paper, until now, or has not been done on a wide scale at all. It will require understanding of the data and process needs of stakeholders.
- Lack of understanding of how to use the electronic tools, particularly to help clinicians work with the data to obtain the level of specificity needed for clinical research without interfering with their normal clinical care routines.

In order to implement the **near-term priority areas**, the following specific barriers or enablers would be considered:

- **Participation in clinical research** – would require education of providers concerning the desirability and process for enrolling their patients in clinical studies, and would require better aggregation of data needed to assess potential eligibility in such a way that it fits into the normal physician office workflow.
- **Enhanced lab data analysis** – harmonization of laboratory terminologies would be required, as would ensuring that the results were recorded with the degree of specificity needed to ensure that the results were comparable across locations and usable for research purposes (e.g., would have to identify the test method used to obtain the results).
- **Documentation of patient and family histories** – terminologies and representation methods will have to be developed so that the needs of the clinicians and patients providing the data are accommodated (e.g., clarity, ease of use), while the needs of the research community are met (e.g., specificity).
- **Automated protocol management** – a clear understanding of the workflows required to support collection of clinical trial data in the clinical environment is needed.
- **Patient Consent Management** – further work to harmonize standards in this area is needed, as well as coordination with IRBs and other regulatory bodies and obtaining buy-in from consumer bodies to ensure that the consent process is clear and implementable.

Interagency Health IT Policy Council
Population Health Workgroup Priority Areas
October 31, 2006

Population health management requires the integration of longitudinal individual patient health information, functional and behavioral data and external non-patient data (such as occupational and environment information.) Integrating patient, environmental, occupational, and other data enables a variety of population health management activities, including: recognizing and managing emerging health conditions, identifying patient populations at increased risk for specific disorders, improving clinician performance with respect to particular populations, measuring and reducing healthcare disparities, providing snapshots of population health status at particular times, facilitating translational research, and making available population health management information to clinicians and consumers at the point of care. Federal programs use population health information to: identify the health status of populations; recognize past, present and future health care trends; permit health care organizations to monitor and improve the health of certain populations, prevent the onset or worsening of medical conditions; enable the delivery of needed information to patients with certain health conditions, their family members, and treating health care professionals; and support essential health services research needed to transform and improve health care quality and outcomes.

Efficient and effective population health management is currently limited by the: lack of widespread granular and interoperable electronic patient and population data; gaps in and limited understanding of the requirements needed to integrate patient data over time, across providers, as parts of defined populations, and with other critical data; and limits on the ability to generate information and make available pertinent reports to consumers, clinicians, communities, insurers and policy makers to assist with improving the health and functioning of populations.

Under the Interagency Health IT Policy Council, the Population Health Workgroup has identified 10 priority requirements needed to enable electronic population health management. The use of EHRs at the point of care has enabled the electronic collection of critical data elements that support numerous population health management activities. Further, multi-directional health information exchange between patients, clinicians, public health programs, payers, and other health care organizations is essential for effective and efficient population health management. Given the increasing use of EHRs and the growing need for health information exchange, the Population Health Workgroup has identified the following priorities:

Near Term -- The need to:

1. Identify patients and populations with certain health conditions and/or characteristics.
2. Identify critical data elements and measures that are essential in tracking population health status, including prevalence, incidence, and aggregate health status measures.
3. Protect and maintain the privacy and security of patient and population data (including how data access is controlled by different roles and functions) consistent with federal and other standards. Compliance with HIPAA will support needed privacy and security protections. State and local privacy and security requirements must be considered.
4. Store and/or retrieve (e.g., at the provider, health care facility, local, community, regional, state, and/or national level) longitudinal patient data (e.g., diagnoses, demographics, medications, mortality, claims, etc.) across multiple providers. Patient data would include the date (point in time) of the health care encounter. Data would be retrieved using tools developed to query data by authorized persons.
5. De-identify and reuse longitudinal patient-level data and aggregate de-identified patient data to support analyses of trends and issues for the selected population(s) (such analyses would not be conducted at the individual provider level).

6. Map very granular data to more aggregated data or classification data and harmonizing (if necessary) data collected from multiple EHR systems.
7. Integrate other data available from local, state, and federal data systems (e.g., public health networks, registries (e.g., immunizations, etc).
8. Define, support and implement multi-directional reporting capacity (e.g., through electronic portals or other mechanisms) to patients, clinicians, and/or appropriate health programs for population health management including prevention and treatment.

Mid - Longer Term Priorities – The need to:

1. Implement a standard data element for provider identification. The implementation of the NPI standard will facilitate the identification of providers and clinical specialties for population health management. The NPI will enable provider-level quality improvement activities such as the delivery of needed population health information to clinicians for treatment and education of clinical specialties.
2. Integrate patient data with other data sources including: environmental data, occupational data, school attendance data, geographic data, etc. Linking patient health data with these external data sources provides information that is essential for identifying persons at risk of certain health events for both prevention and treatment. Some external data sources important for population health management may be available but to date have not been integrated into electronic health information systems (e.g., school attendance records). A barrier is that some needed external data is not available or is not available in an electronic format.

Examining the ability of health programs to engage in electronic population health management activities for a few selected health conditions will permit a comprehensive assessment of these near and mid to long-term priorities. The following is an illustrative example for one condition – asthma -- of the different types of data that would be needed to assess the eight priority areas described above using a snapshot of an integrated, longitudinal EHR patient data linked with other data sources:

- Identify patients with asthma electronically within an electronic health record.
- Populate a patient ‘list’ or populations registry with these patients electronically from the EHR.
- Specify explicit definitions for population health measures (including prevalence and incidence) and aggregate health status measures related to asthma (including baseline as well as prior time period measures). This should incorporate certain pre-defined clinical quality measures, and additional measures (e.g., reduction in the number of deaths, hospitalizations, physician visits, emergency department visits, school or work days missed, symptom free days, limitations in activities, asthma action/care plan in place and updated regularly, depression screening, family impact, etc.). Measures would define the population of interest (e.g., asthmatic children diagnosed with depression).
- Specify a minimum data set for the specified population health measures related to asthma. These could include: disease specific data (e.g., health (respiration status), medications, appropriate diagnosis stratification (e.g., mild intermittent asthma) functioning, mental health status, quality of life, mortality, cost, prevalence and incidence, trends), demographic data, claims data, geographic data, environmental data (e.g., ambient air quality), occupational data, school attendance data, and other data available from local, state, and federal data systems.
- Specify the various data sources that are expected to provide the needed data (e.g., electronic health records, and data from other federal, state, and local sources, etc.). Data would be retrieved by those persons who are authorized to access data.

Targeting at least three conditions/populations of interest (e.g., asthma, cancer, substance abuse, frail elderly, persons with disabilities, and/or other populations of interest) and specifying the population health measures to be assessed, and the data and data sources needed, will allow a more comprehensive assessment of the enumerated priorities to support population health management needs.

Federal Agencies: Population Health Priority Areas

Population health management is a critical component of many of the business processes and policies/requirements for many federal health and other programs. The following describes needs for population health information within some federal programs. As described below these programs use population health information to identify the health status of populations; recognize past, present, and future health care trends; advance the ability of health care organizations to improve health of specific populations; prevent the onset or worsening of health conditions; improve delivery of information to specific patients as well as their support and healthcare networks; inform environmental and occupational protection policy; and support health services research.

The missions' of federal programs requires a focus on numerous populations and the use of population health information for a wide array of population health activities. The following is an exemplary list of the health conditions of interest to federal programs:

- Cancer
- Diabetes
- Immunizations
- Mental health (e.g., Major depression)
- Substance abuse (e.g., tobacco dependence)
- Frail elderly
- Cardio-pulmonary disease
- Asthma (particularly in pediatric populations)
- Children with special needs (e.g., autism)
- Injury and violence prevention
- Persons with disabilities
- Comprehensive population health measures

The descriptions below highlight the involvement of some federal programs in population health management activities and their need for/use of population health information. Understanding how data from electronic health records and other data (e.g., environmental, geographic, occupational, school, etc.) is being and could be used and electronically exchanged would enhance population health management activities.

- **Indian Health Service (IHS).** Indian Health Service is committed to raising the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. Achieving this mission requires a robust electronic health record that is capable of supporting population health data sets. Currently, IHS provides comprehensive health services delivery system for American Indians and Alaska Natives. IHS health services include hospital and ambulatory medical care, preventive and rehabilitative services, and development of community sanitation facilities provided directly and through tribally contracted and operated health programs across the United States. This integrated delivery system provides appropriate data elements to our Electronic Health record, facilitating our ability to track population health measures.
- **National Institutes of Health (NIH).** NIH supports and engages in interdisciplinary biomedical research integrating basic research, clinical and translational research, behavioral and social sciences research, and population health research. Analyses are conducted at multiple levels that link population health dynamics to behavioral, psychosocial and environmental factors. For example, NIH supports investigations into how social relationships or environmental exposures influence gene expression and other

physiological systems in individuals and populations help inform decisions on living conditions, health practices, and behaviors that lead to healthier lifestyles and improved disease resistance. Many NIH Institutes and Centers support population health research. For example, NCI conducts and supports basic, clinical, and population research to understand the causes and mechanisms of cancer, accelerate cancer prevention, improve early detection and diagnosis, develop effective and efficient treatments, understand cancer outcomes, improve the quality of cancer care, improve the quality of life for cancer patients, survivors, and their families, overcome cancer health disparities, and measure and report on progress

- **Department of Defense (DoD).** The Department of Defense is responsible for the health of over 9.2 million beneficiaries around the world. TRICARE is the military health plan and includes members of all ages and diverse cultural backgrounds. The military health system is a health care payer and provider. The military health system contributes to basic medical research, clinical trials, and the provision of preventative services based on demographics and environmental factors through individual and group health surveillance. AHLTA, the military's EMR, provides codified data of health status beyond traditional claims and ancillary services (pharmacy, laboratory, radiology) to include individual signs and symptoms of illness (medical history, physical examination, management plan, and patient self-reported health and functional status). This provides a robust starting set of electronic data for population health improvement. However, to fully understand the health of our beneficiaries, population health information from care and assessments provided in the private sector for TRICARE beneficiaries is required. Adding Population Health as a Priority Area is expected to begin making data available from private sector for managing disparities in health and improving the quality years of life of DoD's beneficiaries.
- **United States Environmental protection Agency (USEPA).** USEPA does not in the course of business collect, store nor manage patient health data. However, USEPA increasingly relies on access to exposure and human health disease outcomes data to apply the best possible evidence and outcomes-based science to its business, protection of human health and environment through rulemaking and policy. USEPA has increased its focus on tracking disease trends and changes in public health status related to environmental decision making at the community, state and national level through the development of the Draft Report on the Environment www.epa.gov/indicators This and subsequent reports contain environment and health indicators that make it vital for the Agency to obtain and track a wide range of health tracking and clinical data. Longstanding activities in this area also include the work of the Health and Human Studies Divisions HSD. HSD is one of nine divisions within USEPA's National Health and Environmental Effects Research Laboratory within the Office of Research and Development. HSD with four other divisions, are focused on addressing key questions affecting the assessment of human health effects from exposure to environmental pollutants. Within this context, HSD is responsible for accessing and providing new research results, advice, and leadership by advancing human-based, scientifically-sound research approaches for understanding the exposure, deposition, and biological impacts of pollutants in exposed people.

- **Substance Abuse and Mental Health Services Administration (SAMHSA).** People with behavioral health risks or problems may not recognize them or may not seek help due to social stigma or more tangible negative consequences of disclosure to others. Substance use and mental health problems commonly co-occur with each other and with medical problems. SAMHSA is the primary Federal agency for improving access to behavioral health prevention and treatment services for the uninsured. SAMHSA mainly supports States that in turn operate or fund delivery of prevention and treatment services. To obtain population information, SAMHSA conducts a major population survey (the National Survey on Drug Use and Health), a major survey of hospital emergency departments (the Drug Abuse Warning Network), and collects basic performance data from publicly funded substance abuse treatment facilities (National Outcomes Measures). With SAMHSA's assistance, leading State behavioral health agencies have been able to develop and host electronic health record systems. Currently, these State EHR systems integrate behavioral health treatment with social and criminal justice services, but not with primary healthcare. Identifying Population Health as a Priority Area will enable an examination of integration of behavioral health with primary care EHR systems for the purpose of electronic population health management (such as improving prevention, treatment, and the quality of services needed by these vulnerable populations).
- **Office of the Assistant Secretary for Planning and Evaluation (ASPE).** ASPE uses population health data to support numerous analyses related to the health and welfare of U.S. citizens and other residents. For example, ASPE has used disability and other information from national surveys and the decennial census to study how disability prevalence varies across the US, and to identify trends related to disability and the health and long-term care utilization of Americans. This information is used by policy makers to consider projected health service capacity and costs. ASPE has also analyzed the National Health Interview Survey data which links population health information related to specific medical conditions (e.g., diabetes, heart disease, musculo-skeletal impairments) with health insurance coverage information to make comparisons of the health and functional status of persons with these conditions stratified by those with and without health insurance coverage. ASPE has also supported data collection through surveys of specific populations such as persons with disabilities, elderly Americans needing long-term care and their caregivers, and persons living in assisted living and other residential care facilities. ASPE has relied on data from these surveys to measure disability trends among Americans age 65 and older, changes in patterns of formal/informal services use and use of assistive devices, caregiver health, stress, and burden, and to estimate the future use of paid long-term care. To understand important determinants of the availability of informal care and ability to pay for formal services, such analyses require data regarding the health and functional status of the population be linked with data related to income, marital status, living arrangement (alone/with others), and home ownership. Advancing Population Health as a Priority Area will permit an examination of whether and how the of data needed to support these types of analyses are being used to support electronic population health management activities.

- **Centers for Disease Control and Prevention (CDC).** CDC’s mission is to promote health and quality of life by preventing and controlling disease, injury and disability. As the sentinel for the health of people in the United States and throughout the world, CDC strives to protect people’s health and safety, provide reliable health information and improve health through strong partnerships. The CDC component organizations compile statistical information to guide actions and policies to improve the health of the population and conduct population health research to create and disseminate knowledge and innovations people need to protect their health now and in the future. There are many important synergies between clinical information and population health information that will be further explicated and advanced by including Population Health Priority Area. As noted in a 2001 issue of the Journal of the American Medical Informatics Association, “Public health and clinical medicine – prevention and treatment – must come together along an interactive, integrated continuum, rather than operating in isolated silos of public health professionals, doctors, hospitals, HMO’s and insurers.”
- **Agency for Healthcare Research and Quality (AHRQ).** AHRQ is responsible for tracking the quality of healthcare and prevailing disparities in the United States. AHRQ develops quality measures based on consumer input (e.g., CAHPS), administrative data (e.g., HCUP), and emerging clinical data systems. AHRQ also sponsors demonstrations examining the effect of health IT applications, including EHRs, electronic prescribing, and health information exchange on quality and population health outcomes. Including Population Health as a Priority focus will support AHRQ in its mission.
- **Health Resources and Services Administration (HRSA).** HRSA is the primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable. HRSA’s programs are a key component of America’s health care safety net. Major programs include the health center program, maternal and child health, the Ryan White CARE Act for persons with HIV/AIDS, and programs to improve rural health care and to provide health profession education. HRSA’s grantees are making numerous investments in HIT including electronic health records (EHRs), patient registries, and electronic prescribing. Some of these grantees have made a great deal of progress in using HIT to improve service delivery, and to measure and improve quality of care and patient outcomes. For example, HRSA funded six health center controlled network grantees to invest in EHRs and these grantees have used HIT and the principles of HRSA’s Health Care Disparities Collaboratives Care Model to manage chronic conditions. Some HRSA grantees have used HIT tools to analyze electronic patient data to identify issues with specific populations, (such as persons with chronic illnesses such as asthma and diabetes as well as HIV/AIDs). HRSA grantees have used the results of these analyses along with other HIT tools such as clinical decision support patient reminders to improve care. The population health management tools used by HRSA grantees could be enhanced through a focus on Population Health as a Priority Area.
- **Centers for Medicare and Medicaid Services (CMS).** CMS is the nation’s largest public health service, engaged in paying for and regulating the care provided to over 90

million Americans, including diverse and often chronically ill populations. CMS uses or plans to use population health data for a wide variety of purposes, including risk adjustments, development of appropriate standards of care and the development of quality improvement measurements. CMS' Quality and Value Based Purchasing initiatives are predicated on the reporting of much of the same population information required by other public health organizations. Operationally, initiatives such as the Medicare Health Support Programs rely on the use of Medicare data to identify patients and populations with certain health conditions. CMS is also involved in developing public health databases for chronic care under the provisions of Section 723 of the Medicare Modernization Act of 2003.

As a major manager and provider of data that will be useful for many population health management activities, CMS is vitally concerned with standards for data security and dissemination.

Description of Current, Intermediate, and Desired End States for Consumer Empowerment

	Current (2006)	Mid-State (2009-2012)	End State (2014-2020)
<p>Brief Description</p>	<p>A personal health record (PHR) is a paper-based or computer-based tool that captures personal health information.</p> <p>Information can be entered manually by the patient, or can be captured electronically. Depending on who is sponsoring or operating the PHR, the data could be populated by a provider organization, health plan/employer group, or pharmacy.</p> <p>The business models and architectures vary widely, from standalone to tethered to a provider, health plan, or employer group. Few are interconnected with more than one primary source of data. Some good functionality already exists, with much innovation occurring.</p> <p>While consumers say they value specific services that PHRs can provide, consumer PHR awareness and engagement today is fairly low. Current interest in PHRs is found largely among providers, employers, health plans and software vendors.</p>	<p>Consumer awareness and engagement has increased through demonstration of the value of PHRs. Multiple business models have emerged and many products are on the market.</p> <p>Industry standards exist for core functionality of PHRs, as well as for security, interoperability, portability, and authentication. Some PHRs provide portability of data and decision support tools for consumers. Uniform authentication methods exist to permit consumers to access both PHR applications and network data sources with minimal burden or complexity.</p> <p>Policy standards exist to provide confidence in appropriate handling of personal health information by all PHR offerors, with robust privacy protections for patient data.</p> <p>CCHIT certification criteria for ambulatory EHRs include a requirement that they provide data exchange capability with PHRs in compliance with current interoperability standards.</p> <p>PHRs are available that have the capability to import numerous data streams depending on user needs in compliance with current interoperability standards; these data streams include</p>	<p>A personal health record system is a tool that facilitates the creation of a personalized experience promoting health and wellness and supporting health care of an individual. It provides, in a convenient, easy-to-use format:</p> <ol style="list-style-type: none"> 1. A comprehensive, longitudinal, accurate, privacy-protected, multi-sourced record about an individual's health; 2. Timely, reliable and contextually sensitive information and educational programs from trusted sources that help individuals and their caregivers understand and act on personal health information and health advice; 3. Tools to communicate with authorized stakeholders in the individual's health; and 4. Decision support tools through which an individual can understand the risks and benefits of various pathways of action, and improve the effectiveness of interactions with healthcare providers. <p>The adoption of PHRs is part of a much larger transformation process that includes</p> <ul style="list-style-type: none"> • widespread adoption of EHRs; • a common data set and terminology that is shared among EHRs and PHRs; • a move from procedure- and disease-

Consumer Empowerment

	Current (2006)	Mid-State (2009-2012)	End State (2014-2020)
		<p>claims, pharmacy data, lab results, progress notes, images, and patient reports.</p> <p>A number of incentive programs and policies are now in place to support the adoption of PHRs – through federal, state, employer, and payer-based initiatives.</p>	<p>based healthcare to outcomes and wellness-based healthcare;</p> <ul style="list-style-type: none"> • increased interaction between patients and their health care team, which may include patient advocates or coaches that facilitate coordination of care; • increased health and IT literacy for consumers; • and the establishment of a nationwide health information network wherein many stakeholders can share clinical information to improve individual patient and population health.
Components required to support the vision	<ul style="list-style-type: none"> • A number of early efforts with varying business models and functionality. • Little connectivity with data sources. Little to no portability. Payers are now experimenting with standards-based payer-to-payer PHR portability. • Some standards for interoperability and demonstrations of the capability, but limited use in the marketplace. No functional standards or certification process, though this work is now in progress. 	<ul style="list-style-type: none"> • Establishment of a methodology for the introduction of scalable, incremental improvements in functionality and breadth of interoperability. • Establishment of a common methodology and network for health information exchange. • Robust privacy protections for patient data. 	<ul style="list-style-type: none"> • A nationwide network that facilitates sharing of personal health data to authorized individuals and entities, under the control of the patient. • The data have attributes such as data source, including patient-entered data, and an indicator of whether the information has been modified. • Enforceable uniform privacy protections that transcend local and state boundaries and that pertain to any entity or persons with access to identifiable health data. • Robust, standard security mechanisms (including data access and data integrity controls) throughout the nationwide network • Strong user authentication and authorization controls • Technical interoperability standards (among PHRs and EHRs) that permit seamless exchange of patient data

Consumer Empowerment

	Current (2006)	Mid-State (2009-2012)	End State (2014-2020)
			while preserving meaning, and methodologies that enable portability of data <ul style="list-style-type: none"> • The standards, information exchange infrastructure, and policies enabling PHRs support a wide range of PHR implementations, allowing for growth and innovation in technology and medicine. • Standard terminology codes shared among PHRs and EHRs
Defining Characteristics or Attributes of Health Care System from the Patient Perspective			
Interaction with the health care system	Minimal adoption and awareness among consumers and providers. PHRs facilitate information sharing and communication with a small percentage of integrated delivery systems.	Adoption increasingly common, though the full value of PHRs is available to few.	Viable PHR options exist for nearly all patient populations. A strong, competitive marketplace has emerged. PHRs provide a convenient and reliable means of sharing personal health information between consumers and members of the health care system.
Level/type of consumer engagement in their health or health care	Consumers with PHRs integrated with provider EHRs finding value and engagement; but, percent of population with access to such integrated PHRs very small. Most PHR portals do not provide good tools for engagement: the user has little control, few opportunities to input self-reported data or share data with	Disease management tools using PHRs shown to improve health outcomes and reduce costs.	<ul style="list-style-type: none"> • Majority of consumers have access to interoperable PHRs with comprehensive tools that engage patients in self-management and is complimentary to disease management or care management models.

Consumer Empowerment

	Current (2006)	Mid-State (2009-2012)	End State (2014-2020)
	clinicians.		
Level/type of consumer control of their health information	<p>Patients have rights to access their personal health information, but there are practical and functional barriers to patients accessing their data – especially in electronic form.</p>	<p>Standards and systems for exchanging authorizations have been defined. Common systems for individual authentication are recognized by most data sources and applications.</p> <p>Diverse information exchange models are emerging (consumer to consumer, patient to patient, patient to provider, provider to provider, patient to third party).</p>	<ul style="list-style-type: none"> • Patients have access to their health information in electronic form and receive copies of their personal health information for inclusion in their PHR as a matter of course. Patients’ rights to receive copies of their personal health information under HIPAA are more explicitly defined to include their right to receive their information in electronic format upon request. • Patients have control of the information in their PHR: how it is shared and with whom. This implies that sufficient methods exist for authenticating users, including providers, patients and caregivers. The information that is shared is sourced and tagged to indicate whether it has been altered. • Patients can transfer the information contained within their PHR to another PHR easily and seamlessly without losing data. PHRs can be populated from multiple data sources and portability of core PHR data is standard. • Patients can choose to share their information with third parties (clinical researchers, etc.) at various levels (de-identified, fully identified, aggregated, etc.) in a manner that allows them to maintain control of their data sharing preferences while contributing to the expansion of our

Consumer Empowerment

	Current (2006)	Mid-State (2009-2012)	End State (2014-2020)
			<p>knowledge of wellness and disease.</p> <ul style="list-style-type: none"> • Patients can chose how their information is stored – fully within a PHR, a PHR with functional pointers to data existing within various provider settings, etc.
Implications for Key Stakeholders: roles or issues			<p>Multiple stakeholders can benefit from the existence a common mechanism for querying patient-controlled personal health information in a manner that supports the PHR infrastructure, respects patient privacy, and promotes innovation and patient safety.</p>
Consumers		<p>Consumers are aware that some health services are available across networks. Uniform privacy protection must be in place.</p>	<p>Consumers have no problem finding a suitable PHR and adoption is strong, although not universal. Consumers are finding many benefits from PHRs that integrate more fully with their daily lives. Consumers have control over how their personal health information is used and disclosed.</p>
Providers	<p>Providers don't have strong justification for putting in the necessary infrastructure and workflow changes necessary to interact with PHRs.</p>	<p>Incentive opportunities now exist for providers who encourage PHR adoption by their patients and who actively interact with PHRs.</p>	<p>Healthcare providers (especially primary care physicians) are key partners in realizing widespread adoption of PHRs. This implies that incentives are properly aligned so that providers find value in encouraging PHR adoption among their patients.</p>
Purchasers (Employers, Payers)	<p>Payers are beginning to plan the necessary infrastructure for payer-to-payer exchange of claims-based PHR data.</p>		<p>Inclusion of mechanisms for eligibility verification as a part of PHR functionality streamlines this process for payers, providers and patients and gives patients a clearer window into the financial aspects of their healthcare. Eligibility inquiries continue to rely on transactions between providers and</p>

Consumer Empowerment

	Current (2006)	Mid-State (2009-2012)	End State (2014-2020)
			health plans. Consumers can access health care financial information from their PHR.
Policymakers	There are fundamental requirements for PHRs that are absolutely required and are not fully established – especially privacy protection, authentication for data sharing, access controls, and portability. These must be a priority in order for PHRs to realize more widespread adoption and functionality.	Policymakers will need to be aware of populations and communities that could be left behind as these advances overlook the underserved and the socio-economically disadvantaged. Policymakers will need to place a priority on these communities in their demonstration projects and grantmaking efforts. Policymakers should define a system for promulgating and enforcing policy standards that establish trust across networks.	The PHR development process will move from start-up mode to one of continuous improvement. Policies, standards, and regulations affecting PHRs will need to be facile enough not to hinder future progress and will need to be thoughtfully coordinated with advances in other parts of the HIT infrastructure.
Enablers and Barriers	<p>Enablers:</p> <ol style="list-style-type: none"> 1. Viable business model when employers or providers pay (although sponsored model might restrict interoperability and some functions that are not to the advantage of the sponsor) 2. Some special subpopulations are early adopters 3. Leadership with federal employees or federal health care providers 4. Some early efforts to provide pre-populated data from claims data, etc. 5. Early scholarship provides insights regarding the potential benefits of PHRs and pathways to widespread adoption. 6. Growing public and political demand 7. Legislative and federal action 8. Technological advances and 	<p>Enablers:</p> <ol style="list-style-type: none"> 1. Institutionalized (and self-sustaining) public-private collaboration processes for prioritization, coordination and sequencing of HIT efforts, standards harmonization and HIT system certification 2. Institutionalized PHR adoption facilitation through federal procurement processes and other government mediated programs, including Medicare; rollout is coupled with adequate training and incentives for providers 3. Demonstrations and case studies that clearly show the value of interoperable PHRs for various stakeholders and models for aligning incentives 4. Adoption of policies that protect 	<p>Enablers:</p> <ol style="list-style-type: none"> 1. Public education from trusted sources 2. Comprehensive incentives for supporting PHR adoption and utilization and for providing care online 3. Support for special subpopulations 4. Pre-population of PHRs with clinical data 5. Interoperability 6. Portability 7. Privacy protection 8. Embedding of informatics as a core competency in all health profession disciplines and at all levels of training and continuing education. 9. Establishment of formalized methods for remedying data discrepancies between EHRs and PHRs.

Consumer Empowerment

Current (2006)	Mid-State (2009-2012)	End State (2014-2020)
<p>increasing market maturity</p> <p>Barriers:</p> <ol style="list-style-type: none"> 1. Lack of public education from trusted sources 2. Lack of comprehensive incentives for PHR support, adoption and utilization or for online care. Lack of incentives for information sharing by PHR sponsors. 3. Lack of support for special subpopulations, especially low-income, uninsured 4. Low availability of pre-populated data; lack of timely, low-cost access by patients to their own protected health information. 5. Minimal interoperability or portability 6. Concerns about privacy protection 7. Lack of PHR integration with current provider workflow; generally limited technical capabilities in the physician office. 8. Low health and/or IT literacy 9. Lack of trust by consumer in some sponsors and data stewards, in part due to security breaches and inadequate privacy policies 10. Divergence of needs from adoption rates 11. Premature adoption of standards and particular technologies that hinders market innovation 12. Provider fears of liability increases 	<p>patient privacy and access to protected health information as information exchange becomes more commonplace</p> <ol style="list-style-type: none"> 5. Establishment of messages by federal entities on PHR use for public consumption that are shared with other PHR-promoting stakeholders; Public educational campaign on the benefits and methods for accessing PHRs. 6. Greater adoption of EHRs and electronic prescribing systems among providers that results in ease of access to structured data for populating PHRs (increasing their value to patients and healthcare providers) and functionality 7. Establishment of policies and standards for supporting the linking of PHRs with clinical research (helping patients find clinical trials; patient-controlled use of PHR data for research purposes, etc.) 8. Development of standards for sharing consumer-focused educational information and decision support guidelines. 9. Establishment of policies or clarification of existing policies that enhance the ability of patients to receive copies of their Personal Health Information in standardized, structured electronic format for import into their PHRs. 10. Establishment of formal longitudinal 	<ol style="list-style-type: none"> 10. Establishment of robust record locator services that unambiguously connect patients to their protected health information. 11. Formalization of the role of the PHR facilitator as a valued health services provider (whether tied to a clinical care provider or not) who serves as consumer educator and advocate in managing personal health information and who empowers the patient to make fullest use of the PHR. <p>Barriers:</p> <ol style="list-style-type: none"> 1. Inefficient or rigid workflows impede the more rapid adoption of existing solutions. 2. “Last mile” considerations for rural and other underserved or limited-access communities

Consumer Empowerment

Current (2006)	Mid-State (2009-2012)	End State (2014-2020)	
	<p>tracking of PHR adoption, utilization, and interoperability.</p> <p>11. Establishment of certification for core PHR functions (including robust security and access control) that provides a floor of PHR capabilities while allowing the marketplace to continue to innovate and specialize beyond basic PHR functions.</p> <p>Barriers:</p> <p>1. Providers and staff maintain business practice – based largely on liability concerns rather than actual legal restrictions – that limit patients’ ability to receive their PHI in a useful format or in a timely fashion. Lack of adequate education on these issues and lack of case law perpetuates this challenge.</p> <p>Note: Some forces that could move the process in either direction include employer sponsorship, plan sponsorship, use of patient incentives.</p>		
Date Achieved (Earliest – Latest)	2006 (baseline)	2009-2012	2014 - 2020
Assumptions (e.g., adoption rates and level of interoperability by state of change)			<p>Strong adoption of EHRs and electronic prescribing systems among providers.</p> <p>Widespread availability of internet access among consumers.</p>

Notes: The workgroup placed greatest emphasis on the enablers and barriers for the Mid-term vision as these help to establish the areas of activity and priority the workgroup would like to see acted upon over the next four years.

October 24, 2006

DRAFT

DRAFT

Description of Current, Intermediate, and Desired End States for Public Health Surveillance

[Note: Content of cells to be brief text/bullets. Cells can be expanded as needed.]

	Current (2006)	Mid-State (2010)	End State (2014)
Brief Description	The information in this column is primarily derived from the Priority Matrix developed from the Biosurveillance Working Group combined with information from the scenario presented by John Lumpkin at the Sept 21 BSWG meeting.		An integrated and interconnected public health and health care delivery system that enables real-time, seamless, secure, and appropriate bi-directional exchange of information to meet the needs of public health and health care providers.
Overarching Characteristics of Public Health and Health Care System from the Public Health Perspective	Public health agencies are not interconnected and only a small proportion can receive electronic data from clinical care or public health partners. Real-time public health surveillance is in the proof of concept phase.	<ul style="list-style-type: none"> • A greater proportion of public health agencies at all levels are able to receive data from clinical care or intermediaries. • Early programs have demonstrated the value of real-time public health surveillance. • Data aggregation for population health purposes is piloted and proof of principle established which is changing the paradigm for public health surveillance. • Requirements are defined for integrating data across multiple disparate data sources to support data aggregation, data mining and signal detection for public health surveillance. This will enable detection of 	<ul style="list-style-type: none"> • Infrastructure and policies are in place to enable data aggregation on a regional and as necessary, national level to monitor population health trends, disease outbreaks, and medical product safety. • Interoperability and data sharing between public health and health care providers is enabled as needed by intermediaries with data sharing arrangements supported by a robust business case. • Local, state and federal public health agencies can communicate and share data seamlessly with clinical care and each other.

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
		<p>quality/patient safety issues (adverse events and medical errors), disease outbreaks, disease patterns, and program evaluation and research.</p> <ul style="list-style-type: none"> The business case for data aggregation, automated reporting, and bi-directional communication related to public health is defined and driving change and integration. 	
<p>Defining Characteristics or Attributes of Public Health and Health Care System from the Public Health Perspective</p>	<p><u>Case Reporting</u> – is done at the local, State and national level, is not generally timely and is often a manual process.</p> <ul style="list-style-type: none"> Notifiable disease lists vary in accordance with law in each State. Disease reports are different across States National Notifiable Disease conditions are shared at the national level. Case Reporting is predominantly a passive activity that waits on physicians to recognize and report a case¹. Electronic reporting systems and web-based systems do exist such as the National Electronic Disease Surveillance System 	<p><u>Case Reporting</u> – Develop architecture and standards for disease reporting and case messaging.</p> <ul style="list-style-type: none"> Standardize disease reporting by harmonizing definitions of reportable diseases across states and nation. Finalize standards for electronic reporting of notifiable diseases (message formats, data elements, data vocabularies, etc.) and approve standards by a recognized standards panel (e.g. HITSP) Harmonize and adopt public health standards for web-based electronic case reporting Integrate Pulsenet⁵ Extend Electronic Laboratory 	<p><u>Case Reporting</u> – Integrate with EHRs.</p> <ul style="list-style-type: none"> Decision support algorithms notify clinician that a case fits criteria for reporting to public health. EHR, in parallel, initiates report to local health department and sends abstract to State and CDC. <p><u>Case Investigation</u> –</p> <ul style="list-style-type: none"> Enable automated electronic requests for additional information, including laboratory test orders and results, essential to a public health case investigation and subsequent automated electronic exchange of that information.

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
	<p>(NEDSS) Base System, and state versions that support case reporting.</p> <ul style="list-style-type: none"> • Many registries² exist, but registry integration to EHRs is still early. 	<p>Reporting standards beyond testing for Nationally Notifiable Diseases.</p> <p><u>Case Investigation</u> –</p> <ul style="list-style-type: none"> • Enable remote, secure, electronic querying to enable authorized individuals to obtain additional information, including laboratory test orders and results, essential to a public health case investigation.³ 	
	<p><u>Bi-Directional Communications</u> – technologies exist to support bi-directional communications but basic infrastructure to support this in an automated fashion is still under development.</p> <ul style="list-style-type: none"> • Health Alert Network (e-mail safety alerts) • E-mails to professional organizations by relevant medical specialty • Automated drug recalls • FDA’s Structured Product Labeling (SPL) repository • Secure web-based communication and collaboration forums, such as Epi-X, are available. • Use of email or web based electronic methods to send 	<p><u>Bi-Directional Communications</u> – Establish protocols, directories and infrastructure for communication among health departments and clinical care.</p> <ul style="list-style-type: none"> • Establish directories of contact information have been established. • Standardize directory exchange and approved by a national standards body (e.g. HITSP) • Implement automated directory exchange to ensure contact information is kept up to date. • Link existing emergency medicine regional and state based systems into integrated standards-based national 	<p><u>Bi-Directional Communications</u> – Use to provide rapid, targeted communications.</p> <ul style="list-style-type: none"> • During an outbreak, guidelines and special warnings are disseminated to EHRs, clinicians, PHRs, and the general public. • During an outbreak investigation Laboratories are notified to expedite suspect case samples for testing. • Pertinent case reports are communicated to federal agencies that need to be involved in the investigation or response. • Updates to decision support algorithms based on public health case definitions are

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
	<p>alerts and or queries to clinicians that do not consistently employ EHRs.</p>	<p>network for real-time communication between emergency departments, pre-hospital EMS and public health (especially for exchange of situational awareness information).</p> <ul style="list-style-type: none"> • Develop a central web repository for grouping existing and new links between clinicians and public health. (Apply lessons learned from communication issues during the SARS and anthrax outbreaks. • Address Pandemic Influenza communication as prototype and as a priority. • Develop a central, authoritative web repository for documentation of standards, including standard vocabularies, message formats, lists of reportable diseases (by state?), case definitions including signs, symptoms, LOINC and SNOMED mappings. 	<p>disseminated to EHRs.</p> <ul style="list-style-type: none"> • Make reports available to clinicians that are based on information reported in real time, with capacity to channel info, feedback and questions from clinicians to public health. Report examples to include public health analysis, work flow, executive summary type and detailed reports.
	<p><u>Response</u> – this is a broad area that encompasses applications to support registries, pharmaceutical stockpile management, allocation and distribution of medical</p>	<p><u>Response</u> – Establish integration standards, work flows and application requirements.</p> <ul style="list-style-type: none"> • Determine workflows and standards to integrate medical 	<p><u>Response</u> – Implement applications and integration standards to provide on-going awareness of supply and demand of drug products, medical</p>

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
	<p>supplies and drug products, outbreak investigation, countermeasure administration and long-term follow-up.</p> <ul style="list-style-type: none"> • Vaccine supply and distribution system • Pharmaceutical stockpile management • Automated immunization registries • Protecting first responders • Long-term follow-up • Utilization /staffed hospital bed availability reporting • Outbreak investigation and exposure contact tracing • Countermeasure administration and tracking • Mass casualty management 	<p>supply with medical demand.</p> <ul style="list-style-type: none"> • Track prophylaxis status of responders (including volunteers?). • Determine interoperability and infrastructure requirements for emergency prophylaxis and treatment systems and implementation on NHIN. • Standardize data exchange for tracking of drug product distribution from manufacturer to distributor to clinician. • Develop integrated solutions that can be accessed by local, State and federal partners for medical surveillance, disease outbreak detection, or potential bioterrorism event. (Ensure active collaboration with CDC in their BioSense project). • Expand electronic Immunization Registries to cover adult immunization. • Integrate Vaccine Supply and Distribution management system with registries and countermeasure administration to plan for mass vaccination, e.g., if available for response to 	<p>personnel and hospital capacity (beds, ICU).</p> <ul style="list-style-type: none"> • Integrate EHRs with immunization registries. • Enable interoperability between commercial sector supply chain and resource demands • Implement hospital bed capacity and resource monitoring at a regional and national level. • Integrate response activities with on-going monitoring and outbreak investigation. • Ensure availability of granular data for each jurisdiction and analytic data for entire outbreak. • Implement isolation and quarantine tracking systems at a national level. • Implement solutions for tracking and triaging bodies following mass casualty events. <p><u>Outbreak Investigation</u> – Integrate with EHRs, Case Reporting and Communications.</p> <ul style="list-style-type: none"> • Incorporate case definitions and case criteria into decision support algorithms used by EHRs.

DRAFT

Current (2006)	Mid-State (2010)	End State (2014)
		<p>Pandemic Influenza (and possibly to intentional infectious outbreak).</p> <ul style="list-style-type: none"> • Design and implement early versions of systems addressing the AHIC emergency response use case utilizing a lightweight past medical history and patient tracking system. • Pilot isolation and quarantine tracking systems locally that are an integrated component of HIT. • Implement a National Electronic Death Certificate Registry. • Define requirements for tracking and triaging bodies following mass casualty events. • Define integration requirements and work flow with Emergency Responder EHRs. <p><u>Outbreak Investigation</u> –</p> <ul style="list-style-type: none"> • Enable remote, secure, electronic querying to enable authorized individuals to obtain additional information , including laboratory test orders and results, essential to a public health outbreak

- Enable automated electronic requests for additional information, including laboratory test orders and results, essential to a public health outbreak investigation and subsequent automated electronic exchange of that information.
- Integrate work flow and solutions with Emergency Response EHRs.

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
		investigation. ³ •	
	<p><u>Adverse Events</u> reporting is supported through a variety of avenues, though they are disparate:</p> <ul style="list-style-type: none"> • FDA Medwatch program - report adverse events related to medical products • Nosocomial infections - reported to Nosocomial Infection Surveillance System • Medication Errors - reported to USP Medication Errors Reporting Program • Medical Errors - reported to Patient Safety Organizations 	<p><u>Adverse Events</u> –</p> <ul style="list-style-type: none"> • Begin to implement automated reporting of adverse drug events from EHRs • Develop standards for Adverse Events Reporting • Consolidate existing Adverse Events systems to standardize reporting process. • Enable EHR's to query FDA's SPL (Structured Product Labeling - currently drug label information, future plans for vaccine and potentially all medical products) database to review drug interactions and allergy information to prevent adverse events. 	<p><u>Adverse Events</u> – Automate EHR prompting and filing of Adverse Event Reports for all medical products (inclusive of drugs)</p>
Implications for Key Stakeholders: roles or issues			
Consumers			
Public health (local, state,			

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
and federal agencies)			
Providers			
Policymakers			
Enablers	<ul style="list-style-type: none"> • Some certification of State PH information technology solutions by CDC • Public health has started to identify its business processes and accreditation requirements. • Public Health Information Network – existing progress and momentum in definition of requirements and standards in this related domain. • Progress has been made to establish data/information sharing agreements with public health and the private sector and across public health jurisdictions: <ul style="list-style-type: none"> ○ Within states ○ Between states ○ With CDC ○ Between public health and the private sector • RHIOs that include PH at the table • Improved partnerships with hospitals resulting in benefits for both clinical care and 	<ul style="list-style-type: none"> • Ensure NHIN is available for use by all entities that need to exchange data/information ⁴. • Consider compatibility with pre-existing reporting systems. • Develop policy to require notifiable disease reporting based on standards. • Recommend that CCHIT (Certification Commission for Health IT) incorporate certification requirements for notifiable disease reporting capability, bi-directional communication and public health and decision support functionality. • Active involvement by public health IT in IT standards panels and certification bodies. • Define governance process for adding diseases to the national notifiable list (needs to work in the context of informatics component to document and communicate 	<ul style="list-style-type: none"> • Strong state legislation is in place to protect data collected by public health. • Secure infrastructure is in place to protect data during transport.

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
	<p>public health</p> <ul style="list-style-type: none">• Increased awareness by the public in HIT and how it benefits the consumer• Improved technology resulting in a lower price point. As the market matures it will benefit public health.	<p>reporting requirements to our many partners).</p> <ul style="list-style-type: none">• Develop policy to mandate Adverse Events reporting• Create national standards for EHR to be used by all providers.• Consider lower cost alternatives such as how to capture valid information for ambulatory care/outpatients from third party payer/insurer source, e.g., mandatory reporting; standard definition for high priority data elements.• Design and implement early versions of systems addressing the AHIC emergency response use case utilizing a lightweight past medical history and patient tracking system to realize a relatively low cost solution.• Develop robust certification for PH systems and ensure it is inclusive of local public health.• Accreditation of intermediaries that have to serve PH in order to get accredited.	

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
Barriers	<ul style="list-style-type: none"> • Lack of clearly defined business case that articulates benefits and supports requirements that can differ across stakeholders • How to provide incentives adoption • Addressing questions over protection of privacy - educating the public • Funding to support the cost of implementation • Extremely low rate of adoption of technology and tools by providers and public health • Funding to support the cost of implementation. • Workforce development 	<ul style="list-style-type: none"> • Clear attention to privacy and confidentially concerns including clearly established legally identified rights to see personal identifiable data. • Provide education on strategy for protection of privacy • Develop policy to clarify mandatory versus voluntary reporting requirements in an electronic environment. • Underreporting of Adverse Events. • How to include indigent care population in surveillance, tracking, and response? • Incorporating and integrating legacy systems into HIT solutions • Developing solutions that support daily activities but are scalable to support episodic nature of public health. • Consistency and uneven quality of data collected across multiple organizations • Relatively low rate of adoption of technology and tools by providers and public health • Concerns with responding to too many signals that lack adequate specificity (enablers) 	<ul style="list-style-type: none"> • Broad establishment of data/information sharing agreements with public health and the private sector and across public health jurisdictions: <ul style="list-style-type: none"> ○ Within states ○ Between states ○ With CDC ○ Between public health and the private sector

DRAFT

	Current (2006)	Mid-State (2010)	End State (2014)
		<p>are intelligent systems, adequate work force and competency development, also use of intermediaries)</p> <ul style="list-style-type: none"> • Conflicting requirements moving vertically versus horizontally (Horizontal is sharing data between different providers and agency within a community. Vertically is sharing data at the regional, state or national level) • Inadequate priority and authority given to public health information systems • Developing solutions in recognition that health issues don't usually follow jurisdictional boundaries 	
<p>Date Achieved (Earliest – Latest)</p>			
<p>Assumptions (e.g., adoption rates and level of interoperability by state of change)</p>		<p>Infrastructure will be in place to support connectivity among public health organizations and between public health and clinical care. This includes high speed internet connectivity.</p>	

DRAFT

DRAFT

Notes and examples -

1. Case Reporting – For example: SARS case reporting application, NEDSS Base System, State implementations of case reporting
2. Registries - Refers to Public health and Clinical Registries. For example: immunization, blood and organ, birth and death, volunteer health responder, 9/11 first responder registry, injury, drug and substance abuse, asthma, cancer, diabetes, other clinical registries, other chronic disease registries
3. Examples are the Investigative Monitoring Capability in use in certain hospitals in NC who voluntarily have such system installed to facilitate public health investigations; also, ASTHO has a project across all 50 states to support query-back capability.
4. Examples include: all entities required to report adverse events (including manufacturers); intermediaries; service providers; federal agencies that participate in public health.
5. PulseNet - is a national network of public health and food regulatory agency laboratories coordinated by the Centers for Disease Control and Prevention (CDC) and consisting of: state health departments, local health departments, and federal agencies (CDC, USDA/FSIS, FDA). PulseNet participants perform standardized molecular subtyping (or “DNA fingerprinting”) of foodborne disease-causing bacteria by pulsed-field gel electrophoresis (PFGE).