Towards a Functional Standard on Electronic Data Exchange between Clinical Care and Public Health

Final Report

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Submitted by:
Anna Orlova, PhD
Principal Investigator
Executive Director
Public Health Data Standards Consortium
624 N. Broadway Room 382
Baltimore MD 21205

Submitted to:
Jessica Townsend
Project Officer
Public Health Analyst
Health Resources and Services Administration
5600 Fishers Lane, Room 10-49
Rockville MD 20857

Baltimore, Maryland
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CONTRIBUTING ORGANIZATIONS

Public Health Data Standards Consortium (PHDSC, Consortium)
PHDSC was responsible for the overall conduct of this project including the preparation of this report. Dr. Anna O. Orlova, PHDSC Executive Director and Visiting Associate Professor, Johns Hopkins School of Medicine, was a Principal Investigator of the project. The report has been reviewed by members of the Consortium.

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EXECUTIVE SUMMARY

With the growing availability of clinical data in Electronic Health Record Systems (EHRS), public health programs stand at the threshold of change in the way in which they gather the data needed to carry out the essential services that make up their mission. Historically, public health has had to rely on physicians and other providers to submit data by filling out and sending in forms. The time and effort required to do this has limited the amount of data that could be demanded. The advent of electronically available data has the potential to change the ways in which public health relates to the clinical world. Extraction from EHRS of a wide and more accurate array of patient data promises to fuel activities that have been difficult or impossible for public health agencies to carry out. In the future, traditional disease reporting can be broadened. Health promotion and disease prevention initiatives can be built on and evaluated using up-to-date patient data aggregated at the community level. For the first time, public health will be able to have a sufficient data base that enables the assurance function by identifying gaps in care and linking people to the services they need. As an extension of this function, public health agencies run many programs that make care available to underserved populations (e.g. programs for mothers and children, homeless people and people with HIV). Detailed patient information from EHRS can improve the effectiveness and efficiency of such programs.

Traditionally, the focus has been on the movement of information from clinical settings to public health agencies. Clinicians have received very little information back from public health agencies in exchange for their reporting effort. In the future, bi-directional EHRS-based data exchanges between public health practitioners and clinicians have the potential to transmit to clinicians individual and community level information that can, for example, inform clinical decision support, improve care coordination and strengthen response capabilities to a public health threat. The same information will help the clinical community move toward a long embraced goal—that of Community Oriented Primary Care which asks providers to treat their patients in the context of an epidemiological understanding of their community. In the new era of electronic data exchange, a community’s health problems can be addressed by marrying the strengths of population interventions with individual treatment.

To discover what this new world might look like on the ground, the Health Resources and Services Administration (HRSA) commissioned the Public Health Data Standards Consortium (PHDSC) to study data exchanges among the New York City (NYC) Department of Health and Mental Hygiene (DHMH) School health Program, NYC Syndromic Surveillance Program and a Community Health Center with an EHRS in NYC. For each program, the study documented the work processes (workflows) of clinicians and public health staff and the data flows from the EHRS needed to support this work via the requirement elicitation process in the format of the functional requirements analysis document (FRAD) – a structured document that can guide programmers in developing EHR products with public health reporting/data exchange capabilities. The study was designed to provide the foundation for the move beyond a description of one agency’s workflow in a particular domain/program to a systematic way of documenting workflows and data to be exchanged between clinical and public health settings. This is essential to assure that clinical and public health systems are interoperable and that data can be transmitted and exchanged not only between one clinical setting and one public health agency’s program, but that the process can be also be replicated elsewhere. The FRAD was
proposed to be viewed as a prototype of the functional standard. To date, there is no consensus on the format, content, and approach for how to specify these standards.

The goal of the current project was to validate the FRADs for School Health and Syndromic Surveillance programs developed in the NYC study. The validation was conducted by an ad hoc Panel of experts – national leaders in health information exchanges from public health & clinical communities and standard development organizations (SDOs). The Panel meeting of over 30 participants was held on December 5-6, 2006 in Washington, DC.

In order to validate the usefulness, feasibility, and generalizability of NYC study outcomes, the panelists addressed a series of questions. One primary question was whether the workflows/data flows described by NYC represented current or future activities with electronic data exchanges envisioned by public health. Panelists agreed that in general, NYC is ahead of many jurisdictions but that similar data exchanges are in early developmental stages or are being contemplated in other places. Panelists also noted that as these data exchanges move to implementation, it will be important to continue the work started in the NYC study—namely documenting workflows and the data flows that support them using the functional requirements elicitation framework and the FRAD format.

The Panel made recommendations for specific activities designed to advance the development of a consensus around the need for a functional standard. Panelists also emphasized the importance of bi-directional electronic information exchanges between clinicians and public health practitioners. The Panel recommendations can be summarized as follows:

1. Use the NYC FRAD specifications as working documents towards the development of the functional standard document;
2. Expand the NYC specifications by describing other public health domains/programs in the FRAD format to facilitate the development of the software applications in the EHR systems to transmit/report/exchange data across clinical and public health information systems;
3. Form public and private partnerships with clinical and vendor communities to develop interoperable clinical-public health information systems; and
4. Educate public health and clinical communities about their roles in the development of the functional standards and overall standards development and harmonization processes.

Information about the project and the Panel meeting presentations were posted at the PHDSC Web-site. The Panel findings were presented at the Spring Congress of the American Medical Informatics Association on May 24, 2007, Orlando, Florida.

This report presents an overview of the Panel meeting discussions and recommendations followed by a section that describes the proposed further steps towards achieving interoperability of clinical and public health information systems. Further steps include (1) an integration of the Business Process Analysis methodology into the selection of national Use Cases for health information exchanges and (2) the use of the FRAD approach in refining the national Use Case interoperability specifications to address local, state and regional needs of health information exchanges.
TOWARDS A FUNCTIONAL STANDARD ON ELECTRONIC DATA EXCHANGE BETWEEN CLINICAL CARE AND PUBLIC HEALTH

BACKGROUND

The missions of public health are to protect the public from health threatening diseases and assure disease prevention by providing access to care and promoting wellness. In order to fulfill these population-based and patient-centric missions of public health, health care providers and public health agencies need to be capable of exchanging pertinent health information about individuals and communities they serve.

With the growing availability of clinical data in Electronic Health Record Systems (EHRS), public health programs stand at the threshold of change in the way in which they gather the data needed to carry out the essential services that make up their mission. Historically, public health has had to rely on physicians and other providers to submit data by filling out and sending in forms. The time and effort required to do this has limited the amount of data that could be demanded.

The advent of electronically available data has the potential to change the ways in which public health relates to the clinical world. Extraction from EHRS of a wide and more accurate array of patient data promises to fuel activities that have been difficult or impossible for public health agencies to carry out. Traditional disease reporting can be broadened in the future. Health promotion and disease prevention initiatives can be built on and evaluated using up-to-date patient data aggregated at the community level. For the first time, public health will be able to have a sufficient data base that enables the assurance function by identifying gaps in care and linking people to the services they need. As an extension of this function, public health agencies run many programs that make care available to underserved populations (e.g. programs for mothers and children, homeless people and people with HIV). Detailed patient information from EHRS can improve the effectiveness and efficiency of such programs.

Traditionally, the focus has been on the movement of information from clinical settings to public health agencies. Clinicians have received very little information back from public health agencies in exchange for their reporting effort. In the future, bi-directional EHRS-based data exchanges between public health practitioners and clinicians have the potential to transmit to clinicians individual and community level information that can, for example, inform clinical decision support, improve care coordination and strengthen response capabilities to a public health threat. The same information will help the clinical community move toward a long embraced goal—that of Community Oriented Primary Care which asks providers to treat their patients in the context of an epidemiological understanding of their community. In the new era of electronic data exchange, a community’s health problems can be addressed by marrying the strengths of population interventions with individual treatment.
VALIDATING THE NEW YORK CITY CASE

To discover what this new world might look like on the ground, with support from HRSA, the PHDSC developed a prototype for the functional standard for the Electronic Health Record – Public Health (EHR-PH) electronic data exchange - *a Functional Requirements Specification Document* – for two public health programs in the New York City Department of Health and Mental Hygiene: School Health and Syndromic Surveillance. [1] The study documented the work processes of clinicians and public health staff – tasks and workflows – and the data flows from the EHRS needed to support this work. The domain-specific information for the specification was obtained through a requirements elicitation process, i.e., interviews with clinical and public health staff on their work processes and data-generating activities. The specification was developed in the format of the Functional Requirement Analysis Document (FRAD) [2] that represents user perspectives (clinical and public health staff) for electronic communications based on the EHR system installed in a clinical setting – a Community Health Center.

The study was designed to provide the foundation for moving beyond a description of one agency’s workflow in a particular domain/program to a systematic way of documenting workflows and data to be exchanged. The study produced two functional requirements analysis documents - FRADs - that described actual work processes of the NYC DOHMH program staff and clinicians that requires data exchange in a structured format of the requirement analysis document that can guide programmers in developing EHR products with public health reporting/data exchange capabilities.

Once it is understood what data needs to be exchanged there must be a standard format for the information exchange with detailed specifications, i.e., functional standard. This is essential to assure that systems are interoperable so that data can be transmitted and exchanged not only between one clinical setting and a public health agency, but also so that the process can be replicated elsewhere. The functional standard has been established as a separate category of interoperability standards by the national Health Information Technology Standards Panel (HITSP) [3] in February 2006. The functional standard will serve as a foundation for the implementation of all other standards. To date, there is no consensus on the format, content, and approach for how to specify these standards. The NYC FRAD was proposed to be viewed as prototype of the functional standard.

The goal of the current project was to validate the FRADs for NYC School Health and Syndromic Surveillance programs as prototypes of the functional standards. The validation was conducted by an ad hoc Panel of experts – national leaders in health information exchanges from public health & clinical communities and standards development organizations (SDOs). The Panel meeting with over 30 participants was held on December 5-6, 2006 in Washington DC.

In order to validate the usefulness, feasibility and generalizability of the NYC FRAD specifications, the panelists addressed a series of topics. The topics for discussion (see below) were developed prior to the meeting by the project team in consultation with the HRSA project staff. The first group of topics was designed to elicit panelists’ perceptions of current activities in their states and their forward thinking about public and clinical electronic data exchange. The second group of topics focused on the NYC study and whether the activities in New York reflect...
a realistic future vision. Furthermore, panelists were asked if the PHDSC analytic approach provides a way to promote a better understanding of what needs to happen to facilitate the development of the electronic public health/clinical data exchange. In summary, the overriding question was whether the workflows/data flows described by NYC FRADs represented current or future activities being envisioned by public health.

### Discussion Topics

**Roundtable Discussion 1 (Day 1). Building Public Health / Clinical Health Information Exchanges: The Experience to Date.**

1. Community e-Health Data Exchanges: Purpose/Value Proposition for Public Health and Clinical Providers in the Community
   - Role of the Health Department in Being a Resource for Providers
   - Engaging Providers in the Public Health Mission of Protecting the Public from Health Threats and Improving the Effectiveness of Primary Care
   - Examples of Emerging e-Health Exchanges and How They are Bringing Together Public Health and Providers
2. Key Implementation Activities, Choices, and Problems
3. Accomplishments and Lessons Learned

**Roundtable Discussion 2 (Day 2). Responses to the NYC Functional Requirements Specifications**

1. Does the NYC specifications framework adequately describe user needs in terms of system goal, actor, function, workflow and dataflow?
2. Does it include necessary elements needed to build the user requirements? What is missing?
3. Is it reusable for other public health domains/programs/jurisdictions?

The panelists discussed statewide and national activities around the Nationwide Health Information Network (NHIN) in order to determine how public health bi-directional information exchange with clinical systems fits into the broader efforts to establish healthcare systems interoperability.

Panelists also addressed the question of whether the PHDSC FRAD is a useful tool that can contribute to emerging processes to create necessary standards and electronic health record systems that deploy them. They discussed how the FRAD could be used to assure that the standardized data content will be available to support the workflow between public health and the clinical community.
Re-examining Public Health Information Management

Representatives of several states presented their current activities and future directions at the meeting. The picture they drew was one of organizing themselves to shape what data exchange might look like to serve the needs of that state. For example, the Minnesota (MN) e-Health includes the MN Public Health Information Network (MN-PHIN) as an integral part of the health information exchange to support both clinical and public health communities of practice. The use of shared (clinical and public health) data will help to better protect communities against health risks or threats, improve safety and quality of care and reduce costly inefficiencies within and across clinical and public health settings. [4] The MN Health Department aims to drive improvements in the community of practice through the use of informatics (Table 1).

Table 1. MN-PHIN Informatics Capabilities for Public Health / Clinical Community of Practice

<table>
<thead>
<tr>
<th>MN-PHIN Informatics Capabilities</th>
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<tbody>
<tr>
<td><strong>Business Level</strong></td>
</tr>
<tr>
<td>- Create strategic directions for information management within the agency and MN eHealth</td>
</tr>
<tr>
<td>- Assure effective management of information resources</td>
</tr>
<tr>
<td>- Communicate with policymakers, staff &amp; the public</td>
</tr>
<tr>
<td>- Evaluate and improve information management processes</td>
</tr>
<tr>
<td><strong>Functional Level</strong></td>
</tr>
<tr>
<td>- Evaluate and improve information technology adoption within the agency and MN eHealth</td>
</tr>
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</table>

The Colorado Community e-Health Data Exchange, funded by the Agency for Healthcare Research and Quality (AHRQ), is aimed to incorporate public health information systems into a shared health information resource for providers, payers and public health practitioners. They have identified innovative uses of aggregated population-level information that is found in public health information systems to inform clinical practice (clinicians) and business of medicine (payers) (Table 2). Colorado’s goal is to engage providers in the public health mission of protecting the public from health threats and improving the effectiveness of primary care. [5]

During the Day 1 roundtable discussion, participants agreed that to date the public health agencies efforts to built electronic data exchanges with clinical information systems were targeted to specific programs, e.g., immunization, communicable diseases, etc.. Participants also agreed that engaging primary care providers in the electronic data exchanges had been challenging and not done broadly because it requires significant workflow redesign for both clinicians and public health practitioners. To date, the emerging electronic data exchanges within healthcare organizations, e.g. Massachusetts, has had difficulties defining the business case to sustain the information exchanges within the healthcare system.
### Table 2. Colorado eHealth Information Exchange between Clinicians, Public Health and Payers

<table>
<thead>
<tr>
<th>Integrated Clinical &amp; Public Health Information Systems: Business Lines of Services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Point of care (for patient and/or provider)</strong></td>
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<tr>
<td>• Aggregation of clinical information across hospitals &amp; providers</td>
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<tr>
<td>- Immunization history (Colorado Immunization Information System)</td>
</tr>
<tr>
<td>- Individualized medication lists (Pharmacy Benefits Managers/Retailers)</td>
</tr>
<tr>
<td>- Allergies, laboratory, radiology, procedures, EKG</td>
</tr>
<tr>
<td>• Decision support for clinical guidelines</td>
</tr>
<tr>
<td><strong>Clinical messaging (from provider to provider)</strong></td>
</tr>
<tr>
<td>• Laboratory test orders/results exchange (to/from CDPHE, LabCorp, Quest)</td>
</tr>
<tr>
<td>• ePrescribing</td>
</tr>
<tr>
<td>• Case reporting, electronic laboratory reporting</td>
</tr>
<tr>
<td>• Ancillary/referral service results (e.g., radiology, consultant reports)</td>
</tr>
<tr>
<td><strong>Administrative (for provider and payer)</strong></td>
</tr>
<tr>
<td>• Claims submission</td>
</tr>
<tr>
<td>• Eligibility, credentialing</td>
</tr>
<tr>
<td><strong>Population/public health (for provider, payer and/or public health)</strong></td>
</tr>
<tr>
<td>• Analysis of quality, disparities, morbidity monitoring, pay for performance</td>
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<tr>
<td>• Registry development</td>
</tr>
<tr>
<td>• Registry support: immunization</td>
</tr>
<tr>
<td>• Bio-surveillance</td>
</tr>
<tr>
<td>• Community health assessments</td>
</tr>
</tbody>
</table>

Participants agreed that the adoption of health information technology (HIT) and interoperability standards across clinical and public health systems are the keys to improving healthcare and public health services & healthcare outcomes and fulfilling the public health mission of protecting the public’s health. Functional requirements and other standards are needed to move things along.

Participants also agreed that consumers are the key stakeholders in the HIT adoption efforts. Consumers should be involved to better understand their needs and improve the way of communication with them via the means of HIT.

*During the Day 2* roundtable discussion on the need for functional standards, participants agreed that the NYC functional specifications adequately described user needs in terms of system goals, actors, functions, workflow and dataflow. The suggested FRAD format includes the necessary elements of the user business rules needed to build user functional requirements specifications. This format can be recommended to be used to describe functional requirements for other public health domains/programs and jurisdictions. The participants also agreed that the requirement elicitation process used to develop the NYC specifications is a sound approach in developing functional specifications. Participants agreed that the NYC specifications for School Health and Syndromic Surveillance should be extended to include requirements for bi-directional communication between public health staff and clinicians to inform clinical decision support and coordination of public health response activities with healthcare providers.
Participants discussed what would be an appropriate term for the specification document, i.e., Functional Requirements Specification, Use Case Description, Functional Standard, or Functional Requirement Analysis Document (FRAD). They agreed that the functional requirements have not been standardized before and therefore there is no agreed upon definition on the format and content of the functional standard. All these types of documents are currently in use in the standard development industry. Participants agreed that there is the need to define the content, format and the development approach for all these types of documents in order to build a consensus on the format, content and developmental methodology for functional standards for the EHR-PH systems. Participants agreed to call the NYC specifications prototypes Functional Requirement Analysis Documents and to consider them to be working documents towards the development of the functional standard document.

Conclusions of the Panel Meeting Discussions
Participants identified the following next steps (roadmap) in developing the functional standards for the interoperable clinical and public health systems:

1. Work with public health (local & state public health agencies, HRSA, CDC), clinical communities, e.g., American Medical Association, American Academy of Pediatrics, American Association of Family Practice, and vendors associations, e.g., Integrating the Healthcare Enterprise (IHE) [6] to finalize the representation of the public health functional requirements for interoperable clinical-public health systems.
2. Expand the NYC specifications by describing other public health domains/programs in the FRAD format to inform the development of the IT applications in the EHR-based systems to transmit/report/exchange data across clinical and public health systems.
3. Facilitate a dialog between clinical and public health communities and vendors on the development of the functional standards for interoperability specifications for clinical-public health data exchanges via participation of public health representatives in the American Health Information Community (AHIC) [7], HITSP and Certification Committee for Health Information Technology (CCHIT) [8] and IHE.
4. Develop a Panel summary document on the Panel meeting outcomes for AHIC, National Committee on Vital and Health Statistics (NCVHS), DHHS Office of National Coordinator for Health IT (ONC), RWJF and broader public health and clinical communities.
5. Work with PHDSC member organizations to organize education sessions on functional requirements standards for information systems at their annual meetings, e.g., NACCHO, CDC Public Health Information Network (PHIN), RWJF grantees forums, etc.
6. Work with CDC and National Library of Medicine/RWJF public health informatics training programs to include functional specification development course in the public health informatics training curriculum.
Towards Interoperability of Clinical & Public Health Information Systems

To integrate the public health information systems into the emerging electronic health information exchanges, there is a need to re-examine the ways the information systems in public health have been built to date and to introduce the ‘disciplined’ informatics approach into the public health information systems design, i.e., to develop a common methodology of structured analysis of information needs at the individual user (stakeholder) level, the community of practice (enterprise) level and the agency level, that will guide the health information technology projects within the health information exchanges. Based upon the Panel discussions, we would like to propose a structured approach in developing interoperable electronic health information exchanges between clinical and public health information systems. The section that follows describes this proposed approach.

National Framework Context

Interoperability is defined as the ability of two or more systems or components to exchange information and to use the information that has been exchanged. [9, 10] Because both clinical and public health information systems have been developed in the past as stand-alone, “siload” systems, the lack of interoperability across these systems is the major barrier for health information exchanges across healthcare and public health information systems. The goals of a Nationwide Health Information Network to interconnect clinicians and streamline public health/population health surveillance systems [11] can be achieved only if clinical EHRS and public health systems (EHR-PH systems) will become interoperable.

Having begun to lay out the goals of a NHIN, the Department of Health and Human Services (DHHS) recognized the need to form a number of entities—each charged with working on a different aspect of the foundations of interoperability. The American Health Information Community (AHIC) serves as a public-private partnership to identify national Use Cases for EHRS-based health information exchanges; the Office of the National Coordinator for Health Information Technology (ONC) develops the Use Case documents and coordinates the overall standardization efforts; the Health Information Technology Standards Panel serves as a national Use Case Interoperability Specification development entity largely through its participative technical committees; and the Certification Commission for Healthcare Information Technology serves as a national EHRS certification entity.

Fig 1 presents a schematic view of the DHHS framework for achieving health information systems interoperability via the standardization of health information exchanges. This view is developed in a format of the Unified Modeling Language (UML) sequence diagram for a problem-solving process (problem identified→characterized→managed→evaluated/solved) [12] for the problem of non-interoperability.
The DHHS approach consists of the following steps:

Step 1 (Problem Identified) - Identify National Use Case to describe electronic information exchanges across information systems within healthcare enterprise;

Step 2 (Problem Characterized) - Develop Use Case Document to describe identified Use Cases using a common (standardized) template

Step 3 (Problem Managed) - Develop Use Case Interoperability Specification using common (standardized) specification template that identifies selected standards needed to support health information exchanges. This step includes interoperability specification testing by information technology vendors.

Step 4 (Problem Managed, continued) - Develop Certification Criteria for EHRS Use Case Interoperability Specification to assure that they support the implementation of standards specified by the specification in the EHRS products

Step 5 (Problem Evaluated) – Implement Use Cases by implementing certified products and established standards

During 2006-2007, HITSP developed interoperability specifications for the six national Use Cases as follows: Biosurveillance; Consumer Empowerment – Patient Registration and Medication History; and EHR-Lab Result Reporting [13]; EMS-First Responders; Quality; and Consumer Empowerment – Consumer Access to Clinical Information. Six new national Use Cases are currently under the development by ONC for 2008 (Remote Monitoring, Remote Consultation, Consultation and Transfer of Care, Immunizations & Response Management, Public Health Case Reporting, and Personalized Healthcare), and additional Use Cases are being considered for subsequent years.
The Use Case-based approach in achieving health information system interoperability has been faulted for its lack of a holistic view of the healthcare enterprise by focusing on individual Use Cases. The fear is that this may create systems that address specific, stand-alone problems as well. Furthermore, there is no mechanism that assures that the high level interoperability specifications developed by HITSP could be implemented by local and regional health information exchanges that may have specific data and information needs that have not been captured/addressed by the national level specifications.

**Building a Roadmap towards Health Information Systems Interoperability**

The proposed approach to overcoming the problems of stand-alone systems and lack of attention to local needs is two-fold. The first is to use the Business Process Analysis (BPA) [14] as the method for identifying/selecting Use Cases for improving information technology applications. Second is to add an additional validation step prior to the implementation of the interoperability specifications. This additional step is the elicitation of the functional requirements for the Use Case implementation across users at the local, state and regional levels. The outcome of this additional step is the development of the Functional Requirement Analysis Document(s) - FRAD - that will provide a more granular level of interoperability specification to address local/state/regional health information exchanges needs. The FRAD can serve as a basic format for representation and standardization of end user functional requirements for health information exchanges in a particular domain, i.e., it may become domain’s functional standard.

**Business Process Analysis**

Business Process Analysis (BPA) helps an organization improve the ways of conducting its activities in order to reduce overall costs, provide more efficient use of resources, and better support customers. It introduces the notion of process orientation of concentrating on and rethinking end-to-end activities that create value for customers, while removing unnecessary, non-value added work.

Business Process Analysis focuses on identifying requirements in the context of helping organizations to achieve strategic goals through internal changes to organizational capabilities, including changes to policies, processes, and information systems. Some professional business analysts believe that BPA can be broken down into six major knowledge areas [14]:

1. **Enterprise analysis** focuses on understanding the needs of the business as a whole, its strategic direction, and identifying initiatives that will allow a business to meet those strategic goals.
2. **Requirements planning and management** involves planning the requirements development process, determining which requirements are the highest priority for implementation, and managing change.
3. **Requirements elicitation** describes techniques for collecting requirements from stakeholders in a project.
4. **Requirements analysis** describes how to develop and specify requirements in enough detail to allow them to be successfully implemented by a project team.
5. **Requirements communication** describes techniques for ensuring that stakeholders have a shared understanding of the requirements and how they will be implemented.

6. **Solution assessment and validation** describes how the business analyst can verify the correctness of a proposed solution, how to support the implementation of a solution, and how to assess possible shortcomings in the implementation.

Business Process Analysis includes the Requirement Analysis step to formulate tasks in achieving an organization’s strategic goals. The requirements analysis is targeted to the following categories of business practice: business, user, functional and non-functional (Table 3). [15]

**Table 3. The Requirement Analysis of Business Practice by Requirement Categories**

<table>
<thead>
<tr>
<th>What do you want to achieve?</th>
<th>How are going to achieve it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Business Requirements</strong></td>
<td></td>
</tr>
<tr>
<td>• What the organization hopes to achieve</td>
<td>• How will this product improve the business or organization?</td>
</tr>
<tr>
<td>• The business benefits that the product will offer</td>
<td>• What will you be able to do that you cannot do now?</td>
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<table>
<thead>
<tr>
<th><strong>User Requirements</strong></th>
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<tbody>
<tr>
<td>• What is the goal of the user work?</td>
<td>• What business rules, guidelines and procedures the user must follow to complete the tasks (workflow)?</td>
</tr>
<tr>
<td>• What are the tasks that user have to complete to achieve this goal?</td>
<td>• What data do user need and generate to perform these tasks (dataflow)?</td>
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<table>
<thead>
<tr>
<th><strong>Functional Requirements</strong></th>
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</tr>
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<tbody>
<tr>
<td>• What the software system should do - what user requirements the system must support</td>
<td>• How will the product support the business rules, data representation requirements, logical models and acceptance criteria that the user will employ?</td>
</tr>
<tr>
<td>• Input Information</td>
<td>• Input Information</td>
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<tr>
<td>• Output Information</td>
<td>• Output Information</td>
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<tr>
<th><strong>Non-Functional Requirements</strong></th>
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<tr>
<td>• What the software system should do - quality attributes that affect how the system must perform</td>
<td>Examples:</td>
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<td>• Standards</td>
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<td>• Government regulations</td>
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<td>• Constraints</td>
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<td>• Interfaces</td>
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<td>• Platform</td>
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Forty to sixty percent of errors in systems have been traced back to the requirements and analysis phase. Seventy to eighty-five percent of total revisions can be attributed to requirements errors. [16] The tasks identified by the BPA may include the improvement of the use of information technology, and, therefore, lead to the development of Use Cases for information technology implementation.

The Public Health Informatics Institute has been advocating for the implementation of BPA in public health practice. [17] Business Process Analysis will be implemented in 2007-2009 in several public health agencies - grantees of the Robert Woods Johnson Foundation’s Common Ground Program - to better understand the organization and information needs of local and state health departments.

Functional Requirements for Health Information Management

Functional Requirements Analysis is a part of the Business Process Analysis (Table 3) because the organization’s strategic goals may include the improvement of the use of information and therefore to improve the utilization of information technology.

In the information system design, the Functional Requirements are gathered through the Requirement Elicitation and Analysis to formulate end user needs for an information system (IS) in the format of the Requirement Analysis Document.

The Functional Requirement Analysis Document - FRAD - consists of the following sections:

- **Problem/Domain (Use Case) Description** – a description of the problem/domain (Use Case) for which IS will be needed
- **Information System Goals** – program/domain goals that IS will help to achieve
- **Actors** - participants involved in information exchanges that IS will support
- **Functional Requirements** – list of end user function that IS will support (e.g., collect/enter data, send data, receive data, generate reports, etc.)
- **Storyboard** – examples of life-situations in end user work that IS will support
- **Diagrams** (Use Case Diagrams, Workflow and Dataflow Diagrams) – UML-based representation of end user interactions with the IS
- **High Level System Architecture** – graphic representation of end user view of IS operation
- **Non-functional Requirements** - list of features that IS will have (secure information exchange, user-friendly interfaces, time/periods of IS operation, etc.)
- **IS Development Timeline and Deliverables** – a chart or table that describes the timeline for IS design, development, pilot testing, implementation and full operation and correspondent documentations developed at each step of IS development.

Both Business Process Analysis and Information System Design include the Requirement Elicitation and Analysis steps. In BPA, the outcome of the Requirement Analysis is the formulation of organization’s high level strategic goals and tasks to achieve these goals. For the tasks related to information technology, this can be done in the Use Case format that specifies the goals and tasks for improving information management. In the Information System design, the outcome of the Requirement Analysis is the functional requirement specification for an information system to improve information management in achieving the organization’s strategic
goals and tasks. The Functional Requirement Analysis Document, e.g., the NYC Functional Requirement Specifications for School Health and Syndromic Surveillance presents the format for describing the information systems functional requirements.

**We propose to incorporate both Business Process Analysis and Information Systems Functional Requirement Analysis (FRA) methodologies into the development of the interoperability specifications for HIT applications.** This will allow guiding the information systems development based on a structured representation of (a) the organization’s goals/needs for the information system identified via BPA in the format of the Use Cases; and (b) the work processes that the information system must support identified via FRA in the format of FRAD.

The documentation on the functional requirements for electronic health information exchanges developed at one setting – FRADs - will serve as functional standards and will allow the replication of the system at other settings to support similar work processes.

**Enhancing the Interoperability Specification Development Process**

The current DHHS process for the development of interoperability specification (Fig.1) can be enhanced by using (a) Business Process Analysis methodology for selecting Use Cases and (b) by adding the Functional Requirement Analysis steps into the validation of national interoperability specifications to assure that the needs for health information exchanges at the local, state and regional levels are addressed in the specification. Fig.2 represents the schematic view of the current interoperability specification development process (Fig.2a, Steps 1-5) and the proposed enhancements for this process (Fig. 2b) by adding BPA methodology into the Step 1-Identify Use Case - and Functional Requirements Analysis (Steps 5-7).

The proposed modifications to the current DHHS process (Fig. 2b) are presented in italicized red-colored inserts below:

Step 1 – Identify National Use Cases to describe information exchanges across information systems within healthcare enterprise based on Business Process Analysis;

Step 2 – Develop a Use Case Document to describe identified use cases in a common (standardized) template

Step 3 – Develop an Interoperability Specification for the Use Case using a common (standardized) specification template that identifies selected standards needed to support health information exchanges described by each Use Case. The HITSP methodology includes the Functional Requirements Analysis of the National Use Case prior to the development of the interoperability specification. This step also includes an interoperability specification testing by information technology vendors.

Step 4 – Develop Certification Criteria for EHRS to assure that they support standards specified by the Use Case Interoperability Specifications

Step 5 – Develop Functional Requirement Analysis Documents - FRAD – for Use Case implementation tailored to the information needs of a particular jurisdiction (local, state and regional health information exchanges)

Step 6 – Conduct Pilot Testing of the health information exchange designed based on the FRAD to support health information exchanges in a particular jurisdiction (local, state and regional)
Step 7 – Refine the Certification Criteria for EHRS based on the outcomes of the pilot testing of the information system to support health information exchanges in a particular jurisdiction (local, state and regional)
Step 8 (former Step 5) – Implement Use Cases

Fig. 2. Process for Achieving Health Information Systems Interoperability.
a – Current DHHS Process; b- Proposed BPA- and FRAD-based process.
The proposed approach to enhance national efforts of achieving interoperability of clinical and public health information systems via (1) integrating the Business Process Analysis methodology into the selection of national Use Cases for health information exchanges; and (2) using FRAD approach in refining the national Use Case interoperability specifications to address local, state and regional needs of health information exchanges, represents potential methodology that may assure successful implementation of national interoperability specifications in the regional and national health information exchanges. Using this approach, regional health information exchanges could develop their own Use Cases and interoperability specifications. Developed based on the standardized methodology of BPA and FRAD, both national and regional Use Cases and their interoperability specifications can expedite nationwide health IT adoption efforts.

The BPA and FRAD methodologies, if used separately, may have limitations in achieving the ultimate goal of effective use of information through interoperability of clinical and public health information systems. The BPA may not be granular enough to actually guide the development of the interoperable information systems as it addresses high level organizational goals that are broader than the use of information technology. The FRAD approach could be too narrow as it focuses on addressing user needs in the information system design for a particular Use Case (problem/program). Both BPA and FRAD working in conjunction could potentially lead to effective way of guiding the adoption of health IT in public health and clinical settings because together they cover both strategic and tactical goals of guiding the development and implementation of IT applications.

Both methodologies (BPA and FRA) are widely used by IT community. However, they are almost unknown to clinicians and public health workforce. With the efforts led by the Robert Woods Johnson Foundation, the BPA methodology will be soon known to public health practitioners.

With regards to the FRA approach, the PHDSC has been collaborating with the IT vendors to learn more about the representation of user needs in the information systems design. We anticipate developing a training course for public health professionals on the role of users in the information system design and the development of the FRA specifications.

In conclusion, we propose (1) to work with the Public Health Informatics Institute to refine the proposed approach of integrating BPA and FRA into the national interoperability specification development efforts; and (2) to present the proposed approach to the successor of the American Health Information Community as a methodology for (a) selecting national Use Cases and (b) refining the national Use Case interoperability specifications to address local, state and regional needs of health information exchanges.
ACKNOWLEDGEMENTS

We would like to thank HRSA project officers (Ms. Jessica Townsend and Dr. Michael Millman) for their continuing support of the PHDSC efforts to standardize clinical and public health information exchanges and specifically for their guidance on project activities.

We also would like to thank the PHDSC NHIN Committee members for the input to conduct the validation of the NYC functional specifications.

Lastly, we would like to thank invited panelists and all Panel meeting participants for their review of the NYC functional requirements specifications and input in the development of a roadmap for standardization of the functional requirements (standards) for the electronic health information exchanges between clinical and public health systems. We specifically would like to thank Dr. Noam Arzt, HLN Consulting, LLC, PHDSC member, for his critical suggestions in the preparation of this report and its review.
REFERENCES


6. Integrating the Health Care Enterprise. URL: http://www.himss.org/ASP/topics_ihe.asp


## AGENDA
**DAY 1 – Tuesday, December 5, 2006**

<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>2.30pm – 3:30pm</td>
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| 3:30pm – 3:45pm | WELCOME AND INTRODUCTIONS  
Dr. Michael Millman, HRSA and Dr. Walter Suarez, PHDSC |
| 3:45pm – 5:45pm | BUILDING PUBLIC HEALTH /CLINICAL HEALTH INFORMATION EXCHANGES: THE 
EXPERIENCE TO DATE  
Efforts in Colorado, Indiana, Minnesota, Nebraska, New York City, Texas 
and Wisconsin  
**Moderator:** Dr. Walter Suarez, PHDSC  
**Participants:** Invited Panelists |
| 5:45pm – 6:15pm | ROUNDTABLE DISCUSSION  
**Moderator:** Dr. Anna Orlova, PHDSC |
<p>| 7:00pm – 9:00pm | DINNER (AGENDA TO BE DETERMINED) |</p>
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<tr>
<td>8:00am – 9:00am</td>
<td><strong>BREAKFAST</strong></td>
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<td>9:00am – 9:15am</td>
<td><strong>DAY 1 REVIEW AND INTRODUCTION TO DAY 2</strong></td>
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<td><em>Dr. Anna Orlova, Executive Director</em></td>
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<td>9:15am – 10:30am</td>
<td><strong>THE CASE FOR ELECTRONIC HEALTH INFORMATION EXCHANGES IN PUBLIC</strong></td>
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<td><em>HEALTH AND THE NEED FOR FUNCTIONAL STANDARDS</em></td>
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<td><em>Moderator: Lori Fourquet, Healthsign Systems</em></td>
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<td>- The Need for a Functional Requirements Standards in Public</td>
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<td>Health – <em>Dr. David Ross</em>, Public Health Informatics Institute</td>
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<td>- Electronic Health Record System in Community Health Center in</td>
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<td>NYC – <em>Dr. Neil Calman</em>, Institute for Urban Family Health, NYC</td>
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<td>- School Health Functional Requirements: NYC Case Study – *Dr.</td>
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<td>Oxiris Barbot*, NYC Department of Health &amp; Mental Hygiene</td>
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<td><strong>DISCUSSION</strong></td>
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<td>10:45pm – 12:00pm</td>
<td><strong>Syndromic Surveillance Functional Requirements: NYC Case</strong></td>
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<td><em>Study – Dr. Farzad Mostashari</em>, NYC Department of Health &amp; Mental</td>
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<td><em>Hygiene</em></td>
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<td>- A Functional Requirement Standard: National Efforts and User</td>
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<td><em>Role – Dr. Anna Orlova</em>, PHDSC*</td>
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<td><strong>LUNCH</strong></td>
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<td><strong>RESPONSES TO THE NYC FUNCTIONAL REQUIREMENTS: ROUNDTABLE</strong></td>
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<td><strong>DISCUSSION</strong></td>
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<td><em>Moderator: Dr. David Ross, Public Health Informatics Institute(PHII)</em></td>
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<td>2:30pm – 2:45pm</td>
<td><strong>BREAK</strong></td>
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<td><strong>ROADMAP FOR PUBLIC HEALTH FUNCTIONAL REQUIREMENTS STANDARDS:</strong></td>
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<td><strong>ROUNDTABLE DISCUSSION</strong></td>
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<td>4:00pm</td>
<td><strong>MEETING ADJOURNMENT</strong></td>
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APPENDIX 2: List of Participants

Public Health Data Standards Consortium
Expert Panel in Public Health/Clinical Electronic Data Exchanges
Participants List
December 5-6, 2006

Dr. Todd Albright
Chief, Division of Urogynecology
U.S. Army
Walter Reed Medical Center
Dep’t of OB/GYN
Washington, DC 20307
Ph: 202-782-8433
Fx: 202-782-9278
Em: todd.albright@wreid.army.mil

Dr. Oxiris Barbot
Medical Director
NYCDOHMH Office of School Health
2 Lafayette St, 22nd Floor
New York, NY 11218
Ph: 212-676-2469
Fx: 212-676-2474
Em: obarbot@health.nyc.gov

Dr. Neil Calman
President & CEO
The Institute for Urban Family Health
16 E. 16th Street
New York, New York 10003
Ph: 914-713-1391
Em: ncalman@institute2000.org

Mr. Larry Carlson
Injury Prevention Instructor
United Tribes Technical College
3315 University Drive
Bismarck, ND 58504
Ph: 701-255-3285, ext. 1350
Fx: 701-530-0505
Em: lcarlson@uttc.edu

Ms. Kathleen Cook
Informational & Fiscal Division Manager
Lincoln-Lancaster County Health Department
3140 N. Street
Lincoln, NE 68510
Ph: 402-441-8092
Fx: 402-441-6229
Em: kcook@lincoln.ne.gov

Dr. Art Davidson
Director, Public Health Informatics
Denver Public Health
605 Bannock Street
Denver, CO 80204
Ph: 303-436-7364
Fx: 303-436-7211
Em: adavidson@dhha.org

Ms. Angela Fix
Director, Public Health Informatics
Association of State and Territorial Health Officials
1275 K. Street, N.W. Suite 800

Dr. Peter L. Elkin
Professor of Medicine
Mayo Clinic College of Medicine
Baldwin 48, Mayo Clinic
Rochester, MN 55905
Ph: 507-284-1551
Fx: 507-284-5370
Em: elkin.peter@mayo.edu

Ms. Lori Fourquet
Owner/Consultant
e-Healthsign, LLC
1056 Durham Road
Wallingford, CT 06492
Ms. Marjorie Greenberg  
Chief, Classifications and Public Health Data Standards Staff  
CDC/National Center for Health Statistics  
3311 Toledo Road  
Hyattsville, MD 20782  
Ph: 301-458-4245  
Fx: 301-458-4022  
Em: msg1@cdc.gov

Ms. Beverlee Hall  
Discharge Data Analyst  
Arizona Department of Health Services/Bureau of Public Health Statistics/Cost Reporting and Discharge Data Review  
150N. 18th Street, Suite #550  
Phoenix, AZ 85007  
Ph: 602-542-1242  
Fx: 602-542-2940  
Em: hallb@azdhs.gov

Ms. Vicki Hohner  
Senior Consultant  
FOX Systems, Inc.  
6263 N. Scottsdale Rd, Suite 200  
Scottsdale, AZ 85250  
Ph: 360-970-6856  
Em: Vicki.hohner@foxsys.com

Ms. Laurel Holmquist  
SPARCS/AMI Project Coordinator  
New York State Department of Health  
800 N. Pearl Street  
Albany, NY 12204  
Ph: 518-473-8144  
Fx: 518-486-3518  
Em: LBH03@health.state.ny.us

Dr. Holly H. Howe  
Executive Director  
North American Association of Central Cancer Registries  
2121 W. White Oaks Drive  
Springfield, IL 62704  
Ph: 217-698-0800  
Fx: 217-698-0188  
Em: hhowe@naaccr.org

Ms. Eithne Keelaghan  
Physician Consultant  
Department of Health, State of Maryland  
216 Hopkins Road  
Baltimore, MD 21212  
Ph: 410-377-9313  
Ph: 410-767-0815  
Em: ekeelaghan@dhmh.state.md.us

Ms. Hetty Khan  
Health Informatics Specialist  
CDC/National Center for Health Statistics  
3311 Toledo Road  
Hyattsville, MD 20782  
Ph: 301-458-4311  
Fx: 301-458-4022  
Em: hdk1@cdc.gov

Dr. Martin LaVenture  
Director, Center for Public Health Informatics  
Minnesota Department of Health  
6717 West Shore Drive  
Edina, MN 55435

Dr. David Lawton  
Administrator, Health Surveillance Section  
Nebraska Health and Human Services System  
301 Centennial Mall South  
Lincoln, NE 68509
Ms. Karen Lipkind
Statistician
National Center for Health Statistics/CDC
3311 Toledo Road
Hyattsville, MD 20873
Ph: 301-458-4346
Fx: 301-458-4032
Em: klipkind@cdc.gov

Ms. Denise Love
Executive Director
National Association of Health Data Organizations
448 East 400 South, Suite 310
Salt Lake City, UT 84111
Ph: 801-943-6266
Em: dlove@nahdo.org

Dr. Marie Mann
Maternal Child Health Bureau
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Room 18A-19
Rockville, MD 20857
Ph: 301-443-1080
Fx: 301-443-8604
Em: mmann@hrsa.gov

Dr. Michael Millman
Director, Research and Data Policy Group
Office of Planning and Evaluation
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Room 10-49
Rockville, MD 20857
Ph: 301-443-0368
Fx: 301-443-2286
Em: mmillman@hrsa.gov

Ms. Dara Moore
Data Coordinator Training Manager
Illinois Hospital Association
1151 E Warrenville Road
Naperville, IL 60566
Ph: 708-296-4400
Fx: 630-276-5402
Em: dmoore@ihastaff.org

Dr. Farzad Mostashari
Assistant Commissioner
New York City Department of Health and Mental Hygiene
225 Broadway, 23rd Floor, Rm 10
New York, New York 11215
Ph: 212-341-2298
Fx: 212-778-3241
Em: fmostash@health.nyc.gov

Ms. Judith Nugent
Section Chief
Wisconsin Department of Health and Family Services
1 W Wilson Street, Room 372
Madison, WI 53702
Ph: 608-266-2863
Fx: 608-264-9881
Em: nugentjg@dhfs.state.wi.us

Dr. Anna Orlova
Executive Director
Public Health Data Standards Consortium
c/o Johns Hopkins Bloomberg School of Public Health
624 N. Broadway, Room 382
Baltimore, MD 21205
Ph: 410-614-3463
Fx: 410-614-3097
Em: aorlova@jhsph.edu

Dr. Michelle Puryear
Chief, Genetics Services Branch
Division of Services for Children with Special Health Needs
Health Resources and Services Administration

Mr. Thomas Rainer
Medical Economist
Arizona Department of Health
P.O. Box 1437, slot 19-H
Little Rock, AR 72203-1437
Mr. Michael Rodrian  
Deputy Director  
Health Information Division  
California Office of Statewide Planning and Development  
818 K Street  
Sacramento, CA 95814  
Ph: 916-323-1416  
Fx: 916-324-9242  
Em: mrodrian@oshpd.ca.gov

Dr. David Ross  
Director  
Public Health Informatics Institute  
750 Commerce Drive, Suite 400  
Decatur, GA 30030  
Ph: 866-815-9704  
Fx: 404-371-0415  
Em: dross@phii.org

Dr. Barbara Rudolph  
Director of Leaps and Measures  
The Leap Frog Group  
C/O The Alliance  
30 Kessel Court, Suite 201  
Madison, WI 53744  
Ph: 608-210-6641  
Fx: 608-276-662  
Em: brudolph@leapfroggroup.org

Dr. Tom Savel  
Science and Research Lead  
National Center for Public Health Informatics/CDC  
1600 Clifton Road, MS E-78  
Atlanta, GA 30333  
Ph: 404-498-3081  
Fx: 404-498-3070  
Em: tsavel@cdc.gov

Dr. Craig Schneider  
Director of Health Policy  
Massachusetts Health Data Consortium  
460 Totten Pond Road, Suite 385  
Waltham, MA 02451  
Ph: 781-768-2503  
Fx: 781-768-2510  
Em: cschneider@mahealthdata.org

Dr. Gulzar Shah  
Director of Research  
National Association of Health Data Organizations  
448 E 400 S #301  
Salt Lake City, Utah 84111  
Ph: 801-688-4771  
Em: gshah@nahdo.org

Ms. Paula Soper  
Senior Analyst  
National Association of County and City Health Officials  
1100 17th Street, N.W.  
Washington DC 20036  
Ph: 202-783-5550  
Fx: 202-783-1583  
Em: psoper@naccho.org

Ms. Jessica Townsend  
Public Health Analyst  
Health Resources and Services Administration  
5600 Fishers Lane, Room 10-49  
Rockville, MD 20857

Ms. Marcia Veenstra  
Director of Ambulatory Product Development  
CPMRC/Eclipsys  
600-28th St. SW  
Grand rapids, MI 49428
Mr. Edward Welsh  
Manager  
Arizona Department of Health Services  
150 N. 18th Avenue, Suite 550  
Phoenix, AZ 85007  
Ph: 602-542-2960  
Em: welshe@Azdhs.gov

Dr. Deborah Willis-Fillinger  
Senior Medical Advisor  
Center for Quality  
Health Resources and Services Administration  
5600 Fishers Lane, Room 10-49  
Rockville, MD 20857  
Ph: 301-443-6614  
Em: DWillis-Fillinger@hrsa.gov