Response to HHS Request for Information:
Personalized Health Care, Health Information Technology and Genomic Information

February 2007

Issues and Questions

The Healthcare Information and Management Systems Society (HIMSS) is pleased to submit our comments regarding the HHS Request for Information "*Improving Health and Accelerating Personalized Health Care Through Health Information Technology and Genomic Information in Population- and Community-based Health Care Delivery Systems*" posted in the Federal Register on November 1, 2006 [FR Doc. Vol 71, No. 211, pages 64282-64284]). As an organization, HIMSS is committed to achieving the benefits healthcare information and management systems provide to care delivery and process improvement throughout the healthcare continuum. Collectively HIMSS members' expertise covers a broad number of healthcare industry areas; however, for the purpose of the response we have confined our comments to intersection between HIT and genomic Information.

As many of the challenges associated with HIT and genomic information gathering and exchange are still largely theoretical, HIMSS appreciates the Department's foresight in discussing the intersection between the technological advances. The RFI provides a forum for industry to engage in a dialogue with the federal government regarding expected technical, privacy, and security requirements well in advance of expected federal requirements. There is a great deal of information available to stimulate discussion amongst the various organizations. The following response was developed by, and submitted on behalf of, the HIMSS membership.

1. *HHS Question: Concepts on anticipated approaches for the use of EHR and population- and community-based health care system databases for longitudinal data collection in addressing:*

1.1 Disease susceptibility
1.2 Clinical course and outcomes
1.3 Treatment response
1.4 Evidenced-based clinical decision support
1.5 Optimal healthcare delivery systems

Electronic Health Information—from patient-centric, clinically-based EHRs; to population, community and regional databases (as well as other less-centralized, or "federated", mechanisms for aggregating data from disparate sources within a geographic region); to the establishment of a

Nationwide Health Information Network (NHIN)—represents a key enabler for personalized health care and the robust, longitudinal data needs required for its success.

Healthcare IT solutions are currently underway that address the five areas – disease susceptibility, clinical course and outcomes, treatment response, evidence-based clinical decision support, and optimal healthcare delivery systems--specified in this question. These current approaches are vital to understanding the synergies between Healthcare IT and personalized healthcare and how the increasingly interlocking relationship between these two areas is essential to the integration of molecular and genetic information that will be subsequently addressed throughout this document.

The Electronic Health Record is "a longitudinal electronic record of patient health information produced by encounters in one or more care settings." (*HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations).* As such, the EHR is the nexus of all patient-centric, clinically-derived information over time and throughout multiple care settings. The patient-centric information required for evaluating disease susceptibility, optimal course of care, outcomes and treatment response over time is all contained in the EHR.

Full EHR functionality depends on the seamless flow of data between and across care settings in communities and regions (as well as the eventual establishment of linkages between regions to form a complete Nationwide Health Information Network (NHIN). Hundreds of organizations and regional collaborations have been emerging all over the United States to promote Health Information Exchange. (A continually-updated interactive map of these regional efforts can be accessed at **www.hitdashboard.com**) Fully functioning Health Information Exchanges (HIEs) and Regional Health Information Organizations (RHIOs) will, by their very nature, be able to serve as sources of clinically-rich, patient-centric information for community and population data aggregation needs. (Further background on current EHR Interoperability efforts are contained in the attachment "Question 1 Supplemental Information: Electronic Health Records and standards harmonization efforts to achieve data interoperability across communities, regions and the nation")

2. ***HHS Question: Anticipated applications of genomic-based clinical testing in medical decision-making, safety assessment, and risk management***

   Genomic-based clinical testing will have dynamic applications in all medical specialties with particular impacts upon medical decision making, safety assessment, and risk management.

   Medical decision making- Genomics will help providers more accurately diagnose, sub-classify, and stage diseases. These types of determinations may assist providers with selecting preventative measures, determining the appropriate treatment for a patient, and formulating a patient's prognosis. Genetic determinations may benefit medical decision making not only for the immediate patient but also for the patient's relatives who may be at risk as well.

Aligning Genomics and Clinical Decision Support:-However, the real question is not whether we can derive critical genomic information from individuals which can improve their quality of care, it is whether this information can be made available to Physicians and other Care-Givers in a way that it can be used efficiently, effectively and practically at the point of care. For these potential life-saving uses of genomic information to move from theory to widely-adopted medical practice it is essential that they be seamlessly incorporated into Healthcare IT tools such as Clinical Decision Support (CDS), used by clinicians to optimize care. CDS has become a key component of advanced Healthcare IT deployments in many of our nations leading Healthcare Establishments from Large Health systems such as Kaiser Permanente and the Cleveland Clinic to Small Practices as part of their complete EHR system.

As genomic data becomes more available, caregivers must not be expected to adopt a secondary information system to accommodate such data. Doctors should not be expected to be practicing "medicine" one moment, and "genomics" the next. Just as Genomics is moving from a concept in the research facilities of the Biotechnology sector to practical, real-world applications, so to must genomic information be incorporated into the same advanced Healthcare Information Systems now being established to advance the broader continuum of care.

Safety assessment and risk management- With regard to safety, genomic tests will help predict potential toxicities a patient might experience due to one's genetic profile. This will allow healthcare providers to tailor a treatment plan that will be the safest option for the individual patient based upon their profile, while offering the greatest therapeutic benefit. On a larger scale, genomic testing may be used as a predictive tool to evaluate the severity and risk of a public health threat or infectious disease, while also being used to determine the required response.

3. ***HHS Question: Establishment of biospecimen resources obtained from clinical medical services for application in research, clinical trials, health services planning, clinical effectiveness, and health outcomes evaluations***

HIMSS is aware of recent initiatives to expand the scope, size and availability of biospecimens for the purpose of advancing genomic and other forms of biomedical research are giving rise to broader, more complex forms of biospecimen resource management. Sometimes referred to "biospecimen networks" or "biobanks", these collections of samples of human bodily substances (e.g. cells, tissue, blood, or DNA) can be associated with personal data and information on their donors. Therefore, biobanks serve the dual purpose of being collections of physical samples on the one hand, and collections on the other. Accordingly, to reap their full ROI, biospecimen networks must be infused with quality data from healthcare information networks.

Aligning biospecimen data management with healthcare information management will broaden the perspective of biobank data systems from being merely focused on "tissue

information" to more robust, continually updated, clinically-rich information about the human beings from whom the tissues, and other biospecimens, were derived.

The future importance of biobanks in disease research cannot be over emphasized. A Public participation is critical to the biobanks becoming valuable research tools. At the same time, however, there are many privacy concerns and remains to be seen how the public will react to the development of biobanks. Public perception, participation, and support of these and other efforts to advance genetic and personalized medicine will be closely tied to the emerging societal discussion around the ethical, legal and social implications – especially as they related to the area of personal privacy. These issues will be addressed in detail in our response to questions 4 and 6.

(Further information on the data requirements of biospecimen resources can accessed at the NIH's National Biospecimen Network site:http://prostatenbnpilot.nci.nih.gov/blue_full4.asp)

4. ***HHS Question: Organizational or institutional practices to address ethical, legal, and social implications regarding the use of patient information, including genetic data, to support personalized health care.***

The Director of Health Information Management for a large California-based outpatient facility, responding to HIMSS on this questions, reports that she is in the process of updating all policies and procedures on department functions, HIPAA Privacy, documentation to meet State and Federal standards, HIPAA authentication of entries and system security, etc., to prepare for the IMQ Survey (Institute for Medical Quality Accreditation Survey). However, nowhere in any of the standards organizations or certification bodies does one find mention of handling of genetic data.

HIMSS encourages organizational bodies like the Joint Commission (www.jointcommission.org), Institute for Healthcare Improvement (www.ihi.org), and the Public Responsibility in Medicine and Research (www.primr.org) and others to take a leadership role in developing guidelines for responsible handling of genomic information.

To support the delivery of "personalized health care", policies should be founded upon the IOM's six "aims for improvement" from its 2001 report, *Crossing the Quality Chasm*; including "safety, effectiveness, patient-centeredness, timeliness, efficiency and equity". These guidelines should apply equally to government purchased health care, health insurers, and private pay clients. The relationship between the patient and clinicians, implies a partnership between the patient and healthcare professionals, and requires ensuring that decisions respect the patient's needs and preferences.

The "patient centeredness" aim is of particular importance in addressing the social, legal and ethical implications of personalized medicine. The healthcare system is peculiar when looked at from a systems, or process-flow perspective, in that the central object flowing through the system happens to be a self-conscious entity, i.e. the "patient" or "consumer". Therefore, information tools that put the "person" back into "personalized health care" will empower this entire process.

One mechanism for achieving patient-centered care is the use of a personal health record (PHR). Incorporating key data (including lab results and genetic profile data) from the EHRs, which is the clinician's primary information tool, into the PHR, which is the primary tool for the patient, is essential to empowering the consumer as a full partner in their health care decisions.

Particular attention needs to be paid to the ethical, legal, and social implications around pharmogenetic screening. Pharmogenetic screening holds the promise to transform the care process around high risk, fragile conditions such as asthma – and many predict such screening will become routine. A genetic profile needs to be performed just once because, unlike other lab tests, this is a result that does not change over time. Cost effectiveness, safety, and timeliness of effective treatment are all served by performing genetic profile checking for adverse drug reaction to given drugs prior to ordering a medication. Cost benefit analysis would show resource savings, timeliness of performing the right treatment the first time, redundancy of multiple drugs ordered avoided; risk to patient for side effects, complications, and death would be avoided. Results from pharmogenetic screening should be presented to the patient, physician, pharmacist, and nurse.

Prospective genetic screening should be available to patients who request it based on a family or medical history that warrants risk assessment for early prevention or disease management. Population prospective genetic screening has a high potential for abuse. Thus, such screening should be conducted by objective bodies, such as universities and the "selling" of such data to third parties, such as Pharmaceutical companies needs to be strictly regulated.

In the instance in which genetic screening is performed, only certified genetic counselors (which may include general caregivers, such as physicians and nurses, who have received special certification in this area) should be allowed to review the results with the patient and their family. Counseling on life options in response to genetic screening results should be performed only by health personnel certified in genetic counseling.

Finally, it should be noted that the ethical, legal, and social implications addressed here reach far beyond institutional walls and the policies and practices of any individual health care organization. The intersection of genetic/molecular medicine, Healthcare Information Technology, and Personalized health care require a broader societal/public discussion. (These issues will touched upon in question 6.)

5. *HHS Question: Examples of utilizing large clinical data repositories for practical clinical research to discover effective technologies, therapeutics, diagnostics, and prevention strategies for different populations*

Large clinical data repositories in conjunction with the use advanced Healthcare IT tools, such as comprehensive data mining techniques, have enabled the discovery of effective technologies, therapeutics, diagnostics and prevention strategies for life-threatening conditions amongst

various populations. One such example is The University of Pittsburgh Medical Center's (UPMC) use of its clinical repository to solve the growing clinical problem, fulminant C. Diff colitis and the subsequent implementation of life-saving therapeutic interventions related to the growing risk of Clostridium difficile enterocolitis:

In 2000 and 2001 clinicians and researchers at UPMC noted a nearly 100% increase in the incidence rate of C. difficile colitis in hospitalized patients (an increase in the baseline form 0.68% to 1.2%, and increase from 1.6% to 3.2% in incidence of patients with C. difficile colitis developing life-threatening symptoms). Forty-four patients required a colectomy and 20 others died directly from C. difficile colitis.

Researches commenced an extensive review of all available patient information related to the condition. Using the UPMC MARS (Medical Archival System) clinical data repository, they were able to utilize detailed clinical data for 2334 patients over a twelve year period Jan 1989-Dec 2000). Dr. G. Daniel Marich, MD, VP and Associate Chief Medical Officer at UPMC, describes how the MARS database enabled the discovery of life-saving solutions and their implementation on both a population and personalized level:

> "With the use of our MARS database, the researchers identified individuals who had positive C diff toxin assays, those who underwent colectomy for C. diff colitis, and those with necropsy evidence of C. Diff enterocolitis, but negative assays ante-mortem over a multi-year period. The follow on approach to the matter has been to both be diligent in our surveillance for C. diff in patients who might be at risk (i.e. on broad spectrum antibiotics, high WBC, etc…) as well as providing prophylaxis for high risk populations (i.e. transplant recipients, critically ill others, etc…)."

Dr. Ramsey Dalla, a UPMC surgical residents at the time, lead the research effort and the results were published in 2002 in the Annals of Surgery. According to Dr. Marich, "The results in practice changed as a direct result. In speaking with colleagues around the country/world, treatment beyond the walls of UPMC has changed as a result of this research."

(For complete Information on this study: ANNALS OF SURGERY Vol. 235, No. 3, 363–372 © 2002 Lippincott Williams & Wilkins, Inc.)

6. *HHS Question: Issues and challenges associated with incorporating genomic information as a part of a broad longitudinal data collection*

Individual Genetic data is becoming a more regular and integral part of broad longitudinal data collection efforts to promote both population-based and personalized health care efforts. However, with the beneficial and potentially life-saving benefits of this information come a host of legal, ethical, political, and cultural implications around the areas of individual privacy and societal protections against the potential of "genetic discrimination". An individual's genetic profile is not merely another piece of information to be added to one's Electronic Health Record. It is an entire health record, and entire health information system (when viewed in perspective of proteomics and

molecular medicine), itself – one's "health record at birth" if you will – but a "record" not only of where one's health is in the moment, but where it may likely be in the future.

These are no longer challenges for science fiction writers or future societies to ponder. This brave new world of genetic/molecular medicine, empowered by advanced healthcare information systems is here today. Organizations such as Northern California Cancer Center (NCCC) already collect genomic information for use in cancer research purposes. The NCCC shares information with the State of California as well as the National WHO (World Health Organization) and International WHO in order to achieve have even broader longitudinal data collection that could be shared for other health purposes. These organizations report their efforts to adhere to the highest standards with regards to the ethical, legal, and social implications related to their use of individuals' genetic information. However, the intersection of genetic/molecular medicine, health care Information Technology, and personalized health care broader will require a broader societal/public discussion.

Of all the issues and challenges associated with the advances discussed throughout this document, none is more daunting, none is more capable of completely halting the scientific and medical progress being achieved than the legal and ethical issues surrounding individual privacy and societal protections against potential discrimination. HIMSS applauds the various institutional, societal, and political efforts now underway to better discuss these issues. Even as this document is being written and edited bipartisan attention around this area is building. A White House statement, echoing discussion during President Bush's NIH visit on January 17 states,

> "Unwarranted Use Of Genetic Information, And The Fear Of Potential Discrimination, Threatens Both Society's Ability To Use New Genetic Technologies To Improve Human Health And The Ability To Conduct The Research Needed To Understand, Treat, And Prevent Diseases." (http://www.whitehouse.gov/news/releases/2007/01/20070117-1.html).

Health care professionals, government official, business leaders, the science community, employee groups, and other stakeholders are concerned about the potential for employment discrimination, or discrimination by insurance carriers leading to coverage denial, based upon a person's genetic information. In October 2005, IBM was the first major corporation to establish a genetics privacy policy that prohibits current or prospective employees' genetic information from being used in any employment decisions. A further area of concern revolves around conclusions based on race-related factors which may lead to a host of socio-ethical issues for which the broader discussion needs to be prepared.

As the public discussion around these issues advances we encourage the review of analysis and research already well under way. One such effort is the Canadian Biotechnology Advisory Committee -- a body of external experts established in September 1999 by the Government of Canada to provide comprehensive advice on current policy issues associated with the ethical, social, regulatory, economic, scientific,

environmental and health aspects of biotechnology (http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/ah00436e.html). HIMSS also encourages the continued synchronization of these privacy-related discussions within the broader frameworks addressed by the AHIC and the Office of the National Coordinator for Healthcare IT. In particular, the efforts around HITSP, CCHIT, the NHIN contracts, and, of course, the Privacy and Security area need to be prepared to accommodate the implications of the broader discussion around the privacy and protection of genomic information.

7. *HHS Question: Needs for community-wide standards or best practices that will facilitate large-scale data integration and exchange to benefit personalized health care*

Personalized health care will, by necessity, involve the integration of a myriad of clinical and laboratory data sets for research. From the laboratory side, genomic data sets may be used to identify specific clinical manifestations of those prototypes. From the community perspective these data sets may be used to first identify segments of the population expressing common clinical characteristics and then research done to identify where there may be common genetic profiles.

This wide scale integration of data sets and the requirement of normalization for research demands that data be shared – and preferably collected and stored – in a standardized form. In order for this to be effective there must be a limited number of standards recognized and used.

Today clinical data is collected at the point of care and stored in the provider's system of choice. These systems involve many "standards" many of which are not compatible. This incompatibility of systems is exerting a major impact on our ability to move forward with the sharing of healthcare information.

It is imperative that, as we move forward to incorporate genomic information in our personal records, we avoid creating the situation of incompatible data. Therefore national or international standards are needed. These standards should be incorporated into the NHIN as well as funding for state or local initiatives.

Areas to consider when developing standards for facilitating large-scale data exchange:

- Interoperability among data bases
- Standardization of queries and input
- Open access across platforms
- Compatibility of the data models of the applications and databases where the clinical data is stored
- Accessibility
- Common, central data base performance
- Consistency of the meaning and context of the data
- Efficiency of interchange – without standards all data transactions between databases will require a translation and context check to assure validity within meaning and context

Areas to consider when developing best practices for facilitating large-scale data exchange:

- Security
- Reliability
- Accessibility
- Optimization
- Normalize the statutes that apply to genomic information, healthcare information and public data base information
- Use already existing standards and policies as much as feasible – e.g. FDA for pharmaceutical clinical trials

The foundation for not only a community-wide, but a nation-wide, information system capable driving personalized health care is already being laid. The incorporation of genomic information into this equation is being specifically addressed through the NHIN - Laboratory Results Query/Response -- A proposed framework, which would support the transport of genetic test results: The NHIN EHR Harmonized Use Case describes a requirement for an authorized requester (usually a system used by providers of care) to query for lab results for a specified patient from a specified source. This response describes a standardized message and supports the forwarding of this search request across an NHIN. The response to the query will be a standardized message including the laboratory results.

(For more details about these efforts, including the HL7 Clinical Genomics specifications and its underlying paradigms, see the following publication in the Pharmacogenomics journal: Shabo, A. (2006). Clinical genomics data standards for pharmacogenetics and pharmacogenomics - Special Report. Pharmacogenomics, March 2006.)

8. ***HHS Question: Feasibility and potential benefits for establishing linkages of institutional or organizational data resources with private and publicly available health databases***

Fully utilizing the potential of personalized health information will require that linkages between public and private data bases be realized. Accomplishing this will involve overcoming a variety of obstacles.

HIMSS notes that technology does not pose a barrier to linking multiple databases. Rather the key issues reside in the areas of privacy and security and in a common understanding of the context of the data.

There are a multitude of standards that are in use today for coding health information – and there are variations within the standards. It will only be through the standardization and general adoption of those standards that the context of vast amounts of data can be understood. We highly support the efforts of the various federally sponsored initiatives such as HITSP and HISPC and believe that it requires this type of national “top down” approach to making the data meaningful.

As data resources around genomic and molecular research continue to evolve in the Life Sciences sector it is important that said efforts be compatible with the standards and interoperability efforts currently underway in the Healthcare IT realm. While the move toward real-world data interoperability is still in its early stages in both the Healthcare IT and Biotechnology arenas. It is essential that communication and coordination between these efforts occur today – while "track widths" are being determined, rather than when we are further along and potentially incompatible tracks have been laid.

HIMSS encourages public – private collaboration in this area. Leadership from the Federal Government, and coordination between entities involved with Healthcare IT, (such as the AHIC and ONCHIT) with those involved with Life-Sciences (such as NIH, FDA, NSF) will help to achieve the seamless flow of relevant data across the entire healthcare continuum.

9. ***HHS Question: Development of ontologies across different clinical data repositories that will facilitate the utility of the data for answering clinical research questions***

HIMSS is aware of programs being developed at locations across the U.S. to address the issue of connecting clinical data repositories. One example is the effort at the University of Pittsburgh, where the University is developing a new Department of Biomedical Informatics and a Center for Clinical and Translational Informatics. We understand that the effort will include the implementation of a grid computing architecture to support application development, and more importantly data sharing. HIMSS looks forward to the further maturation of this and other efforts to assist in the advancement of data exchange of genetic information and the associated benefits to EHRs and other HIT solutions.

The Cancer Biomedical Informatics Grid (caBIG) and the Biomedical Informatics Research Network (BIRN) have both successfully developed approaches to using ontologies across disparate data resources for biomedical (including clinical) research. Researchers are connected using advanced networks, such as Internet2, to form virtual organizations that allow research teams to conduct studies using data from independent and often otherwise incompatible resources.

10. ***HHS Question: Models for linking clinical data repositories across disparate care providers***

The advent of advanced networks, such as Internet2, enabled researchers and educators to consider the ability to link data repositories and to link researchers and educators in ways that were previously not possible. Both caBIG and BIRN mentioned previously are examples of projects that have taken disparate resources and brought them together into a coherent system. Educators like those who participate in the SUMMIT project at Stanford University are using resources such as the 'visible human' to improve the quality of medical education both on campus and at remote locations. The 'visible human' is the result of a project by the National Library of Medicine to provide, anatomically detailed, three-dimensional images by sectioning complete cadavers. By

leveraging advanced network connections, these educators now can exchange resources between Australia, Wisconsin and California as model of what can be accomplished worldwide. Clinicians are increasing their use of telemedicine and telehealth which requires quality of service of the network. Second opinion, surgical planning, assisted surgeries, telepathology etc. all depend on access to resources, both data and human expertise, at remote locations.

As stated in question nine, HIMSS is aware of programs being developed at locations across the U.S. to address the issue of connecting clinical data repositories. One example is the effort at the University of Pittsburgh, where the University is developing a new Department of Biomedical Informatics and a Center for Clinical and Translational Informatics. We understand that the effort will include the implementation of a grid computing architecture to support application development, and more importantly data sharing. HIMSS looks forward to the further maturation of this and other efforts to assist in the advancement of data exchange of genetic information and the associated benefits to EHRs and other HIT solutions.

11. ***HHS Question: Examples of the use of disease registries to track specific diseases and response to drug therapies across different subpopulations***

HIMSS appreciates the necessity of receiving industry input on the "examples of the use of disease registries to track specific diseases and response to drug therapies across different subpopulations." Given that the question is outside the defined scope of HIMSS' organizational expertise, we will not submit a response to the question.

12. ***HHS Question: Models for prioritizing analyses to fill gaps in evidence of effectiveness of therapeutic interventions for different populations***

HIMSS appreciates the necessity of receiving industry input on the "models for prioritizing analyses to fill gaps in evidence of effectiveness of therapeutical interventions." Given that the theme of the question is outside the defined scope of HIMSS' organizational expertise, we will not submit a response to the question.

13. ***HHS Question: Strategies for accumulating patient data necessary for research that may not be available through EHRs***

HIMSS appreciates the question, particularly given the complexity of the issue and the necessity of incorporating non-EHR-based patient data into the clinical encounter. A tremendous amount of information is generated by patients that are not available to clinicians. For one pharmaceutical agent used for mental health, 50% of patients stop taking the drug, against their physicians' recommendations, over a period shorter than the follow-up interval. Clearly, these patients have experienced something that resulted in this action; however the causes are rarely well understood by the clinician because of poor out-of-office data collection.

Several organizations are developing strategies for collecting unverified patient information using computer systems. Two large organizations, Kaiser Permanente and the United States Government's Veterans Health Administration, have developed systems for continuous at-home collection of patient data. Kaiser Permanente (KP) has developed, as reported by Medical Director Warren Taylor, an "*eCare tool* for individualized care on the web… for hypertension and diabetes." The system was piloted for patients with depressive and bipolar disorders. While KP's *eCare* monitors symptoms and medications, elements commonly part of the medical record, it does so at a frequency that is not possible in a typical EHR collection environment and using data that is unverified, collected using home-quality equipment, and evaluated by minimally-trained patients. In addition, information that typically is not part of the medical record is included in *eCare* for monitoring: "early warning signs, triggers, and coping strategies."

Similarly, the VA's remote monitoring solution collects at-home readings from an array of home diagnostic devices and provides that information to physicians. Physicians typically use such information for deciding whether or not to ask the patient to schedule an appointment, not using home monitoring for medical decision making but rather for scheduling an office visit and using the data collected in the office to manage care. However, in these new models, organizations like the VA are managing care using patient-generated information.

Remote data collection has, in several environments, moved past the research phase and been proven effective for clinical care decision making. In several discrete but substantial markets, the EHR model has been expanded to encompass the range of data from clinical collection to subjective patient self-evaluations. This broader collection will provide valuable insight not only into interventions for health, but into opportunities to educate patients on their own decisions that affect their health. Tools to impact both these areas are already on the market and available to clinicians and researchers. Evidence to date suggests that these tools, and the data collection paradigm shift that they enable when coupled with state-of-the-art clinical repositories, will create the environment in which the next revolution in medicine will occur: a revolution of efficiency creating a cost-effective, scalable system. Early reports from early adopters of this model report 50% or more improvements in efficiency.

14. *HHS Question: Concepts or models on the potential use of clinical data and related resources for research applications*

HIMSS appreciates the necessity of receiving industry input on the "potential use of clinical data and related resources for research applications. Given that the theme of the question is outside the defined scope of HIMSS' organizational expertise, we will not submit a response to the question.

15. *HHS Question: Models of cost-benefit analysis for integrated data systems, EHR, and clinical resources to inform medical decision-making.*

HIMSS Davies Awards of Excellence continue to identify the successful and ongoing implementation of the electronic medical record-electronic health record (EMR-EHR)

The Nicholas E. Davies EHR Recognition Program encourages and recognizes excellence in the implementation of EHR systems. The program recognizes healthcare provider organizations that successfully use EHR systems to improve healthcare delivery. The program's objectives are to:

- Promote the vision of EHR systems through concrete examples;
- Understand and share documented value of EHR systems;
- Provide visibility and recognition for high-impact EHR system; and
- Share successful EHR implementation strategies.

Originally created by CPRI-HOST in 1994, the program is named in honor of Dr. Nicholas E. Davies, an Atlanta-based practice physician committed to the ideal of improving patient care through better health information management. He was a member of the Institute of Medicine (IOM) Patient Record Study Committee, which coined the term "computer-based patient record.

Statistics are as follows:

Award	**Year Initiated**	**Organizations Recognized**
Organizational Davies Award	1994	24 healthcare organizations recognized
Ambulatory Care Davies Award	2003	13 practices recognized
Public Health Davies Award	2004	7 public health entities recognized

Return on investment: *A calculation used to determine whether a proposed investment is wise, and how well it will repay the investor. It is calculated as the ratio of the amount gained (taken as positive), or lost (taken as negative), relative to the basis.*

---"Hard return on investment"---

Two measurements: Quantifiable returns that can be demonstrated in financial terms and process improvements that would suggest cost savings that may fit an identifiable—or measurable—metric. Three major categories: patient flow, materials and staffing reductions, and billing improvements.

---"Soft return on investment"---

Soft ROI carries just as much—and possibly more—importance to healthcare institutions, because many soft-return factors are transformative.

- Medication error reduction via decision support systems saves lives
- Access to a patient's entire healthcare history helps improve care
- Aggregated data analysis assists in focusing providers on performance enhancements

Capture lost charges- *"Hard Benefit"*	IF charges are now being lost	1%-5% revenue gain	**Roswell Pediatrics ('03) – 9 MDs, 3 sites, 82,000 visits/yr** ▪ Before go-live, 18.3% of procedures performed escaped documentation, therefore not billable ▪ 1-year post implementation, billing for procedures (e.g. venipuncture), increased from 353 to 8,324, the number of handling fees jumped from 968 to 1,734 and medical management charges jumped from one to 34
Reduce claims denials and delays – *"Hard Benefit"*	IF denials or delays are common	15-30 day A/R speed up	**Riverpoint Pediatrics ('04) – 1 MD, 1 site, 6,800 visits/yr** ▪ Increased collection rates from 52% to 88% in 4 years ▪ Eliminated claims denied due to coding errors ▪ Insurance-payment turnaround time fell from between 30 and 60 days, to approximately 15 days
Increase preventive & management services – *"Hard Benefit"*	IF new services are profitable AND capacity exists	5% revenue gain	**Southeast Texas Medical Associates ('05) – 24 MDs, 3 sites, 200,000+ visits/yr** ▪ Improvements in E&M service coding increased average billable charges for office visits 4.23%, adding more than $150,000 in billable charges
Reduce transcription – *"Hard Benefit"*	IF dictating AND willing to change	$5k - $15k/yr costs cut	**North Fulton Family Medicine ('04) – 7 MDs, 2 sites, 51,000 visits/yr** ▪ Elimination of transcription, recouped costs since implementation total ~$775,000 ▪ Transcription processing time per day reduced from 705 minutes to zero
Increase physician productivity – *"Soft benefit"*	IF physicians have extra capacity AND get "faster" with EMR	0% - 15% revenue gain	**Wayne Obstetrics and Gynecology ('05) – 1 MD, 1 site, ~6,000 visits/yr** ▪ Work hours devoted to documenting patient encounters decreased by 4 hours/week ▪ Number of patients clinicians able to see increased 225 %
Staff efficiency – *"Soft Benefit"*	IF overtime being paid, or IF staff ratio can be reduced	0%-15% cost reduction	**Southeast Texas Medical Associates ('05) – 24 MDs, 3 sites, 200,000+ visits/yr** ▪ Number of administrative staff required to handle patient charts decreased by 76.7% (from $2.65 per visit down to $0.62 ▪ Annual savings of more than $120,000 in administrative costs

Reduced chart pulls – *"Soft Benefit"*	IF practice charged for pulls	$5/pull or $6k/yr /MD	**Sports Medicine & Orthopedic Specialists ('05) – 4 MDs, 1 site, 20,000 visits/yr** ▪ Spends $1,000 per month on the EMR, post-implementation, compared with the $6,000 per month the practice used to spend pulling paper charts ▪ The systems freed up an estimated $75,000 in staff time. ▪ 23% increase in net patient revenues after the EMR implementation, with positive patient volume influence
Reduce costs of chart storage and archuving – *"Hard ROI"*	Citizens IF office goes paperless	$1k/yr per physician	**Pediatrics @ the Basin ('04) – 2 MDs (1FTE), 1 site, 4200 visits/yr** ▪ As a result of paper charts no longer being pulled in the office, $4 per chart request saved, totaling approximately $16,800 per year http://www.himss.org/content/files/davies/2005/CMH_FULL_APPLICATION.pdf
Patient Flow – Reducing and Reallocating Resource	Memorial ('05) – 74 beds and chart room eliminated Evanston Northwestern ('04) – 200+/facility		▪ Savings - Increased volume with its EMR equivalent to eliminating 65 full-time employees throughout the corporation ($4M); eliminating forms, a scheduling system, and dictation ($1.94M) ▪ Not having to conduct written data entry saved another $1,400 per year, while eliminating transcriptions added $10,000 to the bottom line ▪ $5,000 annually by eliminating storage costs

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s – *"Hard ROI"*		http://www.himss.org/content/files/davies2004_evanston.pdf
Billing Improvements *– "Hard ROI"*	Maimonides Medical Center ('02) – 705 beds	▪ '96 profits $761,000, '01 profits $6.1M post- implementation; 25% revenue increase from EMR, 9.4 % ROI annually. ▪ 4.84-year payback on its $43.8 million investment http://www.himss.org/content/files/davies_2002_maimonides.pdf
Patient Safety *– "Soft ROI"*	Maimonides Medical Center ('02) – 705 beds	▪ 58% decrease in medication orders, 55% decrease in medication discrepancies ▪ Decision support feature -- "High alert medications," confusing look-alike and sound-alike drug names, patients with similar names ▪ Identified 164,250 alerts, resulting in 82,125 prescription changes http://www.himss.org/content/files/davies_2002_maimonides.pdf
Process Improvement *– "Soft ROI"*	University of Illinois Chicago Medical Center ('01) – 450 beds	▪ 75% reduction in chart pull requests, expected to increase ▪ 12 paper forms eliminated ▪ 100% availability patient records (previously 40%) http://www.himss.org/content/files/davies_2001_uiccmc.pdf
Regulatory Compliance – *"Soft ROI"*	Ohio State University Health System ('01) – 849 beds	▪ Full compliance institutional do-not-resuscitate orders and restraint orders ▪ Allows daily reports to Ohio State Pharmacy Board, controlled substances compliance http://www.himss.org/content/files/davies_2001_osuhs.pdf

16. *HHS Question: Opportunities and challenges for the development of electronic tools to aid in the integration and analysis of large datasets of clinical parameters to assist in outcomes evaluations*

Evidence-based medicine, as applied to the treatment of chronic disease, relies on the frequent analysis of a patient's condition to consider whether the prognosis has changed from the expected course of the originally diagnosed condition. While most physicians are examining patients for evidence of recurrence of a remittent condition or degradation of a stable one, using electronic medical records it is increasingly possible to anticipate such a recurrence or degradation. In addition, as care advances, a worsening or recurring condition may call for changes in disease management and this is also best facilitated in the context of computer-assisted care.

Traditionally in working with electronic medical records, clinicians will identify a set of predictive criteria that are then coded into a vector representation. This vector represents an observation or set of observations indicating clinically relevant phenomena. If the criteria set forth in the vector are satisfied, an alert will be displayed to the clinician. In this way, based on historical experience, a set of symptoms, measures, or other collected data, outcomes can be predicted.

Over time, and with a large dataset of clinical experience, patients can be grouped into four categories, depending on whether or not an alert was generated and the clinical determination of the presence or absence of monitored complications:

Category	**Alert**	**Complications**	**Assessment**
1	No	No	True negative
2	Yes	No	False positive
3	No	Yes	False negative
4	Yes	Yes	True positive

The system should be optimized to minimize patients falling into category~3, the false negative, however in the context of any new information the alert system might require adjustment to ensure accuracy and satisfaction of the system requirements.

The forward vector equation, mapping data to outcomes through the alert vector, is quite simple and thus can be inverted based on known patient data and known outcomes and solved for an unknown alert vector. By solving for the alert vector as a function of monitoring results and outcomes, it is possible to optimize the components of the alert vector to optimally satisfy the requirement of accuracy given that false negative readings (category 3, above) are minimized.

Due to the tremendous volume of data required to solve this inverted equation, a closed-form solution would be a substantial challenge. Instead, by integrating iterative results with a system incorporating the artificial intelligence model of learning atoms, threshold values for the alert function can be evaluated within atoms and optimized to arbitrary precision using a linear combination of, for example, golden-section or fibonacci searches. Because of the stochastic aspect of monitoring results and patient history (i.e., two patients will not self-evaluate the same symptoms in exactly the same manner, and two physicians will not assess the same patient with exactly the same result), this atomic model will yield confidence intervals in its evaluation.

At each interval, this model results in defining the optimal alert function to be one that gives, based on the experience to date, warning for patients who have complications and not for those who do not, computed retrospectively on patients for whom complete monitoring results and follow-up history is available.

Caution is necessary in implementing such a system. It is important to include demographic and temporal data in the model, so that uncaptured regional, cultural, and

temporal trends can be at least identified for their influence if not their cause. In addition, the cautionary tail of the Swedish medical data collection project and the so-called "cancer clusters" phenomenon provide ample evidence of the need to establish causal relationships above the strict correlation model described here. However, discovering previously unknown correlations often leads to the discovery of new causal connections, and the development of large datasets, combined with the broad vision matrix model described here (as opposed to variable by variable comparisons), can lead to a deeper understanding of correlations.

For example, the investigator can take a well-functioning alerts model and the data collected during its use and determine the sacrifice in accuracy (i.e., new false positives) in order to have the system generate alerts at an earlier time. Through this alerts model, not only can this question be answered deterministically, but also the model that would generate those early warnings can be determined and, if sufficiently accurate, can be implemented immediately.