“Modern technology hasn’t caught up with a major aspect of health care, and we’ve got to change that.”

President George W. Bush
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This report is based on the discussion and recommendations of the Intergovernmental Advisory Board (IAB) of the American Council for Technology (ACT).

The ACT is a nonprofit organization that promotes information technology and seeks to foster an open and constructive dialogue and exchange of ideas and information among federal, state and local governments, as well as with industry representatives.

Members of the IAB

Established in 1997 by the ACT, the IAB goal is to promote knowledge and understanding of intergovernmental IT issues at the federal, state, local and tribal levels and to provide advice and guidance to the ACT on emerging IT intergovernmental issues and challenges over the next 12 months. An IAB written annual report is presented to the ACT and contains intergovernmental IT issues that may lead to improved services for US citizens through intergovernmental cooperation or awareness.

The IAB recommended this research study on Health IT in Government: Transforming Health Care and Empowering Citizens.

The IAB consists of 12 members with four members each representing federal, state, and local government. The IAB is chaired by Denis Gusty, Director of the Office of Intergovernmental Solutions, GSA Office of Citizen Services and Communications.

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The Institute of Medicine has highlighted how between 44,000 and 98,000 Americans die each year from medical errors. This heightened the issue of patient safety and quality for the public and decision-makers. Early in 2004, President Bush called for widespread adoption of interoperable electronic health records within the next 10 years, believing that electronic health records will reduce medical errors, cut healthcare costs through increased efficiency, and ultimately result in improved patient care.

Advancements in health IT and the interoperable environment that supports it will address this problem.

Generally, interoperability may be defined as the ability of two or more systems or components to exchange information and to use the information that has been exchanged accurately, securely, and verifiably, when and where needed.

Health care interoperability also assures the clear and reliable communications of meaning by providing the correct context and exact meaning of the shared information as approved by designated communities of practice. This adds value by allowing the information to be accurately linked to related information, further developed and applied by computer systems and by care providers for the real-time delivery of optimal patient care.

This report was developed by soliciting input from federal, state, local and international governments and their industry partners regarding how they are advancing health IT by using interoperable standards in data and information systems. In particular, we solicited input in the following areas related to the use of health IT by intergovernmental and public health services providers:

**Best Practices – Government’s Leading Health IT Initiatives**

- Electronic Health Records (EHRs)
- Health Information Exchange (HIE) Systems
- Public Health Information Network (PHIN) Applications
- Public Health Disease and Bio-surveillance
- Open Source Software (OSS) Solutions

**Future Innovations in Health IT**

- Genomics and Health IT
- wearable Computing
- Nanotechnology
- Hybrid Solar Systems and Health IT

Seventeen case studies and articles were selected from the public and private sectors. Each case study provides a point of contact for obtaining further information that may assist other efforts to implement similar projects.
Federal Agencies
Examples of leading-edge projects that boost the coordination, adoption and use of interoperable health care IT systems are presented from the Centers for Medicare and Medicaid Services, the Veterans Health Administration, the Department of Defense, the Indian Health Service and the National Aeronautics and Space Administration.

State and Local Agencies
State and local leaders, as well as health care, consumer and business leaders are collaborating to develop shared principles, priorities, strategies and projects for improving health and health care through the use of health IT and health information exchange.

International
The United Kingdom is spending several billion dollars to empower its National Health Service with electronic health records. These cases highlight the nation’s approaches to meeting the challenges of collaboration while improving health, people’s experience with health care delivery and the efficiency of the health service.

Future Health IT
It is certain that the nation’s health care system must soon change radically. To leap forward, change should be driven by quality and cost. Recent developments in genomics, micro-and nanotechnology, wireless communication and information processing are ready for introduction into the marketplace in the form of non-invasive and mobile biomedical measurements and health monitoring technologies. These studies survey the emergence of the next generation of health IT systems.
Background

President Bush outlined his vision for transforming health and his health IT plan in the State of the Union Address, January 20, 2004. The President’s plan states that, “innovations in electronic medical records and the secure exchange of medical information will help transform health care in America.”

In April 2004, the President signed an executive order announcing his commitment to the promotion of health information technology, and calling for widespread adoption of interoperable electronic health records within 10 years.

The President’s emphasis on using information technology to improve health care for all American citizens offers an opportunity for better quality health care, reduced medical errors and lower costs. The strategy of developing a Nationwide Health Information Network will link disparate health care information systems together to allow patients, physicians, hospitals, public health agencies and other authorized users across the nation to share clinical information in real-time under stringent security, privacy and other protections.

This vision for transforming health care, involving the use of IT in developing consumer-centered health care services, is based on the following expectations:

• Medical information will follow consumers so that they are the center of their own care.
• Consumers will be able to choose physicians and hospitals based on clinical performance results made available to them.
• Clinicians will have a patient’s complete medical history, computerized ordering systems, and electronic reminders.
• Quality initiatives will measure performance and drive quality-based competition.
• Public health and bioterrorism will be seamlessly integrated into care.
• Clinical research will be accelerated.

Over 80 percent of health care providers in the United States in 2005 did not have electronic health record systems. Of the systems that do exist, few are interoperable. A recent report on interoperable health information systems explains:

Under the current paper-based system, patients and their doctors lack instant, constant access to medical information. As a result, when a patient sees more than one doctor, no doctor knows exactly what another doctor is doing, or even that another doctor is involved. The consequences range from inconvenient or even fatal. Each time an individual encounters a new health care provider, the patient must recall his or her medical history. Not only is this redundant, it can introduce error and imprecision, ensuring that no two copies of a personal medical record will be exactly alike. In an emergency, delay and lack of information can be deadly.
To address this and other problems related to health care nationwide, President Bush named the first National Health IT Coordinator in 2004, bringing Dr. David Brailer to the Department of Health and Human Services.

Under Dr. Brailer’s leadership, federal, state and local governments, as well as communities, non-profits and provider organizations are beginning to plan, develop and initiate health IT collaboration with effective progress. Four goals are guiding the market-driven strategies and actions in realizing the vision for improved health care:

**Goal 1:** Informing clinical practice is fundamental to improving care and making health care delivery more efficient.

**Goal 2:** Interconnecting clinicians will allow information to be portable and to move with consumers from one point of care to another.

**Goal 3:** Consumer-centric information helps individuals manage their own wellness and assists with their personal health care decisions.

**Goal 4:** Population health improvement requires the collection of timely, accurate, and detailed clinical information to allow for the evaluation of health care delivery and the reporting of critical findings to public health officials, clinical trials and other research, and feedback to clinicians.

Managers across federal, state and local governments are helping to lead the way through their coordination and collaboration with public-private partnerships.

For example, the Agency for Health Research and Quality’s health IT initiative in fiscal year 2005 included $139 million in multiyear funding for more than 100 projects and contracts across the country. Its Transforming Healthcare Quality Through Information Technology grants and State and Regional Demonstration contracts portfolio, will affect 40 million Americans. These initiatives are exploring different innovative health IT applications with the potential to transform everyday clinical practice and help build 21st century health IT infrastructure.

The combined will of the public and private sector health care leaders and organizations can move health care delivery toward improved quality and safety. By leveraging the best practices of American information technology, communities can coordinate knowledge, plans and budgets to develop a nationwide system of health care information aimed directly at reducing the costs in injuries, wasted resources and lost lives.

**Case Studies**

This report offers a selection of recent cases describing health IT applications that exemplify the leadership, collaboration and innovation that is taking place among partnerships of governmental health care providers and private organizations.

These examples of leading-edge projects and future directions are meant to help raise awareness of some of the early successes in adopting interoperable standards-based health IT systems and applications. Following is a summary of the seventeen cases that illustrate specific health IT applications and innovative directions that contribute to the body of knowledge and emerging experiences.

**Federal Agencies**

Federal agencies are developing projects that boost the coordination, adoption and use of interoperable health care IT systems. Some leading-edge projects are presented from the Centers for Medicare and Medicaid Services, the Veterans Health Administration, the Department of Defense, the Indian Health Service and the National Aeronautics and Space Administration and two exemplary projects recognized by the Health Information Management Systems Society.

“CMS Paper on the Medicaid Information Technology Architecture” Medicaid Information Technology Architecture (MITA) is aligned with the goals of the Nationwide Health Information Infrastructure. MITA is intended to foster integrated business and information technology transformation across the Medicaid enterprise to improve the administration of the $300 billion Medicaid program.
“Interagency IT Solution: Federal Health Information Technology Architecture” Under sharing arrangements between the Department of Defense and Veterans Health Administration (VHA), the Federal Health Information Exchange is enabling the secure transfer of protected electronic health information from DoD to VA at the point of a military service member’s separation.

“Meeting the Healthcare Challenge, the Role of Open Source Software” Open source versions of VHA’s VistA (Veteran’s Health Information Systems and Technology Architecture) are providing opportunities for sharing and collaboration with other nations worldwide for developing low-cost, high-performance EHRs.

“NASA Electronic Health Record System Initiative” The National Aeronautics and Space Administration (NASA) is implementing an EHR system agency-wide at its health clinics, as the result of a sharing arrangement with the Indian Health Service, to leverage and customize the strengths of its Resource and Patient Management System. Moving to an EHR system for all NASA employees will employ advances in data security, order entry, and standardization of terminology.

“The Impact of the Electronic Health Record: Real World Examples from the HIMSS Davies Award Program” Each year a project is recognized by the Health Information Systems Society as an exemplary effort in the field of electronic health systems: The Indian Health Service Clinical Reporting System of 2005 is presented.

State and Local Agencies
State and local leaders are collaborating with health care consumers and business leaders for improving health through the use of health IT and health information exchange. These projects exemplify techniques of collaboration for sharing health IT innovations in the use of electronic health records and current directions in public health disease and biosurveillance systems.

“States’ Rights: Public-private Collaboration Statewide Could Boost Health Care into the Future” Analysis suggests that collaboration of health care provider organizations and state health departments on how to design, develop and implement health information systems could help save time and money, leading to better public health in our states and local communities across the country.

“NCHICA Health IT Case Studies” Projects undertaken in North Carolina Health Information and Communications Alliance provide lessons learned related to Immunization Registry and Hospital Emergency Surveillance Systems. Also, the North Carolina Healthcare Quality Initiative is underway to implement Medications Management, Electronic Lab and Radiology Order and Report and Electronic Health Records.

“An Open Source Electronic Health Record and Regional Health Information Exchange Model for Safety Net Clinics” The Primary Care Coalition of Montgomery County, Maryland shares its experience in deploying a regional-centric, web-based, open source electronic health record system for safety-net providers and clinics. It is a comprehensive process for region wide collaboration in developing an interoperable, standards-based health information system.

“A Standard (HL7 V3) Based Health and Regional Health Information Exchange Model for Safety Net Clinics” Los Angeles County, California relates its experience deploying the Operational Data Store, an architecture based upon the Public Health Information Network initiative published by the Centers for Disease Control. This aligns the county public health system with federal directives and national initiatives on surveillance for bioterrorism, control of disease outbreaks and the tracking of epidemiological information.

“Implementation of an Electronic Medical Record in a County” The Denver Public Health Department has gained savings through implementation of an electronic medical record system for its Sexually Transmitted Disease network.

Immunization Registries: Lessons Learned for e-Health Initiatives” State public health agencies and Medicaid have played a leadership
role in developing immunization registries. Lessons learned from early adopters show how public health agencies and Medicaid worked together with public and private providers to integrate registry “silos” into statewide immunization systems, based on connectivity, communication and collaboration.

International

The United Kingdom is spending several billion dollars to empower its National Health Service with electronic health records. These cases highlight the nation’s approaches to meeting the challenges of collaboration while improving health, people’s experience with health care delivery and the efficiency of the health service.

“United Kingdom Study of Health IT in Government: Challenges to Achieving the Vision of a Universal Electronic Health Record” The United Kingdom’s Department of Health describes the challenges to implementing a universal electronic health record and its project to implement the Quality Management and Analysis Systems.

Future Innovations in Health IT Systems

Health organizations on the cutting-edge of technologically advanced health care delivery, are beginning to collaborate on research, development and testing of forward-looking health IT systems that will contribute to revolutionizing patients’ and clinicians’ experiences in the future. Four articles are presented that offer insight on innovations in emerging health IT.

“Genomic Information Systems and Electronic Health Records” An exploration of unifying clinical record and genomic information systems, involving collaboration between public and private sector organizations.

“Nanotechnology, Nanomedicine, and Health IT Systems” A discussion of nanomedicine and health IT systems shows how higher performing nanotechnology solutions will revolutionize health care in the coming decades.

“Wearable Health IT Systems” A survey of innovations in wearable computing points toward how wearable health IT systems for physicians and patients will emerge over the next decade.

“Hybrid Solar Powered Health IT Systems” With a vision of the future for diversified energy, conservation and increased usage of solar power across all sectors of the economy, projects are highlighted that demonstrate innovations with hybrid solar powered health care facilities and systems.

The problems facing health care in America are well understood and documented: rapidly rising costs, with little corresponding improvement in health to show for the trillions of dollars the nation is spending. There is a consensus that the nation needs to develop an integrated health care infrastructure in an intelligent network. This will transform the quality of care while streamlining and automating the health care industry, saving billions of dollars annually.

Succeeding at this challenge, transforming the nation’s health care system, requires unprecedented collaboration among every participant in the health care environment, including federal, state and local government, all industries and all health care providers. Transforming health care with information technology and innovation has become a matter of national priority, safety and security for all citizens.
Background
The Medicaid program, a jointly funded program between each State and the federal government, provides healthcare services to more than 53 million low-income and disabled citizens across the country. In the most recent fiscal year, total Medicaid spending topped $300 billion.

Unlike Medicare, a Federal program with a national set of eligibility standards and uniform benefit package, Medicaid varies widely from state to state. Many believe this diversity has allowed states a much needed opportunity to customize the program to meet the needs of their highly diverse populations, as well as their differing health care needs. This variation in policies and programs has also contributed to individual claims processing and information retrieval systems that do not easily share information across system platforms, much less, interdepartmental or state boundaries. As a result, states and the federal government experience considerable difficulty developing comprehensive views of Medicaid client needs and services in light of the multiplicity of organizational and technological “silos.” These silos inhibit, rather than enhance, this much desired, but seldom achieved, holistic, client-centric perspective.

MITA Overview
The Medicaid Information Technology Architecture (MITA) is an initiative of the Centers for Medicare & Medicaid Services (CMS). It is aligned with the goals of the Nationwide Health Information Network, and the Strategic Framework from the Office of the National Coordinator for Health Information Technology. MITA is intended to foster integrated business and information technology transformation across the Medicaid enterprise to improve the administration of the $300 billion Medicaid program.

MITA’s common business and technology vision emphasizes:

- Medicaid client-centric view not constrained by traditional organizational barriers
- Common standards with, but not limited to, Medicare
- Interoperability between state organizations that provide services to Medicaid clients within and across states, as well as with other agencies involved in healthcare delivery
- Web-based access and integration
- Software reusability
- Use of Commercial-off-the-Shelf (COTS) software
- Integration of public health and clinical data

MITA establishes national guidelines for technologies and processes and includes an architecture framework, processes, and planning guidelines. The MITA approach is designed to enable state Medicaid enterprises to meet objectives within a common framework while still supporting
The MITA architecture framework is a consolidation of principles, business and technical models, and guidelines that combine to form a template, for use by States, to develop their own enterprise architectures.

The MITA processes provide guidance for State Medicaid enterprises to use in adopting the MITA framework through shared leadership, partnering, and reuse of solutions.

The MITA planning guidelines help States to define their own strategic MITA goals and objectives and to develop tailored enterprise architectures that are fully consistent with the CMSO expectations. In the future, the guidelines will serve as the basis for states’ requests for appropriate Federal Financial Participation for their Medicaid Management Information Systems.

MITA Goals

- Develop seamless and integrated systems that effectively communicate, achieving common Medicaid goals through interoperability and standards
- Promote an environment that supports flexibility, adaptability, and rapid response to changes in programs and technology
- Promote an enterprise view that supports enabling technologies aligned with Medicaid business processes and technologies
- Provide data that is timely, accurate, usable, and easily accessible to support analysis and decision making for health care management and program administration
- Provide performance measurement for accountability and planning
- Coordinate with public health and other partners, and integrate health outcomes within the Medicaid community.

MITA Objectives

- Adopt data and industry standards
- Promote secure data exchange
- Promote reusable component through modularity
- Promote efficient and effective data sharing to meet stakeholder needs
- Provide a beneficiary-centric focus
- Support interoperability and integration using open architecture standards
- Promote good programmatic practices, such as the use of the Software Engineering Institute’s Capability Maturity Model, as well technical practices such as the use of a data warehouse to separate On Line Analytical Processing from On Line Transaction Processing
- Support integration of clinical and administrative data to enable better decision making
- Break down artificial boundaries between systems, geography, and funding (within the Medicaid program)

MITA Approach

MITA has adopted a business-driven, service oriented architecture solution. MITA is firmly grounded in enterprise architecture principles and defines a business transformation over a five year and long-term (10 years and greater) timeframe. It includes a technical architecture and a transition strategy to enable the business transformation. To this end, the MITA Architecture Framework consists of a Business Architecture and a Technical Architecture.

The Business Architecture includes the following components:

- Concept of Operations – defines and structures the vision of future Medicaid operations.
- Common business process model – describes what an organization or business does, including the predecessors or triggers that initiate a process and the results of these processes.
- Business capabilities – describe the business processes at different levels of maturity.
- Business services – a package of components including inputs, outputs, and software that performs the business process. MITA business services are defined by their inputs and outputs.

MITA does not define how the
The definition and adoption of these standard inputs (trigger) and outputs (results) enable MITA goals of interoperability and modularity (plug and play). States can use the MITA business architecture to define their own target technical architecture including business vision, business processes, capabilities, and services.

The Technical Architecture includes the following components:

- **Application architecture** – defines the service infrastructure necessary to orchestrate the MITA services.
- **Data architecture** – defines the data (at a conceptual and logical level) necessary to support the business.
- **Technology architecture** – defines the technical services like security and privacy that also are necessary to support the business.
- **Technical capabilities** – show the essential technologies that are necessary to create the various business services.

Collectively, the components of the technical architecture define a set of technical services and standards that states can use to plan and specify their future systems.
authorized payment for expected medical services. The EHR system will provide the necessary clinical content to satisfy a service flagged for prior approval and all of these actions occur in real time.

As the clinical record is updated in the EHR, the EHR “invoices” the Medicaid agency, again via the MITA framework, for care provided. The Medicaid agency then performs real-time coordination of benefits with other insurers and they (as well as any other insurers) initiate electronic fund transfers (EFT) to the doctor’s bank account. The doctor then knows, at the time of the visit, exactly how much money (if any) the patient owes.

In the example given above, the exchanges between the EHR system and the Medicaid agency result in the following benefits:

- The provider’s administrative overhead, currently associated with billing and communications with Medicaid and other health care insurers, is significantly reduced
- The doctor’s practice realizes immediate cash flow (with real time EFT) while lowering the cost of operations.
- The patient receives better access to care due to the real time communications between the EHR system and the Medicaid agency.
- The Medicaid agency benefits from a lower cost of operations as nearly all of the communications with the doctor occur at a system to system level.
- The lowered cost of operations for the doctor and the insurer translate directly into lower overall cost for medical care.

Additionally, EHR systems potentially enable the Medicaid systems to assess the quality of care delivered by various health care providers. If Medicaid systems (and other health care payers) can scan clinical records (dependent upon rules and regulations regarding EHRs and privacy), then they may be able to assess the quality of care given by specific providers. This capability is also dependent on workgroups that are developing quality of care measurement methodologies. Once quality of care measurement methodologies and access to clinical information are available, it will be possible for health care payers and consumers to pay for performance.

Similarly, the Medicaid agency can scan the clinical records of its providers to assess the overall health of the Medicaid members. This allows the Medicaid agency to design benefit packages and disease management programs that most effectively and efficiently meet the needs of its members. It also enables the Medicaid agency to better assess the effectiveness of its programs and benefit packages. Most of what is described in the EHR example above is not possible in today’s world of MMIS processing silos.

**Early Adopters**

Collaboration is a core principle of MITA, and it is expressed through the MITA’s early adopter effort. Early adopters are state Medicaid agencies that volunteer to work with the CMSO and the MITA team on specific State projects. These relationships allow MITA to receive early feedback from States, and they enable the States to engage on MITA sooner. To date MITA team has worked with over 15 States.

**Problems Experienced**

- Like most enterprise-wide initiatives, MITA was faced with the daunting challenge of bridging long-standing technical, organizational and cultural differences among participating stakeholders. In MITA’s case, this meant developing a national architectural framework that 50 different states and the District of Columbia could all rely on to meet their unique programmatic requirements while, at the same time, enable them to share critical health IT with others.
- Given a model with such broad scope, it is difficult, though not impossible, to identify the appropriate level of business service and technical details necessary for MITA--too little detail and the model cannot be easily applied; too much and the model becomes unwieldy and proscriptive for practical application.
- Development of the MITA model
is dependent on the ongoing development of standards. Healthcare lags behind other industries in automation and adoption of standards and this could hinder progress on MITA.

• The Medicaid program is one silo, admittedly by far the largest, among many other healthcare silos at State and local levels. Individual applications of the MITA model within given States could depend heavily on these other silos adopting the architecture that enables interoperability.

• Providers are key players in the medical claims cycle and providers have been slow to adopt EHRs.

Summary

MITA remains a work in progress. CMS will continue to monitor and participate in various national Health IT standard-setting bodies to keep MITA current. In addition, we will work with the early adopter States to build the MITA foundation and to test MITA concepts under real procurement scenarios. Intergovernmental coordination with other federal and state agencies will play a key role in promoting the widespread utilization of MITA within the larger health care enterprise.

For more information contact Rick Friedman, Director, Division of State Systems Centers for Medicare and Medicaid Services, at richard.friedman@cms.hhs.gov.
The Federal Health Information Exchange (FHIE) contributes to enhanced continuity of care when service members transition to veteran status. The Department of Defense (DoD) service members change to veteran status when they are discharged or retired from the service. While in the service, a member’s electronic health information is kept in DoD’s Composite Health Care System (CHCS). When a veteran presents to the Department of Veterans Affairs (VA) for care, the VA depends upon obtaining the paper military health record and then, starting a new collection of electronic health information in the Veterans health Information System and Technology Architecture (VistA). The FHIE system transfers clinically pertinent electronic health data to a shared repository where it is available for viewing by VA clinicians using VistA.

The FHIE solution enables the secure transfer of protected electronic health information from DoD to VA at the point of a Service member’s separation. Data being transferred are: laboratory results (clinical chemistry, blood bank information, microbiology, surgical pathology, and cytology); radiology results; outpatient pharmacy data from military treatment facilities, retail network pharmacies, and DoD mail order pharmacy; allergy information; discharge summaries (inpatient history, diagnosis, and procedures); admission, disposition, and transfer information (admission and discharge dates); consult reports (referring physician and physical findings); standard ambulatory data record (diagnosis and procedure codes, treatment provided, encounter date and time, and clinical services); and patient demographic information (name, social security number, date of birth, sex, race, religion, patient category, marital status, primary language, and address).

The FHIE program leverages existing agency and interagency systems’ investments to provide a solution that is effective, affordable, secure, standards-based, and expandable. FHIE has greatly enhanced the continuity of care for retired and separated Service members receiving care in the VA. Prior to FHIE, there was no electronic transfer of health care information between DoD and VA on these individuals, and it could take months for the VA to obtain the paper records. Today, DoD has transmitted protected electronic health information to the FHIE repository on over 2.4 million unique retired or discharged Service members. This number grows monthly as health information on recently separated Service members is extracted and transferred to VA. Of the 2.4 million unique patients, DoD and VA have identified approximately 933,500 as having presented to VA for care, treatment, or claim determination. VA providers, at all VA sites of care, have access to data on separated Service members to enhance delivery of health care and adjudication of disability claims. FHIE is also compliant with the Health Insurance Portability and
Accountability Act and other privacy regulations.

The successful iterative FHIE development process serves as a model for improved health data sharing between DoD and VA. This is evidenced by the development of the Bidirectional Health information Exchange which leveraged existing Government investments in FHIE to rapidly and cost effectively create a near real-time bidirectional solution that is applicable for use at joint venture sites and DoD and VA medical facilities with sharing agreements. Electronic health information is accessible for shared patients – DoD providers can view VA health information and VA providers can view DoD health information for patients treated in both healthcare systems.

The DoD/VA experience and lessons learned in developing FHIE have also served to forge the way to future DoD/VA sharing projects with the next generation systems, DoD CHCS II and VA HealtheVet VistA. DoD and VA are working on interoperability between the DoD Clinical Data Repository and the VA Health Data Repository in the next generation systems to provide a more robust bidirectional real-time exchange of clinical health care data for shared patients. The lessons learned in FHIE are being applied to this new development effort.

FHIE is consistent with DoD/VA Departments’ “long-range plan to improve sharing of health information; adopt common standards for architecture, data, communications, security, technology and software; seek joint procurement and/or building of applications, where appropriate; seek opportunities for sharing existing systems and technology, and explore convergence of DoD and VA health information applications consistent with mission requirements.”

For more information contact Greg Donham, Program Manager, FHIE, Veterans Health Administration, Office of Information (VHA OI) at Greg.Donham2@med.va.gov.
Challenges for government in provision of healthcare

Governments across the world face major challenges in seeking to improve the health of their populations. Developed countries struggle with aging populations, increasing expectation and lifestyle diseases, as well as HIV/AIDS and poverty. Whatever the context, the key to effective management of healthcare delivery and health quality improvement is the availability of information about clinical activity, outcomes and resources. However, across the world clinical practice still relies largely on paper based health records and manual procedures. Sophisticated electronic healthcare systems are available for both primary and secondary healthcare providers, but these are expensive both to install and maintain. This paper presents a case study of an alternative low cost model for the development of healthcare information systems.

The VHA experience

An example of the effective use of healthcare information systems is provided by the US Department Veteran’s Affairs (VA). The US Government funds the VA, which provides care to approximately 4.5 million veterans. The Health division, the Veterans Health Administration (VHA) employs approximately 180,000 healthcare professionals at 170 hospitals, more than 800 community and facility-based outpatient clinics, over 135 nursing homes, 43 domiciliaries, 206 readjustment counseling centers, and various other facilities. In addition the VHA is the nation’s largest provider of graduate medical education and a major contributor to medical and scientific research.

VHA medical centers are affiliated with more than 152 medical and dental schools, training more than 80,000 health-related students and residents each year. More than half of the U.S. practicing physicians have received training in VHA hospitals. The VHA is the second largest funder of biomedical research in the U.S. The VHA also provides healthcare services to active military personnel during wartime and the general population in times of national disasters.

From its inception the VHA adopted an in-house development strategy for the provision of its information systems, resisting pressures to buy in commercially available systems. Development of its core operational system, now known as the Veteran’s Health Information Systems and Technology Architecture (VistA) started in 1984 and continues to this day. From an initial limited set of functions, which included patient registration, outpatient clinic scheduling, inpatient admission/discharge/transfer (ADT), pharmacy, laboratory, and radiology, the system was enhanced with the release of the Computerized Patient
Record System (CPRS) for clinicians in 1997 and the integration of imaging facilities in the late 1990's and early 2000's. Implemented in every VHA Medical Centre, and associated outpatient and long term care facilities, VistA is now recognized as one of the most advanced health information systems in the world, providing a comprehensive electronic health record for all veterans.

The richness of information available to clinicians, administrators and patients from this ubiquitous clinical support system enables the VHA to actively manage its resource allocation and effect on-going quality improvement through evidence-based practice and a proactive approach to patient care. The VHA is generally recognized in the USA as a model for patient-centered, high-quality, high-value healthcare. It cares for more patients with proportionally fewer resources than any comparable US healthcare provider and sets national benchmarks in patient satisfaction, and for 18 indicators of quality in disease prevention and treatment.

Open and closed source software licenses in healthcare

VistA software was developed with US government funding and is thus in the public domain. Under the requirements of the Freedom of Information Act (FOIA) such software is freely available to anyone requesting it and therefore falls into the category of FLOSS (Free, Libre and Open Source Software) well known examples of which are the operating system LINUX, the Web server software APACHE and Open Office, an integrated set of office applications. There are a variety of different types of FLOSS licenses but in contrast to more common closed software licenses, they all allow users to access and modify the code.

Access to the source code of application software does not necessarily present problems in sectors where information requirements and operational practice are reasonable static, but the requirements of healthcare organizations are constantly changing in response to evolving health priorities, organizational change, developments in clinical practice and new technologies. Healthcare information systems thus:

• are subject to a process of continuous evolution
• are embedded in the operational practices and structures of the organization and so difficult to replace
• are safety critical
• have to meet the requirements of diverse and demanding healthcare professionals and are best developed by a rapid development process involving close collaboration between developers and users
• need to interwork and exchange data with systems in other organizations.

In the established model of software development, development is carried out by the supplier following detailed requirements analysis, and all modifications are subject to detailed contractual negotiations. There is evidence that this closed source model of information system development does not fit the healthcare sector well and has these impacts:

• results in systems that are expensive to implement and maintain; the supplier is in a monopoly situation as changing the system and supplier is a highly disruptive and costly process; complex sensitive patient data has to be preserved for clinical and legal purposes
• results in systems that lack detailed functionality required at the operational level and are thus subject to high levels of user dissatisfaction
• inhibits changes in organization and clinical practice
• slows the process of healthcare information standardization and interworking.

While the cost of information systems can be absorbed in high cost healthcare delivery systems such as those in Europe and America, the ownership cost of typical commercially available systems may exceed the total operational budget of hospitals in developing countries.

The model of open source software
development, by contrast is characterized by collaboration between diverse groups, with code released early and often and so subject to peer review and user evaluation at all stages. Code with an open source license can be modified by anyone for their own use and enhancements valuable to the whole community of users passed back into the core system. This model has been successfully used in many areas, particularly for Internet services and applications, but to date has not yet become widely adopted in the healthcare sector. VistA provides the best example of the open source model in healthcare.

Since the start of its development, as the code is freely available, VistA has been taken by other healthcare organizations both within the US and across the World, and either used without significant modification or has provided the basis for further development to meet local requirements. Many of these developments have been used within the VHA itself. The investment by the VHA in VistA has thus benefited many other healthcare organizations, and in turn the VHA has itself gained from their experience and efforts.

**VistA-based Healthcare systems around the world**

The following provides a summary of the most significant of the numerous VistA based healthcare systems currently in use, or being implemented, both by US organizations and by Government healthcare providers across the World.

- **Within the USA.** The US Department of Defense (DoD) uses modified version of VistA known as the Composite Health Care System (CHCS) in all major Military Treatment Facilities around the world. The VHA and DoD continue to collaborate on a number of health information systems, although CHCS is developed independently of the VA. The **US Indian Health Service** uses a modified version of VistA - the Resource and Patient Management System (RPMS) in hundreds of its healthcare facilities across the country. A number of software modules e.g. Health Summary, Women’s Health, developed by the IHS have been incorporated into the VistA system and used within the VA. VistA and RPMS continue to be closely aligned.

  The Centers for Medicare & Medicaid Services (CMS) are collaborating with the VHA on an initiative to provide a version of VistA suitable for deployment by small primary care practices. This project was initiated in response to direction received from the President of the United States following concerns expressed at the level of computerization among these providers. VistA Office EHR is an alternative to more costly solutions being made available from private vendors that are not affordable to smaller practices and healthcare provider organizations.

- **American Samoa.** The Lyndon Baines Johnston (LBJ) Tropical Medical Center in Pago Pago is the only medical facility in America Samoa. The facility is a 160-bed hospital that provides health care to approximately 70,000 people. Before they implemented the VistA system, LBJ had no computer system at all and all record keeping was paper-based. The system was successfully deployed in 2003 by a collaboration involving the Honolulu VHA Medical Center, VHA Headquarters, WorldVistA, US Air Force and National Guard, University of Hawaii and a number of small IT vendors. The system is now supported by local IT staff and over 85% of the population of America Samoa has their EHR on the system. The Center intends to continue to use the standard system released by the VHA keeping it patched and up-to-date.

- **Finland.** Developers in Finland have used core the VistA tools and the VistA kernel to create their own country specific healthcare information system known as MUSTI. This project started during the 1980’s and MUSTI is now used in over 30 major public hospitals in Finland. MUSTI incorporates some VHA modules together with a variety of applications from a half a dozen different vendors.

  During the 1990’s MUSTI was enhanced by the addition of a Graphical User Interface (GUI) and this work has substantially influenced a similar development
within the VHA itself. An R&D project was initiated in 1998 to further modernize MUSTI by developing a Web based interface. This multi-year project was funded by the National Technology Agency (TEKES) and consisted of a consortium of four vendors and three university hospitals. It was tested on a small scale in 1999 and was scheduled for initial release in January 2000. One of the results of this project was the development of a plan of the next phase of the migration path, where the core functionality of the information systems will be encapsulated into business components, and a foundation laid for the application of alternative database management systems. Funding for this long-range project for 2001 was provided by TEKES.

The Finnish experience provides an example of multi agency collaboration (Government, private and academic) in an open source development. Finland had successfully developed and deployed a comprehensive electronic health record (EHR) system tailored to fit the requirements for everyday use of the healthcare delivery system in Finland. Developers in Finland continue to work closely with their counterparts in the VHA and have also contributed to the development of a system in Nigeria.

• **Nigeria.** The important role of Information Technology (IT) in Africa's development is recognized by several international agencies, including the United Nations, World Bank, USAID, and International Development Research Centre. However, appropriate software packages for African hospitals and health centers cannot generally be found. One significant exception, is the "Made-In-Nigeria Primary Healthcare and Hospital Information System (MINPHIS)" developed as part of a joint R&D project by Obafemi Awolowo University (OAU) in Ife-Ife Nigeria and the University of Kuopio in Finland. MINPHIS is deployed in 8 teaching hospitals in Nigeria.

OAU is one of the biggest universities in Nigeria with approximately 20,000 students and 5000 faculty and staff. The OAU Teaching Hospital Complex consists of two hospitals (342 and 212 beds), two urban and one rural health centre, a dental hospital, and schools of nursing. The development of MINPHIS started in 1989 using VistA and MUSTI software technology and has been under operation and refinement in the Hospital since 1991. MINPHIS package has been implemented in least four other tertiary hospitals in Nigeria as of 2004.

A bye-product of the project has been the emergence of a multidisciplinary Health Informatics Group in Ife-Ife, which it is currently the strongest Health Informatics Research and Development centre in Sub-Saharan Africa outside of South Africa. The intention is to continue to extend the system to become a more comprehensive electronic health record (EHR) solution that can be deployed across the three tiers of the Nigerian health care system.

• **Egypt.** In 1990 a project was launched to implement a health information system at the National Cancer Institute (NCI) in Cairo, Egypt. NCI is the leading cancer centre in Egypt, delivering cancer care for about 12,000 new cancer cases every year. Customization and conversion to Arabic of many parts of VistA was achieved in-house, with cooperation from staff at the VHA and the University of Wurzburg in Germany. VistA software applications that were implemented included: Patient Registration, Inpatient ADT, Surgery, Laboratory, Pharmacy, Radiology, Record Tracking, Nursing, Engineering, and an early version of the VistA Clinical Imaging module. In 2000, NCI started working on a GUI interface for ADT, Lab, Radiology, and other modules. Some of this software is purely in Arabic, some in English, and some mixed.

The Nasser Institute Hospital (NIH) the largest tertiary reference center for the Egyptian Ministry of Health & Population is currently implementing VistA with US AID funding. The project is being carried out by a local company with support from IT staff at the NCI. Both the NIH
and the National Cancer Institute NCI plan to implement the Computerized Patient Record System (CPRS) and VistA Imaging modules and integrate their VistA systems with their other existing IT systems: Telemedicine, Cancer Registry, Quality Assurance and Decision Support.

- **Mexico.** The Instituto Mexicano del Seguro Social (IMSS), the Mexican government’s social security healthcare system, operates a chain of 40 large public tertiary hospitals, 223 regional hospitals, and over 1200 clinics. The IMSS is a non-profit state-owned organization and is the main health care provider in the country. Following a successful pilot implementation in 2004 they decided to implement VistA in all of their facilities. Translation, other modifications and implementation are being carried out by in-house staff. By mid 2005 VistA was installed in 4 hospitals with 10 more hospitals gearing up. The Mexican government plans to have 25 tertiary hospitals running VistA by the end of 2005 and approximately 100 additional general hospitals by the end of 2006.

### VistA's future

VistA continues to be developed within the VA. Planned enhancements to VistA include a Personal Health Record module, a Health Data Repository, and a web-enabled front end. The VHA also has in place a program of collaboration with other organizations outside the VHA on health IT standards, electronic health records, personal health records, health information exchange, public health and disease surveillance systems, and sharing health IT expertise.

The VHA is funded by the U.S. government to provide services for veterans and is limited in the support it can provide to VistA implementers and developers outside of the VA. This has been an inhibiting factor on the increased use of VistA, as although the VistA software is freely available, considerable experience and expertise is required to implement it and maintain it in a live setting. In 2000 a group of VistA experts and other interested people formed a not-for-profit company, WorldVistA to address this issue by helping prospective users to install, and maintain the software for their own use. WorldVistA has a number of development efforts under way, aimed at adding new software modules such as pediatrics, obstetrics, and other functions not used in the veterans’ healthcare setting. Within the VHA VistA runs on a platform that includes proprietary licensed software; WorldVistA ports the system to run on LINUX and an open source database management system so that the entire system can be implemented without the payment of any software licenses.

The long-term aim of WorldVistA is to establish a worldwide community of VistA users and developers working on the principles of open, collaborative, peer reviewed software development and dissemination. As interest grows, the number of commercial companies in the US, willing to support VistA implementations has increased and they have formed a trade organization known as the VistA Software Alliance. WorldVistA will encourage the establishment of similar organizations of local companies able to provide implementation support for VistA users in their Regions.

### Conclusions

The experience of the VA’s development of VistA over the last two decades has demonstrated that the implementation of comprehensive clinical support systems across a healthcare organization can provide the basis for significant health care quality and efficiency improvement. However the development of such systems is difficult and costly. The open source model of software development provides a way for Government organizations, academic institutions and commercial companies in different countries to collaborate in an on-going effort to bring the benefits of such technology to healthcare providers across the World.

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Since its inception in 1958, the U.S. National Aeronautics and Space Administration (NASA) has used predominately paper medical records for required employee occupational health data at fourteen medical clinics nationwide. After reviewing the limited commercial electronic systems used at a few clinics, NASA's Chief Health and Medical Officer (CHMO) in April 2002 directed planning to implement an agency-wide electronic health record system (EHRS). The purpose was to provide: greater medical quality assurance to NASA employees with ready access of records, a record backup system to the current paper record, and capability for rapid agency health data collection. Some patient records such as heart rhythm strips recorded on thermographic paper were literally deteriorating and becoming useless. Moving to an EHRS at this time capitalizes on rapid advances in computer technologies, wide scale development and acceptance of large relational databases, deployment of such capabilities in some medical practices and large health institutions, and increased interest in the federal government's eGOV initiatives to establish standards and move toward electronic health record capabilities in the public and private sector.

NASA's EHRS developers visited all agency clinics expressly to learn their specific health evaluation requirements, processes, and practices related to delivery of OH services. The CHMO chartered a working group comprising of medical and computer technology personnel from all NASA centers which produced a process flow to chart EHRS that best met agency needs. This information was summarized for commonalities and unique content. Commercial vendors were sought to demonstrate existing functions and compatibility. Subject matter experts were queried at private industry-government symposia such as Toward an Electronic Patient Record, Departments of Defense, Veteran's Affairs, and Health and Human Services. Consultant expertise was acquired to determine state of the art capabilities, and academic/advisory recommendations were received.

No existing government or private sector EHRS would address all NASA occupational health requirements, most notably occupational health for physical requirements and monitoring of personnel engaged in hazardous operations. NASA's Aerospace Medical and Occupational Health Advisory Committee, the Institute of Medicine and the Agency for Healthcare Research and Quality (AHRQ) recommended NASA consider operational systems within the Federal sector. The Indian Health Service (IHS) Resource and Patient Management System (RPMS), based upon the Veterans Health Administration VistA Computerized Patient Records System, was found to be the closest to NASA requirements. This system was demonstrated to NASA personnel at the IHS hospital in
requirements). Further, much automation will be designed in, such as order entry of evaluation content depending of the employee job requirements, alerts/advisories, and direct access to health information helps. Another major design criterion is standardization—of terminology, of input methods, of data fields—while allowing reasonable flexibility of information recall and display.

Deployment considerations include the paramount “buy-in” and a change of culture for the multi-disciplined occupational health teams at all NASA site clinics. This factor is universally accepted as more challenging than designing and implementing the technology. Highly instrumental to this was the appointment of a multiple-disciplined Task Force with representatives from all NASA centers. The Task Force acts as point of contact for their respective Center, data gatherers, advocates, and central communicants to raise awareness and promote the system. They also reviewed and edited major documents with common impact and helped draft a critical work flow process amenable to all clinics. It is anticipated that many of these Task Force members will become “super-users” who will contribute to the help team available for future system users. Equally important is incorporating into the system maximal user-friendliness.

The cost savings are immediate. NASA obtains the core IHS system and begins implementation of an EHRS system on a very limited available budget. Cost savings will be further be realized in efficient use of the limited number of medical personnel at the OH clinics for patient assessment and care rather than manual data entry and retrieval of multiple paper records. Efficiencies include error reduction and patient safety, and increased quality of services by having all medical record elements linked electronically and immediately available to the medical practitioner. Personnel traveling from one NASA location to another will have immediate clinic access to their medical records as needed. Cost avoidances are anticipated when the EHRS has generated sufficient data to measure (evidence-based) its eventual positive effects on employee health.

NASA is on the threshold of determining final design issues and letting final contracts which should allow deployment of the EHRS in the first clinic in the latter half of FY 2006. Personnel without access to the internet and persons with disabilities can access their records through assistance of NASA occupational health clinic personnel, as EHRS medical data is provided to employees from available OH clinic staff.

For more information contact Alan Gettleman, NASA at Alan.Gettleman-1@ksc.nasa.gov.
The Healthcare Information and Management Systems Society (HIMSS) vision is to advance the best use of information and management systems for the betterment of health care. Through the Electronic Health Record (EHR) Steering Committee, HIMSS has leveraged our member subject matter expertise and a merger with the Computerized Patient Record Institute to support national and local efforts to accelerate the implementation of the EHRs across the United States. HIMSS believes lives can be saved, outcomes of care improved, and costs contained by transforming the delivery of care through the appropriate use of information technology.

As part of the HIMSS vision, the Society sponsors the Nicholas E. Davies Award Program, a national award that recognizes exemplary efforts in the field of electronic health systems. The award is named for Dr. Nicholas Davies, an Atlanta-based physician who was a member of the Institute of Medicine patient record study committee and was committed to improving patient care through better health information management. During its first eight years, the Davies Award Program focused on large health systems and issued 18 awards for exemplary efforts. Over the last three years, the Davies Award Program has expanded to include ambulatory care practices and public health organizations.

The following is an example of the role EHRs play for the 2005 Davies Award winner.

Indian Health Service -- 2005 Public Health Davies Award Winner

The Indian Health Service (IHS) is a federal agency whose stated goal is “to assure that comprehensive, culturally acceptable personal and public health services are available and accessible to American Indian and Alaska Native people.” The mission of the Indian Health Service is “to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.” The IHS Clinical Reporting System (CRS) is a tool that allows the clinicians, administrators, and programs to measure our progress and improve our success in meeting both the mission and the goal of the IHS.

The IHS is first and foremost a public health agency. The IHS Clinical Reporting System (CRS) is a component of the IHS Resource and Patient Management System (RPMS). RPMS are an integrated software system for management of clinical, practice management and administrative data in IHS and tribally operated healthcare facilities. CRS is the reporting tool used by the IHS Office of Planning and Evaluation to improve clinical performance and to collect, report, and evaluate the results quarterly and annually for IHS, as well as the Department of Health & Human
Services (HHS) and Congress. The CRS is available for use by 426 facilities nationwide. In 2004, over 1.16 million patients were represented in the CRS data submission to HHS as part of the performance-based budget submission. Since 1955, the IHS has demonstrated the ability to utilize limited resources to improve the health status of the American Indian and Alaska Native (AI/AN) people by focusing on preventive and primary care services. The IHS, like all federal agencies, is under increasing pressure to demonstrate, in a measurable way, the appropriate utilization of federal budgetary dollars. The Government Performance and Results Act (GPRA) require federal agencies to demonstrate that they are using their funds effectively toward meeting their missions.

Most IHS GPRA measures focus on clinical treatment and prevention measures that affect patient care, as well as population and public health. The GPRA performance measures address the most significant health problems facing the AI/AN population as identified by representatives of local tribal communities and local healthcare facilities, as well as areas of national concern to AI/AN populations.

The GPRA indicators have been measured using the CRS software application for several years. This automated process has helped to improve public health practice by providing comprehensive and longitudinal data in efficient, easy-to-use reports to individual providers, health administrators, community health programs, tribal leaders, and governing boards. Reports are used to identify patient needs and to assist providers with case management of various disease states including two of the most prominent in AI/AN communities: diabetes and cardiovascular disease. The data gathered also provides opportunities to look at the health of the population and epidemiological patterns. For instance, early data evaluation of BMI data, one of the GPRA measures, has illustrated an obesity epidemic that is worsening in AI/AN communities since 2000. Because of the identification of this epidemic, IHS is implementing patient education programs and a National Obesity Initiative to make its patients aware of the negative health consequences associated with a high BMI and to inform them of the nutritional and physical lifestyle changes they can take to improve their health status.

Examples of where the CRS software application is having a positive impact on the delivery of healthcare are the Warm Springs Health and Wellness Center and Cherokee Indian Hospital in Warm Springs, Oregon.

- Both Warm Springs and Cherokee Indian Hospital are using CRS to monitor their challenges and improvements in several areas including:
  - documentation of medication education
  - flu and pneumococcal immunization rates
  - outcomes related to chronic diseases such as diabetes and cardiovascular disease
  - Patient lists from CRS were generated at Warm Springs to ensure that diabetes standards of care were being met during the transition from paper to provider order entry. Quarterly data evaluation helped ensure both hospital administration and the community that patient care was being maintained, and in some cases, improved with the advent of this new technology.

- The Women’s Health program has used CRS patient lists to allocate resources to a “Mammogram Rides” program by generating a list of patients who were delinquent on their mammograms. Information obtained from these patients helped identify the most significant barrier to women needing mammograms (mammograms were not offered on site). The Women’s Health program is also using the CRS to improve data quality in the Women’s Health Registry.

Conclusion

The CRS application has impacted the health of AI/AN populations across the U.S. by providing an efficient, nearly turn-key assessment of the health of the individual communities and
populations. Public health researchers have created lists of indicators that would “paint a picture” of the health of a community; many of the CRS indicators are based on these lists. This system has allowed the generation of provider-specific quality measures, as well as patient lists for individual providers that can be used for case management. When used to its full potential, CRS rapidly identifies when there is a system problem; the application can help to identify and rectify system issues as well as data quality issues almost immediately.

For more information contact Tom Leary, HIMSS at tleary@himss.org.
As federal leadership and nationwide private sector initiatives are important for creating the policies, guidance and innovations for health information technology, they must be coordinated with efforts at the state and local levels of government. Thus, collaboration among interconnected networks of health care providers, consumers and businesses with the leaderships of states and communities must foster the creation of regional data exchange networks, the deployment of appropriate infrastructure, and oversight of projects to achieve the goal of an electronic health record for most Americans within ten years.

Information sharing initiatives between state health departments and healthcare provider organizations could be mutually beneficial. For example, if both public and private organizations exchanged information between their electronic health record (EHR) systems, patient care might be enhanced and state public health and disease surveillance systems would benefit.

Systems analysis

After gathering data from the state health department Web sites on their health information systems (HISs), we found that 10 broad categories of systems and/or databases are common to most states: births and deaths, disease registries, biosurveillance, immunization and vaccines, facilities registries, practitioner registries, environmental health, occupational health, healthcare information systems and emergency department information systems. We then reviewed the information to determine whether states’ HISs were automated (defined as systems with evidence of electronically receiving, storing, or processing data using computers, even though the data may have been submitted by mail, fax, or another method).

Preliminary analysis revealed that most states use automated systems for seven of the categories: births and deaths, disease registries, biosurveillance, immunization and vaccines, facilities registries, practitioner registries, environmental health. These findings point to further opportunities for improved data sharing between healthcare organizations and states.

The facility-based HISs and emergency department categories may offer opportunities for sharing IT (i.e., EHR systems).

Occupational health may be one category where knowledge sharing is in order, so everyone can learn from the few states that have automated this area.

• Data sharing: Every state needs extensive collaboration between public and private organizations on developing common standards, functional requirements, and technical specifications for more effective statewide registries of births and deaths, immunization and vaccines, communicable diseases, healthcare facilities, health practitioners and environmental health.

Examples of major steps needed are adoption of agreed-upon health data, terminology, and communication standards; implementation of secure health information exchange (HIE) solutions between public and private healthcare organizations and their EHR systems and development of semi-automated data entry capabilities for providers without an EHR system. Online directories of public and private healthcare facilities and practitioners across the state should be provided. And capabilities for rapid public health information dissemination, along with geographic displays or
mapping, should be ensured. State biosurveillance systems have high priority nationally. Many states have some form of automated biosurveillance systems under design or development related to the Public Health Information Network and the National Electronic Disease Surveillance System. Private provider organizations may need to actively discuss how they can collaborate with the states in this arena.

- **IT sharing:** Each state has many opportunities for public and private provider organizations to collaborate on a variety of HISs. For example, several statewide emergency department information systems have emerged. The North Carolina Emergency Department Database, sponsored by the Centers for Disease Control and Prevention (CDC), Atlanta, is a system for collection and analysis of timely and secure emergency department data in a centralized database. The data is aggregated and standardized using the CDC-developed Data Elements for Emergency Department Systems.

Many small practice and rural healthcare facilities do not have an EHR system. The Centers for Medicare & Medicaid Services and the U.S. Department of Veterans Affairs are collaborating on a project called VistA-Office EHR aimed at making available a high-quality, public-domain EHR system to individual practices and the EHR industry. The goal is to help stimulate adoption of EHR systems in every state across the country.

Similarly, as we look to the future, there is an opportunity for public and private healthcare organizations to collaborate on the development of emerging personal health record (PHR) systems.

- **Knowledge sharing:** To date, only a handful of states have developed knowledge-sharing systems related to development of statewide occupational HISs. There are also opportunities for public and private organizations across the states to collaborate on making reliable online medical reference information readily available to everyone.

- **Other issues:** Among the additional major issues needing to be faced is safeguarding the intrinsically sensitive nature of patient data in agreements between partners. All partners should ensure that only non-identifiable patient data is transmitted, through secure data transmission methods using encryption and electronic signatures. Only standardized data elements should be exchanged between systems.

Authentication and certification of users accessing healthcare systems must be addressed in accordance with the Health Insurance Portability and Accountability Act (HIPAA) requirements. Secure gateways with firewall protection and the use of virtual private networks to protect systems also need to be addressed.

**Benefits of collaboration**

One of the goals of the National Health Information Network (NHIN) is sharing clinical information and knowledge appropriately so it is available when needed to make the best possible health decisions. Clearly, state health departments already have collaboration projects and plans aimed at enhanced information gathering and process development in the areas of immunization tracking, disease monitoring and biosurveillance. These efforts will help further integrate HISs of private institutions with public health systems and will contribute to the growing broad-based commitment to the NHIN.

Individual organization and state health departments may benefit from further pursuing health information sharing opportunities. For example, sharing of patients’ clinical information between institutions should improve the overall quality of healthcare they receive when they move between healthcare facilities in the state. Also, collaboration of institutions within states should facilitate the spread and adoption of common health data and communications standards, ultimately leading to interoperable systems.

Trend data gathered on patients can be made immediately and confidentially available to public health surveillance systems,
resulting in better protection and security for the general state population. Sharing of healthcare informatics expertise and knowledge may lead to better IT solutions for the entire community and potential cost savings related to the development and implementation of new HISs by organizations in the states. And public-private collaboration should help achieve the national goal of an EHR for every citizen.

**Suggestions for the states**

State health departments should consider establishing statewide health informatics collaboration working groups to address such areas as health data standards, EHRs, PHRs, HIEs, and public HISs and databases. A state health IT-sharing liaison could coordinate and facilitate communications on all collaborative projects. Another consideration should be a database to track information on HISs used by all provider organizations in the state, key contacts, and other relevant information.

A prioritized list of statewide collaborative projects should be developed based on input from public and private-sector participants of the health informatics collaboration working groups. All participants of collaborative projects should sign interagency agreements or memorandums of understanding. The agreements should address the project’s purpose, authority, funding, scope, responsibilities, timeframe and process for amendment to agreement.

Funding and staffing of statewide collaborative projects should be made part of the state public health programs and their IT budgets. A handbook on how to establish and manage collaborative projects should be developed and modified over time as lessons are learned from actual projects.

Collaboration of healthcare provider organizations and state health departments on how to design, develop and implement HISs could help save time and money and bring tremendous benefit to all involved over the long term. These projects could lead to better public health in our states and local communities across the country.

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Background on NCHICA

The North Carolina Healthcare Information and Communications Alliance, Inc. (NCHICA), was created by Executive Order of the Governor of North Carolina in 1994 to “improve healthcare in North Carolina by accelerating the adoption of information technology.” Operating as a 501(c) (3) nonprofit corporation, NCHICA has built trust and collaboration among all sectors of healthcare including agencies of state and Federal government. NCHICA undertakes educational programs and demonstration projects to encourage adoption of technology to improve the safety, quality, effectiveness and efficiency. (Web link: www.nchica.org)

Among the projects undertaken over the 11-years of NCHICA’s existence are three that are highlighted in this report:

1. Provider Access to Immunization Registry Securely (PAiRS)

2. North Carolina Emergency Department Database (NCEDD) and the North Carolina Hospital Emergency Surveillance System (NCHESS)

3. North Carolina Healthcare Quality Initiative:
   - Medications Management
   - Electronic Lab and Radiology Orders and Reports
   - Electronic Health Records

1. Provider Access to Immunization Registry Securely (PAiRS)

Background information: The PAiRS Project consolidated immunization data from three independent databases and allowed healthcare providers across North Carolina to access this data securely. This pilot project was made possible through the collaboration of the following government agencies, healthcare providers and IT vendors: the North Carolina Department of Health and Human Services Immunization Branch, ARCANVS, Blue Cross and Blue Shield of North Carolina, Electronic Data Systems, Future HealthCare/Canopy Systems (now A4 Health Systems), Peak10 (formerly Interpath), Initiate Systems (formerly Madison Information Technologies), Kaiser Foundation Health Plans of North Carolina, /n Software, Quintiles Transnational Corporation and a number of healthcare practices, local health departments and other providers across the state.

NCHICA members contributed over $2 million in in-kind support. The project was active six months from initiation and operated from 1998 until July 2005 when it was replaced with a state-of-the art immunization registry meeting all of the current specifications from the CDC and...
incorporating lessons learned from the PAiRS project. At peak, the project contained over 20 million records on 2 million children and was accessed securely from over 425 locations by over 2500 users.

**Lead organization:** North Carolina Department of Health and Human Services Immunization Branch

**Business challenge:** Healthcare professionals did not have a consistent method for accurately assessing the immunization status of their patients. Many times parents do not know the immunization status of their children, and it is very easy for healthcare facilities to overestimate the proportion of their patients that are fully immunized when information is fragmented and not complete. The collection of information for school and camp registration was laborious and well understood by the state, clinicians and the general public.

**Technical challenge:** Approximately 30% of the immunizations administered to North Carolina children were recorded in the North Carolina Immunization Registry (NCIR) by local health departments. Private healthcare professionals delivered an estimated 70% of the remaining immunizations. Immunizations paid for through claims to health plans are recorded and the health plans have to file reports on those immunizations for regulatory and quality purposes. These records were not linked or accessible through a single source.

**Technical Approach**
The PAiRS Project consolidated immunization data from the North Carolina Immunization Registry, Blue Cross and Blue Shield of North Carolina and Kaiser Foundation Health Plans of North Carolina.

Access to PAiRS was delivered 100% through a web-based solution developed in the first six-months of the project. The combined database was hosted on a Windows NT server with Microsoft IIS. Access was secured using NT Challenge-Response to the database application. EDS and Initiate Systems created the PAiRS database and provided advanced patient search logic. Quintiles offered project management services.

Individual records in the combined database were associated by a fuzzy logic technique built into a proprietary product named Aligndex from Initiate Systems. Aligndex can take multiple records and, based on record content (limited set of demographic information), provide a probability that the records refer to the same individual. The sensitivity of the algorithm could be adjusted to provide the desired number of probable matches from which the healthcare professional could verify the match with the parent or guardian of the child.

**Lessons Learned**
- The clinical champion of the project was the Secretary of the North Carolina Department of Health and Human Services who was a pediatrician. The North Carolina Pediatric Society and local health departments were strong supporters because of the time savings and accuracy of the data.
- The project was very cost effective. After a demonstration period of three years, the total cash outlay from the state to support the project was $79,000 annually.
- The project experimented with PKI as an authentication mechanism but found, at that time, a browser-based solution was cumbersome, costly and difficult to manage in a setting where multiple clinicians were accessing multiple workstations. Digital certificates must be portable to be used in clinical settings, where mobile healthcare providers move among different machines.

**Leveraging what we’ve learned**
- The State has acquired and is implementing a state-of-the-art registry system built by the State of Wisconsin and underwritten by funding from CMS. Modifications were made for North Carolina use based on lessons learned in the PAiRS project.
- The Southern Governors Association Task Force on Medical Technology endorsed the idea of using the secure exchange of childhood
immunization records as a first step in providing better healthcare across the entire region and a resolution supporting this approach to building regional interoperability and exchange was passed by SGA.

2. North Carolina Emergency Department Database (NCEDD)

Background information: A number of emergency physicians from the North Carolina Medical Society approached NCHICA to find a standards-based way to gather electronic clinical information from encounters in emergency rooms across North Carolina for the purpose of developing best practices and undertaking community assessments. A working group led by physicians was formed and with NCHICA Board approval the effort was begun. At the project's initiation in 1999, there was no standardized, electronic reporting of injuries and disease conditions by hospital emergency departments. CDC had developed recommendations on the type of data that should be collected (Data Elements for Emergency Department Systems, or DEEDS). NCHICA is sponsoring a statewide focus group that will use DEEDS as the basis for Standardization and Electronic Transmission of Emergency Records (STEER).

The North Carolina Emergency Department Database (NCEDD) project began in October 1999 and initial funding for the project was provided by CDC, through the North Carolina State Center for Health Statistics (SCHS), in February 2000.

Lead organization: University of North Carolina at Chapel Hill, Department of Emergency Medicine

Business challenge: Emergency Departments (ED) collected information in non-standard paper of electronic form and needed to adopt DEEDS specifications to overcome the variations in the way that ED data are entered into record systems, and to facilitate use of the clinical and administrative data for direct patient care and for public health surveillance and research.

Technical challenge: There is no standard database for emergency departments in North Carolina to facilitate the electronic reporting of injuries and disease.

Approach

The project utilized secure, computer-to-computer transmission of ED data from several of the busiest EDs in North Carolina to a database under the control of our state public health agency in a standard, structured format. In concert with developing state electronic records legislation, and federal efforts to standardize health claims attachment data, the NCEDD project provided a proof-of-concept and laid the foundation for a true standardized, electronic ED record and public health surveillance of population-based episodes of ED care.

The project worked with the Emergency Departments of North Carolina hospitals as well as the UNC Department of Emergency Medicine, North Carolina Department of Health and Human Services' Division of Public Health State Center for Health Statistics (SCHS) and Epidemiology and Communicable Disease Section, North Carolina Office of Emergency Medical Services and North Carolina Trauma Registry.

The initial goals of this project included:

1. Adoption of selected DEEDS data elements by 3-6 EDs in North Carolina.

2. Proof of concept that ED data can be collected electronically at the point of care, and flow in an innovative way to a state agency for the purpose of public health surveillance.

3. Demonstration of secure data exchange via electronic reporting of ED data to a central repository.

4. Development of the North Carolina Emergency Department Database (NCEDD), a central repository of data from at least 3 EDs with different computer systems.

5. Demonstration of data linkage between NCEDD and other state data repositories (e.g., pre-hospital database, trauma registry) to describe an episode of emergency care.

6. Assess the potential for real-time electronic reporting of ED data to NCEDD.
Subsequent event:
As a result of the 911 terrorist attacks, the NCEDD project was deemed essential to NC’s strategy for early detection and response to an adverse event and steps were taken to increase funding to substantially expand the number of emergency departments reporting information and the frequency was moved to daily reporting and analysis. Additional syndromes were developed and innovative research for coding of non-structured text such as first report of injury, chief complaint and triage nurse notes was completed. In 2004 the State’s General Assembly passed a law requiring all emergency departments in NC (124) to begin reporting in 2005 and a contract with the NC Hospital Association was completed to facilitate the additional data collection with the continued involvement of UNC’s Department of Emergency Medicine’s NCEDD team continuing to provide data analysis and support for the NC Division of Public Health epidemiological and surveillance staff.

Lessons Learned:
- Clinical leadership was crucial in moving the project forward. When CIOs and other staff in hospitals knew what the clinical and public health imperatives were, they became highly supportive.
- While HIPAA is permissive in reporting to public health, explicit reporting mandates under state law was helpful in providing a comfort zone for hospital attorneys.

Potential benefits: By the end of the initial 3-year project, NCEDD demonstrated the ability to collect ED data electronically at the point of care, thereby eliminating manual data abstraction and re-entry into electronic registries, and transmit that electronic data to a state agency for public health surveillance purposes. The Division of Public Health was able to detect suspicious events much more quickly and respond with appropriate inquiries to the reporting hospital.

3. North Carolina Healthcare Quality Initiative
The North Carolina Healthcare Quality Initiative seeks to improve the quality, safety, effectiveness, and efficiency of healthcare in our state through the application of secure and standards-based information technology. During Phase I, this will be accomplished by providing clinicians with a patient’s medication history at the point of care, and integrating this information with the automated refill, formulary list, and e-prescribing process. Phase II of the initiative will emphasize point of care lab and radiology ordering and results, and Phase III will focus upon broader adoption of electronic health records. The initiative will begin in the Triangle region where a demonstration project will be constructed and implemented with the leadership of major employers, health plans, and providers. Plans are to collaboratively extend the medication management capability to all areas of the state as additional support and resources are available.

Vision
To enable North Carolinians access to the highest quality, safest, and most efficient health system possible by providing a secure exchange of clinical information in an interconnected community of stakeholders

Goals – specific measures expected for each of these goals
Improve medication administration, coordination and safety by
a) Making standards-based medication history/prescription information available
b) Facilitating automated refill processing
c) Assisting in widespread access to patient level formulary information
d) Accelerating the adoption of ePrescribing under appropriate procedural authority, to providers of care and those directly involved in care management.

Improve quality and efficiency of diagnostic procedures through point of care lab and radiology ordering and results
Enable improvements to provider office efficiency by incentiving the adoption of automated tools for
practice management and clinical information exchange

Implement and as necessary create a new financing mechanism(s) linked to process redesign to support pay for performance programs

Investigate potential avenues within the framework of Stark laws to allow organizations to provide direct assistance for clinical information system adoption in provider’s offices when supporting broad interoperability solutions for the state.

Implement and/or develop infrastructure to manage clinical information exchange capabilities throughout the state of NC – prototype NHIN

Offer assistance with accelerating the adoption of standards-based, electronic health record solution(s) to providers in NC. These solutions to promote interoperability among all stakeholders statewide (e.g. Doc-to-Doc sharing, electronic consult, PHR, etc) with an emphasis upon the policy changes and community acceptance elements necessary for success

Environment

We recognize that more and more healthcare providers are leveraging technology to assist them in the practice of medicine, however we also recognize that community, regional and statewide sharing of information to improve patient outcomes and drive efficiency will require significant collaboration and coordination across the state, as well as creation of standards based exchange utilities for secure, usable sharing.

Strategy

Phase I During the first phase this is accomplished by providing clinicians with a patient’s medication history at the point of care, and integrating this information with the automated refill, formulary reference, and e-prescribing process.

Phase II The second phase of the initiative will emphasize point of care lab and radiology ordering and results, and

Phase III The destination phase for the initiative will focus upon broader adoption of electronic health records.

In all cases, collaborate with a broad range of NC-based organizations to ensure appropriate statewide leadership and consensus for change. These organizations will include virtually all health related industry, policy, occupational and commercial organizations as well as leadership groups such as the Institute for Emerging Issues. Leadership and building consensus for change will be critical success factors.

All efforts will occur within the categories of clinical adoption of technology, creation of standards based secure information exchanges and policy development.

Conclusion

This project is underway and preparations are being made in the Triangle (and subsequently the rest of North Carolina) to accelerate the adoption of healthcare IT by providing a secure exchange of clinical information in an interconnected community of stakeholders. This acceleration will be specifically directed at enabling North Carolinians’ access to the highest quality, safest, and most efficient health system possible.

For more information contact Holt Anderson, NCHICA at holt@nchica.org.
An Open Source Electronic Health Record and Regional Health Information Exchange Model for Safety Net Clinics

By Thomas L. Lewis, M.D., Erin Grace, Guy Fisher

The following describes our experience in deploying a regional patient-centric, web-based, open source electronic health record system for safety-net providers and clinics. The system is designed to meet local communities' needs for improved primary health care and public health services for the medically uninsured population. We then discuss our progress, strategy, and implementation model for a regional health information exchange connecting our safety-net clinics to the mainstream health care environment.

Background and significance:
Nationally, over 40-million Americans lack health insurance and consequently have difficulty accessing quality health care. These people are sicker and die sooner. Although Montgomery County, Maryland is among the most affluent communities in the country, 80,000 to 100,000 of its residents are without health insurance. Approximately 40 percent of the populations are minorities, and almost 27 percent are foreign born. Montgomery County does not provide direct care through a county clinic model, but instead provides financial assistance to independent, nonprofit safety-net clinics. In January 2000, the county government asked the Primary Care Coalition to develop a system of care for the county’s working poor. At that time, four clinics provided care to two thousand people. By 2005, this had increased to ten clinics serving 12,000 people, with the county using PCC to manage this collective effort. Based on this success, in December 2004, the county executive and county council announced long-term financial support for “Montgomery Cares.” This program will provide primary care and medications to 40,000 low-income, uninsured people annually through a network of community-based clinics by the year 2010, more than three times the number supported in 2004.

Recognizing that patients cross jurisdictional borders, PCC has formed partnerships with contiguous Prince Georges County, the District of Columbia (DC), and Northern Virginia safety-net providers, foundations, and government representatives to address shared needs and challenges. Organizations in the DC metropolitan area representing the specific interests of the uninsured population believe that a single “Community of Interest” should be formed across the region, as: (1) the population is mobile across jurisdictions, warranting a regional view of health care for the uninsured; (2) individual safety-net providers and political jurisdictions face similar challenges; (3) funding from foundations and all levels of government is limited and must be maximally leveraged; and (4) the uninsured population and the safety-net clinic environments have significant differences from the insured, warranting a focus on the uninsured for a regional health information exchange. Key members include the PCC, the Montgomery County government,
Maryland State government, District of Columbia Primary Care Association, the DC government, the Regional Primary Care Conversation, county hospitals, safety-net providers in Maryland, DC, and Northern Virginia, and many others.

The PCC in conjunction with the Montgomery County Department of Health and Human Services has embarked on a strategy to deploy health information technology (HIT) to help eliminate the disparity and uneven provision of primary health care for the uninsured population within Montgomery County. HIT initiatives are integral to the successful implementation of Montgomery Cares. Without Montgomery Cares, the ability to shift unnecessary ED visits to safety-net clinics (a key element of the HIT strategy and first-priority area of focus) would not be possible. Without the HIT strategy delivering evidence-based, decision-support tools and a longitudinal health record, it would be exceedingly difficult for the safety-net clinics to deliver and document high-quality care.

Unique Safety-net clinic needs: Health information technology is especially important in the safety-net environment because of the unique characteristics of the patient population and the clinics that serve them:

- HIT is critical to the safety, quality, and efficiency of care provided at the community-based clinics because of the extensive use of volunteer providers, patient mobility, and the frequent use of emergency departments by choice (or when community-based clinics are not open).
- Care is typically fragmented among multiple providers, clinics, EDs, and even counties.
- The same medical information is collected multiple times in multiple places and is typically not available or is inconsistent.
- Critical information (lab results, x-ray studies, medications, allergies, problem lists) is not shared.
- Uninsured patients often are not aware of the safety-net clinic alternatives and instead rely on local emergency departments for treatment.
- Patients frequently see a different provider at each safety net visit (rare in the insured world):
  - Providers at safety-net clinics are more likely to work infrequent hours (volunteer providers may work only several hours a month).
  - Decreases the efficacy of “continuity of care” models.
  - Increases the benefits of electronically shared and presented data for clinical decisions.

Because of the lower likelihood of a patient’s adopting a clinic as a medical home and of the same provider repeatedly seeing a patient who makes return visits, it is clear that the effective sharing of data among clinics and between clinics and local emergency departments, as well as the use of HIT at the point of care (for decision support and managing care to guidelines), are more critical for the uninsured and can be viewed as an imperative to helping to improve the quality of care provided.

Health Information Technology Strategy: The HIT strategy comprises three key elements: (1) provide an EHR with clinical decision support at the point of care, to facilitate a shift from episodic care to evidence-based continuity of care; (2) share health information of patients across the safety-net clinics, to align with a mobile population; and (3) share health information between the safety-net clinics and mainstream health care delivery organizations, to provide improved quality, safety, and efficiency of health.

Conceptually, these three components may be thought of as a three layer cake, each layer building on the capabilities of the layers below. The first two layers are represented by CHLCare, a basic shared EHR at layer one and a shared database at layer two. The architecture for regional health information sharing, MeDHIX (Metro DC Health Information Exchange), forms the third layer and will be implemented in stages under a recently awarded AHRQ “Transforming Healthcare Quality through Information Technology” implementation grant.
Layer 1:

Individual safety-net clinic HIT capability

CHLCare. CHLCare is an Electronic Health Record system designed to meet local communities’ needs for improved primary health care and public health services for the medically uninsured population. Local communities have increasingly become the party of last resort in providing primary health care to the uninsured. Care is often provided by independent clinics, often a combination of non-profit, volunteer-based organizations, with some support from county infrastructure and with various sources of funding. In spite of intensive efforts by largely volunteer staff, gaps remain. Problems include inconsistent coverage of the population, missed continuing care needs of chronic illnesses such as diabetes and hypertension, and no aggregate information to support public health services and to secure future funding through promotion of its own effectiveness.

These impediments to improved health care and public health can be addressed by linking the local independent primary care clinics as well as the other community providers, such as local Emergency Departments and specialty physicians into a more unified system of delivery.

In 2001 the Health Resources and Services Administration (HRSA) awarded a three-year Community Access Program (CAP) grant to PCC to implement a shared electronic health record (EHR) system for the safety-net clinics within the county. With this grant, PCC designed, developed, and implemented an approach to health records not commonly seen in the safety-net world: a single EHR for use by multiple, independent safety-net clinics wherein patient information forms one record shared by all clinics.

CHLCare, is positioned to support all three elements of the HIT strategy. CHLCare currently facilitates a longitudinal view across visit records and is positioned, as an open source, web-based application, to have new capabilities readily added. As an example, PCC has begun work on a new medications management module for CHLCare to enable bar-code scanning of point-of-service (POS) medications (provided through Montgomery Cares), so that medication data can be easily entered in CHLCare; adverse drug reactions can be checked; data shared with other providers; and recalls can be facilitated. Once this data is scanned into CHLCare, it
will be available as critical data for use in MeDHIX, in particular during patient visits to emergency departments or other providers to help reduce medication ambiguities and potential errors.

Other examples of using an open architecture approach to HIT evolution include the following. Under a grant from the National Library of Medicine, PCC implemented a “clinical desktop”, where clinicians and patients have ready access to various clinical resources via the Internet. The safety-net clinics in Montgomery County currently use CVDEMS for assisting in patient diabetes management. PCC plans to add disease-management functionality to CHLCare and convert the clinics from CVDEMS to this new capability. In addition to simplifying the process for the safety-net clinics, having the disease-management capability within CHLCare will enable sharing of the clinical data with other health care delivery organizations via MeDHIX, so that area hospital EDs will have access to diabetes and other disease metrics at the time of patient ED encounters. These are incremental steps to integrating specific clinical resources into CHLCare for direct decision support.

CHLCare is positioned to link independent clinics into such a unified system of delivery:

- **Patient-centric model.** CHLCare is built on a patient-centric model, so that all providers across independent clinics have a single view of a patient’s medical record. CHLCare promotes compliance to HIPAA by tracking patient authorizations, tracking user access and blocking access that is not authorized by the patient.

- **Web-based.** CHLCare users need only browsers, for ease of use, minimal hardware requirements, and widespread secure availability. It is also planned to provide secure linkages to other information sources on the Internet.

- **Open Source.** CHLCare operates on an Open Source platform, keeping community costs low and security high. The CHLCare application itself is also Open Source, to facilitate addition of new features as well as to keep costs low.

(The diagram above depicts how independent clinics will be linked to one another as a systems approach.)
CHLCare is currently in use in Montgomery County, Maryland at 21 clinic sites and in Washington, DC by 1 clinic, with over 50,000 patient records and 120,000 visit records. Eighty percent of visits to safety-net clinics in the county are included in CHLCare.

Access the CHLCare demo site at https://www.community-healthlink.org/training/index.php, select Clinic Location = SCC -- Langley Park Adults; User Name = demo; Password = demo. For more information about CHLCare, please contact the Primary Care Coalition at 301-628-3415 or erin_grace@primarycarecoalition.org.

Layer 2:
Connecting safety-net clinics to each other

CHLCare, in addition to being positioned for improving clinical care, has centralized the information-technology (IT) function for EHR. This will have a dramatic impact on our ability to successfully deliver the third HIT strategy element: “sharing health records with mainstream care delivery organizations.” The safety-net clinics in the county are small operations with thin or non-existent IT support. Prior to CHLCare, the health records systems were primarily small, volunteer-built, one-of-a-kind Microsoft Access applications with little or no ongoing support. The likelihood of interconnecting these applications into an HIE such as MeDHIX was extremely low both because of the nature of Microsoft Access applications and the limited availability of clinic IT support to manage such an interconnection. With CHLCare, only one shared connection to MeDHIX will be needed, rather than one per clinic. The operational issues will be managed centrally and the application is web-centric, greatly increasing the likelihood of success of this HIT strategy.

Layer 3:
Connecting safety-net clinics to mainstream health care

• Safety-net clinics provide a large amount of much needed care to low income uninsured individuals. Typically, they focus on delivering high quality primary medical care for chronic and acute ambulatory diseases. However, they are dependent on others for specialty consultations and treatments, emergency surgical and medical care, and laboratory and radiological diagnostic studies. Sharing health records between the safety-net clinics and mainstream health care delivery organizations is a critical success factor if the safety-net clinics are to deliver more health care, of higher quality, at lower cost.

• As a first step in implementing our regional health information exchange MeDHIX, we plan to connect our safety-net clinics and hospital emergency departments to one another, building on an existing, sophisticated medical data acquisition and display system (called Azyxxi) developed at the Washington Hospital Center. This will allow us to quickly achieve the near term benefits of sharing personal health information, at low cost, without waiting for the NHIN prototypes or sinking substantial money into systems that may not be compatible with the eventual national direction.

Patient safety, care quality, and cost of care are adversely affected when pertinent medical data about a patient is not available at the time and place of care. This is even more of a problem in the safety-net setting where care is often episodic, patients see multiple providers, information from other healthcare encounters is typically not available, and patients often have limited understanding of their underlying disease.

The proposed safety-net HIE will facilitate access to medication information, allergies, problem/diagnosis lists, assessments, and lab results to authorized providers. Hospital emergency departments (EDs) are the source of significant amounts of care for this group of patients. Data exchange between EDs and safety-net clinics can expect to achieve the following kinds of benefits:

• EDs can more rapidly assess, triage, and effectively treat safety-net patients
• Decrease likelihood of inappropriate or duplicative medication administration
• Shift care from hospital EDs to safety-net clinics
• Decrease inappropriate ED visits
• Identify uninsured patients in
## MeDHIX goals: Benefit Scenarios for Three Priority Areas

### List of Benefit Scenarios for the Three Priority Areas

<table>
<thead>
<tr>
<th>Priority Area</th>
<th>Benefit Scenario</th>
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<tbody>
<tr>
<td>Inappropriate use of the ED</td>
<td>1. Reduce level of inappropriate visits to the ED</td>
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<td></td>
<td>2. Reduce duplicative/unnecessary ED-associated tasks</td>
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<td></td>
<td>3. Reduce medication errors in the ED</td>
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<tr>
<td>ED medical care</td>
<td>4. Reduce duplicative/unnecessary PC (primary care clinic) associated tasks</td>
</tr>
<tr>
<td>Primary care clinic care</td>
<td>5. Reduce medication errors in PC clinics</td>
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</tbody>
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- Increase the use of safety-net clinics for primary care through appropriate referral
- Avoid multiple workups caused by lack of access to recent patient data—
  - ED does not have safety-net data
  - Safety-net clinic does not know that an ED visit occurred
  - ED does not know patient seen recently at another ED
- Detect instances of “doctor shopping” and medication abuse/addiction

**Key MeDHIX information sharing infrastructure:** Azyxxi, developed under the leadership of Dr. Craig Feied, Director of Informatics at the Washington Hospital Center, has grown from an ED application within Washington Hospital Center to an electronic health data integration system that captures and displays data from all MedStar hospitals as well as selected external hospitals. The system, used not only by the ED’s but by many other hospital departments, provides many of the functions envisioned for a health information exchange/RHIO. Azyxxi offers a rare opportunity to visualize how an HIE across disparate applications will improve the delivery of health care to the low-income uninsured without the need for extensive up-front hardware and software investments or the time delays associated with their acquisition and deployment. This is especially important while NHIN and RHIO standards evolve, and reference models and implementations are developed.

Key features include:

1. A variable patient-identification system, to permit extremely tight assurance of record matching to the proper patient for clinical care and more loosely matching models for public health applications.

2. Sophisticated data-mapping
mechanisms, to permit the useful display of information from multiple source systems.

3. Speed of response and bandwidth, to address the need of real-time acquisition of large amounts of data, including video.

4. User authentication and data-segment-level access controls to ensure privacy and security.

**Long-term objective:** The long-term objective of the proposed project is to implement a sustainable Metro DC – Regional Health Information Exchange (MeDHIX), linking the electronic health record systems of the region’s safety-net clinics with each other and with mainstream healthcare providers to improve patient safety, care quality, and efficiency for the region’s most vulnerable populations. MeDHIX will form a regional community of interest focused on the specific needs of the uninsured and the safety-net environment.

Considering the breadth of coverage expected of RHIOs in particular, covering the insured population and the large number of smaller provider offices, and the responsibilities to be defined for such RHIOs, we do not intend MeDHIX to be the metropolitan DC RHIO. We expect that there will be a tier below RHIOs of HIEs that form around communities of interest and “report in” to their region’s RHIO and that these HIE’s must be positioned to work seamlessly within their RHIO. These HIEs will represent their members regarding RHIO/NHIN governance issues, such as HIPAA and local-jurisdiction health privacy and security regulations and trust issues, and help in providing system interconnectivity. In addition, these HIEs will use health information technology (HIT) to form virtual communities, stitching together like entities in the region, for the purposes of improving the quality, safety, and efficiency of health care. MeDHIX will be such a community of interest formed by the participants in providing health care to the uninsured.

**Implementation strategy:** With the national guidelines for formation of a National Health Information Network (NHIN) and Regional Health Information Organizations (RHIOs) still in the formative stages, our project proposes to proceed with a health information exchange (HIE) that will fit within the evolving NHIN/RHIO framework. It will be structured as an HIE “community of interest” for safety-net providers within a metropolitan DC (District of Columbia) RHIO.

MeDHIX will be implemented in three phases. The objective of Phase 1 is to quickly implement a proof of principle HIE with a significant number of patient records, using existing technology. Using existing technology will decrease the amount of time and money spent developing technologies that may not be compatible with federal standards, protocols, and operating guidelines currently being developed to guide RHIOs and the NHIN. The MeDHIX infrastructure will use Azyxxi, the computer application developed and used by Washington Hospital Center in DC, and by its parent company, MedStar Health, that manages multiple hospitals in Maryland and DC.

The specific aim is to improve safety, quality and efficiency of health care for the uninsured by implementing MeDHIX as an HIE, linking the electronic health record systems of the region’s safety-net clinics with each other and with mainstream healthcare providers. We plan to meet this objective in three phases as follows:

1. **Phase 1** will rapidly implement a pilot safety-net HIE using existing technology. At the completion of Phase 1, a significant number of safety-net patient records and providers will be linked in a safety-net HIE. This includes the records of a majority of the treated uninsured patients in Montgomery County, Maryland, a substantial number of treated patients from one DC clinic, patients of MedStar Health (an integrated delivery system with multiple hospitals in Maryland and DC), and at least one hospital in Montgomery County.

2. **Phase 2** will implement MeDHIX in a “NHIN/RHIO-compliant” model, when the standards, protocols, and operating guidelines necessary for HIE integration into a RHIO are issued. Phase 2 will either modify Azyxxi as might be needed or replace portions of Azyxxi, depending on what is required to conform to NHIN/RHIO requirements. An
additional Montgomery County hospital will be added to MeDHIX, as well as migrating the Phase 1 interconnections to the Phase 2 infrastructure.

3. **Phase 3** will further modify MeDHIX infrastructure based on Phase 2 experience and further definition of the NHIN/RHIO model. More safety-net clinics and hospitals will be added, along with related services such as laboratories; diagnostic imaging services; and specialty providers who provide frequent consultations for safety-net patients.

For more information contact Dr. Thomas L. Lewis at tom_lewis@primarycarecoalition.org
Challenge

Public Health applications have been previously developed to assist public health programs in meeting individual program's goals and objectives. This has led to the development of systems that collect data only for explicit purposes, without clear efforts to improve the integration, efficiency, and usefulness of public health data. The evolution of these disparate, fragmented public health data systems has led to duplication of effort, and placed limitations on local public health agencies to accomplish the mission of safeguarding and improving the health of the community and to respond effectively to large-scale threats to public health.

The Los Angeles County Department of Health Services has created an initiative to support consolidation of critical clinical and public health data across diverse individual IT systems [4]. The adoption and integration of knowledge-based decision support systems such as Data Warehouse, Business Intelligence toolset, and use of a central master person identifier are promoted. This initiative requires that existing investments in legacy systems be leveraged and merged with standards-based web enabled systems to provide a synchronized view of public health data and resources across all program areas.

Solution

The Los Angeles County (LAC) Operational Data Store (ODS) architecture is based upon the nine elements of the Public Health Information Network initiative published by Center of Disease Control and Prevention (CDC) and influenced by CDC’s National Electronic Disease Surveillance System (NEDSS) [2, 3]. Deployment of the ODS and related components introduces an integrated standards-based system in LAC that provides a synchronized view of public health data and resources across all program areas.

Architecture Deployed

ODS is the core component of the PHIN architecture. The strategic objectives of PHIN are: Enhance the ability of Public Health to conduct surveillance for bioterrorism and other communicable diseases; Assist in the control of disease outbreaks and offer critical surge capacity for the tracking of epidemiological information; Broaden the communications capabilities of the public health
system; Implement mechanisms to support broad CDC initiatives while complying with requirements of local jurisdictions; Align the public health system with federal directives and national initiatives.

Key components of the architecture include: 1) Infrastructure & housekeeping services to provide authentication, directory and security services for the system and enable single sign-on. 2) A knowledge management module that manages translation and mapping of data from other systems to the ODS in a standardized format. 3) HASTEN provides the single sign-on portal for authentication & entry into the system. It also incorporates an event alerting mechanism. HASTEN provides the human interface. 4) HEDEX provides an electronic interface to systems that need to send data to and receive data from the ODS. 5) Analysis and Visualization services provide data analysis, reporting and GIS services. 6) Unique Person Identifier is an effort at the LAC to cross-index and assign unique identifiers to individuals who receive care or are referred to LAC facilities. 7) Data Warehouse at LAC is a patient-centric data store that pools data from hospitals, emergency care and public health programs. 8) The Incident Management System is the core component of the PHIN architecture that provides case management and program area support for managing disease specific interactions.

Figure 1: Los Angeles County Public Health Information Network Architecture Overview
**ODS:** The ODS provides persistent and patient-centric storage for data from multiple public health programs. The ODS is a relational database designed in an abstract-extensible style consistent with the HL7 V3 Reference Information Model (RIM). The database is implemented in three phases. In the first phase, the ODS merely mimics the data currently maintained by existing Program Area Modules (PAMs), such as the EDS [1]. In the second phase, the ODS is expanded to support the expansion of PAM capabilities and the introduction of Common Area Modules (CAMs), such as Knowledge Management System. In the third phase, the ODS replaces PAM specific local databases as the database of record for non-transient PAM-specific data. PAM specific databases are used for transient data only. The ODS also includes a staging area for the temporary storage of data received from external systems and data intended for export to external applications or bulk transport. Structured Query Language/Extract Transform and Load (SQL/ETL) tools are used to transform data to and from the persistent storage areas of the ODS.

**ODS-API:** The ODS-API handles healthcare transactions by exposing the HL7 V3 RIM objects that can be manipulated by client applications and provides the ability to persist the transaction in a relational database using Object-Relational Mapping technology, freeing the client application from having to deal with the physical data model [6]. Initial scope of this layer is to provide an XML message interface for incoming and outgoing messages from the other components of the PHIN System. As the development matures and the interface stabilizes, the ODS-API, in its final form, will be published as the only interface to the LAC Public Health ODS and all new applications developed internally and externally will be required to use this Interface to store and retrieve data to/from the LAC Public Health ODS.

The final steps will be the implementation of the ODS-API with Reference Information Model (RIM) Interface towards automating the population of ODS. The ODS-API will allow newly developed public health applications to directly store the operational data in the ODS and will remove the need of duplicate data stores. This ODS-API will be build on top of ODS-API layer which consumes the XML messages for healthcare events.

**Benefits**

The ODS is under deployment and the legacy systems are now being integrated with it. The ODS-API is under development. The Reporting services have been deployed and can report on ODS data. Several systems will be integrated into the infrastructure over the coming years including PAMs to support integrated case management activities for Public Health.

The PHIN compliant systems will specifically address the following [7, 8]:

- The development of a web-based system architecture for Public Health programs and health districts that is capable of supporting electronic data exchange from public health partners using a HL7 based integration hub,
- The development of management tools and applications to assist public health response and
- Recovery activities while providing resources to support departmental integration.

The PHIN/NEDSS systems will leverage individual system components for the overall improvement of public health information technology infrastructure while contributing to the development of a common enterprise data warehouse that will unify public health and clinical data under a unique person identifier.

There are multiple systems in place that support communications for public health labs, the clinical community, and state and local health departments. However, most of these systems operate in isolation. Numerous benefits will start accruing as parts of the system are built and integrated into the business processes of the local health services. The implementation of a unifying system will further improve access to laboratory data and response protocols, advanced capabilities for rapid notification of public health partners, response agencies, the media, and the general public. There will be an enhanced capability to train public health staff and a uniform data exchange standard for exchanging data between the public health partners.
Real-time collection of data from heterogeneous healthcare systems, program area modules, consolidation and cross-indexing of data, integrated directory infrastructure for public health personnel and identity management, integration of related healthcare and patient data from heterogeneous systems into a common interface, provide access through a ubiquitous web-based portal that will obviate the necessity of client-side implementations of application systems, provide a mechanism to disseminate critical and public-interest information to the community in general are additional benefits.

Conclusion/Lessons Learned

The primary objectives of this initiative was to enhance the ability to conduct public health surveillance, provide electronic applications to assist in the control of disease outbreaks, develop advanced training tools for public health partners, and broaden the communications capabilities of the public health system in Los Angeles County in order to effectively prepare and respond to bioterrorism and other public health emergencies.

It is expected that the Public Health Information Network System effort will expedite the consolidation of critical clinical and public health data across diverse individual IT systems. It will leverage existing investments in legacy systems and merge them with standards based web enabled systems to provide a synchronized view of public health data and resources across all program areas. The ODS can be queried for a person-centric view of health-related data across all program areas. The visualization services provide a dashboard view and drill-down report capabilities for decision support and alignment of critical public health resources.

The use of a model driven Service Oriented Architecture has allowed the County to take advantage of state-of-the-art information technologies while at the same time leveraging the investment made in its legacy application system. The use of industry standards positions the system to be interoperable with similar efforts conducted in other jurisdictions such as in neighboring Counties, the state of California, and the CDC.

A difficult issue to overcome was the inertia and tradition of autonomy enjoyed by program area leaders. We were fortunate enough to benefit from the coincidental coming together of three factors. First, the vision expressing the necessity of data sharing and leveraging data as a department wide asset was clearly communicated by the highest level of the County management. Second, CDC’s effort to define standards for use in enabling a public health information network had reached a level of maturity that was useful for our purpose. And finally, the national recognition of the vulnerability of our public health system motivated Congress to allocate the funds necessary to underwrite the cost of development. Without these influences, the project would not have achieved the benefits so urgently needed.

Acknowledgements

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A lthough five years into a new millennium, Denver Public Health (DPH) sexually transmitted disease (STD) Clinic was still capturing clinical information with a computer system developed in 1987. Using two optical mark recognition (OMR) forms, many paper logs, disparate small database systems, and a fragile OMR scanner, it was time for change. Clinicians were frustrated with scanning and a multitude of file cabinets for official paper charts, laboratory result logs, and other forms completed for grants/contracts, research and special studies. A golden opportunity to improve patient flow and data collection processes was at hand.

Denver Public Health’s STD Clinic is a complex organization that consists of an STD Clinic, a Teen Clinic, a Family Planning Clinic, a Continuity Clinic, an Outreach Clinic, an HIV Testing and Counseling Center, and an STD laboratory. Furthermore, DPH is part of a larger organization, Denver Health (DH); DH is an integrated safety-net healthcare system comprised of a public hospital and community and school-based outpatient clinics serving 20% of Denver’s population. Change would affect one or more units, business processes, and interactions between various teams. Coordination with the DH Information Systems department was a prerequisite to ensure design and implementation met the parent organization’s expectation. All parties must be included in the change process and decision-making.

Identified options for improving the current STD Clinic systems included:

- replace the old OMR scanner and forms with an updated scanner and newer optical character recognition software
- develop a comprehensive database that links all forms and tables to the primary clinical databases on a real-time basis to ensure better data quality and integrity, or
- develop a complete electronic medical record (EMR) that eliminated dependence on paper files and documentation.

Given a complex organization combined with the plethora of data systems, experts were called to assist in process analysis and make recommendations for design and implementation. Two consulting companies each made recommendations and proposals on how to replace the old system with newer technology. The upfront analysis should have improved the change process to save time, money, and potential downstream headaches.

DPH management reviewed consultant recommendations and decided the best solution was a complete electronic medical record implementation. The proposed solution included merging XML-based electronic forms software, pen-tablet hardware, and components (i.e., registration...
The EMR implementation has yielded numerous improvements. Results, directly entered into a unified database, are readily accessed by clinicians in the exam room rather than walking to the laboratory for review. A patient’s entire STD Clinic history is accessible and available in the new system, HealthDoc, with improved clinical care, integrated data systems, and elimination of inefficient paper records.

### Background

The STD Clinic, one of several clinical services within DPH, provides STD care and testing for most of the Denver Metro area with a population of 2.4 million people. Servicing 15,000 to 20,000 patient visits each year, most of the diagnostic tests are conducted in-house with some tests sent to the DH laboratory or to the Colorado Department of Public Health and Environment (CDPHE) lab.

Using a time-tested, protocol-based encounter form for approximately 30 years, the clinic provides quality care and has served as a training site for health professionals for decades. When a new patient comes to the clinic, a clinician reviews the person’s past STD history, sexual behavior and risks, discusses family planning issues if appropriate, performs a physical exam, orders STD diagnostic tests, and provides medication as appropriate. Information charted on the encounter form has been entered into a computer system since 1987 using OMR technology and a PC-based database system developed for electronic capture. With nearly 200 data elements in a concise OMR format, clinicians filled the “bubbles” and then scanned the document; a computer program checked the answers for completeness or data conflicts, and then provided messages for the clinician to update the form until rescanned with no errors. Once considered complete, an attending physician reviewed and signed off on the “medical chart” and then it was filed.

Some lab test orders and results were marked on the form. If lab results required additional processing time, the form would be removed from the medical record files, marked with those results, and rescanned. All lab orders and results were kept on laboratory logs; some were transcribed onto patient census logs so that results could be communicated to patients when calling by phone. Clerks entered most lab results into a computer system for reporting and analysis. Based on a previous paper-based system, this was much improved and provided a means to collect and analyze STD information.

However, over time the clinic implemented new diagnostic tests and/or received new funding, each with additional data requirements (e.g., novel data to be defined and collected). Early on, clinic forms were revised, but each revision was costly and required database modifications and extensive programming changes. As form modification was problematic, software could not meet the changing clinic requirements.
Supplementary paper forms and data tables were created resulting in heterogeneous data systems. Over several years, different databases lost their referential relationships with consequent data integrity issues. A continual programmer effort was to ensure that all databases were in-sync one with another.

The HealthDoc™ System

The new system, HealthDoc, is a complex integrated system developed by Interlink Group but adapted to this environment through efforts of many individuals. Patients are initially registered in the Siemens Invision System, the DH registration system. Demographic data are then automatically transferred to HealthDoc through an interface. HealthDoc is a web-based system which captures registration, clinical and laboratory information. After the registration process, a clinician selects the patient from an electronic waiting list, adds appropriate electronic forms based on client needs, orders lab tests, prints bar-coded specimen labels, and documents clinical information. A laboratorian scans specimens received and posts results. All forms are integrated into the HealthDoc system using Countermind’s Mobile Intelligence Platform (MIP), an XML-based tool. MIP provides capability for form use on various hardware platforms (e.g., pen-tablets, personal computers, and PDA devices). In addition to the standard questionnaire formats (radio buttons, check boxes, open text), the software also has the capability of providing diagrams for detailing exam findings and open boxes for capturing signatures and handwritten notes if desired.

Another feature of the HealthDoc system is the integration with Siemens Medical Systems rules engine to enforce data integrity and validity. The rules engine software provides error messages when required fields are incomplete and ensures appropriate lab tests are ordered for specific diagnoses. Rules engine technology reduces mistakes and ensures better clinical documentation.

All information is posted using pen-tablets or desktop computers. During HealthDoc implementation, wireless pen-tablet computers were provided to clinicians to maintain flexibility of recording clinical information while they move between exam rooms and the laboratory. Label printers were installed and bar-coded labels attached to the specimens. Scanners were deployed in the laboratory for quick retrieval of specimen information.

HealthDoc is a flexible EMR that allows all clinical information to be captured electronically. Forms are easily modified in a visual environment that permits automated conditional form execution or new forms creation as requirements change. As it is XML-based, data structures are more flexible and a nightly routine exports the XML structure to a SQL database. Rules can be added or modified to ensure data integrity, and all the data are now captured in one central data repository. Historic data conversion allows quick retrieval of medical information from 1987 to the present.

Lessons Learned

Significant change in a complex environment requires a sufficient time to: 1) comprehensively understand and document processes, 2) design a database to handle all the needs and requirements of each functional team, 3) provide training and 4) gain buy-in from all affected parties. For this particular implementation, nearly 3 years transpired from initial analysis to complete development and finally integrate with ancillary systems ready for go-live. Delays occurred due to extensive analysis of which rules engine to implement, issues related to response time, timeliness of a composite on-line report display used by attending physicians for sign-off, and hardware issues related to server configurations and load-balancing. The requirements for a fast, reliable, flexible system were critical. The go-live date slipped several times until various technological issues were overcome and consistent high speed response times were achieved.

Another critical element for project success was getting all contributing parties engaged and directly communicating so that everyone was on the same page, understood the issues, and worked together to resolve problems. At times it took everyone involved to evaluate their portion of the system to determine
an issue’s cause and come to an appropriate solution. The core technical team worked together to resolve issues, stayed positive, and never resorted to finger pointing and blame. Everyone wanted to see this project be successful; the “can-do” attitude was essential to success.

Adequate training was vital for successful project execution. Each clinician and staff member that used the HealthDoc system went through 3-4 training sessions to cover the critical topics and then was provided opportunities to go to an open lab session for further practice if they felt warranted. Those already computer literate understood the system quickly and were helpful to others when the system went live. Those with little or no experience were given additional opportunities to become more familiar with the computer system to reduce the anxiety. Shorter sessions of 1-2 hours seemed to work best to avoid overwhelming or frustrating the learner during the training process.

One drawback with the new system has been issues with the pen-tablets. Screen size is smaller creating problems for some users and the pen-tablets have “hung up” or “frozen” during the docking and undocking to the base stations. Some freezing may be operating system related (Windows 2000 instead of Windows XP) which is being upgraded. However, some clinicians have opted to use personal computers in their exam rooms rather than the pen-tablets to minimize these issues.

The Future

HealthDoc has been successfully operating for more than 6 months now. Clinicians and laboratorians have become familiar with the system and believe it is an improvement over the previous system. Registration clerks are extremely happy with the new system because it has significantly reduced the amount of paperwork, filing, and data entry from various paper logs that existed in the former system. Future plans include sending electronic messages to CDPHE for required communicable disease reporting, additional direct interface of lab results from test equipment, and adding rules to other forms to improve data integrity.

Implementation of an EMR in the STD Clinic has been an enormous undertaking. However, the product is a more complete and flexible system that captures and records all clinical visit data elements. Savings have been gained through reduced space needs, reduced medical records filing, paper documentation, and computation of statistics. Clinicians more easily retrieve medical histories, take less time for documentation, and have improved data quality through use of the rules engine. Denver Public Health has finally built a 21st century STD Clinic information system that can help providers give improved care.

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Health care services and delivery are undergoing a dramatic transformation. This is creating, and depending upon, a similar transformation in both public and private healthcare administration. Adding to this already complicated landscape of change are accelerating technology advancements in clinical informatics and information technology.

Achieving change in such an evolving marketplace is never easy. It requires frank discussions around some very hard questions. In addition, it requires making decisions and moving ahead when some factors are simply unknown.

Constituencies engaged in the current healthcare transformation include public and private providers, consumers and purchasers. These groups are facilitating transformation while attempting to keep day-to-day operations running smoothly. With this in mind, transformation leaders must balance “doing it right” through well-thought out processes with the need to accommodate immediate clinical, administrative and financial demands. Sometimes doing the right thing, the first time, on-time becomes critically important for all participants.

Immunization Registries – A Study in Healthcare Transformation

Medicaid and public health have been engaged in a leadership role in immunization registries. Their efforts have resulted in the implementation of an information technology tool that has benefited public and private providers, purchasers, government and the education system.

The implementation of immunization registries has not been an easy process. Difficult conversations related to politically and operationally sensitive issues were addressed, not ignored. Less than perfect decisions were made and key lessons learned emerged – lessons that are transferable to the design, development and implementation of current and future e-health initiatives.

From a financing perspective, immunization registries were the first “expansion” of Medicaid Management Information System (MMIS) funding beyond the traditional “core.” From a federal agency coordination effort, the Centers for Disease Control and Prevention (CDC) and Centers for Medicare & Medicaid Services (CMS) effectively maximized their parts to make a better whole. CDC worked effectively and efficiently with CMS at the federal level to facilitate the funding for design, implementation and operation of immunization registries and worked with State Public Health Agencies and Medicaid Agencies to encourage collaboration.

In developing the registries, States chose to adapt the immunization registry of an early adopter — Wisconsin, which Wisconsin licensed at no cost, — rather than
design a registry from scratch. Some states, notably Wisconsin and Minnesota, utilized a joint development team to support their registries. States also chose to accept and promote standardization and harmonization with CDC functional standards. Public Health Agencies and Medicaid Agencies worked together with public and private providers to integrate registry "silos" into statewide immunization registries. They also worked with legislative issues such as privacy and accountability, to ensure that the immunization registries would be user friendly for all parties.

Strategically, States developed and implemented roll-out plans for the immunization registries through geographically piloted approaches that allowed for appropriate buy-in and acceptance from providers and consumers. The buy-in included finding ways to deal with consumer-sensitive issues such as real-time identification, matching of the individual with the appropriate records, de-duplication of records, and authentication for access. A conscious effort was put forth by States from the beginning to engage consumers and advocates, balancing the need to manage expectations with assuring that critical concerns related to privacy were adequately and appropriately addressed.

States also worked to balance the cost and effort to improve performance management through better metrics and measures without adding unnecessary administrative burden to providers. Continual provider feedback resulted in automatic recall and reminder functions, linkages with electronic birth certificates and automated inventory tracking, thus eliminating hand-written charting.

Discussions with stakeholders continued from concept through implementation. These discussions remain an ongoing operational component of the immunization registries. This is important because health care issues are constantly changing and those issues resolved today will require continued communication to avoid future problems.

**Strategies**

Several key strategies contributed to the success of the immunization registries program and provide additional learning for future transformation projects. Whether designing and implementing other clinical registries or developing a broad-based statewide, regional or national e-health initiative, starting with the immunization registries strategies, and enhancing them, will allow for quicker and more effective IT implementation. In addition, this approach will lead to early successes. It will also result in less unanticipated barriers to improving the quality, efficiency, and safety of health care for all Americans through the use of information technology.

**Begin with People**

The overarching strategy by State and Federal government agencies was to begin with people. Questions like, “what do they need?,” “what do they fear?,” “what is an incentive?,” were asked. From there, it was critical to define the business processes so the information technology tools worked for person and team rather than the reverse.

**Start with the Impact to Children**

Interestingly, one of the more significant insights gained was to start with the impact to children. Often information technology and policy strategies begin with addressing an issue of the elderly or working adults—children are simply “add-ons.” By designing the immunization registries to meet the needs of children, the parameters became broad enough to also accommodate the needs of the adults. The reverse would not necessarily have been true.

**Determine Public Policy and Clinical Parameters First**

In order to define the business processes, public policy and the clinical parameters were required. Only then did the technical specifications and approaches come into play. Things that sounded simple were not necessarily easy to define. For example, what characteristics would have to be present to allow a match? If a child’s name is Richard, would Rick be good enough? If the child’s name is correct but the birthday is not the same, would this be a match? If the individual is Hmong, who all use June 1 as their date of birth, what are the implications for matching?
Make Sure Additional Key Questions are Asked and Satisfactorily Answered

Other questions that were clinically-oriented, operational or related to public health policy also needed to be asked. These questions include the following:

• What immunizations needed to be tracked?

• If the registry was to be usable, who could access it and who could input information into the system?

• What technical requirements were needed to assure interoperability with public health clinics and private physician offices?

• How could the registry be made available to schools for mass immunizations each fall?

• How could the registry be made accessible to parents, so they would no longer need to track their children’s immunization records on a paper card?

• What “alerts” would have to be provided back out to providers?

• When and how should those alerts be used to avoid “alert fatigue”?

• What is the definition of “fully immunized”?

• What anticipatory guidance would be followed to assure evidence-based medicine?

• By what age should an immunization have occurred?

• How could the registry reduce the time between an immunization being given and being recorded in the system?

Questions such as these all required satisfactory answers before proceeding with the initiative.

In concept, it was easy to agree that there should be open access to online immunization data. It was also easy to get agreement that the processes and workflows should be automated, integrated and patient-centric to keep the process efficient, affordable and producing quality information. Issues arose in the “how” and to what extent.

Establish a Governance Structure Early

Establishing a governance structure early in the process was key to the success of the immunization registries program. As a result of historical issues related to roles and responsibilities of public health and Medicaid agencies, governance was not always an easy discussion. Medicaid pays for up to 50 percent of the births, and more than one in four children are Medicaid recipients. This made it critical that immunization registries be designed and implemented in a way that created administrative efficiencies for both the public purchaser and the provider community.

Public health also had a huge stake in the outcome because immunization registries must accommodate the clinical and administrative needs of all populations, whether publicly funded or not. As immunizations are a clinical preventive service, the ability to facilitate, track and measure the individual and community population was critical.

In addition, in order to assure adequate financing and engage all stakeholders, all participants needed to view this as a sustainable ongoing endeavor. Where there was success, practical approaches regarding staffing, leadership, logistics, financing and management were worked out up front – not left “for later.”

Identify and Address State and Federal Security and Privacy Issues

Regulatory issues were identified and addressed related to privacy and security. Although mental health information was not within the scope of immunization registries, interested parties were concerned that precedence could be established through the development of the registries. In addition, data issues beyond those directly relevant to immunizations, such as privacy issues related to behavioral health data, had to be confronted in order to keep the process moving forward.

Identify State and Federal Interfaces and Determine Compatibility

The need to assure appropriate compliance with state and federal laws and regulations required first identifying where the interfaces existed and then determining compatibility. This was a multifaceted approach that encompassed public health policy issues, liability issues and technical
infrastructure issues. In states where there were defined IT architecture specification requirements, analysis was required to assure that the immunization registries, using internet and software, fit in seamlessly with the state system infrastructure.

**Address State Ongoing Oversight Responsibility**

State ongoing oversight responsibility required identification and funding for an ongoing administrative structure and staffing. Potential operational issues were proactively identified by providers and the state to create seamless operations. Incorporating project management techniques and oversight from the initiation of the project resulted in on-time, hassle-free implementation. Agreement on translation of any local formats and data definitions to accommodate federal data terminology and transaction parameters made the information accessible and usable.

**Ensure that States are Prepared to be Active Participants**

At the same time states were resolving their oversight roles, they were preparing to be active participants. As major providers of immunizations, states needed to assure adequate IT capability at their local public health clinics. They needed to determine financial implications (if any) and how to adhere to the requirements of the immunization registry. They also needed to know what additional training their own staffs would require. The states that maximized the use of the immunization registries also determined how to use this tool to gain administrative efficiencies and address some of their other child health initiatives.

**Engage Medicaid Agencies Simultaneously with other Constituencies**

Medicaid agencies, simultaneously, make payment, coverage and claims processing decisions relevant to immunizations. In order to encourage the engagement of providers, Medicaid claims payments became automated outputs of registry inputs. This resulted in administrative efficiencies and quicker payment. Aligning the immunization registry approach with the Medicaid Information Technology Architecture framework made federal financial draw-down more assured. In addition, creating population-based and provider level reports based on quality measurements allowed for better program management.

**Summary**

No effort is flawless. All registry efforts benefited from the knowledge gained by those who went before and the leveragability of the IT tool and business processes. The same will be true of future e-health initiatives. There will be many paths with various bumps and curves. Staying on the path, anticipating the unexpected, and allowing for imperfection facilitates the transformation— one incremental step at a time. Taking from the immunization registries experience, a few years ago there were multiple, non-connected, proprietary “silo” registries or none at all. Now there is a system of immunization registry networks benefiting consumers, providers, Medicaid and public health – and it is expanding every day. From Wisconsin to North Carolina, from Minnesota to Puerto Rico, it is a nationwide opportunity – and a potential international opportunity.

Success in transformation is not a point in time, but an ongoing goal – successful design, successful implementation, successful operation and successful validation of usefulness. These immunization registries are valued information technology tools because of three consistencies: connectivity, communication and collaboration. The efforts are sustainable because the leaders followed repeatable best practices regarding people, processes and technology, and they continually re-evaluated each component from multiple perspectives. As health information technology moves forward, this approach will be core to effective and efficient future e-health design, implementation and operations.

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Worldwide interest has increased for using health information technology to improve healthcare for citizens and to support public health priorities for disease prevention, education and tracking. The United Kingdom (UK) and its National Health Service initiated a project to implement the National Program for IT to deliver 21st century health services. A central goal of the National Program for IT is the creation of a single electronic health record for every individual in the UK. The UK’s health IT project is the largest scale initiative underway in any country. The following studies highlight some of the UK’s challenges and successes.

The National Health Service in England’s Care Records Service (NHSCRS) will provide a means of ensuring that the key details of a patient’s care and treatment are held in an easily accessible, electronic format. Once the service is fully implemented, the clinical and personal information available to doctors about patients through the NHSCRS will be complete, accurate, and accessible to them. Though there is still much to do by way of implementation, the technical and logistical challenges have now been largely overcome.

However, others have still to be fully addressed. Whilst the NHSCRS will incorporate the most stringent and up-to-date safeguards to protect confidentiality, some doctors and patients see electronic records as a threat to the confidentiality of information. Some NHS staff continue to regard the NHSCRS and the associated technologies, systems and services that make up the National Programme for IT in the NHS as just an IT project. Others remain sceptical about the value of the benefits of the programme relative to what they fear will be a period of disruption during the change process needed to achieve them.

In the past the focus on procuring, developing and delivering systems has meant that these concerns have not always attracted the attention they deserve. Active steps are now being taken to rectify this.
like their address, date of birth and NHS number. Eventually, it will also record their health and care history. It will include information such as whether a patient is diabetic or has a drug allergy, as well as details of the treatment and care they have received, building up a comprehensive patient history. Patients will in time be able to see their own record electronically, add personal information and preferences and point out errors.

The NHSCRS will contribute enormously to improving the quality of the patient experience and of treatment and services. It will help improve health by giving people access to information about themselves and knowledge and tools to look after their health. It will enable them to take more responsibility for their own health and care. It will be a means to improve care through better safety and outcomes. It will do this through ensuring that information and knowledge is available when it is needed to support better decision making; and to prevent decisions that may cause harm or risk of harm. This requires all parties to have timely access to relevant information and better communication between them.

People’s experience of health care will be enhanced through better shared participation in care decisions, and through being able to contribute to their own record. Finally, the efficiency of the health service will be improved through better communication between care professionals and organisations, through fewer wasted consultations or repeat investigations because records are missing, and the reduction in the numbers of people being unnecessarily harmed through poor access to records or the knowledge base to support good decision making.

The architecture of the NHSCRS has been commissioned, designed and is in the process of being built. The logistical and technical success of this endeavour has been widely reported elsewhere. The focus of strategic attention is starting to switch more strongly than ever before on ensuring the technology and its benefits are understood, and will be actively embraced by people accessing health care, and those working in the NHS.

**Public acceptance of electronic health records in practice**

People have a legal and moral right to expect that the clinical and personal information kept about them by the NHS will be complete, accurate, accessible to them, and remain secure and confidential. It is, however, an uncomfortable reality that a small number of people, doctors as well as patients, see the ease with which electronic records can be shared with other NHS staff as a threat to the confidentiality of the information they contain. These concerns need to be taken very seriously.

The consequences of patients choosing not to participate in the NHSCRS in significant numbers as a result of these fears would be very serious for both the individual and the NHS as a whole. There will be consequences for the patients themselves if future care has to be given - perhaps in a life-threatening emergency - in the absence of knowledge of existing conditions, earlier treatments, and medications. Inevitably, those who do make that choice will not receive the same quality of care as other patients. Clinicians will inevitably be put in the position of having to carry out unnecessary investigations or re-investigations on such patients, with all the consequent costs, inconvenience, and possible harm where these are invasive. Patients will also lose the benefits that an electronic record will provide - greater convenience, easier shared participation in care decisions, and direct access to their personal health information. In addition, there would be consequences for the NHS as a public service, such as increased costs when treating patients whose record is not held on the NHSCRS, less robust healthcare statistics and financial flows; and constraints on the ability to quality assure and learn lessons from care provision and outcomes.

Health Ministers in England have made it clear that NHS patients wishing not to have a record of their treatment held electronically within the NHSCRS will have that choice, and that patients who choose not to have some or all of their records held electronically within the NHSCRS need therefore have no fear that they will be ‘de-registered’.
from the NHS or otherwise being denied NHS care. Officials are therefore looking very closely, in consultation with organizations representing the interests of patients, citizens and health professionals, at the circumstances where it may be appropriate for patients to exercise this choice. Equally importantly, strategies are being adopted to ensure that ‘opting out’ is a step that few if any people will, on reflection, wish to take.

**Ensuring confidentiality and security**

The key first step has been to provide robust technical defences against risks to confidentiality and security. The NHSCRS will benefit from the most stringent and up-to-date safeguards to protect confidentiality. Patients will have control over who, outside of emergency situations, may see the Detailed Care Record or the Summary Care Record. If people feel that specific information about them is particularly sensitive and they do not wish even those providing them routine care to have it, they will be able to place it in a ‘patient’s sealed envelope’ so that it can only be made available with their express permission.

Up-to-the-minute security protection has been designed in across the system. International security standards are applied across all system implementations. These include the use of encryption to communication links between systems, and to user interfaces with systems. The quality of both the logical and physical security of data centres used by the NHSCRS are assured using both international and British standards, and all contractors to the DH are contractually bound to auditing their adherence to these.

With regard to access controls, only those staff that have a ‘legitimate relationship’ with the patient will be able to see a patient’s record. Even with a legitimate relationship, a member of staff will only have access to the parts of the record they need to do their job – known as ‘role based access control’. In addition, everyone who accesses a patient’s record will leave behind a log of who they are, what they did, and when. Patients will have a right to see information from the log. This is in marked contrast to the present position with paper records, which can be easily inspected and copied without leaving any audit trail.

**Engaging public and professional support**

However, these technical and procedural safeguards will count for nothing if patients have no confidence in their effectiveness, or have insufficient understanding of the changes being introduced and the benefits of having an electronic health record. And those benefits will never be realised unless the project achieves a genuine connection with GPs, nurses, hospital doctors, therapists, managers, booking clerks – in short, everyone who works in the NHS – through a commitment to use the new technologies to their maximum advantage. These issues are being tackled in a number of different ways.

Ministers have authorised establishment of a Care Record Development Board (CRDB) to give clinicians, patients and the public a say on the development of the NHS CRS and the whole National Programme. The board’s main role is to identify and articulate the values, principles and processes of care, as well as the risks and difficulties with managing information. Its job is to provide advice at all stages of the Programme to make sure these are taken into account when IT systems are implemented and will also ensure that ethical issues are adequately addressed.

In May 2005 the CRDB published the ‘NHS Care Record Guarantee for England’. The Guarantee sets out the rules that will govern information held in the NHSCRS when it goes live next year. The Guarantee covers how records will be used, people’s access to their own records, controls on others’ access, how access will be monitored and policed, options people have to further limit access, access in an emergency, and what happens when someone cannot make decisions for themselves.
local health community is connected to the NHS Care Records Service. This campaign will educate NHS staff in advance of each go live and will be supplemented by a public information campaign early next year, with the Care Record Guarantee as its focus that will ensure patients are provided with the information they need to make choices about storing, sharing and accessing their health information.

Bringing the NHS on board

For too long and for too many people in the NHS, delivering the National Programme for Information Technology has been seen as something best left to the technical community. While local IT managers and teams are crucial in bringing about the success of what is the world’s largest civil IT programme, the benefits of improved quality and safety of care which are the whole purpose of the NHSCRS will only be secured by capturing the commitment of the people who will actually use the technology.

A Service Implementation Team has been created within NHS Connecting for Health to work with clinicians and other NHS staff. The Team will engage with frontline staff to ensure that maximum benefit can be derived from the technology, not simply IT functionality, to ensure they can exploit its potential for better, safer patient care and improved job satisfaction. This will involve gathering consistent, knowledge-based evidence and ensuring that the needs and requirements of patients, as well as staff, are met by the full range of National Programme services being delivered.

The Service Implementation Team has seven clinical leads whose job it is to develop and maintain a two-way flow of communication between NHS staff and NHS Connecting for Health. This genuine dialogue, where staff have clear channels of communication and can readily influence and improve the technologies with their own ideas. As well as representing their direct clinical communities, the clinical leads also represent the wider professional groups associated with their areas.

To assist all those involved in implementation, extensive guidance has been produced. This continues to be regularly updated to provide a structured and consistent mechanism for implementation and to confirm the critical tasks necessary to maximise benefits. The NHS Connecting for Health website is also a core communications tool. It provides a full library of available information and guidance about the National Programme and is just one element of a comprehensive communications programme to all stakeholders. This communications programme, through a programme of conferences, and utilising media relations and the production and dissemination of a wide range of materials to the NHS and the public, has ensured that tailored national and local communications roll out as each key development and implementation takes place so that all stakeholders are fully informed.

Conclusion

Recent survey evidence has shown that NHS staff feels the NHS CRS is an important priority for the NHS and they are supportive of what the programme will achieve. It is seen to be an important initiative - the programme’s importance ratings compare well with other current NHS initiatives. The technology is proven, and within the next year will begin to be rolled out in phases across the country. The key priority now for NHS Connecting for Health is to build engagement and communications further with the public and frontline staff so that these expectations become a reality.

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Abstract

During 2003, the Department of Health in England (DH) oversaw the negotiation of a new National Health Service General Medical Services contract. Among other key developments, this led to changes to the way in which primary care general practitioners (GPs) are paid. Officials in what is now the NHS Connecting for Health agency within the Department were asked to develop the functional requirements for the system changes required to support the new contract. Three major system changes were required; an update to the GP payments system; software to support individual practice annual quality review visits; and the creation of QMAS, the Quality Management and Analysis System to support a Quality and Outcomes Framework (QOF), aimed at rewarding GP practices on the basis of the quality of care they deliver to patients. The successful delivery of all three of these elements to the demanding deadlines set for implementation of the new contract has been among the most notable early achievements of the National Programme for IT.

A revised General Medical Services (GMS) contract came into effect on the 5th April 2004. The revised contract was introduced to deal with the inadequacies in the previous arrangements for the remuneration of GPs and to better incentivise delivery of key aspects of primary care.

Given the high regard in which primary care services in the NHS are generally held by individual patients, the public generally, and internationally, it is perhaps remarkable that reimbursement arrangements under the previous GMS contract placed greater emphasis on high volume than on quality of care. Immediately prior to the change, less than 4 per cent of the total spend on fees and allowances explicitly derived from quality of care. This emphasis runs counter to GPs’ professional instincts and priorities, the interests of the wider NHS, and in particular the interests of patients.

Under the previous contract, practices had received a mix of per-doctor payments such as the basic practice allowance, capitation fees, and item of service payments. These historic arrangements have meant that:

- case mix is not adequately reflected
- differing practice circumstances are not adequately taken into account
- resources follow the distribution of doctors rather than patients and their needs
- resources are lost if the number of doctors in a practice reduces
- practices do not have security of income
- changes in skill mix are not encouraged
- practices have limited financial incentive to provide high quality care.
The new contract has introduced a global sum payment, combined with new rewards for quality, aimed at addressing these flaws. It does this through the introduction of a QOF, based on the best available research evidence. Under the new contract high achievement against quality standards will bring very substantial rewards.

The QOF represents, we believe, the first example of a public healthcare system in any developed country that will systematically reward practices on the basis of the quality of care delivered to patients. This approach is very much in line with the ethos of the health care professions, but also reflects the commercial reality that a determination to deliver higher quality care is most likely to be achieved through the use of incentives. This in turn will benefit both patients and the wider NHS. One example of this is the reduction in avoidable hospital admissions which should result through improved chronic disease management.

The QOF measures achievement against a scorecard of 146 evidence-based indicators, allowing a possible maximum score of 1050 points. It contains four ‘domains’. Each domain contains a range of areas described by key indicators. The indicators describe different areas of achievement. These are

- **Clinical Domain**: 76 indicators in 11 areas (Coronary Heart Disease, Left Ventricular Dysfunction, Stroke and Transient Ischaemic Attack, Hypertension, Diabetes Mellitus, Chronic Obstructive Pulmonary Disease, Epilepsy, Hypothyroidism, Cancer, Mental Health and Asthma) worth up to a maximum of 550 points (52.4% of the total).
- **Organisational Domain**: 56 indicators in 5 areas (Records and Information, Patient Communication, Education and Training, Medicines Management, Clinical and Practice Management) worth up to 184 points (17.5% of the total).
- **Patient Experience Domain**: 4 indicators in 2 areas (Patient Survey and Consultation Length) worth up to 100 points (9.5% of the total).
- **Additional Services Domain**: 10 indicators in 4 areas (Cervical Screening, Child Health Surveillance, Maternity Services and Contraceptive Services) worth up to 36 points (3.4% of the total).

Other points can be earned through three additional ‘depth of quality’ measures.

QOF is not about performance management of contractors, but rather about rewarding good practice. Its key underpinning philosophy is that incentives are the best single overall method of resourcing services, driving up standards and recognizing achievement.

### The Projects

The GMS payment project, within the National Programme for IT in England (NPfIT), developed and delivered, to time, the information systems required supporting the new GMS contract - that is, the making of automated calculations and disbursement of monies from primary care organizations (PCOs) to practices. As a result, the first payments were made in April 2004.

NPfIT has also developed a number of IT enhancements within practices’ existing clinical systems to support the data entry and management of activity to support the Quality and Outcomes Framework. These include:

- Tools to facilitate data entry of the QOF clinical indicators via guidelines, templates and forms;
- Suites of GMS clinical reports which enable practices to develop manage and verify their virtual disease registers. The reports also allow practices to drill down to individual patient level and by using other system functionality, set user defined prompts, post-it notes and reminders which are triggered when a patient record is accessed.
- Clinical achievement data extracts, based on a national specification developed by the National Programme, which enables the automated monthly extraction of data from the clinical system and its subsequent transmission to QMAS.
Analysis System (QMAS) is a new single, national IT system, which gives GP practices and PCOs objective evidence and feedback on the quality of care delivered to patients. The system shows how well each practice is doing, measured against defined national achievement targets. As general practices are now rewarded financially according to the quality of care they provide, it is essential that the payment rules that underpin the GMS Contract are implemented consistently across all systems and all practices in England. QMAS ensures that this is achieved.

This new single national system ensures consistency in the calculation of quality achievement and disease prevalence, and is linked to the payment systems. It provides PCOs and practices with access to the same information, and allows the user base to:

- Assess, whenever they wish, their current quality achievement points against their aspiration, estimated relative prevalence, and current achievement payment;
- Compare their current position with the average achievement of other practices in the PCO. Such comparisons do not involve disclosure of information that identifies other practices;
- Check that the data they are inputting is correct and complete.

Under the direction of NHS Connecting for Health the leading GP clinical system suppliers have developed suites of GMS reports to enable the practices to set up disease registers quickly and efficiently, together with data templates to assist the practices in using the correct clinical codes to record the data. It is these clinical codes that are used to define the business rules for the data submission for the calculation of points.

For the areas where non-clinical data is required NHS Connecting for Health has delivered a web service to allow all practices to enter data that may not be stored on the clinical system. The service also provides those practices that have not as yet moved to a clinical system the ability to submit both clinical and non-clinical information. This ensures that no practice is unable to take part in the Quality and Outcomes Framework and, importantly, does not disadvantage patients of these practices from benefiting from the quality of care improvements intended to be delivered through the QOF.

Clinical achievement data is sent automatically on a monthly basis from clinical systems to QMAS. Practices are also able to send ad-hoc reports whenever they wish. Non-clinical information (the Yes/No organizational, patient experience and additional services indicators) is added by the practice via the web browser interface within QMAS.

The diagram below outlines the data flows:
QMAS allows GP practices to analyze the data they collect about the number of services and the quality of care they deliver, for example maternity services and chronic disease management clinics. This provides a positive incentive for GPs to offer patients treatment in the community for procedures such as diagnosis or minor operations rather than referring them to hospital.

Implementation and rollout of QMAS covers all of England’s eight and a half thousand or so general practices, 303 PCOs, 28 Strategic Health Authorities, and the NHS Bank. The introduction of QMAS was required to interface to 17 versions of GP clinical systems supported by 10 separate GP supplier organizations and 84 payment systems operated by the 84 lead Payment agencies operating on behalf of PCOs for the collection of reference data and the issuing of payments.

Achievement

NHS Connecting for Health delivered the upgraded payments systems on time for payment to practices in England and Wales on 30 April 2004. National rollout of QMAS to all practices and PCTs in England proceeded on schedule, and to budget, to the very considerable satisfaction of users – payments in respect of QMAS quality measures generated an additional £1.2bn (over $2.1bn) income for GPs for the year 2004/05 – and the first year’s QOF achievement reports were available for practices to review on 2 April 2005.

QMAS can be seen as a model example of the potential for constructive co-operation between the public and private sector stakeholders in the UK National Health Service. Its success has been due to the active participation and collaboration of colleagues in the Department of Health, the General Practitioners Committee of the British Medical Association, clinicians, and GP clinical system suppliers working with NHS Connecting for Health.

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The initial change to patient-centric health care delivery in the early 21st century is well underway, but the transformation will be more complete when the next generation of health and medical informatics operates in the mainstream. The next generation of innovation in health IT will build beyond the current generation of electronic health record systems, to bring an unprecedented degree of change in the processes of health care delivery and level of patient-centered health care. The following articles survey emerging health IT systems in genomics, nanomedicine, wearable health IT systems and hybrid solar energy in health IT systems.

Washington D.C. 30 August 2005  This is a time of great opportunity for organizations in the public and private sector to work together on mutually beneficial ventures to construct an Electronic Health Record (EHR) of the future that will unify clinical record and genomic information systems. It is becoming clear that genomic information will become a standard component of a person's medical record in the coming years. Much of the work being done in this area involves collaboration between public and private sector organizations with a heavy emphasis on standards and "open source" solutions. By integrating computerized patient records with genomic biorepositories, bioinformaticists will be able to begin development of sophisticated applications that will truly transform health care delivery in the 21st century.

General Overview

Genomic technologies and computational advances are leading to an information revolution in biology and medicine. It is likely that the major genetic factors involved in susceptibility to common diseases like diabetes, heart disease, Alzheimer's disease, cancer and mental illness will be uncovered in the course of the next 5 to 7 years. (From "A Brief Primer on Genetic Testing - World Economic Forum" - January 24, 2003; Francis S. Collins, M.D., Ph.D.)

By integrating computerized patient records with genomic biorepositories, bioinformaticists will be able to work on sophisticated applications that will truly transform healthcare delivery in the 21st century. These applications will use advanced statistical and computational analytic techniques and will combine human genome research with the identification of proteins within chromosomes that cause inherited diseases and predispositions toward diseases that might be triggered by environmental, dietary, and other catalysts. These advances could usher in a new era of individualized preventive medicine.

In this not-so-distant-future, genomic information could routinely become part of a person's medical record. In fact, researchers are currently developing a computer language that allows clinical information to be embedded in DNA sequence. Health care providers could potentially have access to integrated longitudinal health records that include genomic, personal, and clinical information, including online images such as electrocardiograms, magnetic resonance imaging, and cat scans. Empowered with this more comprehensive patient record, health care providers will also have access to powerful clinical decision support tools that assist in evidence-based diagnosis, predictions, and care recommendations. Health care providers will be able to use these planned electronic health record (EHR) systems to determine treatment outcomes and practice effective preventive medicine, in
addition to obtaining guidelines on practice management.

Dealing with genomic information is far more challenging than working with other types of clinical information. Expressions of genomic information are much more sophisticated than simple field values contained in lab tests. There are interesting challenges in trying to display complex genomic information within today’s electronic health records (EHR). The availability of genomic information may force an entirely new way of looking at the clinical process. To manage and utilize this complex, sophisticated genomic information will most likely require a new EHR system framework that allows genomic information, clinical information, and personal information to coexist in a complex patient record envisioned for the future.

The introduction of genomics into clinical practice combined with new techniques and technologies gives rise to many challenges. This paper attempts to provide a preliminary analysis into the subject of genomic information systems and associated databases and their potential integration within larger, unified EHR systems of the future.

**Biorepositories and Genomic Information Systems**

The creations of biorepositories are closely linked with the development of genomic information systems. The availability of human biological specimens for research purposes is crucial for the advancement of medical knowledge and in understanding, diagnosing, and treating diseases that affect the general population. The need for good clinical data, as well as a biological specimen from patients, has become clearly apparent. In the past, this need was not quite so great, and was met by individual researchers who were able to collect a limited number of specimens, along with some clinical data, and use it in their own research, as well as making it available on limited basis to other researchers.

The need for biorepositories has, however, continued to grow. Several institutional level biorepositories have arisen over the past few years. There are governmental ones that have been established in the United States at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention, and within the Department of Defense.

Several universities have also created such a resource. In industry, there are about a half dozen companies that are attempting to create similar resources. For example, nTouch Research Corporation has a biorepository and genetic sample program, in which properly consented donors from its registry of thousands of patients have provided genetic samples for future research.

**Other Major Issues**

The challenges of creating an EHR that integrates an organization's clinical record system with a biorepository and a genomic information system involve complex organizational, social, political, and ethical issues that must be resolved. Concerns about patients' safety, rights, informed consent, privacy, and ownership of genetic material require careful attention. These issues are being addressed by both public and private organizations worldwide. Some of them are briefly listed here.

Informed consent and information management are important aspects of any genetic test or research study. Because of the often profound impact of genetic testing and the potential uses of genetic information, patients should be adequately counseled about the specifics of that test.

Release of information is limited by laws and policies. These restrictions are designed to help an organization make sure patients' rights and welfare are protected at every stage.

**Non-medical consequences** - The public has a fear that genetic testing could be made a condition for access to certain services or facilities, such as insurance or employment.

**Psychosocial harm** - Psychological harm may result from learning genetic information about oneself. Social risks include stigmatization, discrimination, labeling, and
possible changes in familial relationships.

**Intellectual property** - Many research scientists believe that science will advance more rapidly if researchers enjoy free access to knowledge. The law of intellectual property rests on an assumption that, without exclusive rights, investment in research and development will not happen.

**Technical Security** - Most population-based registries have developed a wide range of written and implied policies and procedures to assure secure handling and processing of all data collected. Implementing a wide range of effective physical and technical security solutions must be addressed from day one in any development effort.

**Regulations and Laws** - Currently in the United States, no regulations are in place for evaluating the accuracy and reliability of genetic testing. Only a few states have established some regulatory guidelines. No federal legislation has been passed relating to genetic discrimination in individual insurance coverage or to genetic discrimination in the workplace.

## Findings and Conclusions

Over the next decade, a goal for genomics will be to transform knowledge about the human genome into improvements in clinical practice. For a number of years we have collected information on many of the known genomic information systems initiatives and have been monitoring their progress. Numerous Federal agencies and private clinical research enterprises engaged in developing genomic information systems are embracing collaborative ventures and open source solutions. The role of "open" computing and "open" standards will be to support global collaboration between public and private health care organizations in this arena. Collaborating within this community of genetic researchers, biomedical drug developers and clinicians is essential if substantial progress is to be made over the near term.

The importance of collaborating in knowledge and data sharing in the field of genomic information systems makes the adoption of open source solutions a key direction organizations should take with regards to acquiring a system to meet their needs. Pursuing an open source solution that possibly integrates a "biorepository" with an existing clinical record system will serve to facilitate the provision of clinical data to bio-researchers and serve as a catalyst in the development of an EHR of the future that consists of a unified clinical and genomic record system. The integration of computerized patient records with genomic biorepositories will enable bioinformaticists to develop sophisticated clinical applications that will transform health care delivery in the 21st century.

## Options for Acquiring a Unified Clinical and Genomic Record System

Organizations have the option of using ready-made commercial-off-the-shelf (COTS) products that have been purchased from a commercial vendor, developing custom-made solutions from scratch, or accessing Open Source Software (OSS) solutions. There are advantages of each option. In-house development allows one to address the unique needs of the organization and ensures flexibility and control over how the solution evolves. COTS offers brand name quality and peace of mind, offers assurances of product support from the vendor, but at the same time does not require use of scarce IT staff that may not have the needed expertise. OSS offers access to free or publicly available source code that is maintained by an "open" community of developers. This may provide a more cost-effective long-term solution focused on interoperability and a more level playing field with others playing in this same arena.

## Recommended Next Steps

Health care organizations need to be more proactive in collaborating with other public and private sector organizations on construction of a unified clinical and genomic record
system. It is anticipated that genomic information will routinely become part of a person’s medical record in the coming years. Much of the work being done in this area involves collaboration between public and private organizations with a heavy emphasis on standards and “open source” solutions. Organizations should consider taking the following next steps:

- Health care organizations should consider establishing a council addressing the integration of their clinical record systems with genomic information systems into a unified EHR of the future.
- Organizations needs to survey existing genomic and bioinformatics systems for emerging languages, standards, and open source solutions that may be used or adapted to meet their needs.
- Organizations should consider establishing a pilot project to acquire and/or build the genomic information system that will eventually be incorporated into the EHR.
- Begin to collaborate further with other organizations on the collection of genomic data that could potentially be shared with to the mutual benefit of everyone involved.
- Investigate changes in clinical practices and business processes that the organization will need to make in anticipation of using genomic information in the future.

Genome Related Projects and Activities

**Armed Forces Repository of Specimen Samples for the Identification of Remains (AFRSSIR)** - http://www.afip.org/Departments/oafme/dna/afrssir/

The Armed Forces Repository provides reference material for DNA analysis to assist in the remains identification process.


BLAST is a set of Open Source Genomic software applications and databases produced by the National Center for Biotechnology Information (NCBI) and others

**Disease InfoSearchTM** - http://www.geneticalliance.org/DIS/

The Genetic Alliance provides the Disease InfoSearchTM tool to assist you in finding sp

**DOE Genomes** - http://www.doeigenomes.org/

Genome programs of the U.S. Department of Energy

**GeneCards Project** - http://bioinfo.weizmann.ac.il/cards/index.html

GeneCards is a database of human genes, their products and their involvement in diseases. It offers concise information about the functions of all human genes that have an approved symbol, as well as selected others.


Provides current, authoritative information on genetic testing and its use in diagnosis, management, and genetic counseling.


Researchers are developing the Genomic Messaging System (GMS), which is a computer language that allows clinical information to be embedded in the streams of DNA sequence.


Genetics Home Reference, the National Library of Medicine’s web site for consumer information about genetic conditions and the genes responsible for those conditions.

**Genetic Modification Clinical Research Information System (GeMCRIS)** - http://www.gemcris.od.nih.gov/

GeMCRIS is a comprehensive information resource and
analytical tool for scientists, research participants, institutional oversight committees, sponsors, federal officials, and others with an interest in human gene transfer research.

**Genome Hub** - http://www.genome.gov/10001674
Web links provide information about the human genome sequence, projects to sequence the genomes of other organisms and additional relevant information for genomic researchers.

**Human Genome Nomenclature Committee (HGNC)** - http://www.gene.ucl.ac.uk/nomenclature/
HGNC is a non-profit making body which is jointly funded by the UK Medical Research Council (40 percent) and the US National Institutes of Health.

**Human Genome Epidemiology Network, or HuGENet** - http://www.cdc.gov/genomics/hugenet/default.htm
HuGENet is a global collaboration of individuals and organizations committed to the assessment of the impact of human genome variation on population health and how genetic information can be used to improve health and prevent disease.

Presents information on official nomenclature, aliases, sequence accessions, phenotypes, EC numbers, MIM numbers, UniGene clusters, homology, map locations, and related web sites.

**Medical Genetics and Rare Disorders Database** - http://chid.nih.gov/subfile/contribs/mg.html
The National Human Genome Research Institute and the NIH Office of Rare Diseases jointly produce the Medical Genetics and Rare Disorders database to provide contact information for organizations that focus on genetic testing and gene therapy, inherited disorders, and rare disorders and information on available publications.

NCBI's Web site serves an integrated, one-stop, genomic information infrastructure for biomedical researchers from around the world so that they may use these data in their research efforts.

OMIM is intended for use primarily by physicians and other professionals concerned with genetic disorders, by genetics researchers, and by advanced students in science and medicine.

**Other Genetic Analysis Software** - Links:
http://linkage.rockefeller.edu/soft/list.html
For more information contact Marc Wine, Program Analyst, Health IT, GSA Office of Intergovernmental Solutions at marc.wine@gsa.gov.

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Introduction

Nanotechnology has the potential to revolutionize almost every industry including health care, pharmaceuticals, communication, computers, manufacturing, materials, energy, and security. Biologists, physicists, chemists, materials scientists, computational scientists, and mechanical and electronic engineers are all collaborating to share knowledge of tools and techniques and information on the physics of atomic and molecular interactions. This article attempts to pull together relevant information about the development of nanotechnology in health care to date, highlight major issues, and offer a set of recommendations to healthcare organizations on possible next steps to take.

General Overview

Federal funding for nanotechnology research and development (R&D) has increased substantially since inception of the National Nanotechnology Initiative (NNI) in 2001. NNI is a federal R&D program established to coordinate multi-agency efforts in nanoscale science, engineering, and technology. Twenty-three federal agencies are participating in the initiative including the DoD, NIST, HHS, DOE, EPA, and Commerce (see NNI partners). Nanotechnology federal funding increased from $464 million in 2001 to an estimated $1.24 billion in 2005. The United States, Asian countries (including Japan, China, and Korea), and several European countries recognize the tremendous economic potential of nanotechnology. While difficult to measure accurately, it is estimated that world-wide government funding has increased to about five times what it was in 1997, exceeding $2 billion in 2002 and still increasing.

Definitions/Terms

The term ‘nanotechnology’ was first used in 1974 by a Japanese researcher at the University of Tokyo to refer to the ability to engineer materials precisely at the nanometer (nm) level. The primary driving force for miniaturization at that time came from the electronics industry’s attempt to develop tools to create smaller electronic devices on silicon chips. The definition of nanotechnology continues to evolve.
Nanotechnology

The NNI calls something "nanotechnology" if it involves the following criteria:

- Research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1 - 100 nanometer range
- Creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size
- Ability to control or manipulate on the atomic scale

Nanomedicine

Nanomedicine deals with comprehensive monitoring, control, construction, repair, defense and improve human biological system at molecular level using engineered nanostructures and nanodevices.

The National Science and Technology Council Committee on Technology (NSTC) and the Interagency Working Group on Nanoscience, Engineering, and Technology (IWGN) has produced an informative brochure entitled Nanotechnology: Shaping the World Atom by Atom. It explains nanotechnology and its potential in laypersons terms.

The literature highlights two different approaches to nanotechnology — 'top down' and 'bottom up'. “Top-down involves starting with a block of material, and etching or milling it down to the desired shape. Bottom-up, or molecular nanotechnology, involves the assembly of smaller sub-units (atoms or molecules) to make a larger structure. These two methods have evolved separately and have now reached the point where the best achievable feature size for each technique is approximately the same, leading to novel hybrid ways of manufacture.”

A breakthrough for the 'bottom-up' stage has been the discovery of spinning molecular structures, which has huge applications for medicine and information technology.

Nanotechnology Developments

The ability to build and control engineered objects on the scale of nanometers (one-billionth of a meter) has been an essential element in the 'Information Revolution' with the development of ever-faster and more powerful electronic devices to manipulate, transmit, and store data.

Numerous products featuring the unique properties of nanoscale materials are available today including magnetoresistance (GMR) heads in computers to increase storage capacity; non-volatile magnetic memory; automotive sensors; and solid-state compasses.

Early nanomedicine applications include: focused pharmaceutical delivery systems; "laboratories on a chip" that perform multiple medical tests invitro or invivo; health related imaging nanodevices; nanosurgical tools; and nanotechnology implants and tissue scaffolds. Currently available health-related products using nanotechnology include burn and wound dressings, water filtration, a dental-bonding agent, and sunscreens and cosmetics.

Within two to five years, advanced drug delivery systems are expected to become commercially available, including implantable devices that automatically administer drugs and sensor drug levels and medical diagnostic tools, such as cancer tagging mechanisms, and 'lab-on-a-chip' real time diagnostics for physicians. Also expected are sensors for airborne chemicals or other toxins; nanomaging devices; nanosurgical tools; nanorobots or nanomedibots; super-conductive circuits and ultra-fast computers.

In this rapidly growing field of nanotechnology, it is difficult to keep pace with developments, especially since much of the R&D is proprietary information. Some of the examples listed on the Nanotechnology Now Web site is presented here to give some idea of the far-reaching effects of nanotechnology applications:

Nanocomposites are constituents that are mixed on a nanometer-
length scale, often resulting in properties that are superior to conventional microscale composites and can be synthesized using surprisingly simple and inexpensive techniques. One example is a coating process to make sponge-like silica latch onto toxic metals in waters. Metals such as lead and mercury are captured and then recovered for reuse or contained in-place forever. A plastic nanocomposite, currently being used in some automobiles, is scratch-resistant, light-weight, rust-proof, and stronger, resulting in fuel savings and increased longevity.

Nanocrystals absorb and then re-emit the light in a different color – the size of the nanocrystal determines the color. Examples include an antimicrobial dressing covered with nanocrystalline silver that rapidly kills a broad spectrum of bacteria in as little as 30 minutes; and semi-conducting nanocrystals (Quantum dots) that, when illuminated with ultraviolet light, emit a vast spectrum of bright colors that can be used to identify and locate cells and other biological activities (e.g., MRSs).

Nanoparticles of a material behave differently than bulk amounts of the same material. At the nanoscale, a material may be stronger, lighter, more water-soluble, more heat-resistant, or a better conductor of electricity. It takes only small amounts of a nanoparticle, precisely placed, to change a material’s physical properties. Adding nanoparticles of clay to a polymer used to wrap power lines increases strength and reduces flammability, for example. Other examples involve nanoscale cloth treatment currently used to repel stains; sunscreens that utilize nanoparticles that effectively absorb light in the UV range (due to particle size, they spread more easily, cover better, and save money because you use less); and vitamins that are formulated as nanoparticles so they can be mixed with cold water and absorbed by the body.

Nanocomposite coatings extend the shelf life of a variety of products. Examples include tennis balls that bounce twice as long and automobile tires that are lighter (better mileage) and last longer (better cost performance).

All-carbon nanotubes (1.2 nanometers in diameter) are promising for applications ranging from new structural materials that are stronger and lighter weight to electronic components for new super-computers to drug delivery systems.

**Nanotechnology Activities in Health Care**

It is widely accepted that R&D in nanotechnology requires an interdisciplinary collaborative approach. The following are just a few examples of nanotechnology initiatives in the health care arena:

**Purdue University**

Researchers at Purdue University, the University of Alberta, and Canada’s National Institute for Nanotechnology have discovered that bone cells called osteoblasts attach better to nanotube-coated titanium than they do to conventional titanium used to make artificial joints.

Purdue University researchers have shown that extremely thin carbon fibers called nanotubes might be used to create brain probes and implants to study and treat neurological damage and disorders. These nanotubes not only caused less scar tissue but also stimulated neurons to grow 60 percent more fingerlike extensions, called neurites, which are needed to regenerate brain activity in damaged regions (Purdue News, Jan 2004).

The Purdue Research Foundation has partnered with Theron Research Technologies to develop and market technology discovered at Purdue University that provides doctors with a more advanced way to take the vital signs of premature infants and monitor blood in a non-invasive manner. Because premature babies have such small veins, doctors must use a technique called direct umbilical artery catheterization (threading a catheter through the baby’s umbilical cord) to measure aortic pressure (Purdue News, Jan 2003).

**Massachusetts Institute of Technology (MIT)**

A chemical engineer and professor at MIT was awarded the Albany (N.Y.) Medical Center Prize in Medicine and Biomedical Research, America’s top tribute in medicine, for his research on polymer-based drug-delivery systems that allow clinicians to control the release of...
large molecules in a steady, controlled manner through surgically implanted plastic devices. His work has spawned revolutionary advances in cancer treatment (Modern Physician MP Stat, May 3, 2005; free subscription required).

MIT and the US Army Institute of Soldier Nanotechnologies, a research unit devoted to developing military applications for nanotechnology, are attempting to incorporate wound detection and treatment systems within uniforms made of ‘smart materials, such as a responsive system that provides an instant splint for a broken bone.

Northwestern University Institute for Nanotechnology

Northwestern University developed the “Bio-Barcode Assay,” a highly sensitive diagnostic test that could revolutionize the detection of disease. The technique involves nanotechnology and the use of magnets, gold, DNA and antibodies. Experts are already exploring ways of using it to spot early markers of Alzheimer’s disease and in the future it could also be used to diagnose the earliest signs of cancer, HIV infection, or the human form of Mad Cow disease. (News.scotsman.com; Nov 2004).

Potential Nanomedicine Collaborations by Healthcare Organizations

Nanotechnology will lead to new generations of prosthetic and medical implants designed to interact with the body, fundamentally altering the management of illnesses, patient-doctor relationships, and medical culture in general. Three major areas in which nanotechnology applications will be potentially valuable to health care organizations include:

- **Implants and prosthetics** – “With the advent of new materials, and the synergy of nanotechnologies and biotechnologies, it could be possible to create artificial organs and implants that are more akin to the original, through cell growth on artificial scaffolds or biosynthetic coatings that increase biocompatibility and reduce rejection. These could include retinal, cochlear and neural implants, repair of damaged nerve cells, and replacements of damaged skin, tissue or bone.”

- **Diagnostics** – “Within microelectromechanical (MEMS), laboratory-on-a-chip technology for quicker diagnosis which requires less of the sample is being developed in conjunction with microfluidics. In the medium term, it could be expected that general personal health monitors may be available. Developments in both genomics and nanotechnology are likely to enable sensors that can determine genetic make-up quickly and precisely, enhancing knowledge of people’s predisposition to genetic-related diseases.”

- **Drug delivery** – “With nanoparticles it is possible that drugs may be given better solubility, leading to better absorption. Also, drugs may be contained within a molecular carrier, either to protect them from stomach acids or to control the release of the drug to a specific targeted area, reducing the likelihood of side effects. The ultimate combination of the laboratory-on-a-chip and advanced drug delivery technologies would be a device that was implantable in the body, which would continuously monitor the level of various biochemicals in the bloodstream and in response would release appropriate drugs. For example, an insulin-dependent diabetic could use such a device to continuously monitor and adjust insulin levels autonomously.”

A quick listing of some areas that are converging on the field of nanomedicine includes: Biotechnology, Genomics, Genetic Engineering, Cell Biology, Stem Cells, Cloning, Prosthetics, Cybernetics, Neural Medicine, Dentistry, Cryonics, Veterinary Medicine, Biosensors, Biological Warfare, Cellular Reprogramming, Diagnostics, Drug Delivery, Gene Therapy, and Clinical Imaging. Looking forward to the next decade, the linkage of these nanotechnology diagnostic, drug delivery, or implant devices to a patient care information system and personal health record become very real possibilities.
Government Funding Considerations

The challenge for interested health care organizations is to help governments to formulate long-term strategies that promote the cost effective development of nanotechnology that meet as many needs as possible, especially with regards to health care. Early involvement by health care provider organizations might prove useful in providing guidance about funding efforts to link nanotechnology solutions to electronic health record (EHR) systems of the future.

Potential Costs/Benefits

Major long-term cost-benefits related to investments in nanotechnology for health care include:

- Significant investment must be made over time before achieving major benefits
- Potential for radical advances in medical diagnosis and treatment are high
- Powerful capabilities built into future health IT systems utilizing nanotechnology sensors
- Improvements in personal health information and personal care products
- Early involvement and investment should lead to standards, interoperability, etc.

Other Issues

The public is very concerned about safety, privacy and ethical issues. For example:

- With computing expected to be so cheap and powerful, it is possible that nanotechnology products will be able to process, sense and transmit information without our consent or knowledge.
- The values of natural human life and what society is and is not willing to accept lack current definitions in the realm of applied nanotechnology (e.g. replacing living body parts with man-made mechanisms).

The evolution of nanotechnology will likely involve extensive testing of solutions coupled with consideration of the social and ethical consequences of deploying them. "Like any powerful new technology," says National Science Foundation (NSF) Director Rita Colwell, "nanotech also has the potential for unintended consequences--which is precisely why we can't allow the societal implications to be an afterthought."

In March 2005, a European Commission was launched to promote international dialogue on the social, ethical and legal benefits and potential impacts of nanotechnology. Other challenges or issues that need to be addressed include the need for standards, overcoming legal barriers, collaborative research, development of interfaces to health information systems, patient safety, and interoperability to name just a few.

Next Steps

Cheaper and higher performing nanotechnology solutions, combined with convenience and greater functionality, will revolutionize health care in the coming decade(s) and will change the daily business practices of healthcare organizations and how they provide patient care. The following set of recommendations is presented on possible next steps for large health care provider organizations to take:

- Consider becoming involved in the NNI Initiative or other research and development efforts in nanotechnology that relate to the delivery of patient-centric healthcare and health information systems.
- Identify potential nanotechnology pilot projects involving healthcare related product development and implementation that may benefit your patients in the future (e.g., drug delivery, gene therapy, diagnostics).
- Investigate changes in clinical practices and business processes that your organization may need to make in anticipation of implementing nanotechnology applications/devices.
- Conduct a cost benefit analysis and return on investment for these types of initiatives.
- Obtain lessons learned from existing nanotechnology projects, especially as they relate to
healthcare and IT systems.

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Other Key References


Nanotechnology and Occupational Health - http://www.cdc.gov/niosh/topics/nanotech/


Nano Science and Technology Institute - http://www.nsti.org/


DoD Integrated Research Team (IRT) on Bio-Medical Nanoscience - http://www.tatrc.org
The 1980s were dominated by the use of personal computers (PC). The 1990's saw the widespread acquisition and use of laptop computers. This decade is seeing the acceptance and use of personal digital assistants (PDA) by many people. It appears the current decade may be dominated by the production and use of wearable information technology (IT) systems. Wrist watches, pagers, cell phones, pocket calculators, PDAs, and Blackberries are all examples of simple wearable information systems that are already in use. However, the next generation of wearable systems is now starting to emerge. While still on the "bleeding edge," it may be time for some of the larger, more technologically advanced health care institutions to begin collaborating on further research, development, and pilot testing of wearable IT systems in the healthcare setting. This article pulls together relevant information about the development of wearable health care IT systems to date, highlights major issues, and offers a set of recommendations on possible next steps to take with regard to this emerging technology.

Wearable Computing

Wearable IT systems owe a lot to the early work of Professor Steve Mann of the University of Toronto, often referred to as “the grandfather of wearable computing.” He offered a definition in his keynote address at the First International Conference on Wearable Computing in May 1998:

"Wearable computing facilitates a new form of human-computer interaction comprising a small body-worn computer (e.g. user-programmable device) that is always on and always ready and accessible. In this regard, the new computational framework differs from that of hand held devices, laptop computers and personal digital assistants. The always ready capability leads to a new form of synergy between human and computer, characterized by long-term adaptation through constancy of user-interface." [http://wearcam.org/icwc/empowerment.html]

The Massachusetts Institute of Technology (MIT) Media Lab, which has sponsored much research into wearable computing, adds, on its website:

“A person’s computer should be worn, much as eyeglasses or clothing are worn, and interact with the user based on the context of the situation. With heads-up displays, unobtrusive input devices, personal wireless local area networks, and a host of other context sensing and communication tools, the wearable computer can act as an intelligent assistant, whether it is through a Remembrance Agent, augmented reality, or intellectual collectives.” [http://www.media.mit.edu/wearables/index.html]

The idea of wearable computers goes back to the 1960s, but early attempts to create these types of systems were hampered by the size of the hardware. In order for a computer to be "wearable" it has to be fairly small, lightweight, be able
to be attached to clothing, or even be integrated into clothing fibers. It must be unobtrusive and conveniently placed on the body, i.e., it should not interfere with a user’s normal activities but help simplify them. An essential characteristic which distinguishes wearable computers from digital wrist watches or "walkman radios" is their versatility. They should be able to perform a wide variety of tasks, rather than be limited to tightly restricted functionality.

With ever accelerating innovations and technology, it is difficult to keep pace with developments in this field. Several recent advances have profoundly impacted wearable computer technology:

- New fibers called Aracon, made of Kevlar, which are super strong, can conduct electricity and be woven into ordinary-looking clothes.
- A chip packaging allows wearable computers to be washed and dry-cleaned. The electronics are insulated and directly woven into clothing and other textiles.
- A flexible video screen made of optical fiber can be woven into clothing that can display static and animated graphics downloaded from the Internet, a desktop computer, or a mobile terminal.
- Head-mounted displays allow users to focus on a task while at the same time, check information on a computer.
- On-body and off-body enabling technologies are becoming more sophisticated and include VPNs, PANs, ISM, DECT, GSM, and Bluetooth wireless.

- Nanotechnology is playing a significant role, making computing and communications systems microscopic in size and more conducive to on-body usage.

**Wearable IT Systems - Non-Healthcare Related**

Companies are already manufacturing and distributing wearable computer systems to various types of organizations. Examples of non-healthcare related wearable IT systems include:

- **Nomad Display Systems** - The Nomad® Expert Technician System is a wireless, wearable computer with a unique, head-worn, see-through display - enabling technicians to work using both hands and simultaneously see service and dealership management system (DMS) information. Nomad superimposes text and diagrams from DMS and online repair content directly over the workspace. Service advisors can greet customers at their vehicles, access vehicle history, and fill out work orders while maintaining face-to-face contact with the customer. Wearable computers are already in the workplace at Volvo and Honda. [http://www.microvision.com/nomadexpert/video_testimonials1_2005.html](http://www.microvision.com/nomadexpert/video_testimonials1_2005.html)

- **Display and Sight Helmet**

**Wearable Healthcare IT Systems**

Although wearable computers have started to enter health care delivery environments, wearable systems for both physicians and patients will more fully emerge over the next decade. Wearable computers for physicians will allow them to treat patients and complete their rounds
while connected via wireless networks to computerized patient records. Wearable computers are already allowing physicians to remotely observe patients’ vital signs and monitor progress of surgery from outside the operating room using palm held devices.

Medical sensors are now available for use by patients, ranging from conventional sensors based on piezo-electrical materials for pressure measurements to infrared sensors for body temperature estimation and optoelectronic sensors monitoring blood oxygen, heart rate, heart recovery ventilation, and blood pressure. Other health monitoring devices, such as the vestibular-ocular test apparatus, the glucose counter, and the insulin delivery system can also be hooked up to a wearable computer without wiring the patient's body.

The following are some examples of Wearable Health IT Systems:

- **The Ring Sensor** is an ambulatory, telemetric, continuous health monitoring device developed by d’Arbeloff Laboratory for Information Systems and Technology at MIT. It combines basic fundamental photo plethysmographic techniques with low power, telemetry. Worn by the patient as a finger ring, it is capable of monitoring vital signs related to cardiovascular health. Remote monitoring is possible via a wireless link transmitting patient’s vital signs to a cellular phone or computer. Clinical trials have been done in conjunction with Massachusetts General Hospital’s Emergency Room, and researchers are now working on commercialization of the ring-sized device (from Technology Review Magazine, April 2004).

- **The Sensate Liner for Combat Casualty Care or “SmartShirt”** was first developed by researchers at the Georgia Institute of Technology under the auspices of the U.S. military’s 21st Century Land Warrior Program and the Defense Advance Research Projects Agency. The “SmartShirt” is a fiber optic-laden garment with a built-in patented conductive fiber/sensor system that relays a soldier’s vital signs in real-time, his location and the exact time of injury. This technology can also be woven into children’s sleepwear, possibly preventing sudden infant death syndrome (SIDS) by alerting parents (via PDA or wristwatch) the moment a baby stops breathing.

- **Vigilance** is being used by anesthesiologists at Vanderbilt University Medical Center. A portable computer and high-tech eyepiece allow them to simultaneously monitor multiple operating rooms. Vigilance integrates information from multiple pre-existing sources: the operating room’s anesthesia machine, heart monitor and video cameras are connected to Vanderbilt’s secure data network, and surgical teams use in-room workstations to document care and vital signs. The physical package was assembled from off-the-shelf components, but its software was developed at Vanderbilt.

- **The Vocera Wearable Communication System** is being used at the Providence Portland Medical Center. This wireless system provides hands-free, voice activated communications within networked buildings/campuses. Aimed at mobile workers in hospitals, retail operations, and other industries, the system allows users to wear a device that weighs less than two ounces to interact with each other instantly and make decisions quickly with simple voice commands.

- **BodyKom** is a new system being tested by a Swedish technology company called Kiwok, TeliaSonera AB and Hewlett Packard that connects wirelessly to sensors on the patient. If changes are detected in the patient’s body, the hospital/health care services are automatically alerted over a secure mobile network connection. It could be used to monitor heart rate, diabetes, asthma, and other diseases that require timely intervention.

- **BodyMedia**, a Pittsburg company, makes a special "smart band" that is worn on the upper arm and collects data on the wearer’s physical state, such as the way the body releases heat. It is also scheduled for release to health clubs as a weight-loss monitoring tool. Within the next
year, BodyMedia plans to release special bands for monitoring the well-being of infants and the elderly.

- **The LifeShirt System**, developed several years ago by VivoMetrics, in Ventura, California, is being used in several top medical schools. The garment, which collects and analyzes its wearer’s respiration flow, heart rate, and other key metrics, demonstrates in real-time whether a new treatment is working. There will also be a shirt for emergency-services workers, such as firefighters, that will wirelessly alert commanders when a firefighter’s core body temperature or stress levels reach critical levels. VivoMetrics expects to introduce a shirt in 2006 that will allow parents to monitor asthmatic children.

- **U.S. Army Institute of Soldier Nanotechnologies**, a research unit devoted to developing military applications for nanotechnology, is working with MIT and attempting to incorporate wound detection and treatment systems within uniforms made of smart materials, such as a responsive system that provides an instant splint for a broken bone.

**Future Scenarios**

The following scenarios provide a glimpse at the not-so-distant future of health care computing and patient monitoring involving wearable IT systems:

- A **physician** is making morning rounds. Using his wearable PC, which has a wireless connection back to the hospital’s electronic health record (EHR) system, the physician is able to readily view the patient’s medical record on a small head mounted display (eyeglasses) and place orders while moving from patient to patient on a particular ward. While walking the floor the physician can also receive alerts, lab results, and other desired information without breaking stride.

- A **patient** requires hospitalization for examination, treatment, and rehabilitation periods. The health care provider offers the patient a chance to reduce their hospital stay through home health monitoring. The patient is fitted with wearable computing technology that monitors the patient’s vital parameters (e.g., intraocular pressure, glucose levels, blood pressure, temperature, etc.) and wirelessly transmits the information to the patient’s PDA or similar device. The data is transmitted through a network to a database storing patient records. The health care provider keeps track of the patient’s file and communicates instructions to the patient at home. If any irregularities in the patient’s vital signs are detected, an ambulance is automatically sent to the patient’s location, which is determined via GPS in the patient’s PDA (or similar device).

As sensor and computing technologies continue to evolve, their integration into wearable medical devices for monitoring, diagnosis and treatment of illnesses likely will become commonplace. A personalized health management device would allow a person to be more interactive and more conscious of his/her own condition in a way to adopt a healthier lifestyle and obtain personalized therapy. These devices could also help health care providers monitor patients during rehabilitation, thereby decreasing hospitalization time.

**Potential Benefits**

Wearable IT systems offer potential benefits for providers, patients, and healthcare organizations.

For health care providers, wearable IT could enhance their ability to respond rapidly to medical care regardless of geographic barriers, particularly in rural and underserved areas. It could improve timely access to a patient’s electronic medical record (EMR) where and when it is needed, provide timely access to clinical protocol and operational procedures, and allow providers to complete a number of complex tasks in less time and with less effort.

For patients, it could improve their quality of life due to speedier recoveries and fewer, shorter hospitalizations. It could promote more healthy lifestyles, reduce medical care costs for the patient, cut travel expenses for medical appointments, and possibly even lower death rates for a number of chronic diseases (e.g., cardiac...
Finally, for healthcare organizations, it could reduce hospital operating costs while possibly increasing the number of patients receiving care.

Other Issues & Challenges

*Innovations@Georgia Tech* web site lists four limitations to wearable computing, including:

- **Power** - the more features added to the computer, the more power is needed, and the larger and heavier the battery will be, causing discomfort due to size and amount of generated heat.

- **Networking** - involves networking off your body to the Internet, and networking between the computer's components on your body. An on-body wireless bus (an internal electrical pathway along which signals are sent from one part of the computer to another) is an area of research.

- **Privacy** - wearable computers give access to information you normally don't have, e.g., personal notes, recorded conversations, schedule, diary, medical record. This amount of information in one place requires a combination of security measures like encryption, guarding your computer, and keeping your computer on you.

- **Interface** - involves how we communicate with the computer and how it communicates with us for maximum efficiency and comfort.

Conclusions & Next Steps

Current and emerging developments in wireless communications integrated with developments in pervasive and wearable technologies will have a radical impact on future health care delivery systems. It is anticipated that wearable computing will become a routine part of health care delivery and patient self-management in the coming decade. Public and private organizations around the world are collaborating on research, development and testing of wearable computers, some of which are already being used in medicine, mining, automobile and aircraft maintenance, telecommunications, aerospace, military defense, education, and travel.

We recommend that technologically advanced healthcare organizations consider taking these next steps with regard to wearable health IT systems:

- Consider establishing an inter-disciplinary workgroup to identify functional requirements and/or potential uses of wearable health IT systems for physicians and patients.
- Identify potential partners to collaborate with on the development of wearable health IT systems and determine each organization's roles (e.g., research, development, pilot testing).
- Conduct a feasibility study and cost benefit analysis for this potential initiative.
- Conduct a detailed literature search and obtain lessons learned from existing projects in this field.
- Establish a pilot project to acquire, develop, and test wearable technology that could eventually be incorporated into the healthcare organization.
- Investigate changes in clinical practices and business processes that may need to be made in anticipation of utilizing wearable computing technology.

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The Bush Administration has set a goal to increase the use of solar and other renewable forms of energy in all parts of the U.S. economy. Its vision for the future includes having more and more of the nation’s information technology (IT) infrastructure, web sites and computers powered by a "hybrid" energy system that taps into solar, wind, and traditional electrical energy sources.

Today, widespread deployment of renewable, non-polluting solar and related energy sources would support key policy goals related to national defense, improved health status through reduced pollution, hybrid energy sources not totally reliant on the electricity grid, and energy security.

More efficient solar-energy systems are now being produced at lower costs, becoming attractive alternatives as the price of oil climbs ever higher. The number of examples where commercial-off-the-shelf (COTS) solar energy components are being used to power computer systems has increased dramatically, including installations by numerous individuals and organizations around the world. Today’s solar energy solutions are often configured as hybrid systems that utilize solar panels and small wind-powered generators that plug into the existing traditional electrical systems already installed in most buildings. Many are commercially viable.

Solar-Powered Health IT Systems

Solar power is an important source of efficiencies for health care providers as well as other segments of the economy. There are numerous examples of solar-powered health IT projects that have been completed across the country and around the world. For instance:

U.S. Centers for Disease Control and Prevention (CDC) Health Care Facility in Kenya – The CDC Health Initiative facility in Homa Bay, Kenya, benefits from a solar energy power system that delivers reliable power and reduces losses of vital medicine and laboratory test samples. The facility houses an on-site laboratory that supports a project to reduce diarrhea diseases using a simple household-based method to improve water quality.

U.S. Agency for International Development (USAID) and Kakuuto Hospital in Uganda - Youth volunteers from the United States traveled to rural areas of East Africa to work with "Solar Light for Africa", a faith-based non-governmental organization, in providing power to clinics, orphanages, schools and churches. With USAID assistance, the organization electrified the Kakuuto Hospital in...
Uganda’s Rakai District using solar energy, which has improved the health of patients and enabled staff to treat them more effectively.

http://www.usaid.gov/stories/uganda/fp_uganda_solar.pdf#search='solar+powered+hospital+computers'

**World Health Organization and Pan American Health Organization Cold Chain** - The Cold Chain uses solar power to provide reliable refrigeration to conserve vaccines from manufacture to distribution to point of use. It plays a key role in the fight to eradicate polio and other childhood diseases. Solar electricity is used in rural and other non-electrified communities to maintain a safe supply of vaccines and to freeze icepacks for transport to the most remote populations. Vaccine refrigeration, lighting, safe water supply, communications, and medical appliances are powered by solar electricity at rural health care facilities throughout Latin America.

**Monmouth Ocean Hospital Service Corporation (MONOC)**, the largest emergency medical services agency in New Jersey, has flipped the switch on a 119 kilowatt solar energy system that will generate about 20 percent of its electricity needs and contribute to a cleaner, healthier environment. MONOC is believed to be the only major healthcare organization in the state to invest in such a renewable energy system. MONOC provides ambulance and paramedic services for more than 100 municipalities in New Jersey, as well as medical and specialty care transport programs for over 20 hospitals in the state. More than 700 panels installed on the roof of the headquarters can generate as much as 20 percent of the electricity needed to run the building.

**Internet Village Motoman** was launched in Sept 2003 by First Mile Solutions (FMS), bringing technology to 15 solar-powered village schools, telemedicine clinics, and the governor’s office in a remote province of Cambodia. The system relies on an Internet access hub in the provincial capital, wireless-equipped solar-powered computers, and five motorcycles, each with a storage device, a wireless transmitter card, and an antenna fitted to the back. Each of the schools can send and receive email and also browse the Internet using a non-real-time search engine. Telemedicine clinics have a link with Massachusetts General Hospital. The network was implemented within one month in three villages, at a cost of approximately $500 per village.

**Major Issues**

**System Security / Disaster Recovery** - Solar powered systems are excellent alternatives that can be used as temporary power backup systems. When Hurricane Katrina hit the Gulf Coast of the United States in 2005, large parts of the region quickly found themselves operating in third world like environments. Solar energy systems could have proven invaluable. Health facilities that can deploy backup systems may find they are more readily able to manage continuity in the delivery of services and connected information systems.

**National Security / Energy Independence** - Of course, alternative energy solutions need to be pursued as part of national policy to lessen dependence on oil producing nations that could hold the country hostage. This is a national security issue that will increase over time. As the implementation of standards-based public health disease and biosurveillance systems evolves, support from alternative energy sources could prove vital in communications of health information for citizen’s security and safety.

**Cost Benefits / Tax Incentives** - In the United States, both the federal government and state governments offer some limited tax incentives to individuals and corporations that install alternative energy sources, (e.g. solar, wind power), but more can and should be done. In 2003, the United States spent 15.3 percent of its Gross Domestic Product (GDP) on health care. It is projected that the percentage will reach 18.7 percent in 10 years. Considering financial incentives to
encourage the use of solar energy sources to support health care information technology systems may help demonstrate their effectiveness and cost benefits.

Next Steps - Some recommendations on next steps senior managers may want to consider taking in the very near future:

- Commission a detailed systems requirements analysis and cost/benefit study into the potential uses of hybrid solar energy systems in health IT settings
- Conduct a small pilot test of solar powered health IT computer systems
- Implement a solar powered production environment, e.g. corporate web site, for health IT facilities.
- Expand use of solar powered systems over time.

Conclusion

While the costs of traditional non-renewable fossil fuel energy sources are escalating, commercial off-the-shelf solar energy solutions are becoming more readily available. Solar energy can even be part of a hybrid solution that uses solar, wind, and traditional electrical energy sources, all working together. It is more than likely that the use of solar energy will help keep down the cost of health care in the future, and make it more universally available.