



“There’s no way to transform the healthcare system without information technology.”

*David Blumenthal, MD, National Coordinator for Health Information Technology, (Source: Wall Street Journal, June 15, 2009)*

## Overview

Greater availability of accurate, complete, relevant clinical data allows care providers to deliver higher quality, more efficient and cost-effective care. Studies have shown the eHealth initiatives that include electronic health record (EHR) systems connected to a health information exchange (HIE) result in reduction in redundant tests, increases administrative efficiencies, and speeds processing of referrals, prescriptions, and hospital discharges. eHealth can improve patient safety by eliminating transcription mistakes, thereby reducing medication errors and adverse drug events. In addition, the capture and exchange of patient clinical data opens the door to new alternatives to face-to-face care provider visits which are equally effective, less costly and more efficient for patients and providers.<sup>1</sup>

The progress of large-scale eHealth initiatives in the United States has been very slow. A review of all 145 HIEs found only 32 HIEs still active and only 20 of them were achieving modest success.<sup>2</sup> There is also a very high failure rate with more than 25 percent failing in a short timeframe. Funding and participation, legal and regulatory, and technical issues were the three top obstacles cited in the 2008 Robert Wood Johnson Foundation study on the lack of progress.<sup>3</sup>

Health reform, a top priority for the Obama administration, requires EHR and HIE technology solutions to be successful. The recently enacted Health Information Technology for Economic and Clinical Health (HITECH) Act is re-invigorating discussion activities surrounding state and regional eHealth efforts by addressing a number of the current obstacles.

- HITECH provides over \$300 million in funding to regional health IT efforts to create the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States.<sup>4</sup> It also offers provider incentives for using EHRs contingent upon their ability to support HIE.
- HITECH emphasizes the importance of privacy and security by expanding upon existing HIPAA legislation and establishes new breach notifications for providers and business associates.
- HITECH created the HIT Policy Committee and the HIT Standards Committee which report to Office of the National Coordinator (ONC) and are responsible for establishing standards, implementation specifications and certification criteria (all of which are long- standing technical issues that prevented widespread eHealth initiative deployment).<sup>5</sup>

The stage is now set for the United States to make substantial progress in designing and building large-scale eHealth solutions that can eventually be connected to form a national health information network. However, even under the best-case scenarios, these initiatives are organizationally, technically and politically complex, and costly, and take years to complete. Electronic capture and storage of health information always brings forth differing, often very strong, opinions about patients’ rights, providers’ needs, and government intervention and responsibilities. Understanding the risks and issues from similar efforts can help avoid making the same mistakes.

Fortunately, comparable efforts do exist. European countries tend to be more advanced than the United States in implementing large-scale eHealth initiatives, starting more than a decade ago. In countries such as Denmark, the Netherlands and Norway, EHR adoption by general practitioners (GP) is approaching 100 percent, compared to 20 percent, at most, in the United States.<sup>6 7 8 9</sup> Denmark, Sweden, Norway and the United Kingdom (UK) have had great success implementing these enormous health information exchange solutions that are already demonstrating positive results. These pioneering efforts provide country-wide success stories of routine data exchanges that are now an integral part of care delivery.<sup>10</sup>

Our first-hand experience in Europe (Denmark, the Netherlands and three regions in the UK) and our U.S. healthcare and technology knowledge have enabled us to identify major decision points, best (exemplary) practices and lessons learned that are transferrable to U.S. projects. While the size of the European efforts is far smaller than the United States, they are comparable to our state efforts, and often have encountered many of the same issues under discussion at the national level.

The report is organized under five major topics to highlight the chief interdependencies, since decisions are often interrelated (Table 1). For example, decisions related to the health program will set expectations for the technology requirements and are critical for defining the success criteria and how value will be measured.

<b>Topic</b>	<b>Decision Points</b>	<b>Best Practices/Key Lessons Learned</b>
<b>1. Planning and Sustaining the Initiative</b>	Setting Expectations	These are healthcare initiatives, supported by technology
	Value Definition and Measurement	Build a value program into the plan with health-based measures calculated before and after installation
	Determining IT Requirements	Broad scope for setting requirements, periodic review
	Funding and Sustainability	Those who gain from the value need to be willing to pay the cost
<b>2. Major Issue Management</b>	Privacy and Security	Early communication regarding options, role-based access-preferred option with ability to break the glass  Data sharing — opt in, opt out, opt in with restrictions, assume opt in
	Patient Identification	Clean PHI data, unique ID number is the preferred approach
<b>3. Governance and Communication</b>	Governance	Involve all key stakeholders, centralize decision making whenever possible, seek input
	Communications	Comprehensive strategy executed by governance group, communicate to each constituency using the right method, two-way interactions
<b>4. Technology and Interoperability</b>	Technical Architecture	Fit to meet healthcare reform program and policy needs, foundation for the future
	Standards and Certification	Must-haves
<b>5. Implementation</b>	Planning	Strong link to policy, continuous planning with process and resources to support changes
	Implementation Rollout and Support	Pilot and roll out incrementally, support continuously

For each major decision point, best practices, challenges and applicability to U.S. efforts are described using specific examples and scenarios to highlight where issues are likely to occur, and how they were addressed. At the end of each topic there is a summary of the latest updates from ONC and its committees (“HITECH Update”) that includes a comparison of their decisions and progress to European experiences.



## 1. Planning and Sustaining the Initiative

Many HIE efforts in the United States failed because there was not a clear, specific business reason for forming the exchange. The availability of grant funding and the overall agreement that the access to accurate and complete patient data improves care created many short-lived HIEs that struggled to answer questions on how to set up governance, what data should be exchanged, who should be included in the HIE and how will the solution be architected and maintained. Without a clear focus and healthcare-directed business case, these important questions could not be answered, leaving these pilots to be no more than planning and/or technology connectivity exercises, which ultimately ended after the initial pilot stage.

### **Setting Expectations**

The first critical decision is to define the *healthcare* purpose for the initiative, starting with a targeted objective (e.g., improve prescription processing efficiency and patient safety through e-prescribing).

**These are all healthcare initiatives that are supported by eHealth solutions, not technology projects.**

This allows the stakeholders to set realistic expectations, define success criteria and measure the value for the investment — all in healthcare-directed terms, not technical ones.

In Europe the initiatives started or were primarily driven by the Ministers of Health, with the purpose of improving access, care quality and cost efficiency. In the Netherlands, the aging population with a long life expectancy (82 years for women and 77 for men) is putting demands on the healthcare system to do more with less and to offer extramural care. Information access and sharing and provider communications were identified as critical to providing more efficient and effective healthcare. To that end, the National IT Institute for Healthcare (NICTIZ), a foundation supported by the Ministry of Health, established a national EHR infrastructure.<sup>11</sup>

Denmark's goal is to allow patients to get the best care wherever they are so data needs to follow patients, not vice versa. Currently, Denmark's ehealth program has implemented more than 50 standard messages for data exchanges related to patient referrals, diagnostic test requisitions, test results, prescriptions, hospital discharge information, homecare data and physician notes, allowing important clinical data to be accessible at the point of care.<sup>12</sup> By leading with the health reform requirements instead of the technology ones, stakeholder and end user expectations are focused first on healthcare, and then on using technology to improve efficiency and access.

Even when the overall goal is clearly in support of health reform, eHealth initiatives need to be constantly communicated in healthcare terms. When technology appears to lead the effort, there are likely to be issues with stakeholder and end user buy-in and adoption. This was the case with UK's National Health Service (NHS) program. The fact that the name of the program was the National Program for Information Technology (NPfIT) and the CIO was the responsible person at each health trust lead to a perception of an IT-centric-project, not care-centric initiative. To overcome this perception and gain buy-in, the NHS is considering a rebranding effort.<sup>13</sup>

### **Value Definition and Measurement**

**Success criteria and quantifiable benefits must be part of the overall program to solidify expectations, measure impact and direct the technical requirements.**

Broad value statements need to be converted into metrics and measured before and after the program (and technology) implementation to demonstrate the value in terms that stakeholders understand and that support the goals for health reform. Understanding the effort in healthcare-value terms also directs the implementation since the new applications can be configured to maximize these value measures.

“If there had been a focus on value from the beginning, the system would have been delivered differently.”

*UK IT Program Manager, CSC*

In Europe, comprehensive value measurement was not done. “Before” measures, if they exist at all, were often based on targeted research studies such as avoidable hospital admissions due to medication errors and errors in transferring data between GPs and specialists. Intermittent studies were done by individual medical centers or industry associations and extrapolated for the entire area, and do not deal with the full spectrum of patient, provider and government expectations. Most importantly, they did not address the two most cited reasons for implementing a technology-supported health reform program: improved provider efficiency and patient outcomes.

Benefits and progress were measured in operational terms (time to process a referral, or book an appointment) and technology installation progress and use terms (e.g., number of EHRs installed and volume of exchange messages sent).<sup>14 15</sup> This does not mean that outcome and provider efficiency improvements are not there — they had not been studied and measured. The UK is taking the next step and has started policy and strategy reviews to analyze costs and benefits but no results are ready to be released. Without pre-implementation metrics, the post measures will not be able to quantify the total impact of the IT solution and the health program changes on care delivery. The study results however, will provide valuable information on trends, adoption and care delivery improvements.

### **Determining IT Requirements**

The healthcare reform plan and value expectations direct the technology architecture and are the starting points for documenting IT requirements.

**IT requirements need to cover the broadest scope possible, from the beginning. Furthermore, a change/innovation process is key, leading to a revision cycle of the IT requirements.**



These requirement specifications will need to be detailed enough to identify functions and features and data requirements for each type of end user application, functionality, data storage/data access requirements, connectivity and IT resources and support services that are part of the overarching health exchange solution.

IT requirements need to be regularly reviewed and potentially updated when the implementation timeframe spans several years. In the UK, output-based specifications written in 2002 were still required in 2009 although the practice of care delivery had changed. Outdated requirements become a source of debate which takes time and resources to resolve. For each change, there needs to be a decision about whether it is an enhancement (out of scope of the budget) or necessary change (part of the program's scope).

Clarity of design and detail specifications is particularly critical when implementations are decentralized and managed by different vendors and software solutions. For example, in the UK, there was overall agreement about the goals, but requirements, scope of delivery and expectations were allowed to be determined at the region level. Separate negotiating teams working with at least 12 different shortlisted suppliers bidding for five contracts, led to inconsistencies and end user confusion on what they were getting. In Denmark, allowing requirements to be defined at the county level resulted in a number of failed health record projects due to lack of agreement on requirements and data sharing standards. They have since changed to a more central requirements model under Connected Digital Health in Denmark.

### **Funding and Sustainability**

Most studies in the United States have shown that the payers (and patients) are the beneficiaries of the improvements made by eHealth (e.g., fewer redundant tests, fewer re-admissions and reduced admissions due to medication errors) but the hospitals and physicians are the ones paying for the implementation and support of clinical applications. For large-scale eHealth initiatives to be sustaining there needs to be a financial balance. Specifically,

**The stakeholders who gain the value from the eHealth initiative must be willing to pay for it.**



In our experiences in Europe, funding was not an issue. The eHealth efforts were government funded, whether the countries supported a government-funded (Denmark and the UK) or private (The Netherlands) healthcare system. In Denmark, the government paid for the infrastructure and central services, and sometimes pays for upgrades to end user applications to meet new regulatory requirements.<sup>16</sup> The UK's Connecting for Health central program has budget ownership and contract management responsibilities for the national infrastructure and services and the EHR software. Trusts are responsible for their own implementation costs, end user training, hardware and local area networks, but their budgets are government funded.<sup>17</sup> The Netherlands also paid for the core national infrastructure system called the Landelijk Schakelpunt (LSP) or National Switch Point.<sup>18</sup> The Ministry of Health was the driving force behind the eHealth initiative. It coordinated and funded the implementation and supports it without charging the providers a transaction fee for use.<sup>19</sup>

Although the European experience may not provide a direct answer for the United States, these efforts all considered government funding essential for building the infrastructure, the central services, adding or replacing core clinical systems, and providing some ongoing financial support.

### ***HITECH Update***

HITECH aligns well in this topic area with best practices cited from our European experiences:

- **Setting Expectations:** The draft recommendations for Meaningful Use use the top five health outcome policy priorities for healthcare reform as the framework for setting expectations, measuring value and defining IT requirements. These policy priorities include: Improve quality, safety and reduce health disparities; Engage patients and families; Improve care coordination; Improve population and public health; and Ensure adequate privacy and security protection for personal health information.
- **Value Measurement:** The draft Meaningful Use matrix aligns health-specific measures by health reform priority as listed above. The 2011 measures are focused on data capture and patient safety and quality reporting. The 2013 and 2015 measures build on the 2011 measures, raising the bar to include adoption, efficiency and patient outcome measures. The measures are used to prove Meaningful Use to qualify for the financial incentives.
- **IT Requirements:** The matrix also identifies high-level IT application requirements, called objectives, as they relate to delivering care (e.g., active medication allergy list), rather than technology function and feature-based. The 2011 objectives focus on data capture in coded format and reporting. Future objectives to guide and support care are introduced in 2013 and to improve care and outcomes in 2015.
- **Funding and Sustainability:** HITECH will likely provide implementation grants and will offer financial incentives for systems in production that meet the meaningful use objectives. The incentive is largest in 2011 and decreases annually. By 2015 care providers without certified EHRs will pay penalties that increase over time — tying rewards with costs.

## **2. Major Issue Management**

Identifying, prioritizing and addressing “show-stopping” road blocks are critical for program momentum and success, especially those requiring regulatory changes. Special work groups and subcommittees may be needed to research, get input, present alternatives and help the program leadership and constituents come to consensus on the best option. Although these appear to be one-time decisions, we have found that decisions made by consensus have to be continually reaffirmed as leadership and the environment changes.

Two decision points that often raise questions, concerns and lengthy debates are patient privacy and security and patient identification. Depending on the circumstances (and country/region), these can be simple or very complex policy decisions with equally simple or complex technology requirements. However, even when the path seems clear, the vocal minority can stall progress if not addressed. No matter the approach taken, poor decisions related to policy, communications, adoption or technology solution requirements can delay or derail the project prior to implementation and can have significant consequences for patients, providers and the long-term viability of the initiative after implementation.



### Privacy and Security

Privacy and security involves both authorized and unauthorized access to shared data. Authorized access allows authenticated end users to view some or all of the patient's information, typically based on their role or relationship with the patient. Organizations such as the Patient Privacy Rights advocacy group and HealthDataRights.org have worked to raise public awareness about the rights already protected under HIPAA and also direct debate towards increasing patient access and control over their own health data. Their belief is that patients should have the right to decide who can see and use patient clinical data and who cannot.<sup>20 21</sup>

Based on our experiences in Europe, their authorized access policies, procedures and associated system requirements are aligned with many of the requirements cited above.

**Best practices for authorizing access to shared patient data includes role-based and legitimate relationship-based authentication. A frequently used practice for obtaining patient consent for shared data is to automatically include them and have them inform the program if they want to Opt Out or Opt In with restrictions. A full audit trail to record access and updates needs to be provided, accessible for patients.**

Table 2 summarizes the authorized access practices set up in the UK, Denmark and the Netherlands:

Table 2. Authorized Patient Data Access Summary by Country		
UK	Denmark	Netherlands
<i>Sign on Requirements</i>		
End user access to patient data requires the following: <ul style="list-style-type: none"> <li>• End user must have a smart card to sign into the system</li> <li>• Smart card identifies the role or roles for the user – if multiple, then user selects appropriate one</li> </ul>	End user access is via user sign-on and password.	End user access to patient data requires the following: <ul style="list-style-type: none"> <li>• End user must have a smart card (UZI) to sign into the system</li> <li>• Role is stored on a UZI card and can be different for different care settings</li> </ul>
<i>Access Restrictions</i>		
Access to functionality and patient data is based on: <ul style="list-style-type: none"> <li>• Role</li> <li>• Legitimate relationship</li> <li>• Legitimate episode relationship (e.g., ED visit)</li> </ul>	<ul style="list-style-type: none"> <li>• Only physicians can see all patient data</li> <li>• RNs can see only current encounter data for patients on their ward</li> <li>• Restrictions on selected diseases, for example, HIV lab tests and results are blanked out (“trusted answer”)</li> <li>• Patients can restrict access by role, facility, and type of data</li> <li>• Region laws can override national laws in certain instances</li> </ul>	<ul style="list-style-type: none"> <li>• Patients can restrict access unless it is an emergency</li> <li>• Patients can restrict by type of information (psych, HIV), exclude roles of physicians, exclude specific physicians</li> </ul>

Table 2 continues on next page

**Table 2 continued. Authorized Patient Data Access Summary by Country**

UK	Denmark	Netherlands
<b>Auditing Access</b>		
<ul style="list-style-type: none"> <li>• Full audit trail for access and updates</li> <li>• Patients are entitled to know what information is recorded about them.</li> </ul>	<ul style="list-style-type: none"> <li>• Full audit trail for access and updates</li> <li>• Patients are entitled to know what information is recorded about them</li> </ul>	<ul style="list-style-type: none"> <li>• Full audit trail for access and updates</li> <li>• Patients are entitled to know who has looked at their information and what information each person has viewed</li> </ul>
<b>Opt In/Opt Out Policy for Sharing Patient Data</b>		
UK assumes that patients want data to be viewable by other authorized providers. Patients can request to opt out or opt in with restrictions.	Patients do not own their data. They can opt in or opt in with restrictions, but few have selected the latter.	Patients determine if they want to opt in, opt in with restrictions, or opt out.

Getting input and communicating the data capture and collection, and patient consent options for shared data with sufficient time for discussion are crucial for gaining patient adoption. In the UK, the issue of informed consent was addressed by giving patients plenty of advanced notice and allowing them to opt out of the system. In this case less than 1 percent (.78 percent) of patients did.<sup>22</sup>

Conversely, in the Netherlands, informed consent was not addressed until much of the system was built and was ready for rollout. The decision was made to send everyone a letter asking for permission. Citizens were taken by surprise by the consent letter they received in the mail and consequently 300,000 people sent letters back with incomplete or inaccurate information. Every letter needed to be followed up with to get an answer, resulting in a lengthy delay in rolling out the system.<sup>23</sup>

The above procedures and system restrictions address authorized access requirements and help to minimize unauthorized access.

**Best practices to minimize unauthorized access includes two- level end user authentication, hosting the applications and data servers in a secure, 24 by 7 monitored data center, and using architectures that do not store data locally.**

For hosting data centers, facilities need to develop a well-documented security plan with clear policies and procedures that include an aggressive security awareness program and compliance monitoring.<sup>24</sup> Data on the servers should be encrypted and servers frequently need to be physically located in the country or state. In addition to monitoring user access, there needs to be a print monitoring service to track printed reports — who is requesting them and what is printed.

**Patient Identification**

Patients and their clinical data across different care settings can be linked by one of two methods. The first is a unique healthcare number that is used consistently by the patient and care provider. If that is not an option, the second method is to match patient information from different systems by comparing personal data such as name, date of birth, gender and address, and using a record locator service application (RLS) that includes a matching algorithm which assigns a probability to the match. The higher the probability, the more likely the information is for the same person. The matching algorithm software can be fine tuned based on geographic location, population mix and other user-defined criteria.

In the United States there are different schools of thought regarding the matching algorithm sophistication and the data elements involved, but most everyone agrees that patient identification will be based on standardized methodologies, but without a mandated national unique health identifier.<sup>25 26</sup>



We have been involved with both methods and consider a unique healthcare number that is actively managed by all participating systems to be preferable. Even when using a unique identification scheme there can be issues such as authorized use for healthcare and data quality:

- **UK:** A unique NHS patient number is available but not always used. Eighty (80) percent of the patient records that were converted to the new, updated applications had multiple IDs including hospital medical record numbers. Hospitals were responsible for making sure the identifier and patient data were accurate and complete prior to conversion to the new IT systems, which took time and valuable resources.<sup>27</sup>
- **Netherlands:** Every citizen had a Citizen Service Number that is used for several purposes, but not authorized as a healthcare identifier. A new bill, required in order to allow this change, took three years to pass; about two years longer than expected.
- **Denmark:** There were no issues with the identifier since it is assigned by the hospital when a baby is born and used for a variety of purposes, including his/her healthcare identifier.

**Regardless of the patient identification method used, best practice is to cleanse the patient identification data and consolidate records within a care facility or region first, institute policies to prevent duplicates before implementation, and maintain this practice so duplicates are not introduced.**

#### ***HITECH Update***

HITECH is closing some of the HIPAA gaps not imagined possible more than a decade ago and includes stiffer penalties and potential criminal charges against healthcare individuals for breaches. Instead of forming a separate privacy and security committee, ONC has determined that the HIT Policy Committee Workgroups (HIE, Certification and Meaningful Use) will be responsible for addressing privacy and security as it relates to their area.<sup>28</sup> For the HIE workgroup, efforts to determine patient identification, authorized access and patient consent requirements for data sharing have not started.



### **3. Governance and Communications**

There is a strong interdependency between decisions made regarding governance and communication. Governing bodies need to involve key stakeholders and solicit input from end users, and communicate constantly on progress. Setting up a strong governance structure is crucial for planning but needs to stay strong and involved throughout the implementation.

#### ***Governance***

**Governing bodies need to include all major stakeholders and should be centralized whenever possible to speed decision making and progress, especially during the planning and requirements phases.**

The group also maintains control over scope, budget and timelines. A formal process and a central sub-group needs to be established and charged with the responsibility of addressing issues and unexpected changes to determine their impact to the initiative's technology, implementation roadmap and use in care delivery, and whether it is in or out of scope. Without a process and resources in place, unplanned changes create tension among the stakeholders, are a source of debate and ultimately stall progress.

Governance can be decentralized, and/or multi-tiered, depending on the size and scope of the initiative. If so, issue management and decisions should be discussed at the highest appropriate level (e.g., national, state, county, region) and communicated to interested parties and end users to be clear about decision-making authority and process at each level. In Denmark, patient data

access decisions made at the region level can override the national requirements only in selected areas. For instance, in one region, the nurse can see all patient encounters, as opposed to the national standard of viewing only the inpatient encounter. In the UK, data sharing agreements among facilities are made at the Trust level. The individual care entities agree on what data are appropriate to be shared for specific types of medical problems. Specifically, a cancer patient may receive care at an outpatient clinic, hospital, specialty cancer center and hospice. All facilities must agree on the data each will share and then document and approve the agreement before implementation starts.

The problem with decentralized governance occurs when decision making is by consensus only and there are many constituents. In 2006 when the UK's Connecting for Health devolved from region to local providers (to 300 individual trusts), all participants felt they could say "no," which significantly slowed progress of both EHR and inpatient system implementations.

### **Communications**

**A comprehensive communication strategy should be part of the program's overall plan and the responsibility of the governing body to execute the strategy. Each stakeholder and the end users need to receive communication using methods that meet their needs.**

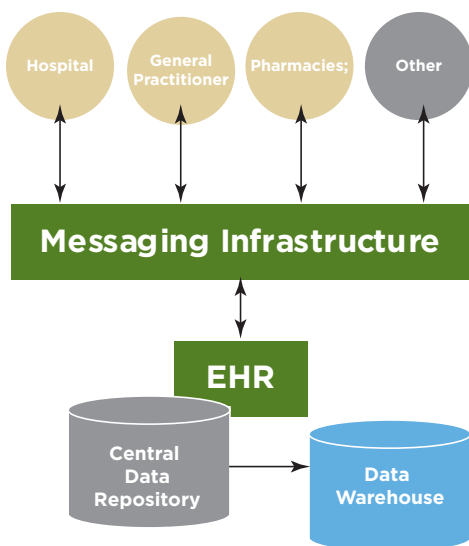
The information should be balanced including good news, such as implementation successes and setbacks, such as budget issues and delays. Communications needs to be two ways which will be a balancing act. Appropriate consultation is needed to gain buy-in, but too much discussion can stall progress. However, spending the time in the planning stages is particularly important to gain buy-in in order to eliminate the fear and criticism that the technology is being forced onto the end users without their consent and understanding.

The UK's Connecting for Health set up its communication channels through a number of structured boards (e.g., architecture, governance, infrastructure and development planning). The boards have regularly scheduled meetings that include vendor representatives, who in turn disseminate information to the regions. Unfortunately this strategy does not include direct communication with patients and physicians who are critical of the process and feel unprepared for the upcoming technology and process changes. To close this communication gap at the local level we found that setting up user groups to involve them in the EHR design, testing, education, local configuration and workflow integration helps for a smooth implementation and improves adoption.

#### ***HITECH Update:***

Governance and communications for HITECH at this early stage meets or exceeds suggested best practices.

- **Governance:** The HIT Standards and HIT Policy Committees have formed workgroups to focus on major topics such as Meaningful Use, certification and implementation specifications, and HIE. The HIE workgroup will make recommendations on policies, governance, sustainability, architecture, and implementation approaches.
- **Communications:** ONC communications strategy has set the bar for best practice. The process for setting requirements and making decisions is completely open. All meetings are open to the public and are available via audio conferencing with all handouts and meeting transcripts posted on their Website. The committees and workgroups present information for review and comment, providing additional time and opportunities to get public input before it is posted in the Federal Register. Anyone can post questions on the ONC website and responses are emailed and/or phoned back in a very timely manner.



## 4. Technology and Interoperability

Determining what functionality and data will be shared and/or centralized (from the planning stage) is important to the overall technical architecture and drives the requirements for application certification, data and network interoperability standards. In addition, the technology design must be able to support all policy, government reporting, privacy and security requirements.

### Technical Architecture

In very simplified terms, the technology architecture is based on what data will be stored centrally, what applications and technical services will be centrally provided, the level of interoperability of the end user systems and how all the applications connect (e.g., the infrastructure network and services). Major components of the architecture, therefore, include data messaging services, locator application, secure network infrastructure (private or Internet-based), connectivity services to the end user applications, and potentially a central patient data repository containing summary or encounter data, a patient portal with view and/or update capabilities, and a de-identified data warehouse for public health and research purposes.

**There is no one best practice for the technology architecture because of the differences in the healthcare systems and country administrations.**

However, in large and federal countries, slim infrastructures and public health applications tend to be on the federal level, whereas the majority of the value-adding applications tend to be setup in regions/states or even by stakeholders, where the care process happens. Factors that will impact the final design of the architecture include regulatory requirements, policy decisions, data ownership and sharing requirements, the population's culture, and most importantly, supporting the needs of the health reform program.

### Standards and Certification

**Data and infrastructure standards and application certification, along with central managing organizations are unconditional requirements for success for large-scale initiative interoperability.**

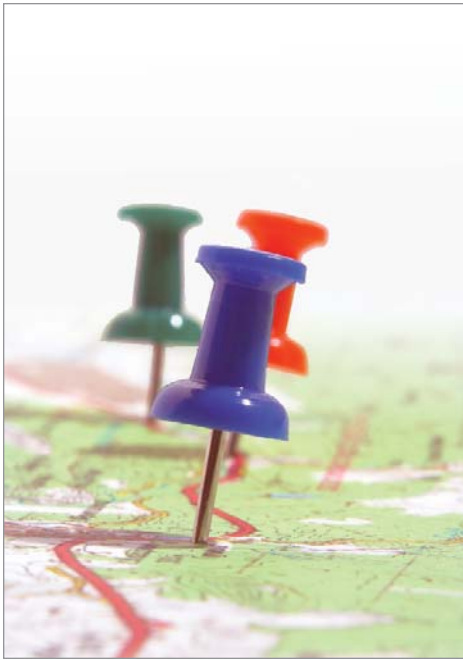
The Netherlands has established a certification system for EHRs and connection-service providers. Certification is based on three types of requirements: functional (how to register and exchange information), implementation (how to connect and secure the system) and utilization (procedural measures to keep information accurate, timely and secure). They use HL7 Version 3.0 message specifications for data sharing between the health information systems and the National Switch Point.

MedCom, a national public project organization in Denmark dictates the standards for the National Data Network. Interoperability standards include an open EDI-mail to ensure compatibility with existing VANS-based communications and IP-based networks. EDI communication (XML, EDIFACT, HTML, HL7 and DICOM) is in wide use. Application certification is also a requirement. There are 15 GP systems and a similar number for hospital systems.

Standards need to be defined to the version level too. The UK has similar standards for certification, data coding, messaging and interoperability but had problems with sharing data when different versions of their READ coding scheme were allowed. Version 3 has much more specificity than Version 2. So Version 3 can be mapped to Version 2 but not vice versa. This was a problem when patients changed GPs and their data (coded in Version 2) could not be exported to the new GP's system if it was using Version 3.<sup>29</sup>

### HITECH Update

With policy committee efforts just underway, there are no updates on architecture. The HIT Standards Committee has been staffed and discussions are underway as to the process that would be required to set appropriate standards based on the draft definition of meaningful use.



## 5. Implementation

Implementations take years, involving many resources, and are never problem-free. Implementation planning starts in the early phases of program development and is ongoing to adjust for necessary changes and unexpected delays.

### **Planning:**

**Pioneering organizations recommend planning with a strong link to health policy and the health reform plan. Efforts should follow an incremental approach based on building a solid foundation and growing the solution by starting with the highest priority needs of the health reform program.**

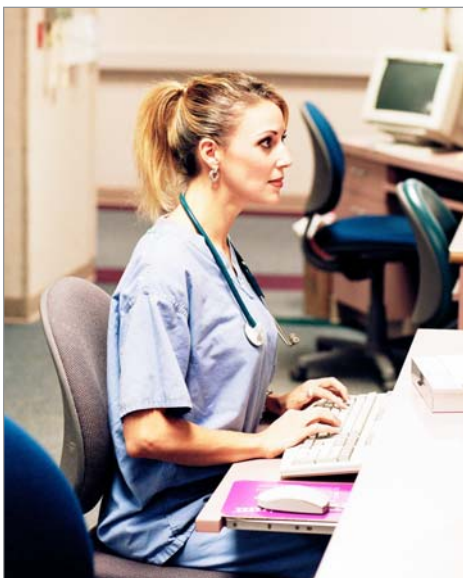
Although IT requirements development starts with the highest level centralized applications and services in mind, building the solution starts from the foundation up. Core systems at the end user facilities and the connecting infrastructure and services must be in place before centralized applications can be put into production. Since Denmark's GPs and hospitals already had applications in place, initial efforts were in building the network infrastructure and developing the messaging services and the central databases. The Netherlands had a similar technology starting point since most of the GPs have been using computers for more than 20 years, focusing their efforts on building the national network and the national switch record locator application. With the issue regarding the use of the citizen number for healthcare purposes resolved, connecting the GP systems to the central infrastructure is underway. NHS emphasis had been on implementing the Spine (infrastructure) and installing/upgrading GP systems to meet national requirements and adhere to regionally approved systems. Now the focus is on inpatient systems implementation and populating the summary care record.

All implementations have problems and changes, but few have time and resources built into the plan for analysis and resolution. Improvements in technology, changes in care practice, missing requirements and policy changes are examples of unexpected issues that need to be explored and addressed. For example, in the UK, a new wait time goal for "referral to service less than 18 weeks" was decided upon by the NHS during the implementation rollout but there was nothing in the plan to make the system and reporting changes. Since the contracts required the vendors to meet all regulatory requirements, these changes had to be completed within the original budget and timeline.

### **Implementation Rollout and Support**

Pilot first then roll out incrementally is the mantra for large-scale eHealth implementations — for several reasons. The technology, especially the infrastructure and central applications, is new. There will be system errors and missing functionality so starting small with a core group of sites willing to invest the time and resources to work through the bugs will prevent major problems as the systems are rolled out. In the Netherlands, the team started with a technical pilot to make sure all of the new technology worked properly before starting the end user pilots. Rollout is underway with more than 1500 sites connected to the national network.<sup>30</sup>

Another important consideration is the impact the technology will have on the end user processes. In physician practices, piloting helps to fine-tune the new or updated application and allows the implementation support team to tailor the training program to match workflow processes. For hospital system installs that involve large number of people and different IT applications, taking an incremental approach is even more important because software and performance problems can result in loss in revenue and lengthy delays. The NHS' Early Adopter program for hospital installs took the pilot and rollout approach to the next level. In this program, the team worked closely with a small number customers (including each type of hospital — e.g., rural, urban, academic medical center) to adapt the system so it would fit for the remaining ones. The install in each early adopter hospital followed a rollout approach: a small number of users was added department by department to make sure performance and interface issues were addressed. The result was applications configured to meet specific hospital needs that met integration and performance requirements.<sup>31</sup>



Support for the implemented applications, infrastructure and HIE services must be immediate and easy for end users, with limited downtime.

**Best practices for support include a central Help Desk to triage all calls, controlled downtime and local expertise to address questions and problems.**

Healthcare is a 24 hour a day, 7 day a week operation so systems must have high availability and performance. When upgrades and application fixes are implemented that require downtime they must be done during non-peak hours (e.g., 2:00 am on weekends) to minimize disruptions. End user questions and problems need immediate attention. In the UK, we found that super-users at each practice and in the hospitals can address 80 to 90 percent of questions and problems. When external assistance is needed, users call one number and the Help Desk analyst triages the problem and is the one responsible for contacting the right service group, either locally or nationally.

### ***HITECH Update***

In its early stages, HITECH has outlined its approach to provide planning and implementation assistance through a Health Information Technology Extension Program consisting of:

- HIT Research Center to collect best practices and provide assistance with EHR and HIE
- Non-profit HIT Regional Extension Centers to provide technical assistance with EHR /HIE efforts.<sup>32</sup>

### **Summary**

The European EHR/HIE initiatives described in this paper are successful, complex projects that are showing positive results. Although the U.S. HITECH effort has just started, the work completed for planning, governance and communications are meeting best practices. However, the hard work is still to come. Tough decisions regarding standards, patient consent, architecture and patient identification need to be made. Once these decisions are set, enormous coordinated resources will be required to install/upgrade thousands of EHRs and connect them to regional, state and eventually the national information network. Fortunately the work in Europe and other national efforts continue to grow, expanding both functionality and connectivity reach to provide additional guidance and shared experiences for the United States to use as it continues its EHR/HIE journey.

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WA09\_0140

July 2009