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NHIN Requirements: A Vendor Perspective

Testimony of

Charlene Underwood

To the

National Committee on Vital and Health Statistics Subcommittee on Standards and Security

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Mr. Chairman and fellow committee members, my name is Charlene Underwood. I work for Siemens Medical Solutions Health Services where my responsibilities include Government and Industry Affairs initiatives that influence and impact the products that we provide to our customers. Our customers include public health systems, integrated health networks, community hospitals, physician practices, imaging centers, and independent physician associations. I also chair the HIMSS Electronic Health Record Vendor Association. I thank you for this opportunity to share with you the views of Siemens on the important topic of "National Health Information Network requirements."

Siemens Medical Solutions of Siemens AG with headquarters in Malvern, Pennsylvania and Erlangen, Germany, is one of the largest suppliers to the healthcare industry in the world. The company is known for bringing together innovative medical technologies, healthcare information systems, management consulting, and support services, to help customers achieve tangible, sustainable, clinical and financial outcomes. Siemens Medical employs approximately 31,000 people worldwide and operates in more than 120 countries. Within the United States, Siemens Medical employs approximately 13,000 people and provides medical imaging technologies, healthcare information systems, management consulting, and support services to nearly 12,000 healthcare providers.

About Siemens and NHIN Requirements:

To highlight the edge and core requirements for the NHIN, I will provide a summary of Siemens enterprise HIT solutions which, by example, parallel the NHIN requirements. As the NHIN goal is to foster widely available services that facilitate the accurate, appropriate, timely, and secure exchange of health information, there are many similarities to enterprise HIT solutions and requirements which provide the opportunity to leverage lessons learned. NHIN efforts should focus and experiment on the areas with theoretical benefit but limited experience, and collaborate with the HIT industry for areas where there is clear overlap and experience.

For purpose of this discussion, I have organized the testimony into these processes necessary to achieve NHIN goals:

- Enabling workflow integration and interoperability.
- Managing diversity.
- Managing central operations.

These represent the broad areas of experience that might be relevant to informing / forming the NHIN.

Healthcare Enterprise Architecture and Relationship to NHIN

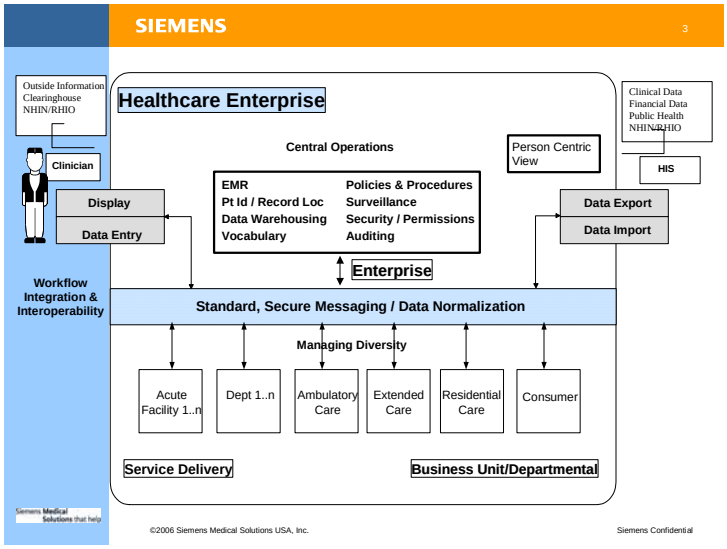
What are the key differences of the NHIN?

- Patient permission management
- Broader stakeholders
- Population scale
- Need for EMR proxy data/servers
- Keep audit of external data displayed/used

What are the key similarities?

- Patient identification and demographics management
- Integrating longitudinal patient health data
- High speed secure reliable access by authorized users
- High volume transaction handling
- Dependence on and integration among multiple HIT solutions
- Integrating data exchange consistently and accurately into end user workflow
- Data management capabilities to handle variations in data content and quality and support aggregate reporting and analysis

The diagrams that follow depict the function and services provided to support health enterprises, regional health information networks, and the national health information network. There are many functional components in common among the various levels. Within each diagram, you will see the three processes identified above. The text that follows corresponds to the functional area on the diagrams.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Outside Information Clearinghouse NHIN/RHIO
Clinician
Display
Data Entry
Workflow Integration & Interoperability
Healthcare Enterprise
Central Operations
EMR
Pt Id / Record Loc
Data Warehousing
Vocabulary
Policies & Procedures
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Person Centric View
Enterprise
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Financial Data
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NHIN/RHIO
HIS
Data Export
Data Import
Standard, Secure Messaging / Data Normalization
Managing Diversity
Acute Facility 1..n
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Ambulatory Care
Extended Care
Residential Care
Consumer
Service Delivery
Business Unit/Departmental
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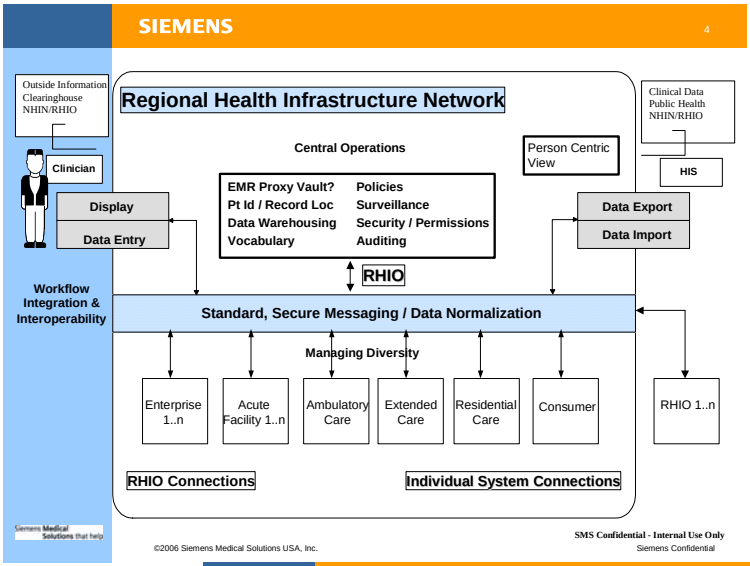
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Central Operations
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Extended Care
Residential Care
Consumer
RHIO 1..n
RHIO Connections
Individual System Connections
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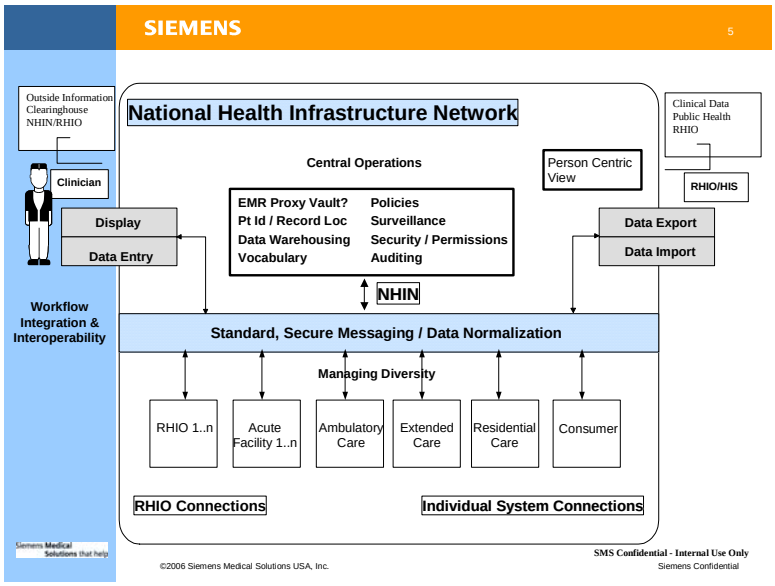
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Managing Workflow and Interoperability

We believe that improving workflows, that bring fullest benefit of standards to our customers by providing improved efficiency and effectiveness, is good for healthcare in general and helps advance our products.

Workflow Integration

A fundamental requirement to achieving end user acceptance and satisfaction with IT enabled processes that depend on data sharing capabilities is the need to integrate data sharing and exchange optimally in the end users' workflow.

Challenges:

- The Business Case - having sufficient stakeholders to connect with to make intrusion in workflow justified.
- Achieving consistency among and across applications to the many touch points where data exchange is necessary to achieve optimum end user workflow.
- Investment necessary in legacy applications to introduce a user-centric workflow on top of applications that are not flexible to fit into a workflow framework.
- Clear expression and understanding of the requirements of various edge systems to enable successful integration of essential data and processes into end user workflows at each edge of the NHIN.

Requirements:

- Ability at the UI level for a single user to switch between the different systems at the UI level…e.g., integrate a Web UI of a NHIN function into the flow of a HIT UI.
- Ability for single signon and access to diverse functions in distributed systems
- General use of ubiquitous Web access.
- Different classes of services so that HIT solutions can to be enabled to expose relevant services for remote access in a distributed, federated environment.
- Standardization of the edge system requirements definition and timeframe is needed to support desired implementation.

Lessons Learned:

- Adopting protocols that enable single signon and shared patient context among multiple applications to create an integrated workflow at the user interface level (which is a complementary approach to asynchronous messaging and **Service Oriented Architecture** <SOA> approaches). This protocol has now evolved to support the **Clinical Context Object Workgroup (**CCOW) standard to share context beyond Siemens applications.
- The concept of a portal that provides personalized role-based access and single sign-on (SSO) to applications and content from multiple vendors across multiple organizations (hospitals, physicians offices, community and RHIO resources) is a key element to make NHIN as well as local resources seamlessly available to users. Nearly everyone appreciates SSO, and a few pioneering organizations are using portals to extend beyond their own enterprises
- HL7 CCOW provides a useful way to synchronize multiple disparate applications and saves clinicians' time in selecting patients. This works well in enterprises that have a preponderance of CCOW-compliant applications along with a CCOW

engine. However, CCOW uptake has been slow and implementation is complex, so few hospitals have advanced CCOW implementations.
- Newer products are adopting approaches using workflow management tools and SOA (with different classes of services, including external Simple Object Access Protocol <SOAP>-based service access) to enable cross application interoperability.

Evidence:
- Siemens and other vendors have CCOW-enabled products that enable them to share user and patient contexts with CCOW-compliant applications from any vendor, thus saving clinicians' time when using disparate systems.
- Siemens and other vendors have live implementations using all levels of interoperability to suit the user's preference, from being relatively non-intrusive (portal), to standards-aware user interfaces (CCOW), to standards-based messaging and document sharing (products supporting HL7 and IHE) to new service-oriented and workflow approaches.
- Service-oriented interfaces to foundation systems were provided long before standards-based approaches such as Web Services / SOAP were established. Newer systems are leveraging these standards-based approaches by providing web services to support use cases that span vendor systems.

Standards and Interoperability

Our commitment to openness and standards is based on the premise that we believe standards improve our products' quality and usefulness to our customers and help to assure that we are meeting interoperability requirements that are increasingly important to our industry today.

Challenges:
- Standards being used to share data are inconsistently deployed.
- Customers configure systems to meet their unique requirements, which complicates interoperability and makes standardization more difficult.
- Variations in quantity and granularity of data being captured at provider sites.
- A problem with HIPAA transactions and semantic interoperability is whether transactions are understood between trading partners, but if data were viewed across various trading partners, there would not be a consistent use of code sets or code values for the same information.

Requirements:
- Ability to exchange large quantities of data between diverse stakeholders, mapping, tracking, transforming, linking, and messaging.
- Ability to use data today and support migration incrementally to increasingly more standard data sharing.

Lessons Learned:
- Sophisticated interface engines are available to enable mapping and transformation.
- Vocabulary management tools are emerging that define links from inbound to internal codes, and conversely. However, the codes sets and values are not standardized.

- Applications process and store data as is, even without common semantic translation capability. In such cases, the data are available for users as free text which is no different from the paper chart, but difficult to assess for aggregate analysis.
- Networks and technologies have evolved making connectivity easier between systems and devices. However, while the Internet has made things easier, there are trade offs with security and privacy – raising concerns about hijacking capabilities and privacy.
- There's been little incentive to deploy interoperability products to measure the event activity (e.g., how many claims, emergency room visits), as the monitoring data are not important enough pieces of information to hospitals or health providers individually. Therefore, since the cost of such features is not perceived as sufficiently beneficial to product purchasers, they are not included. This type of information is very important to health departments and the industry operation but these areas do not directly enough fund product purchases.
- Working with industry consortia promotes higher levels of interoperability upon implementations, through integration profiles/interoperability specifications, combining end-to-end interoperability that considers messaging formats, vocabularies, and infrastructure.
- There is a much larger issue than mere HIPAA conformance, with its focus on financial data. The exchange of accurate and complete clinical documentation in support of patient care is essential to care quality and patient safety, as well as for care providers who may be accused of malpractice when clinical documentation is incorrect or missing.

Evidence:

- Siemens has invested large amounts of effort providing leadership and collaborating with the industry to advance standards and interoperability: notably through HL7 ANSI X12, and HIMSS IHE, EHRVA, and ONC initiatives such as CCHIT and HITSP.
- Hundreds of customers have clinical repositories, which provide seamless access to an integrated view of patient's health data in an enterprise healthcare environment, where the transfer of information has occurred among various systems from a variety of vendors found in a hospital setting and larger Integrated Delivery Networks (IDNs). Such data transfer is frequently based on standards for interoperability.
- HDX processes more than 12 million eligibility transactions per month that are fully integrated with the customers patient admission, registration, and scheduling systems today. These are processed asynchronously in real-time.

Installability / Implementability

Time, resources, cost and customer value derived from implementing an improved process.

Challenge:

- Sustainable business model depends on connections to more stakeholders so that value is justified to each participating party and to end users whose workflow may need to be impacted to support information exchange.

- Conflicting and/or proprietary data exchange standards require that each data exchange must be hand crafted, which ads incredible cost for providers to integrate within and beyond their enterprise.

Requirements:

- Connections to existing systems must be non-intrusive and evolutionary – can't require large unfunded efforts to change existing systems to connect.
- Existing, standard interface transactions and/or documents must be leveraged (e.g., HL7, IHE), and new ones such as for a Record Locator Service (RLS) must be standard and clearly documented.
- Health Information Network must be radically interoperable and scale smoothly from small to large providers and other stakeholders.

Evidence:

- Our install base is evidence that interoperability works across disparate facilities. The funding model allowing them to advance as such is that they have an owned, purchasing model. That is the biggest gap in funding the regional initiatives presently. Our install base illustrates that it is not a technical problem.
- Siemens has over 50,000 interfaces to over 150 different vendor/products running in 20 countries. Included in that number are over 5,000 interfaces running in our state of the art Information Systems Center in our role as an Application Service Provider.
- The HDX model is currently interchanging EDI messages in real-time among more than 800 large institutional provider, over 200 health plans nationally, numerous banks, and other healthcare entities.

Managing Diversity

The health enterprise is a complex and diverse environment, illustrating many of the characteristics of a larger national network. There are multiple HIT solutions, multiple levels of care, multiple terminologies, multiple data models, multiple UIs, multiple policies and procedures, multiple organizational structures, etc. At the enterprise functional level (e.g., scheduling, EHR, disease management), these applications need to be harmonized/synthesized. Therefore, managing diversity means that there is a myriad of options from which to choose, each with individual constraints that limit applicability to all situations. This clearly ties to a lack of standardization and harmonization of existing standards.

It is also important not to confuse "diversity" with "disparity" in clinical care provision and availability, both of which are also very real and largely driven by economics of regions, individuals, or populations. The present health care funding model puts the buying onus on hospital businesses with little subsidy for technology. Therefore, smaller facilities and inner-city facilities may have more difficulty affording solutions impacting both diversity and disparity.

Matching Patients

Identifying the right person is critical in any and all health exchanges. It is the cornerstone function on which all else relies on. Selecting the wrong person could be catastrophic.

Challenges:

- Patients who would not necessarily know or carry a number, even if there was one.
- Multiple patients using common identifiers, such as having the same name, address, and DOB.
- Identity theft and as a result, social security numbers are hard to obtain.
- Patient matching is largely done by health plans using Member Last Name, First Name, DoB, and Member ID assigned by the Health Plan. This has become very controversial recently when X12 tried to allow more search options, but the payer community (especially Medicare) was not very open to change. SSN's are not encouraged, but some health plans will use them to find a member in place of their Member ID when the patient doesn't have their Health Care Card.
- Variations of state and HIPAA laws on privacy and security, all which make accurately identifying patients complex.

Lessons Learned:

- Ambiguities necessitate the need for probabilistic matching capabilities.
- Enterprises use single internal identifier for people in the enterprise, which links to multiple external identifiers.
- People make mistakes during data entry requiring extensive clean up and merge and unmerge capabilities.

Evidence:

- Siemens EMPI supports 147 Enterprises containing 106M people representing 37% of US population
- Extensive services and technology support patient identification processes, such as Duplicate Enrollee Workstation, EMPI Optimization Services, Biometrics/Finger Print Technology, Smart Cards, and Sophisticated Matching Algorithms.
- Siemens HDX Service processes over 12 Million real-time eligibility transactions per month; of these 99.9% are successful inquiries.
- Using a simple approach -- IHE's PIX profile -- for an interoperable patient indexing service enables a single-enterprise EHR registry/repository to become RHIO-wide.

Data Quality

Challenges:

- Data being shared is inconsistent.
- Users cannot determine if data are missing or if the data element (e.g., service, result, diagnosis) simply doesn't exist.
- Source systems have different levels of quality checking.
- Mapping accuracy is variable.

Lessons Learned:

- Standardization is required within local enterprise EHRs.
- Transactional standards for exchange of information have proven successful for assuring complete and accurate information when there are required implementation guidelines that can be checked for conformance.

Evidence:

- Siemens Electronic Health Record solutions handle diverse data types and offer extensive uploading and backloading capabilities and services to help customers capture and standardize data.
- HIPAA transactional standards are generally of high quality, and transactions that don't comply with required elements are not processed or are processed when risk of subsequent problems is minimal.
- HDX processes millions of transactions each month that have a first pass acceptance rate of greater than 98% successful.

Reporting, analysis, mining

Ability to collect, store, transform, enhance, report, analyze and mine the data from the operational systems.

Challenges:

- Data warehousing solutions may offer the best intelligence for the industry, however these systems are not atop the buying priorities in a financially challenged industry.
- Data quality issues above make learning from the data difficult if not impossible
- Full de-identification is important to avoid accidental identification.

Lessons Learned:

- Capturing data to support performance management needs to come as a byproduct of system usage.
- Data Warehouses, with data curation and normalization processes, are necessary to support data mart building and management for cohorts.
- Customers value the ability to capture measures concurrently so that performance data are more readily available and can be acted on sooner.
- Supporting research necessitates tools to perform data extraction and de-identifying patient data, with appropriate permission.
- Complexity of security and privacy cannot be underestimated (global variances must be considered as well).

Evidence:

- Many Siemens customers use Data Warehouses to support performance and quality management improvement processes.
- Customers are buying newer products that embed the capture of process and outcomes measures intrinsically within the workflow.

Managing Operations

Operations are ongoing costs of the business. Poorly executed operations in healthcare have the following ramifications: patient safety, viability of organization's finances, regulatory compliance, system unavailability, and customer satisfaction.

Security

Siemens is committed to enabling secure access by end users and exchange with external interfaces and interoperability between health care operational entities exchanging health information among providers, health plans, pharmacy benefit managers, clearinghouses, and others. A key component of HIPAA interoperability is to insure that the data content

within the standards used to exchange health information is accurate, ***consistent with industry needs***, and ***is used*** by all entities with whom the data is shared.

Challenges:

- Inconsistency in security and privacy laws & regulations among Federal, state, and local jurisdictions.
- Lack of currency with industry and support for changing industry needs, such as the emergence of significant identity fraud threats, while there is a real lack of implemented standards for identity management, e.g., digital identities and signatures.

Lessons Learned:

- Improving workflows, that bring fullest benefit of standards to our customers by providing improved efficiency and effectiveness, is good for healthcare and helps advance our products.
- **For EDI, implementing transaction standards that have value to the customers** requires **that all industry stakeholders** (providers, health plans, and clearinghouses) support and use the standards; otherwise the benefits are never fully realized. Regulations help to ensure that everyone is participating.
- Regular standards updates must also be supported to ensure industry needs are continually being met on a timely basis, which will also eliminate extensive cumulative changes.

Evidence:

- Siemens has addressed the key elements of core NHIN Privacy and Security – authentication, transport security, access controls, audit trials, transport security with the exception of record locators and credentialing.
- Business Agreements: HDX has both Trading Partner and Business Associate Agreements. Trading Partner agreements define our scope of work to be provided and any business obligations of each party. Business Associate agreements define our security and privacy obligations.
- HDX has had 2 successful EHNAC (Electronic Healthcare Network Accreditation Commission) accreditation audits, which review and assure security and privacy measures are being meet as required by HIPAA.
- These key elements are provided as follows:
  - Authentication Services depend on how information is being exchanged
  - Transport security is achieved either with Private ATT Frame/Relay circuits or over the Internet by Secure HTTP (HTTPS) with 128-bit encryption.
  - Access controls are achieved by allowing only authorized entities access to systems or services based on User ID or Entity ID.
  - We also require that all applications initiated by the customer (provider, payer, lab, etc) have authorization policies and procedures, authentication procedures, and access controls locally; that would also require at a minimum within their facility User Id, Passwords, and some sort of role based access controls associated with the User Id. We also recommend audit logs.
  - Audit Trails: All access and transactions are logged and analyzed. HDX logs all transactions that are received, transformed, and sent. These logs are maintained as legally or contractually required.

- Translation Services: The HDX "Customer Gateways" provide translation services between edge system users, and data normalization is done at each entry point gateway as information is received from each entity. Customer data is sent to us in HL7 or proprietary formats, these are translated/mapped into the normalized formats and content used within the HDX products or services. All processing is performed with data in this normalized form. If information is resident on another "edge system" then the normalized data must pass through the edge system's gateway to be transformed into the format and content required by that system to achieve the desired functions. Queries are normally mapped to an exposed API defined at the Gateway.
- Translation Services: Quality assurances are performed during the translation services, if the content is not complete for the required data, the transaction is not processed and errors are reported back to the submitter in real-time or batch based on how it is submitted.

Availability

Percentage of time in a calendar month that an application or system is available to end users regardless of type or origin of downtime.

Challenges:

- In a distributed, federated environment, dependent on the source systems for availability and access; end users won't wait for the response; needs to be asynchronous.
- NHIN itself must be always on and available.

Lessons Learned:

- Network latency, general responsiveness of the source systems.
- Information Services Center (ISC) – how to run big, complex data center and private WAN, and VAN.
- Edge proxies for patient data to avoid direct external access to operational files of enterprise.
- Redundancy everywhere.
- Systems management capabilities (proactive event management, resource and performance management, network management, remote control, etc.).

Evidence:

- ISC operations / 99.9% uptime.
- Edge proxies similar to creating operational reporting extracts of production systems.

Reliability

Frequency with which end users encounter unreliable or unstable results from using the application (these could include server failures, application errors or failures, etc.).

Challenge:

- In a distributed, federated environment, dependent on the source systems for availability and access; end users need to be able to count on having reliable access to data sources.
- NHIN itself must be always on and available.

Lessons Learned:

- ISC – backup and recovery, disaster planning.
- Redundancy everywhere.
- Separation of customer data within single processing complex (similar to "vault" concept for centralized data), but with data pooling capabilities that allow extractions for warehousing and reporting (HIPAA compliant).

Evidence:

- Information Service Center offers:
  - 24 x 7
  - 150M transactions per day
  - 120 terabytes online
  - 866 terabytes offline
  - 1,800 servers
  - 2,200 customer sites
  - 500K user devices
  - Multiple technologies
  - Handles non-Siemens HIT solutions

Upgradeability

Ability to quickly and **without error**, install a software update/patch, release, or version for an application or system with software and/or hardware.

Challenges:

- Upgrading customers to new versions without loss of capability or data.
- Coordinating upgrades of separate applications so that the integrity of data flow is maintained and expected outcomes are achieved.

Lessons Learned:

- Software management capabilities (distribution and control).
- Test/prod environments.

Evidence:

- Central management of distributed customers.

Scalability

Ability for an application or system and its underlying technology to span the needs of a small to a very large enterprise cost effectively, and to allow cost effective growth of an enterprise.

Challenges:

- Variation in levels of IT support and expertise in small to large organizations.
- Ability to incrementally add capacity as IT infrastructure expands.

Lessons Learned:

- Remote Computing Option

Evidence:

- ISC stats above

Supportability

Ability to identify and implement fixes for the root cause of customer encountered problems.

Challenges:

- NHIN itself must be always on and available.
- Rapid response to network problems.
- Difficulty in diagnosing problem ownership in federated network.

Lessons Learned:

- Support service infrastructure – this is actually something that is probably important and that may have been overlooked.

Evidence:

- Customer Service Center (CSC) 24x7 operations and infrastructure to support it.

Summary

- Leverage Healthcare IT vendors' extensive experience in working to solve problems that the NHIN must address – this is not a green field. Practical solutions to complex problems have been developed in many cases, but also many have not. A practical NHIN solution is necessary, and the experience of the HIT community can be leveraged to achieve it. Leverage this experience, so the difficult aspects of a national healthcare information network can be addressed early on. Theories abound, but need to synthesize real experience for an optimal approach. Maximize reuse; use open, proven, and scalable pieces.
- Establish the business case for the stakeholders such that adoption will occur. Understand the total solution before building the pieces. Provide an overall, coordinated design, to enable autonomous development of pieces. Identify the real requirements and effectively prioritize them to establish a clear logical build sequence to the end goal.
- Keep it simple to start…try for small successes, be non-disruptive, build in evolutionary way. Large experiments and implementations may be more visible and easier to sell, but are too complex and take too long to finish, making it hard to demonstrate any early successes and maintain sustained interest. Implement small focused pieces that satisfy clear requirements and that create important pieces of infrastructure, but build in the context of the total solution. Build a solid foundation first, and then add the functional pieces. Use existing networks, interfaces, and standards.
- Create a business model that encourages private industry to invest in NHIN enablement. There must be business rationale for HIT vendors to divert resources from other projects critical to marketplace and competitive needs, business top and bottom lines. NHIN itself must become a clear market driver and revenue producer. The pressures for product development with limited resources will make it difficult to get the attention of R&D efforts. Also, intellectual property of HIT solution providers must be protected. There can be diversity on the edges, as long as there is homogeneity at the center.

Again, I thank you for the opportunity to present Siemens' comments today.

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