

Presentation 1

Slide 1: HIT Policy Committee

Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions

William W. Stead, M.D.
Vanderbilt University Medical Center

July 14, 2009

Slide 2: Central Conclusions of NRC Report

- Current efforts aimed at nationwide deployment of HIT will not be sufficient to achieve the vision of 21st century health care, and may even set back the cause...
- Success will require greater emphasis on providing cognitive support (assistance for thinking about and solving problems).
- In the near term, embrace measurable health care quality improvement as the driving rationale for HIT adoption efforts.

Slide 3: Committee Membership

- William W. Stead, Chair, Vanderbilt University
- G. Octo Barnett, Massachusetts General Hospital
- Susan B. Davidson, University of Pennsylvania
- Eric Dishman, Intel Corporation
- Deborah L. Estrin, University of California, Los Angeles
- Alon Halevy, Google, Inc.
- Donald A. Norman, Northwestern University
- Ida Sim, University of California, San Francisco
- Alfred Spector, Google, Inc.
- Peter Szolovits, Massachusetts Institute of Technology
- Andries Van Dam, Brown University
- Gio Wiederhold, Stanford University

Slide 4: Information-Intensive Aspects of the IOM's Vision for 21st Century Health Care

- Comprehensive data on patients' conditions, treatments & outcomes
- Cognitive support for health care professionals & patients to help integrate
 - patient-specific data
 - evidence-based practice guidelines & research results
- Tools to manage a portfolio of patients & to highlight problems as they arise
- Rapid integration of new instrumentation, biological knowledge, treatment modalities, and so on into a "learning" health care system
- Accommodation of growing heterogeneity of locales for provision of care

- Empowerment of patients and their families in effective management of health care decisions and their implementation

Slide 5: Site Visits

- University of Pittsburgh Medical Center, Pittsburgh, PA
- Veterans Administration, Washington, DC
- HCA TriStar, Nashville, TN
- Vanderbilt University Medical Center, Nashville, TN
- Partners Healthcare, Boston, MA
- Intermountain Health Care, Salt Lake City, UT
- University of California San Francisco, San Francisco, CA
- Palo Alto Medical Foundation, Palo Alto, CA

Slide 6: Site Visit Observations

- Patient records are fragmented.
- Clinical user interfaces mimic paper without human factors & safety design.
- Biomedical devices are poorly integrated.
- Systems are used often to document what has been done, after the fact, for regulatory and legal uses.
- Support for evidence-based medicine and computer-based advice is rare.
- Clinical research activities are not well integrated into clinical care.
- Legacy systems are predominant.
- Centralization is the predominant method of standardization.
- Implementations timelines are long and course changes are expensive.
- Response times are variable and long down times occur.

Slide 7: Principles for Evolutionary Change

- Focus on improvements in care - technology is secondary.
- Seek incremental gain from incremental effort.
- Record all available data to drive care, process improvement, and research.
- Design for human and organizational factors so that social and institutional processes will not pose barriers.
- Support the cognitive functions of all caregivers, including health professionals, patients, and their families.

Slide 8: Principles for Radical Change

- Architect information and workflow systems to accommodate disruptive change.
- Archive data for subsequent re-interpretation.
- Seek and develop technologies that identify and eliminate ineffective work processes.
- Seek and develop technologies that clarify the context of data.

Slide 9: Shifting the Paradigm to Achieve Interoperable Health Information by 2014

- Redefine interoperable data

- Data that can be assembled & interpreted in light of current knowledge & re-interpreted as knowledge advances
- Require data liquidity
 - Separability of data & decision support content from applications
- Limit use of standard data
 - Data whose meaning is explicit and stable

Slide 10: Paradigm Shift

- Old
 - One integrated set of data
 - Capture data in standardized terminology
 - Single source of truth
 - Seamless transfer among systems
 - Clinician uses the computer to update the record during the patient visit.
 - The system provides transaction-level data
 - Work processes are programmed and adapt through non-systematic work around
- New
 - Sets of data from multiple sources
 - Capture raw signal and annotate with standard terminology
 - Current interpretation of multiple related signals
 - Visualization of the collective output of relevant systems
 - Clinician & patient work together with shared records and information
 - The system provides cognitive support
 - People, process and technology work together as a system

Slide 11: The Certification Challenge

- Function
 - Software
 - Patient data
 - Decision support content
- Plus: Use
 - Roles
 - Process
 - Training
 - Incentives
- Equals: Effect
 - Clinical outcomes
 - Efficiency

Slide 12: What can be certified?

Touchstones:

- Less is more
- Requires precise definition
- Avoid “freezing” work flow, content or technology

Suggestions:

- Make liquidity the foundation
 - Data and context
 - Decision support content
 - Audit trails
- Provide explicit definitions for basic, stable functions
 - One process step per function
 - Exclusion(s)
 - Measure(s) of effectiveness
 - Dependencies

Slide 13: What can we measure & report?

- Ease of Learning
 - Set of functions a role needs to do, training time, time to peak efficiency
- Ease of Use
 - Time to complete & error rate for standard tasks, sensitivity & specificity for standard information-seeking tasks
- Cognitive Support
 - % of users handling new information correctly for a set of standard patients
- Adaptation to Change
 - Time from issuance of an urgent drug interaction update to its deployment in 80% of operational systems
- Effectiveness
 - % of alerts overridden by role, % of ADEs following an alert override, % of ADEs in absence of an alert

Presentation 2

Slide 1: Certification Programs and Processes

HIT Policy Committee
Certification/Adoption Workgroup

Cita M. Furlani
cita.furlani@nist.gov
Director
Information Technology Laboratory
National Institute of Standards and Technology (NIST)
July 14, 2009

Slide 2: NIST Mission

- To promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology ...
- ... in ways that enhance economic security and improve our quality of life.

Slide 3: NIST Responsibilities in the ARRA

- The American Recovery and Reinvestment Act (ARRA) substantiates NIST's current roles in health IT; the additional funding provides an opportunity to increase our activities in health IT standards development and harmonization and testing.
 - Specifically, the funding is "... for continued work on advancing health care information enterprise integration ..."
- The ARRA also directs NIST to:
 - Consult on updating the Federal Health IT Strategic Plan;
 - Consult on voluntary certification programs;
 - Consult on assistance on health IT implementation;
 - Provide pilot testing of standards and implementation specifications, as requested; and
 - Establish a grants program for health enterprise integration centers..

Slide 4: Conformity Assessment Overview

HIT Policy Committee
Certification/Adoption Working Group

July 2009

Gordon Gillerman

Chief
Standards Services Division
National Institute of Standards and Technology
gordon.gillerman@nist.gov

Slide 5: What We Do

- Assist U.S. Federal Government Agencies in developing conformity policies and administrative infrastructure
- Design and assist in the implementation of related conformity assessment programs

Slide 6: ARRA and NIST

- **SECTION 3001**
- **“(5) CERTIFICATION.—**
- **“(A) IN GENERAL.—**The National Coordinator, in consultation with the Director of the ***National Institute of Standards and Technology***, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria ...

Slide 7: NTTAA

- **National Technology Transfer and Advancement Act Directs NIST:**
- (13) to coordinate Federal, State, and local technical standards activities and conformity assessment activities, with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures.

Slide 8: Conformity Assessment

“demonstration that specified requirements relating to a product, process, system, person or body are fulfilled”

ISO/IEC 17000

Slide 9: Helpful Terminology

- The Parties – Who Does What?

Conformity Assessment can be conducted by:

- *first party* – seller or manufacturer
- *second party* – purchaser or user
- *third party* – an independent entity that has no interest in transactions between
- the 1st and 2nd parties

Slide 10: Types of Conformity Assessment

- Testing
- Supplier's Declaration
- Certification
- Accreditation

Slide 11: Typical Use – Testing

(1st, 2nd or 3rd Party CA)

- Used when the critical characteristics can be evaluated via measurement under specified conditions
- Type test is a test carried out on samples that represent production for the purpose of determining conformity
- May be an element of a supplier's declaration or certification system
- ISO/IEC 17025

Slide 12: Typical Use – Supplier's Declaration (1st Party CA)

Generally used:

- when the risk associated with noncompliance is low
- there are adequate penalties for placing noncompliant products on the market
- there are adequate mechanisms to remove noncompliant products from the market
- ISO/IEC 17050 parts 1 and 2

Slide 13: Typical Use – Certification

(3rd Party CA)

- Used when the risks associated with non-conformity are moderate to high
- Includes evaluation, compliance decision, attestation of conformity and some form of *surveillance* or follow up
- Always conducted by a third party
- ISO/IEC Guide 65

Slide 14: Typical Use - Accreditation

- Used to assess and ensure/enhance ongoing conformity assessment body and program for competence, management and technical requirements
- Used to attain needed confidence in laboratory testing operation and results
- Used to attain needed confidence in certification system
- ISO/IEC 17011

Slide 15: Surveillance

- Used to ensure/enhance ongoing conformity
- Key part of certification or registration system
- For products pre-market and post-market
- Announced or unannounced
- Inspection, testing and audits are among commonly used methods
- Frequency and rigor should be balanced with the costs (direct and indirect) and

confidence needs

- Typically resource intensive

Slide 16: Conformity Assessment Hierarchy

Slide 17: Example 1 - Conformity Assessment Business Model

Slide 18: Example 2 - Conformity Assessment Business Model

Slide 19: Risk and Conformity Assessment-- How Much Confidence is Needed?

Slide 20: Factors in CA System Design

- The risks associated with non-compliance should be proportional to the rigor and independence of the CA system.
- System over-design will add too much cost.
- System under-design will result in too little confidence of compliance.
- Penalties associated with non-compliance may reduce the needed rigor and independence of the conformity assessment system.
- Timely mechanisms that effectively remove non-compliant products from the market may also reduce the needed rigor and independence of the system.

Slide 21: Conformity Assessment System Examples

Slide 22: Supplier's Declaration Example - IPV6 Conformity Assessment

Slide 23: TIA TSCP Toy Safety Certification Program - Draft

Slide 24: Q & A

- www.nist.gov

Presentation 3

Slide 1: Presentation to the HIT Policy Committee - Certification Adoption Workgroup

July 14, 2009

Sheldon R. Razin,

Chairman of the Board

Quality Systems, Inc.

(parent company of NextGen Healthcare Information Systems)

Slide 2: Quality Systems, Inc.

- FY 2009 revenues \$245 Million
- Publicly traded (NASDAQ: QSII)
- Provider of Ambulatory HIT Systems Exclusively
- 2600 Practices
- Over 40,000 physicians licenses in market

Slide 3: Complete Integrated Solution Certification Body

- NextGen Healthcare strongly supports the certification process.
- We believe there should be one certification body.
- The HIT Policy Committee should consider adopting CCHIT as this body or at least use the work of CCHIT as the basis for the required certification program.

Slide 4: Certification Criteria

- Criteria should be carefully developed and reflect a high level of IT solutions functionality that will support the plans for meaningful use.
- A review of overall system capability should be embodied in the criteria, such as clinical decision support and client notification support when/if errors in software might be discovered.

Slide 5: Certification Criteria (con't)

- Consider a review of company financials to include long term viability.
- Criteria surrounding interoperability and the ability to submit progressively more complex quality indicators should be carefully developed and strictly monitored.
- Product use- not just stated capability needs to be validated at all times.

Slide 6: Certification Criteria (con't)

- Certification should not be treated as a seal of approval but rather a statement on product capability; this platform will then allow the medical provider to determine whether the certified IT solution is right for them.

Slide 7: Non-vendor and Open Source Systems

- All systems need to be subjected to the same level of functionality criteria.
- With regard to non-vendor systems, while we support the right of any provider to develop their own IT capability, care needs to be given to assure that privacy, security, and clinical decision support must perform at the same level as the proprietary systems to support the goal for a unified platform for the plans for the nationwide health information network.

Slide 8: Non-vendor and Open Source Systems

- With regard to open source technology, again care needs to be given to make sure that criteria is adequately met.
- Furthermore, the ability to determine product usability and long term viability should be clearly validated as part of adherence to criteria.

Slide 9: Privacy and Security Considerations

- Privacy aspects are often policies that are more consistent with processes defined by the customer and not necessarily dictated by the EHR. Security requirements are more defined by criteria related directly to the EHR and should be a function of the EHR.
- As items such as disclosure are more clearly defined, there should be incorporations into the EHR to ensure adequate privacy and security protections for health information.

Slide 10: Summary Comments

- We strongly encourage that clarity on the certification process be communicated to the medical provider and EHR Vendor community as quickly as possible.
- The market is expressing a great deal of confusion currently and looking to vendors like NextGen to help them make decisions to meet deadlines while at the same time confirm that product selection will meet all needs in the market going forward.

Slide 11: Summary Comments (con't)

- While we remain confident that our solutions will meet all criteria being consider, with more clarity on final criteria, we will be better able to assuage any concerns that our customers and prospects may have in being able to meet all aspects of meaningful use.

Slide 12: Thank You for your time.

nextgen.com

Presentation 4

Slide 1: HIT Policy Committee

**Certification / Adoption Workshop
Vendor Panel**

David McCallie, MD
Vice President, Medical Informatics
John Travis
Senior Director, Regulatory & Compliance Strategy

Cerner Corporation

July 14, 2009

Slide 2: Hospital EHR Certification – Cerner Corp.

- Define a Sharp Focus for Certification
- Make ARRA / Meaningful Use the Target
- Take a Modular Approach
- Usability Certification is Problematic
- Base Testing Approach on Existing Standards
- Offer Continuous Availability of Testing
- Avoid Hidden Conflicts of Interest
- Questions

Slide 3: Define a Sharp Focus for Certification

- Interoperability
 - Conformance to the necessary interoperability standards to support clinical and quality measurement data exchange between entities, *to achieve Meaningful Use*
- Functional Behaviors
 - The behaviors (functional capabilities) of EHRs necessary to *achieve Meaningful Use* (e.g. by selecting appropriate subsets of the HL7 EHR functional model, etc.)
- Product Integrity
 - To verify the intrinsic security, privacy, integrity, availability and validity of clinical data held within EHRs, to *achieve Meaningful Use*, as recommended by ONC Policy & Standards Committees

Slide 4: Make ARRA / Meaningful Use the Target

- Given the dominant role that ARRA Stimulus and Meaningful Use will play in the next 5+ years, we feel that the Certification process should be focused entirely on achieving ARRA / Meaningful Use

- Avoid introduction of de facto certification / regulatory standards other than specified for ARRA / MU
- Stark interoperability and MIPPA eRX interoperability definitions should be subsumed under Meaningful Use to avoid conflict or confusion between these regulatory requirements and the MU goals
- Adjust the Stark requirement for annual ambulatory EHR certification to match to the certification period for meaningful use which is likely to be based on two year cycles

Slide 6: Take a Modular Approach

- The definition of a Certification “module” should be directly based on subsets of Meaningful Use goals and objectives
- Certification scores should be tallied at the level of Meaningful Use Modules to indicate abilities at the module level rather than as an overall total or pass/fail score
 - Modular certification recognizes that providers may be able in mid-project to replace some older generation systems with newer ones that have been certified
 - Modular certification allows options for providers with mixed production portfolios to meet Meaningful Use by leveraging systems already in use that bear certification

Slide 7: Usability Certification is Problematic

- While usability is an important aspect of a purchaser’s evaluation of a system, it is open to a great deal of subjectivity which makes it problematic as a part of objective certification criteria
 - Definition of “usability” remains too subjective to be fairly applied to complex and rapidly evolving health care software.
 - Implementation choices can introduce significant variability in usability, and production use is what matters – not “out of the box” capability
 - Locking in on a specific definition of “usability” could inhibit innovation
 - A competitive market will address “unusable” systems

Slide 8: Base Testing Criteria on Objective Standards

- Meaningful Use goals and measures (and the matching certification assessments) should be tied to specific definitions established by external standards bodies where possible.
 - Provides a clear basis for understanding requirements
 - Provides a conformance basis for certification criteria
- Interoperability testing should be done using automated testing tools that provide for an objective test result verification
- For human evaluated certification tests, a multi-member panel should be used, requiring a majority vote for evaluating test results

Slide 9: Offer Continuous Availability of Testing

- Certification should be a continuously available process for as long as participation in a Meaningful Use period is available
 - Re-tests or re-application should be open and available to vendors

- Certification, once achieved, should be valid for the entire meaningful use period it is intended to support (e.g. two years for 2011-2012 or until adoption period closes for qualification based on a given MU criteria set)
- Open, standardized, *interoperability test harnesses* should be made available so that deploying sites can perform continuous self assessments of their ongoing implementations

Slide 10: Avoid Hidden Conflicts of Interest

- Certifying bodies should be impartial and should not attach requirements not part of Meaningful Use to certifications intended for Meaningful Use
 - Certification should be based solely on published standards and not inadvertently endorse or sanction a particular network model or network provider
 - For example, networks with additive conformance requirements that go beyond what is needed for connectivity
- Any certification from a deemed certifying body should be on par with any other such certification
 - Vendors should be able to choose which one they pursue and not be obligated to certify with every deemed certifying body
- There should be independent oversight and approval of certification programs (NIST?)

Presentation 5

Slide 1: Presentation to the HIT Policy Committee

- Donald A. Deieso, Ph.D.
- Chairman & CEO
- July 14, 2009

Slide 2: Peri Gen - At a Glance

- Founded in 1995 – US Corporation
- Only Advanced OB Clinical Decision Support System Available
- Over 350 Physician Workyears in Development
- Knowledge Base Contains over 6,500 OB Protocols & Best Practices
- 25 Physicians & 30 OB Nurses & Midwives
- Serving 36 Hospitals
- Supported 295,000 Births / *A Birth Every 7 Minutes*
- Integrated with 10 Ancillary Hospital Systems & EMRs
- Full Suite of OB Risk Reduction Professional Services
- Demonstrated Clinical and Financial Benefits to Clients

Slide 3: What We Do

- Standardized Protocols
- Real Time Interventions
- Improved Documentation
- Robust Reporting & Metrics
- Improved Patient Safety & Clinical Outcomes
- Improved Financial Outcomes

Slide 4: PeriGen's "Expert" Clinical Decision Support "Safety Net" for OB Clinicians

Slide 5: Improved Financial and Clinical Outcomes *High Client ROI*

- Financial Benefits
 - Reduction in Med Mal Costs
 - Improved Charge Capture
 - Reduced Length of Stay
 - Increased Productivity & Lower Staff Turnover
- Clinical Benefits
 - Assures Conformance with Hospital Protocols
 - Provides Extensive Documentation
 - Powerful Clinical Performance and Outcomes Metrics
 - Improved Communication
 - Recognized For Excellence – Joint Commission

Slide 6: The Perspectives of a “Specialty” Solution

- Historically Specialty Firms Have Been Disenfranchised
- To Date, Specialty Certification Has Been Unavailable From CCHIT
- Enterprise Certification Misses Critical Functionality For Specialty Departments, e.g. Surgery, L&D, NICU
- Ambulatory Certification Misses Critical Functionality For Specialties, e.g.
- Obstetrics, Ophthalmology, Orthopedics

Slide 7: What is the Consequence and Why Does it Matter?

- Transformative Advances Have Always Come From Specialty Firms
- Setting Certification Requirements Based on the “Most Common Denominator” of What is Available From the Largest Firms - Institutionalizes the Average and Discourages the Innovative
- The Most Exciting Opportunities for Driving Improvements in the Provision of Healthcare Reside in the Specialty Firms
- HITECH is an Important Moment For the Federal Government to Use the Financial Incentives to Drive Further Advances – Not Inhibit Them

Slide 8: What Must Change?

- **Meaningful Use** Proposal Does Not Include Entire Populations
- For Example, Consider Women’s Health
 - Only Measure is % Mammograms Over Age 50
 - No Pregnancy Measures at All
- Certification Requirements For Specialty Solutions Must be Encouraged
 - While the CCHIT “Modular” Approach is an Encouraging Concept, Hospitals Are Left to Cobble Together Disparate Systems

Slide 9: Defining the Desired Outcome

- Promote “Modularity” of Certification Requirements
- Establish Clear Mechanisms for Disbursement of Incentives – Specialty Solutions v. Enterprise EMRs
- Address Vulnerable and Protected Populations With Early Specificity of Meaningful Use Measures – Specifically Women’s Health and Pregnancy
- Create National Forum to Promote Innovative Solutions That Operate at the Intersection of Clinical and Technological Advances

Presentation 6

Slide 1: HIT Policy Committee

Certification from an Oncology Perspective

Dow Wilson

**Executive Vice President & President, Oncology Systems
Varian Medical Systems, Inc.**

July 14, 2009

Slide 2: Presentation Agenda

- Varian Medical Systems background and views on certification
- Objectives of the initiative and application to oncology+
- The case for specialty certification

Slide 3: About Varian Medical Systems (VMS)

- World's leading producer of medical technology for treating cancer
 - Medical devices for radiation therapy, radiosurgery, proton therapy, and brachytherapy
 - Radiotherapy treatment planning and record & verify software
 - Informatics software to manage cancer patient data more efficiently
 - Founding member of the Integrated Health Enterprise – Radiation Oncology committee (IHE-RO)
 - Our oncology information systems interoperate with enterprise level EHRs to ensure access to cancer patient data anytime and anywhere in the healthcare system

Slide 4: Varian's Oncology EHR

- Installed in hundreds of clinics in the US with hundreds more World-Wide
- Supports the ordering, preparation, and delivery of chemotherapy and radiotherapy treatment
- Encompasses a variety of workflow and operation support features
- Includes comprehensive charting and decision support
- Interfaces with other health care systems to exchange relevant patient information
- Provides Record and Verify component for radiotherapy treatments

Slide 5: Certification and Health Care Objectives

- Several organizations have put forth recommendations to the federal government for implementation of HIT certification
- Recommendations from the Institute of Medicine, National Research Council, and others demonstrate the need for a specialty focused certification for oncology

- While the goals of both a general ambulatory and specialty certification can remain the same, the criteria for implementation should be different

Slide 6: Certification and Health Care Objectives

- ***Recommendation 1: An electronic health record must contain comprehensive information relevant to a patient's condition, their treatment plan, and its outcomes***
 - All EHRs should meet this goal; however, oncology requires specific terminology and data collection to support physicians in the selection, planning, and management of chemotherapy and radiation treatment
 - As a result, test cases for oncology EHRs should include oncology specific elements

Slide 7: Certification and Health Care Objectives

- ***Recommendation 2: EHRs should have the capability to integrate evidence-based practice guidelines and research results into information systems***
 - Oncology-focused EHR products include information for the treatment of cancer and meet this criteria
 - Oncology-specific EHR vendors would have to adjust their software to comply with certification procedures designed for a general ambulatory system
 - Compliance with general ambulatory criteria will delay oncology-specific developments by vendors, and offer little value to the oncology-specialist

Slide 8: Certification and Health Care Objectives

- ***Recommendation 3: All EHRs should allow clinicians to not only manage their own patients and highlight problems specific to the individual, but also recognize when the problem moves beyond one patient and is impacting a larger population***
 - Cancer measures within PQRI identify oncology specific data for the promotion and monitoring of quality care
 - Significant presence of oncology clinical trials
 - Requirements for toxicity grading, adverse events
 - Without specialty certification it will be difficult to determine whether the EHR is capturing the appropriate information to support values relevant to oncology

Slide 9: Certification of Specialty EHRs

- Ambulatory certification criteria should not apply to specialty EHRs
 - Some (but not all) ambulatory requirements are universally applicable
- Relevant certification criteria provides an effective way to establish baseline capabilities specific to the specialty community
- VMS believes it is essential to establish separate, stand-alone certification criteria for Oncology EHRs
 - Some ambulatory criteria do not apply to Oncology
 - Oncology-specific criteria must be developed

Slide 10: Implementation of Objectives

- VMS encourages the HIT policy Committee to continue an open dialogue with oncology professional organizations (such as ASCO/ASTRO)
 - This interaction is essential to developing an appropriate certification process for oncology EHRs in time for Recovery Act implementation
- VMS offers itself as a resource for both HIT Policy Committee and certifying bodies to promote the best interest of the providers who use these products and the patients they serve

Presentation 7

Slide 1: HIT Policy Committee

Certification/Adoption Workgroup EHR Purchaser Panel

Keith Michl, MD, FACP
Solo practice, Internal Medicine
Manchester Center, VT

July 14, 2009

Slide 2: EHR Early Adopter

- Left primary care hospital employed practice in 1998. Two full time employees initially.
- Strong commitment to EMR – low cost software for \$1,000.
- Windows NT server – six client computers = \$15,000.
- Heavy use of scanning paper records into EMR and later to document management software.
- Emphasis on usability, better staff collaboration, patient education, better quality communication with colleagues, avoiding handwriting and transcription costs.

Slide 3: Emphasis on cost and simplicity

- Thin profit margins. Need to borrow for capital improvements.
- Separate practice management and EMR software.
- Four different practice management systems over the last 11 years.
- Purchase of a new EMR program in 2001 [\$7,000] was never implemented – compelling features in demo proved to be vaporware.
- Mentorship – helped another physician leaving employed practice to set up office EMR.

Slide 4: Evolution of Home Grown Patchwork

- 1999: email with patients, then web portal in 2006.
- 1999: free standing fax server for outbound faxes only. 2007: inbound faxes through a web-based service.
- No ability to directly import lab data or other clinical data from hospital HIS – lots of manual data entry and scanning.
- Constant attention to backups resulted in minimal data loss when scheduling system hard disk crashed.
- Constant theme Doctor CIO– very limited networking support. Tech support from vendors good/inexpensive.

Slide 5: Further Evolution

- Standalone patient counseling/tracking program for anticoagulation management.
- Patient history-taking software.
- Adoption of web-based Vermont Immunization Registry.
- 2005: Vermont Blueprint for Health – joined the Bennington Pilot site.
- Chronic disease and population management: the Vermont Health Record electronic registry. No ability to directly incorporate data. Duplicate data entry.

Slide 6: Physician Office EMR Grant Process 2007

- Southwestern Vermont funding for EMR's for primary care offices [Safe Harbors for Electronic Prescribing/HER].
- Guiding principles, including choice, physician ownership. EMR should be established before shared community health record. Physicians should have a financial commitment.
- CCHIT certification was essential as was ability to interface with hospital system, state agency, immunization registry, advance directives registry, Vermont Blueprint registry, VITL Medication Registry.

Slide 7: Practice Approved for Grant in Early 2008

- Grant of \$40,000 for one physician practice. Practice pays 15% and SVMC pays 85%.
- Completed interview tool, readiness lists, tour by regional CMS QIO.
- Grant funding available for up to two years from grant approval.
- Hardware and networking costs weren't covered by grant.
- EMR task force reviewed four products, one was selected as a preferred EMR.

Slide 8: The Long Transition

- Four months of demonstrations and negotiations with vendor to allow shared trainer with another solo internal medicine practice in order to reduce cost.
- Training in practice management starting June 2008, conversion of demographics from old to new system with go-live October 2008.
- Training on EMR starting November. Trainer problems resulting in assignment of new trainer. EMR went live on July 7.
- Realization that full understanding and use of complex software is going to take a year.

Slide 9: Realities/Surprises

- VITL Data Repository two-way disease management integration is a distant mirage.
- Simple interfaces [i.e. one way import of hospital lab data from VITL to office EMR] are expensive – it's not clear who pays!
- Web portal messaging and electronic webVisit integration is economically non-viable for practices.
- Electronic prescribing module isn't currently certified for incentive bonuses.
- Integration of practice management, scheduling, EMR is an important feature.

Slide 10: Realities/Surprises, Continued

- Conversion from one EMR to another involves re-keying of data . Almost as much work as conversion from paper to EMR.
- It's unclear whether usability is a focus of new EMR. Improved data collection, reports, medication lists/interactions are possible but at a huge cost.
- Loss of productivity for six months at least [in an office that has used EMR for 11 years].
- Vendor advertised registry for PQRI purposes is vaporware!
- Most physicians wouldn't have the patience and technical expertise to do what my practice has done.

Slide 11: Recommendations

- Emphasize basic qualifications for software.
- Clarify what costs are associated with full CCHIT certification and who will pay.
- Continue to work on standards for low cost data interchange.
- Provide incentives for funding up front, not down the road.
- Set the bar high, but reward early adopters.
- Primary care practice is teetering on the brink of extinction. Let's not let the EMR adoption pathway push it off the cliff.

Presentation 8

Slide 1: HIT Policy Committee

Impact: Certification and the Adoption of HIT in Rural Community Hospitals

Paula E. Anthony, VP and CIO
ETMC Regional Healthcare System – Tyler, TX

July 14, 2009

Slide 2: ETMC Regional Healthcare System

- 14 acute care hospitals
 - 25 to 550 beds; Level 4 to Level 1 trauma
 - 48,000 admissions; 275,000 ED visits; 1.2 million OP visits
- 2 long term care, 1 behavioral health hospital
- 4 free-standing EDs
- 70 outpatient clinics
- EMS covering 35,000 square miles
- 150 employed physicians
- 750 medical staff members
- 7000 employees
- Located within 31 counties and serving 2 million people in East Texas

Slide 3: ETMC Regional Healthcare System

- Focused on the delivery of exceptional healthcare services to patients in the communities *in which they live*
- Recognized numerous times as a “Top 100 Hospital”
- Recognized numerous times as a “Most Wired Health System”
- Recognized as “one of nation’s fastest growing health systems”
 - Hospital acquisitions largely driven by IT needs
 - Poor state of vendor interoperability has dictated IT strategy to one of standardization (slow and expensive)
- Organized as an IDN ... but still a collection of rural community providers

Slide 4: The Realities of Rural Community Hospitals

- Usually the largest employer, and often the only economic driver in the region
- Providers serve a largely static population with a high incidence of chronic disease
- Patients move to and from referral centers regularly ... the management of continuity of care is critical
- Physicians and other clinical professionals are typically older, with more established practices
- All employees wear multiple hats ... and they can be highly innovative
- Competition for capital, resources and leadership focus is relentless

Slide 5: The Realities of IT in Rural Community Hospitals

- Rural community providers have been and will continue to be the slowest to adopt EHRs
- Implementation, adoption and achievement of real meaningful use is especially difficult
- Less than half of the vendors typically serving the community hospital market are currently certified
- Unintended consequences of certification could be extremely distracting and disruptive
 - More frequent vendor release cycles
 - Focus on feature/function vs. outcomes
 - Rush to implement to ensure incentive payments
- BUT ... the benefits from technologies proposed under ARRA could be most readily realized in small providers

Slide 6: EHR Purchase Considerations

- Scalability: cost and complexity
 - Affordability
 - Resource intensity
 - Sustainability
- Usability: No interest in “reinventing the wheel”
 - Pre-defined, clinical templates and implementation tools
- Ability to leverage existing investments
 - Balance between single-source integrated solutions and “best of breed”
 - Requirement to support local physician IT needs
 - Interoperability is vital
- Support of tele-health initiatives
- Until now, certification not a major consideration

Slide 7: Certification vs. Meaningful Use

- Certification
 - Objective measure of an EHR’s technical capabilities
 - Establishes meaningful baseline for functionality
 - Will leverage competitive forces on vendors based on compliance
 - Drives vendors toward consistency
- Meaningful Use
 - Qualitative measure of EHR adoption
 - Highly dependent upon implementation, training, support, leadership and governance
 - Difficult to achieve regardless of certification status
 - Drives providers toward significant change

Slide 8: Challenges With Certification

- Will the vendors' focus on certification slow down innovation and/or rush poorly architected solutions?
- Will it slow providers' ability to achieve meaningful use while waiting on vendor certification?
- Will the implementation of multiple "certified" systems hinder patient-focused meaningful use?
- How will continuity of care benefit from certified EHRs?
- Will providers' focus on seeking/implementing "certified" applications mask the real challenge of achieving meaningful use?
- Does it really help to drive true meaningful use?

Slide 9: How Certification Can Help

- Focus on identifying a set of core functional requirements that align with ARRA payment incentives
- Incorporate clear requirements for true interoperability (vs. current de facto "standard" of custom interfaces)
- Ensure that certification timelines don't interfere with providers' ability to achieve meaningful use
 - Develop timelines for vendor compliance, and *then* give providers enough time to implement
- Provide adequate requirements for security/privacy compliance
- Remember that certified systems can only provide basic assurances about the *possibility* of success ... real success with IT is always about the intangibles

Presentation 9

Slide 1: HIT Policy Committee

Certification/Adoption Workgroup EHR Purchaser Panel

**Stephanie Reel,
Vice President Information Services
Johns Hopkins Medicine**

July 14, 2009

Slide 2: Johns Hopkins Medicine

- The Johns Hopkins Hospital - 1889
- The Health System – 4 ½ hospitals, community health clinics, primary care sites, home care, health care insurance company
- The University – School of Medicine, School of Nursing, School of Public Health, and other divisions..... extensive research activities
- 2,000+ beds; annually 100,000+ admissions; 2 million+ outpatient visits; 275,000 ER visits
- \$4.5B per year health care enterprise
- Consistently rated as the Top Hospital in America
- Opening new clinical building in 2011 (Cardiovascular / Critical Care Tower and Children's Center - 560 beds; 33 ORs; 1.6M sq feet; \$950M)
- In partnership with the State of Maryland and the City of Baltimore, building new Science and Technology Park with 2M sq ft for life sciences and research

Slide 3: Progress is needed; more than just IT

- To achieve the safest, most effective care, HIT is but one piece of a continuous, coordinated approach.
- Measurable improvement also requires:
 - Quality improvement methods of problem definition, measurement, team facilitation and goal setting.
 - Significant practitioner involvement in defining the problem and developing the solution.
 - Significant patient/member involvement.
 - Iterative assessment and improvement after a new system or process is deployed.
 - Innovation!
- Together, HIT, training, workflow, process improvement and clinical analysis contribute to an improvement “cycle.”

Slide 4: Progress is needed; more than just IT

- No benefits unless you can get it deployed
 - Requires excellent department-level clinician leadership to manage the change process
- 2) Requires profound clinical input
 - To get consensus on and encode best practice in order sets
- 3) Requires careful clinical design
 - To enable useful decision support
- 4) Requires *ongoing* measurement and improvement of clinical processes
- 5) Requires vendor and partner commitment to the patient AND the healthcare provider

Slide 5: Certification Benefits

- Stabilizing force within the industry
 - Standards adoption
 - Meaningful use goals and objectives
- Advances interoperability
- Ensures focus
- Reduces (some) risks
- Provides (some) clarity
- Levels the playing field
- Raises the bar?

Slide 6: Certification Risks

- Future built on a foundation of mediocrity
 - Certification consumes resources
 - Vendor life cycles may not allow for experiential learning
 - Usability is secondary
 - Risk avoidance becomes pervasive
 - Innovation is impossible
 - It's all about the money!
- Barriers to entry
 - Creativity is not rewarded
 - Cost of innovation is too high, and too risky
 - It's all about the money!
- We can't afford to do it twice (It's all about the money!)

Slide 7: Recommendations

- Create certification criteria to ensure that solutions are “basically qualified”
 - Allow vendors to differentiate themselves based on usability/quality of the implementations
- Reward outcomes and “infusion” rather than deployment
 - Encourage clinician input/feedback; create consortia of providers and vendors
- Encourage performance rather than features
 - Leverage best practices in deployment of clinical decision support; encourage collaborative efforts

- Provide guidance/certification related to privacy and security

Slide 8: Recommendations

- Define interoperability; evaluate solutions based on specific criteria
 - Specific, actionable
 - Required for data sharing
- Promote flexibility in addition to functionality; evaluate solutions based on malleability
- Ensure that the certification process is open, explicit and evidence-based, with a broad view of evidence
- Measure outcomes (safety) rather than toolkit
 - Balance quality and cost
 - Be inclusive; encourage dissent

Slide 9: Summary

- It's not about what software package you use; it's about what you DO.
- Start now with a few obvious data elements, and begin sharing them (problems, allergies, medications, labs and immunizations).
- Evaluate solutions based on usability, much like we do for cockpit controls (and other high-stakes domains, where usability issues can kill people).
- Create the channel among providers and patients, and put something useful on the channel.
 - Like building the rail system or airports

Presentation 10

Slide 1: HIT Policy Committee

CCHIT Overview and Plans

Mark Leavitt, MD, PhD

Chair, Certification Commission for Health Information Technology (CCHIT)

July 14, 2009

Slide 2: Overview

Slide 3: Certification Capabilities, 2005-2008 (updated from NCVHS Testimony, April 29, 2009)

- Voluntary, consensus-based criteria development
 - Open recruitment, open development process
 - Public comment on interim and final materials
 - Pilot testing
- Strong engagement from diverse stakeholders
 - Number of participants has nearly doubled each year
 - Over 260 on workgroups this year (>650 applicants)
- Robust, repeatable and efficient inspection process
 - Zero tolerance for conflict of interest
 - Demonstrated scalability

Slide 4: Certification Impacts, 2005-2008 (updated from NCVHS Testimony, April 29, 2009)

- Acceptance by providers
 - Endorsement by 10 largest physician professional associations
- Competitive, diverse marketplace
 - Rapid uptake: over 50% in first year, over 75% by second year
 - Diversity: over 60% are small companies (<\$10M annual sales)
 - Innovation: 39% of companies certified in 2008 are new
- Confidence of payers and purchasers
 - Federal (recognition, Stark exemption, demonstration projects)
 - State eHealth programs
 - Private sector health plans
 - Liability insurers

Slide 5: ARRA Changes...Everything

- Nature of certification:
 - Before ARRA: Voluntary

- After ARRA: (Practically) Mandatory
- Providers Served:
 - Before ARRA: Providers and hospitals seeking extra assurance when investing in new EHRs
 - After ARRA: All Medicare and Medicaid providers and hospitals, at all stages of EHR adoption
- Technology certified
 - Before ARRA: Comprehensive EHR systems
 - After ARRA: Broadest possible array of EHR technologies
- Accountable to:
 - Before ARRA: Providers and payers
 - After ARRA: Providers, payers, & public
- Goals:
 - Before ARRA: Assurance of functionality, interoperability, security
 - After ARRA: Meaningful use to improve outcomes of care, support health reform

Slide 6: Plans

Slide 7 :Broadening Access to Certification

- **New Paths** to Certification
 - Certified EHR Comprehensive EHR-C
 - Certified EHR Module EHR-M
 - Certified EHR Site EHR-S

Slide 8: New Paths to Certification: In Brief

- Certified EHR Comprehensive EHR-C
 - Rigorous certification of comprehensive EHR systems that significantly exceed minimum Federal standards requirements.
 - For providers who seek maximal assurance of EHR compliance and capabilities.
- Certified EHR Module EHR-M
 - Flexible certification of Federal standards compliance for EHR, HIE, eRx, PHR, Registry and other EHR-related technologies.
 - For providers who prefer to integrate technologies from multiple certified sources.
- Certified EHR Site EHR-S
 - Simplified, low cost certification of EHR technologies in use at a specific site.
 - For providers who self-develop or assemble EHRs from noncertified sources.

Slide 9: EHR Comprehensive (EHR-C)

- Definition
 - Certified EHR-C vendors provide comprehensive EHR products that comply with all applicable Federal standards and enable providers to meet all Meaningful Use Objectives.
- Provider applicability
 - Physician offices and hospitals that prefer to rely on a single vendor to provide their EHR and want maximal assurance that it will fulfill their needs as well as qualify for ARRA incentives.
- Certification requirements
 - Functionality enabling providers to comply with all applicable Federal standards, implement adequate security practices, meet all of the Meaningful Use Objectives, and fulfill other requirements deemed essential through CCHIT's consensus-based development process. Also required: evidence of success in meaningful use at multiple user sites.
- Other data published
 - Usability will be evaluated and rated.
- Inspection methods
 - Juried demonstration, documentation inspection, technical interoperability testing, usability evaluation, live site use verifications.
- Cost range
 - ~\$30000 - \$50000 range (for new applicants; pricing for retesting of 08 certified products TBD)

Slide 10: EHR Modules (EHR-M)

- Definition
 - Certified EHR-M modules are applications that comply with applicable Federal standards and enable providers to meet one or more Meaningful Use Objectives (labeling will specify which Objectives and standards are met).
- Provider applicability
 - Physician offices and hospitals that choose to combine technologies from multiple certified sources to qualify for ARRA incentives.
- Certification requirements
 - Basic functionality that enables providers to comply with applicable Federal standards, implement adequate security practices, and meet one or more of the Meaningful Use Objectives.
- Other data published
 - N/A
- Inspection methods

- Demonstration, documentation inspection, technical interoperability testing.
- Cost range
 - ~\$5000 - \$35000 range (depending on scope of module)
 - Scholarships for eligible nonprofit suppliers if grants can be obtained.

Slide 11: EHR Sites (EHR-S)

- Definition
 - Certified EHR-S sites have developed or assembled EHR technologies that comply with Federal standards and enable them to meet all Meaningful Use Objectives.
- Provider applicability
 - Any physician office, clinic, hospital, other facility or network that has self-developed or assembled an EHR from various sources and wishes to apply to ARRA incentives.
- Certification requirements
 - Functionality available (regardless of deployment model) that enables providers to comply with applicable Federal standards, implement adequate security practices, and meet Meaningful Use Objectives.
- Other data published
 - N/A
- Inspection methods
 - Virtual Site Visit technology with offline inspector review and follow-up correspondence.
- Cost range
 - ~\$150 - 300 per licensed provider (ambulatory); hospital pricing model TBD. Scholarships for eligible providers (FQHC, underserved population, critical access, etc) if grants can be obtained.

Slide 12: Options for EHR Developers and Vendors

Comprehensive EHRs with multiple successful installations

- Specialty, small office, 'light' and open source EHRs
 - EHR-C, EHR-M, EHR-S
- ePrescribing applications
 - EHR-M, EHR-S
- PHRs, patient-physician communication applications
 - EHR-M, EHR-S
- Registries, other applications capable of fulfilling one or more meaningful use objectives
 - EHR-M, EHR-S

- Self-developed EHRs and other technologies
 - EHR-M, EHR-S
- Health Information Organizations (could certify EHR and PHR functions, not just HIE transactions)
 - EHR-C, EHR-M, EHR-S

Slide 13: Software Versioning and Open Source

- Version 'lockdown' has not proven helpful or necessary for certification
- EHR-**C** and EHR-**M**: updated or enhanced versions of a code base inherit certified status without need for CCHIT approval.
- For EHR-**S** sites, updates or enhancements do not require recertification
- Open Source advocates have endorsed this solution

Slide 14: Conceptual Application Process for ARRA Incentive Payments

- EHR-C
 - Provider deploys certified EHR-C
 - EHR-C vendor gives provider the certification code (issued by CCHIT) for that product
 - Provider includes EHR-C certification code in their ARRA incentive application
 - Provider submits measure data required for ARRA meaningful use
- EHR-M
 - Provider deploys a combination of certified EHR-M modules
 - EHR-M suppliers each give provider the certification code (issued by CCHIT) for their products/services
 - Provider includes EHR-**M** certification codes in their ARRA incentive application. (Combined modules must cover all meaningful use objectives.)
 - Provider submits measure data required for ARRA meaningful use
- EHR-S
 - Provider develops or assembles noncertified EHR technologies.
 - Provider site applies, is inspected, and receives EHR-S certification. Code issued to site by CCHIT.
 - Provider includes EHR-**S** certification code in their ARRA incentive application.
 - Provider submits measure data required for ARRA meaningful use

Slide 15: Response to New Paths Announcement CCHIT Town Calls held June 16 and 17, 2009; Total votes = 621

- Very favorable – 20%
- Favorable – 51%

- Neutral / not sure – 28%
- Unfavorable – 1%
- Very unfavorable – 0%

Slide 16: Certification Timing Plans (Subject to timing of HHS/ONC decisions and actions)

- 2011 Certification (ARRA 2011-2012 criteria)
 - Oct 2009: Launch Preliminary 2011 Certification programs
 - Jan 2010: Launch Final 2011 Certification programs
 - First half 2010: Launch expansion areas covering additional settings, specialties, and populations
 - Certification valid through Dec 31, 2012
- 2013 Certification (ARRA 2013-2014 criteria)
 - Mid 2011: Launch 2013 Certification programs
 - Certification valid through Dec 31, 2014
- 2015 Certification (ARRA 2015-2016 criteria)
 - Similar timing model to 2013

Presentation 11

Slide 1: HITSP - Healthcare Information Technology Standards Panel

Standards Harmonization

HITSP's efforts to address HIT-related provisions of the *American Recovery and Reinvestment Act of 2009*

Presenter: John D. Halamka, MD, MS, HITSP Chair

Slide 2: Standards Harmonization

- HITSP members agreed that a **standard** is a well-defined approach that supports a business process and . . .
 - has been agreed upon by a group of experts
 - has been publicly vetted
 - provides rules, guidelines, or characteristics
 - helps to ensure that materials, products, processes and services are fit for their intended purpose
 - is available in an accessible format
 - is subject to an ongoing review and revision process
 - Standards Harmonization is required when a proliferation of standards prevents progress rather than enabling it

Slide 3 & 4: HITSP Interoperability Specifications (IS)

- **IS 01 - Electronic Health Record (EHR) Laboratory Results Reporting**
- **IS 02 - Biosurveillance**
- **IS 03 - Consumer Empowerment**
- IS 04 - Emergency Responder Electronic Health Record (ER-EHR)
- IS 05 - Consumer Empowerment and Access to Clinical Information via Media
- **IS 06 - Quality**
- IS 07 - Medication Management
- **IS 08 - Personalized Healthcare**
- **IS 09 - Consultations and Transfers of Care**
- **IS 10 - Immunizations and Response Management**
- IS 11 - **Public Health Case Reporting**
- **IS 12 - Patient – Provider Secure Messaging**
- **IS 77 - Remote Monitoring**

Slide 5: Getting It Done

- The Office of the National Coordinator (ONC) has asked HITSP to assist it in

meeting its requirements for designating standards that support designated ARRA focus areas for healthcare, and ultimately, that support ARRA's notion of "meaningful use"

- HITSP paused its assigned 2009 work, and directed essentially all efforts toward this end
- HITSP organized into focused, quick-moving "Tiger Teams" to accomplish the new task by July 15, 2009

Slide 6: Tiger Teams Focus Areas

- A new EHR Centric Interoperability Specification to meet ARRA requirements
- Security, Privacy & Infrastructure
- Quality Measures
- Data Architecture (Element, Template, and Value Set)
- Exchange Architecture and Harmonization Framework
- Clinical Research

Slide 7: ARRA lead to creation of HITSP Capabilities

Slide 8: HIT Standards Committee – The Workgroups

- HIT Standards Committee has organized into three workgroups
- To assist the workgroups, ONC has added one HITSP volunteer and one HITSP staff member to each group
 - This will ensure that all workgroup members gain an understanding of HITSP's work to date

Slide 9: Clinical Operations Workgroup

- The proposed taxonomy
 - is based on standards maturity and estimated industry ability to deploy within timeframes
 - can include stretch goals, not only what is widely used today
- Category I: Known/Certain for 2011
 - Standards are well-accepted and generally seen as deployable
- Category II: Known/Certain for 2013
 - Standards exist, are determined, but are not in the market yet
- Category III: Work In Process for 2013 or 2015
 - Need to converge/refine standards for 2013 or develop for 2015
- Category IV: Standards to be determined
 - "Gleam in the eye," some concepts exist but no clear path

Slide 10: Example

- 2011 Meaningful Use Objective
 - Generate permissible prescriptions electronically
- **Specific Candidate Standards**
 - HITSP IS07 Medication Management
- **Candidate HITSP Capabilities**
 - Capability 1 Issue Ambulatory and Long Term Prescriptions: Capability 27 Issue Hospital Prescriptions
- **Gaps**
 - Controlled Substance orders; (Possible: Immunization orders)
- **Category I Generally well-defined for 2011**
 - Ambulatory, Long Term and Hospital Prescriptions
- **Category II Generally well-defined for 2013**
 - (Possible: Immunization orders)
- **Category III Guidance/ standards needed for 2013 or 2015**
 - Controlled substance orders
- **Category IV Standards not developed date TBD**
 - (Possible: Controlled substance orders)

Slide 11: Clinical Quality Workgroup

Slide 12: Example

- **% of Hypertensive Patients with BP under Control [OP]**
- Title: Adoption of Medication e-Prescribing
- QDS Datatypes:
 - Age
 - Hypertension diagnosis
 - Ambulatory encounter
 - Systolic blood pressure result
 - Diastolic blood pressure result
- HITSP Capability
 - Communication of Structured Documents using CDA

Slide 13: Privacy and Security Workgroup

- Segment into three categories:
 - Products that can be purchased
 - Certified by CCHIT outside the real-life setting
 - e.g., user and entity authentication, access control, audit
 - IT infrastructure necessary to enable the product to be meaningfully used
 - e.g., identity management, secure email, system backup

- Operational environment in which the product will be used meaningfully
 - e.g., authorization policies, audit review

Slide 14: Example

- 2011 Measures
 - e.g., Full compliance with HIPAA P&S Rules
- 2011 Features & Functions
 - 1) EHR Products (CCHIT Criteria)
 - 2) IT Infrastructure
 - 3) Operations
- Standards
 - HITSP, NIST, ISO, OASIS, etc.
- Certification Criteria
 - HHS Criteria for EHR Reimbursement

Slide 15: Schedule

- HIT Standards Committee schedule
 - Workgroup meetings July 1-July 15
 - Presentation of Standards and Certification Criteria in Meaningful Use matrix July 21

Slide 16: Discussion / Questions

Presentation 12

Slide 1: HIT Policy Committee

Driving Mainstream Adoption and Meaningful Use: Open Source, Certification & Recommendations

Edmund Billings, MD
CMO & EVP Product, Medsphere

July 15, 2009

Slide 2: NEJM: Use of EHR's in US Hospitals

- 1.5% of U.S. hospitals had a comprehensive electronic-records system implemented across all major clinical units.
- If we include federal hospitals run by the Veterans Health Administration (VHA), the proportion of hospitals increases to 2.9%.
- <http://content.nejm.org/cgi/content/full/NEJMsa0900592#T3>

Slide 3: Industry Recognition 2008- 11 Hospitals

Slide 4: Not Crossed the Chasm

- Most current products were developed by and for early adopters.
- These innovators have driven to the 100% case comprehensive solutions, rich in feature functions.
- The comprehensive solutions or “Full-blown EMRs” have been “too much” for the mainstream to afford, implement or adoption.

Slide 5: Disruptive Innovation Needed

- “A DISRUPTIVE INNOVATION IS A TECHNOLOGY THAT BRINGS A MUCH MORE AFFORDABLE PRODUCT OR SERVICE THAT IS MUCH SIMPLER TO USE IN THE MARKET.”
- “AND SO, IT ALLOWS A WHOLE NEW POPULATION OF CONSUMERS TO AFFORD TO OWN AND HAVE THE SKILL TO USE....., WHEREAS HISTORICALLY, THE ABILITY WAS LIMITED TO PEOPLE WHO HAD A LOT OF MONEY OR A LOT OF SKILL”.

Clayton Christensen:
The Innovators Dilemma

Slide 6: Midland Memorial Hospital, Texas

- 320 Beds, 2 Facilities
- ~200 Affiliated MD's
- HIS End of Life: \$20mil upgrade required
- OpenVista 2/05

- Adoption: HIMSS Stage 6
- Meaningful Use: IHI 5 Mil Lives
- Commissioned independent study: Perot Systems

Slide 7: Stage 6: Time and Total Cost

Slide 8: Stage 6: Total Cost per Bed

Slide 9: Total Cost of Ownership

Software License	FREE
Subscription (Implementation/Consulting/Support)	\$5,126,000
Replacement of financial systems	\$700,000
Hardware	\$801,000
Wireless infrastructure	\$226,000
Interfaces, etc.	\$140,000
• Remodeling	<u>\$100,000</u>
• Total (5 year cost)	<u>\$ 7,093,000*</u>
• *1/3 of the incumbent \$20 million price tag <u>before</u> their services	

Slide 10: Physician Adoption: CPOE

Slide 11: Central Line- Primary Bloodstream Infection Rate

Slide 12: Ventilator Associated Pneumonia Bundle Compliance

Slide 13: “Meaningful Use”- % of Un-reconciled Meds

Slide 14: Crossing the Chasm

- The mainstream needs disruptive “complete” solutions that get them “meaningful use.”
- They will buy services and results, not software.
- Connect them first, the network effect drives adoption.
- They need to 80/20 rule, not 100%

Slide 15: Recommendations

- Do not require certification on ‘comprehensive’ criteria.
- Certify solutions only to protect the customer: e.g., support for meaningful use, “plug and play” interoperability, patient safety, privacy, etc.
- Certify modular solutions to support incremental adoption, continuous innovation and customer choice.

- Certify sites on demonstrated “meaningful use.”
- Require and incent for electronic communications.
- Shift payment for value, quality and wellness asap.
- Support Vista, RPMS and NHIN as national assets.

Presentation 15: Principles For Developing 21st Century Public HIT Policy

Slide 1: Are CCHIT’s Interests Aligned With The Public Interest?

Brian Klepper, PhD June 10, 2009

Slide 2:

Principle 1: HIT Policy Must Reflect the Public, Rather Than The Special, Interest

Observation - Founded by And with Leadership From HIMSS, CCHIT Has Projected Special Interest Conflict.

Examples 1) ED Paid by HIMSS thru 2008. 2) Full Interoperability Still Not A Criterion.

Slide 3:

Principle 2: *Broadly Align HIT Policy To Support Reform Goals – Rapid Distribution, Ease of Use, Lower Cost - Through Innovation*

Observation

CCHIT Has Used “Features and Functions” Mode of Certification; High Cost To Certify.

Examples

- 1) Disconnect Between Newer “Meaningful Use” and Older CCHIT Criteria
- 2) More than 400 EHR Criteria, Most with No Relation to “Meaningful Use,” Excludes Many Newer Firms

Slide 4:

Principle 3: *HIT Policy Should Look Forward, Not Backward*

Observation- CCHIT Model Favors the Legacy Technologies of Major HIMSS Vendors, Rather Than Newer, Less Costly, More Flexible Technologies

Examples

- 1) Cost, Complexity and Poor Usability Have Resulted in Adoption Rates ~15%.

2) Proposed HITECH Subsidies Could Cement In Older (e.g., Client-Server), More Expensive Tech

Slide 5:

Principle 4: *Inter-operability is a Priority for Coordination, Data Aggregation, Pricing/Performance Transparency, CER, Decision Support, and Patient Engagement.*

Observation- *Interoperability is antithetical to legacy HIT's goal of proprietary, single vendor designs. CCHIT has dragged its feet, recently announcing Level 1 (text-only) capability.*

Examples

The Market (e.g., Microsoft, Google, BHCAG, CVS/Caremark, Beth Israel Deaconess) is moving forward much more rapidly on data exchange without CCHIT.

Slide 6:

Situational Summary

As it is currently constituted, CCHIT gives HIT's legacy vendors inappropriate influence over policy, and threatens to facilitate a national HIT approach that will fall short of health care reform's goals.

Recommendations

1) *Replace CCHIT's leadership/structure to diminish/eliminate undue vendor influence. Significantly reduce CCHIT's charge in defining certification rules.*

2) *Authorize additional organizations to perform certification after ONC/NIST set new, appropriate certification criteria.*

Slide 7:

Brian Klepper PhD

through Healthcare Performance, Inc. and [Health 2.0 Advisors](#), advises government, health care firms and employers on approaches that can leverage market trends, reduce cost and improve quality. Through [WeCare TLC](#), he develops and manages comprehensive onsite/nearsite primary care clinics for employers and indigent care programs. And he actively writes and speaks on health care change.

Early in his career Dr. Klepper led a health care consulting practice that developed or repaired health care companies and programs. Then, in 1999, realizing that health care was headed for massive systemic disruptions, he changed course to work on reform. That experience allowed him to begin to understand the deep structural mechanisms that underlie the crisis, and what it will take to put the system on a stable footing again.

He is an [Aspen Institute Health Forum Fellow](#), one of only three non-physicians on the Medscape Journal of Medicine Editorial Board, an Editor of [Medpedia](#), Editor-at-Large for the journal [Community Oncology](#), and columnist for [American City Business Journals](#). He writes on two widely-read expert health care blogs: [The Health Care Blog](#) and [Health Policy and Marketplace Review](#). and regularly provides commentary in professional publications and the mainstream media.

He is an [Aspen Health Forum Fellow](#), an advisor to the [Patient Centered Primary Care Collaborative](#) and the only non-physician Board member of [COSEHC](#), Preventive Cardiologists providing translational vascular management.

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Presentation 13

Slide 1: HIT Policy Committee

Modular EMR

**David Kates, Senior Vice President
Prematics, Inc.**

July 15, 2009

Slide 2: Overview and Perspective

- Most physicians practice in small groups
- Unique technology and support needs in those settings
- Incremental approach optimizes adoption and benefit
- Appropriate certification efforts crucial to success

Slide 3: Market Characteristics

- Most physicians practice in smaller groups
- 30% of physicians write 83% of all pre-scriptions in the US²
- Over 90% of the highest prescribers are in smaller practices³

Slide 4: Technology Environment

- Minimal existing infrastructure
 - Computers primarily in administrative areas
 - Widespread internet connectivity in most geographies
 - Limited access to computers and network at point of care
- Lack of IT resources and skills
- Focus is on patient care and supporting activities
- Eager to adopt technology that enhances workflow

Slide 5: Technology Adoption in Small Practices

- Need to walk before they run
- Focus on key workflows with greatest impact
 - Electronic prescribing
 - Lab order entry and results reporting with CDS
 - Problem list management
 - Registries with quality reporting
- Progressively automate documentation of care
 - EHRs' focus on documentation driven to maximize revenues and lower cost under current reimbursement model
 - Focus should be on capturing key discrete data to measure and improve quality and efficiency

Slide 6: Value of Certification

- Inform buyers regarding significant investment

- Trust and confidence outside of core expertise
- Ensure key benefits are achieved within practice
 - Safety, quality, cost-effectiveness
- Foundation for sharing of relevant clinical information
 - Define and consistently implement standards necessary for interoperability and to support continuity of care
 - Leverage info from health plan to improve quality and efficiency
 - Inform providers for effective, efficient care delivery
 - Empower and engage consumers

Slide 7: Modular Certification Approach

Slide 8: Conclusions

- Certification crucial to effectively implement HITECH
- Efforts should be focused to get greatest impact
 - Maximize return on enormous investment in HIT
 - Most care is delivered in small practices
 - This same focus also applies in larger practice settings
- Incremental approach essential
 - Consistent with capabilities and adoption
 - Yields maximum benefit

Presentation 14

Slide 1: HIT Policy Committee

CCHIT – Innovation Killer of In-house Developed HIT?

**Carl Christensen
Marshfield Clinic**

July 15, 2009

Slide 2: Marshfield Clinic

- Formed 1916
- Multi-specialty group
- Physician led – 501C3
- ~780 physicians
- 45 sites
- ~400,000 unique pts/yr
- ~3.5M encounters/yr
- \$1 billion in Revenues

Slide 3: 50+ Years of Informatics@Marshfield

Slide 4: Marshfield Clinic “HIE”

- Shared EHR
- Immunization Network
- Laboratory Network

Slide 5: CCHIT Certification

- Marshfield was the first in-house developed system that received CCHIT certification.
- CCHIT Certified '06 Ambulatory, '08 Ambulatory EHR, Child Health, Preliminary ePrescribing.
- ~65,000 hours spent on '08 certification tasks (over and above '06 tasks).
- Significant portion of the work added little or no value.
- Diverted focus away from “high value” enhancements to CCHIT compliance tasks.

Slide 6: Example - Reporting

- Marshfield has one of the most comprehensive ambulatory clinical data warehouses in the country.
- Capabilities of the clinical data warehouse far exceeds the basic reporting capabilities required by CCHIT.
- The logistics imposed by the CCHIT testing process forced Marshfield to write a parallel reporting system which provided no additional value.
- Unless this requirement is changed Marshfield will be forced to maintain this parallel

reporting system into the future, increasing costs and diverting focus.

Slide 7: Observations

- One of the biggest benefits of CCHIT certification is the reduction of buying risk for purchasers of HIT.
- This benefit does not apply to in-house developed systems.
- The PGP CMS demonstration project had a very positive impact on the quality of Marshfield's HIT, improved the quality of healthcare, and lowered healthcare costs, BEFORE we added the CCHIT 2008 features.
- 2008 CCHIT had minimal impact on the quality of Marshfield's HIT, had a negative impact on quality of care, and increased overall healthcare costs.
- The quality of implementation process is far more important than the feature list.

Slide 8: Recommendations

- Government incentives should be based on demonstrated improvements in efficiency and effectiveness.
 - Competitive scorecards
 - Interoperability using current standards
- Incentives should not be based on a list of product features.
- If we want our HIT to support evidence based care, the required features should be evidence based.