Testimony to National Committee on Vital & Health Statistics
Subcommittee on Standards
On Standards within the Context of Heath IT Initiatives

I am Associate Vice-Chancellor for Health Affairs, Director of the Informatics Center and McKesson Foundation Professor of Medicine and Biomedical Informatics at Vanderbilt University. In these capacities I serve as Chief Information Officer of the Medical Center and Chief Information Architect of the University. In addition, I served on the Commission on Systemic Interoperability (2004-2005); chaired the National Research Council Committee (2007-2008) that recently released the report Computational Technology for Effective Healthcare: Immediate Steps and Strategic Directions; and chaired the National Library of Medicine Board of Regents working group on health data standards (2009). I will begin my testimony by summarizing relevant observations from the NRC Committee site visits and conclude with a synthesis of recommendations from my various perspectives.

The Institute of Medicine's vision for 21st century health care and wellness calls for a system that is safe, effective, patient-centered, timely, efficient and equitable. This vision includes several information intensive aspects:

- 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

The NRC Committee visited 8 health systems - sites that are leaders in use of HCIT to improve quality - to assess the gap between the best of what is deployed today and what is needed. The sites represented a broad spectrum – government, for profit, not for profit – academic, community – commercial systems, home grown systems. While we saw many successes, the information systems we saw, even in aggregate, fall far short of what would be needed to achieve the IOM's vision for 21st century health care. Problematic aspects include:

- Fragmented patient records
- Clinical user interfaces that mimic paper without human factors & safety design
- Poorly integrated biomedical devices
- Systems that are used often to document what has been done, after the fact, for regulatory and legal uses
- Rare support for evidence-based medicine and computer-based advice
- Little integration of clinical research activities into clinical care
- Centralization as the predominant method of standardization, while most innovation is close to the action

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

One of the key observations in the report is that health care uses information technology mainly for automation and transaction processing – supporting work that can be done over and over again with little variation. Health care makes less use of information technology for other purposes than other industries. For example, connectivity - linking people to each other and systems, decision support - making choices clear, and data mining, discovering relationships among data. While automation works well for small well defined systems, the other approaches are more effective for complex systems with diverse data sources. Health care needs to achieve more balance among the four uses of information technology.

I make the following recommendations on standards within the context of health IT initiatives:
1. Redefine the objective of standards initiatives to reflect the challenges identified in the NRC report.
   a. Embrace interoperable health information as the goal. Define interoperable data as data that can be assembled and interpreted in the light of current knowledge, and re-interpreted as knowledge evolves. Re-interpretation requires access to an archive of "raw signal" (voice, image, text, biometrics, etc).
   b. Ensure the separability of data from applications so that other applications can use them.
   c. Limit use of standard data, by which I mean data that can have only one interpretation, to situations where meaning is explicit and stable over time, e.g. drug ingredients, etc.
2. Take a portfolio approach to enabling interoperable health information.
   a. Standard practices - encourage development of standard practices related to cognitive support for health professionals and patients, support for human factors, adaptability to support iterative process improvement, and effective use to improve quality.
   b. Terminology frameworks – use a knowledge-base approach to terminology management, leveraging synonymy and annotation of relationships among concepts & across terminologies, such as in the Unified Medical Language System, to compute interpretation.
   c. Standard product identifiers and vocabulary – Execute on the Commission on Systemic Interoperability recommendation to work with the manufacturers of drugs, devices and test kits to achieve standardized identifiers in labels, packaging, and data outputs of devices and test kits.

Downstream participants in the information "supply chain" could then use this information within their local system much as the retail industry leverages product bar codes. The key idea is to apply the standard at the point of manufacture instead of applying it at the inter-connections among systems.

    d. Data interchange – include standards for authentication of an individual to their record, role-based authorization, etc
    e. Metrics - couple development of standards with development of metrics to assess if technology built to, or using, the standard achieves the desired result when combined with people and process in real health systems.
    f. Invest in tools and services that facilitate adoption and effective use of standards by vendors and providers.

3. Drive to value
    a. Bring together standard developers and users to define and test how information models, clinical data elements and value sets can work together to achieve health improvement in the near term.
    b. Develop test beds to demonstrate high value use scenarios
    c. Create and maintain a roadmap showing what needs to be done in each "lane" of the portfolio, and when specific steps need to be completed to achieve measurable interoperable health information goals.

Consider "end-to-end" medication knowledge management as an example of what might be achieved in the near term through a coordinated effort. The goal would be reduce the time and cost of deploying and updating medication decision support content by linking information published by drug developers, FDA, drug knowledge-base vendors, and later PubMed and ClinTrials.Gov.

1. Extend RxNorm into a medication terminology frame work of ingredients, dose forms, strengths, and classes (e.g., as in NDF-RT). Link NDCs and products to RxNorm during the FDA approval process. Take advantage of NDC link included in the electronic labels. Link commercial drug knowledge-bases by including their linking codes in RxNorm directly or indirectly through NDC.
2. Work with test bed sites to use concept matching algorithms and the information in the above links to automate linking of the site's formulary to ingredient, dose form, or strength (or as many as possible). Then link the site's preferred drug knowledge base to the formulary.
3. Develop machine assisted site-specific filters of alert rules (drug-allergy, drug-drug, …) by user role (clinician, pharmacist, …)
4. Measure interoperability with elapsed time from issuance of an urgent update to its deployment in the operational systems at the site.
5. Measure health care improvement by performance on LeapFrog scenarios, % of alerts overridden by role, % of adverse drug events following an override, etc.

For the long term, as recommended in the NRC report, support research into computable knowledge structures and models needed to make sense of available patient data including: computable guidelines and approaches for comparing, assessing, updating, and

integrating them into a library of guidelines for a given patient; and systems that can infer clinical conditions from raw data (e.g., inferring that "patient is feeling more pain" from the report of an upwards adjustment in the IV drip of a pain management drug). Because the clinical interpretation of data depends on the current state of knowledge about medicine and about physiology and how people respond to treatments and so on, computable structures are important because they connect medical knowledge to patient data in machine-readable and machine-executable form. Thus, they can provide needed abstractions for the health care provider and the clinician to help them understand what is going on with a given patient.