July 6, 2000

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Shalala:

On behalf of the National Committee on Vital and Health Statistics (NCVHS), I am pleased to present to you the Report on Uniform Data Standards for Patient Medical Record Information. This report was mandated by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

HIPAA directed NCVHS to "study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information" and to report to you "not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange [HIPAA Section 263]." This report was prepared by the Computer-based Patient Record Work Group within NCVHS' Subcommittee on Standards and Security.

The report describes how the lack of complete and comprehensive PMRI standards is a major constraint on the ability of our healthcare delivery system to enhance quality, improve productivity, manage costs and safeguard data. It recommends that the government take a leadership role in addressing these issues by accelerating the development, adoption, and coordination of PMRI standards. Further, it addresses the related issues of protecting the confidentiality of PMRI, reducing barriers to the electronic exchange of PMRI caused by diverse state laws, and coordinating the development of PMRI standards within the broader context of the National Health Information Infrastructure.

The NCVHS believes that the recommendations in this report are important to the nation because they will facilitate significant improvements in the quality of care, improve productivity and reduce costs.

Sincerely,

/s/

John R. Lumpkin, M.D., M.P.H.
Chair

Enclosure

cc:
John Eisenberg, Co-chair, HHS Data Council
Margret Hamburg, Co-chair, HHS Data Council

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

Report to the Secretary
of the U.S. Department of Health and Human Services

on

Uniform Data Standards for Patient Medical Record Information

as required by the Administrative Simplification Provisions of the
Health Insurance Portability and Accountability Act of 1996

July 6, 2000

Report to the Secretary of HHS
Uniform Data Standards for Patient Medical Record Information

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I. EXECUTIVE SUMMARY

High quality health care depends on complete and comprehensive patient medical record information (PMRI). This information is essential to support diagnosis and treatment, measure and improve quality of care, advance public health, enhance healthcare productivity, and facilitate reimbursement. Today, however, patient medical record information is primarily written, stored, and transported on paper. This paper-based information is often illegible, subject to delays, difficult to interpret, frequently misplaced or lost, and contributes to unnecessary costs. While health care has adopted information technology for financial and administrative systems, it has made limited progress in utilizing information technology to support patient care. Today, the greatest impediment to the adoption of information technology is the lack of complete and comprehensive standards for patient medical record information.

CALLS FOR ACTION

In 1991, the Institute of Medicine (IOM) set forth a basic vision for use of information technologies in *The Computer-based Patient Record: An Essential Technology for Health Care*. In 1993, the General Accounting Office (GAO) urged the acceleration of message format and healthcare terminology standards development in *Automated Medical Records: Leadership Needed to Expedite Standards Development*. In 1999, the IOM in *To Err Is Human: Building a Safer Health System* drew national attention to medication errors that often occur as a result of illegible and incomplete information. In December 1999, President Clinton directed the Quality Interagency Coordination Task Force (QuIC) to evaluate the IOM's recommendations. In February 2000, QuIC responded with an action plan, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*. In 2000, the IOM released *Networking Health: Prescriptions for the Internet,* which criticizes the health industry for failing to take better advantage of information technologies such as the Internet.

Despite these and other calls to action, the nation still has not adopted the laws, standards, business practices, and technologies necessary to create a health information infrastructure. As a result, health care continues to fall short of its potential to improve quality and productivity and to constrain costs. To achieve further administrative simplification, it is essential that the healthcare delivery system adopt uniform data standards for patient medical record information.

LEGISLATIVE IMPERATIVE

The Provisions for Administrative Simplification in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are intended to "improve the efficiency and effectiveness of the healthcare system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." Section 263 of these provisions requires the National Committee on Vital and Health Statistics (NCVHS) to "study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information" and report to the Secretary of HHS by August 21, 2000 on recommendations and legislative proposals for such standards.

MAJOR FINDINGS

To carry out this legislative directive, the NCVHS sought input from providers, payers, vendors, terminology developers, standards development organizations, professional associations, government agencies, and medical informatics experts. It found that the major impediments to electronic exchange of patient medical record information are limited interoperability of health information systems, limited comparability of data exchanged among providers, and the need for better quality, accountability, and integrity of data.

Interoperability

Interoperability is the ability of one computer system to exchange data with another computer system. Today, health care employs many different information systems, both within an organization and across organizations. For example, a hospital may have a laboratory system from one vendor, a pharmacy system from another vendor, and a patient care documentation system from a third vendor. Physicians affiliated with the hospital also have different systems in their offices, yet need access to data from the hospital on their patients.

To achieve interoperability between different information systems, the healthcare delivery system is developing message format standards. Today, these standards have a high degree of optionality in order to accommodate the variability of workflow and availability of information in different care settings. This optionality creates the need for costly and time-consuming customization when implementing message format standards. In addition, vendors and providers have developed their own implementation guides that differ from the standards. Finally, there is little or no conformance testing of message format standards.

Non-standard implementations result in the need for costly and time-consuming customization to allow information systems to seamlessly exchange data with one another. These customized solutions contribute to high cost of systems. Such high cost, in turn, restricts the broadest possible adoption of information systems by providers. If, by accelerating uniform message format standards development and implementation, the cost of these healthcare information systems can be lowered, their market acceptance would increase. This would contribute directly to improved quality of care, improved provider productivity, and reduced healthcare costs.

Data Comparability

Comparability requires that the meaning of data is consistent when shared among different parties. Lack of comparable data can directly impact patient care. A simple example is the use by physical therapists of a pain scale that ranges from 1 to 4, and another used by nurses that ranges from 1 to 10. Obviously, pain designated at “level 3” carries vastly different meanings to these professionals.

Today, there are no healthcare vocabularies that are designated as national standards. Standard healthcare vocabularies would assure that data shared across systems are comparable at the most detailed level. Information system vendors and healthcare providers who wish to use detailed vocabularies, have had to create their own proprietary set of terms that are not comparable with other vocabularies, or have had to choose from one of several commercially-available vocabularies that do not necessarily cover all clinical areas. Without national standard vocabularies, precise clinical data collection and accurate interpretation of such data is difficult to achieve. Further, this lack of standard vocabularies makes it difficult to study best practices and develop clinical decision support.

Data Quality

It is very difficult to measure the quality of healthcare data, yet every provider can point to examples where data quality has clearly been suspect or could not be validated. Information systems today do not incorporate sufficient data editing capability, uniformity in units of measure, or other controls. Data quality is also impacted by the inability to uniquely identify patients. This can result in loss of data for patient care. The Administrative Simplification provisions of HIPAA address this issue by calling for a unique identifier for patients. However, there is public concern about the issuance of a unique identifier for patients, especially in light of the absence of healthcare privacy legislation. Finally, the criteria for data quality need to be addressed within message format and vocabulary standards in order to improve the ability to exchange accurate data for continuity of care across providers.

Other Issues

Other issues considered in this Report include the need to address the diversity of state laws with respect to retention and authentication of patient medical record information, the business case for standards development, and the need for a national health information infrastructure. Barriers to adoption of Internet applications, such as reported in the National Research Council's 2000 report, *Networking Health: Prescriptions for the Internet,* need to be overcome.

The establishment of uniform standards for patient medical record information also raises a wide range of issues relating to privacy, confidentiality, and security. A complete discussion of all these issues is beyond the scope of this Report. The NCVHS has addressed these issues in prior documents and will continue further study and report on them separately.

RECOMMENDATIONS

This Report reflects the belief that significant quality and cost benefits can be achieved in health care if clinically specific data are captured once at the point of care and that all other legitimate data needs are derived from those data. The standards for patient medical record information that will result from the recommendations in this Report will be consistent and compatible with the HIPAA financial and administrative transaction standards, including the upcoming claims attachment standards.

In consideration of broad industry testimony on these key issues, the NCVHS recommends that the Secretary of HHS:

1. Adopt the Guiding Principles for Selecting PMRI Standards as the criteria to select uniform data standards for patient medical record information (PMRI). These Guiding Principles are based on those published in the notice of proposed rulemaking for selecting financial and administrative transaction standards, which have been modified by adding characteristics and attributes that specifically address interoperability, data comparability, and data quality.

2. Consider acceptance of forthcoming NCVHS recommendations for specific PMRI standards. The first set of these recommendations will be delivered to the Secretary eighteen months following submission of this Report and will include suggested implementation timeframes that consider industry readiness for adoption. For each recommendation for PMRI standards, NCVHS encourages the Secretary to provide an open process to give the public an opportunity to comment on the PMRI standards proposals before final rules are adopted.

3. Provide immediate funding to accelerate the development and promote early adoption of PMRI standards. This should take the form of support for:

    a. government membership and participation in standards development organizations

    b. broader participation of expert representation in standards development

    c. enhancement, distribution, and maintenance of clinical terminologies that have the potential to be PMRI standards through:

        (1.) government-wide licensure or comparable arrangements so these terminologies are available for use at little or no cost.
        (2.) augmentation of the National Library of Medicine's Unified Medical Language System (UMLS) to embody enhanced mapping of medical vocabularies and classifications.

(3.) development and testing of quality measures and clinical practice guidelines, such as published in the Agency for Healthcare Research and Quality (AHRQ) clearinghouses, and patient safety measures for their compatibility with existing and developing healthcare terminologies.
(4.) development and testing in multi-agency projects, such as GCPR (Government Computer-based Patient Record) framework project.

d. coordination of data elements among all standards selected for adoption under HIPAA through the development and maintenance of an open meta-data registry and working conferences to harmonize message format and vocabulary standards.

e. improvement of drug data capture and use by:

(1.) requiring the Food and Drug Administration (FDA) to make publicly available its National Drug Codes (NDC) database registry information
(2.) requiring the FDA to develop a drug classification system based on active ingredients so that all drugs that fall into a given category can be identified by the name of that category.
(3.) encouraging the FDA to participate in private sector development and ongoing maintenance of a reference terminology for drugs and biologics that promotes the ability to share clinically specific information.

f. early adoption of PMRI standards within government programs to provide broadened feedback to the standards development community.

4. For each standard recommended by NCVHS, commit funding for development of a uniform implementation guide, development of conformance testing procedures, and ongoing government licensure of, or comparable arrangements for, healthcare terminology standards.

5. Support demonstration of the benefits and measurement of the costs of using uniform data standards for PMRI that provide for interoperability, data comparability, and data quality.

6. Support increases in funding for research, demonstration, and evaluation studies on clinical data capture systems and other healthcare informatics issues.

7. Accelerate development and implementation of a national health information infrastructure. HHS should work in collaboration with other federal components, state governments, and the private sector on demonstration and evaluation projects and test beds.

8. Promote United States' interest in international health data standards development through HHS participation in international healthcare informatics standards development organizations and, in cooperation with the Secretary of the Department of Commerce, through monitoring the activity of U.S. healthcare information system vendors abroad.

9. Promote the equitable distribution of the costs for using PMRI standards among all major beneficiaries of PMRI. This may take the form of incentives for submission of data using the PMRI standards that can support a variety of purposes, including quality improvement.

10. Encourage enabling legislation for use and exchange of electronic PMRI, including:

a. comprehensive federal privacy and confidentiality legislation. This would ensure that all health information in any medium, used for any purpose, and disclosed to any entity receives equal privacy protection under law.

b. uniform recognition by all states of electronic health record keeping; and national standards for PMRI retention and electronic authentication (digital signatures).

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II. INTRODUCTION

A. Purpose and Scope

This Report has been prepared for the Secretary of Health and Human Services (HHS) in accordance with Section 263 of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191.

These provisions state the National Committee on Vital and Health Statistics (NCVHS):

> "(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;
> (C) shall report to the Secretary not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange;"

Other provisions of administrative simplification address financial and administrative transactions (and the code sets within them), identifiers, security, and privacy. This Report addresses standards that would make the content and structure of patient medical record information (PMRI) more uniform, and hence more easily exchanged between computer systems and understood across systems. PMRI includes patient demographics, orders, observations, diagnoses/problems, allergies, medications, and other information.[1] For a more complete definition of PMRI, refer to the Glossary in Appendix D. As a result of uniform standards for such data and their exchange, PMRI systems will be better able to enhance quality, improve productivity, manage costs, and safeguard patient data.

B. Intended Audience for the Report

This Report is addressed to the Secretary of HHS, in accordance with the Administrative Simplification provisions of HIPAA as cited above. However, it is recognized that many other people will read this report and use it in a variety of ways. The Executive Summary is intended to provide a brief overview of the entire Report. The Background and General Rationale establishes the context for the issues addressed in the Report for those unfamiliar with the topic. The Overview of Standards for Patient Medical Record Information is intended for HHS staff, Congressional members and staff, and the public. It defines the major concepts in the Report, provides a brief historical framework for the standards and terminologies related to the concepts, identifies the issues surrounding these standards and terminologies, and describes the current status of the standards and terminologies that address the issues. The Recommendations section lays out the recommendations in detail.

C. Background and General Rationale

> *A lack of uniform data standards results in a patient's death because information about the patient's allergy to a particular anesthetic was not presented in a standard format and was overlooked when the patient was prepared for surgery.*
>
> *A lack of data communications standards between a home healthcare information system and the physician's information system did not convey the warning of a sudden change in a diabetic patient's serum glucose level, resulting in an emergency admission to an intensive care unit. This admission resulted in life-threatening morbidity and tens of thousands of dollars of healthcare cost that could have been avoided.*

[1] Buck AS. Joint Commission on Accreditation of Healthcare Organizations, Testimony to NCVHS CPRWG on Data Quality, September 16-17, 1999.

A lack of data comparability standards resulted in a patient having a severe reaction to a medication when a nurse administered an incorrect dosage because the standard tablet size described in the formulary at the nursing unit was different from that used by the pharmacy.

Many more examples of the need for uniform adoption of PMRI standards exist, including those described in the recent Institute of Medicine (IOM) report on patient safety.[2] The lack of complete and comprehensive standards for healthcare information systems impairs our ability to improve the quality of care and to control healthcare costs.

1. How does this Report help to address national healthcare issues?

Today, healthcare information systems are beginning to demonstrate that they can potentially improve quality and lower costs at the same time.[3] This report recommends standards that contribute not only to financial and administrative simplification, but begin to address the core clinical issues of our nation's healthcare delivery system. The information age is causing a paradigm shift in which healthcare providers will be able to more explicitly measure the quality of care and translate those measures directly into achieving further improvements in key measures of health care and wellness.

Technologically, the healthcare delivery system in the United States is considered to be among the best in the world. The U.S. has outstanding medical schools, prestigious medical research institutions, numerous local healthcare facilities, state-of-the-art medical technologies, and more well-trained healthcare professionals than in most other countries. During the last few decades the U.S. healthcare system has achieved significant improvements in the health status of our population in many key measures of health care and wellness.

However, the U.S. healthcare delivery system has some complex and serious problems. These problems include the limited ability to measure and improve quality, difficulty in controlling rising healthcare costs, serious problems related to patient safety during the patient care process, and the increasing demand for more data to support clinical research and public health practice. As we examine the root causes of and potential solutions to these problems we discover that quality improvement and cost control in health care are often interdependent, mutually supportive goals.

When we try to measure the quality of health care in the U.S. in comparison to our spending (13.5 percent of Gross Domestic Product in 1997), we see much room for improvement. For example, while the U.S. spends more than any other country on health care as a percentage of its GDP, many other industrialized nations have lower infant mortality rates and longer life expectancy.[4] Additional concern is raised by the recent report from the IOM, which estimated that medical adverse events cause more deaths annually in the U.S. than highway crashes, breast cancer, or AIDS.[5]

2. What has already been done to improve quality and control rising healthcare costs?

Many approaches and methods have been instituted in an attempt to improve quality and control rising healthcare costs. The organizational approaches that have been employed include the expansion of managed care organizations with an emphasis on wellness and disease prevention,

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[2] Institute of Medicine, *To Err Is Human: Building a Safer Health System*, Washington, DC: National Academy Press, 1999.
[3] Greenspan A. *Wall Street Journal*, January 31, 2000
[4] HHS. *Health*, September 1999 (PHS99-1232), p. 283.
[5] Institute of Medicine. *To Err Is Human: Building a Safer Health System,* Washington, DC: National Academy Press, 1999, p. 1.

establishment of integrated delivery networks with an emphasis on continuity of care, the emergence of pharmacy benefit management organizations with an emphasis on improved medication management, and the growth of group purchasing alliances with an emphasis on cost reduction of cost. Administrative and clinical methods and programs to address these issues include risk management, utilization management, case management, disease management, physician profiling, care plans, performance measurement, accreditation programs, wellness programs, and a variety of other techniques.

All of these initiatives have helped to address the quality and cost issues, but they have yet to achieve broad-based quality improvements, cost containment, and the level of productivity gains enjoyed by other sectors of the nation's economy.

3. How have other sectors of the economy been able to improve quality and control costs?

Other industries including financial services, telecommunications, transportation, manufacturing, and retailing have achieved dramatic improvements in quality, cost containment, productivity, and the introduction of new services because these industries have established information infrastructures that have brought them into the information age. For example, the financial industry has developed an infrastructure that includes online banking, automated teller machines, and electronic deposits. The telecommunications industry has developed an infrastructure that facilitates touch-tone dialing, portable phones, cellular phones, voicemail, and Internet access. The transportation industry has developed an infrastructure that facilitates online reservation services, programmed equipment maintenance, advanced scheduling, and traffic flow management. The manufacturing industry has developed an infrastructure that facilitates mass customization, just-in-time inventories, and condensed "time to market" for new products. The retailing industry has developed an infrastructure that facilitates customer relationship management, online sales of products and services, and automated inventory management.

These information infrastructures have improved the accuracy of data, lowered the cost of sharing information, facilitated improved measurements for performance and quality, enabled continuous quality improvements, spawned the availability of new knowledge-based capabilities (such as decision support), and provided new information services that improve effectiveness and efficiency.

4. Why has health care been slower than other industries to implement an information infrastructure to improve quality and control costs?

Many factors have contributed to slower adoption of an information infrastructure in health care. First, healthcare information is much more complex than information in other industries. Clinical data are textual and contextual, not simply numeric, making it more difficult for computers to process. Information technology has not yet been able to fully convert natural language to discrete data elements.

A second issue is the difficulty on the part of the healthcare industry to advance use of information technology. Other industries have typically viewed the establishment of an information infrastructure as a strategic investment and a competitive advantage. In contrast, the healthcare industry still tends to regard information systems as additional cost.

Another issue is one of behavior modification. In many healthcare institutions information systems have been adopted to support financial and administrative processes, automate some departmental systems (such as laboratory and radiology), and computerize some clinical processes (such as order communications and results reporting). However, the basic functions of clinical care, including the capture, process, review, analysis, and communication of clinically specific information as a normal

part of the patient care process is only beginning to be addressed. In most healthcare settings, the capture of patient history and progress notes continues to be performed manually and stored on paper. Physicians continue to write orders that are transcribed into order communication systems by clerical staff. Medical record folders may contain over 100 pages of paper. Information in such folders is often difficult to find, illegible, inconsistent, and incomplete. Moreover, the folder can only be in one location at a given time, so it may not always be accessible to the caregiver when needed. This environment is extremely error-prone and contributes to the caregiver's inability to measure and improve clinical outcomes.

5. How do standards for patient medical record information (PMRI) fit within a national health information infrastructure (NHII)?

An information infrastructure may be defined as including related standards, laws, regulations, business practices, and technologies. For example, information systems standards are needed to facilitate the sharing of comparable data. Federal law is needed to protect the confidentiality of information, to remove barriers to sharing data, and to define the conditions under which individuals' data may be shared—uniformly across our States. Federal regulations are needed that define consistent policies and practices to protect the integrity of and to provide security for healthcare nformation. Cost-effective systems and technologies can then be developed that utilize the infrastructure and translate system effectiveness and efficiency into value for the user.

This report will address the need for standards that support a national health information infrastructure. More specifically it will focus on those standards that have the greatest potential to improve the quality of care and control or reduce the cost of care: these are uniform data standards for patient medical record information (PMRI). PMRI includes patient demographics, orders, observations, diagnoses/problems, allergies, medications, and other information.[6] For a more complete definition of PMRI, refer to the Glossary in Appendix D.

6. What are the consequences of not having complete and comprehensive standards for PMRI?

Not having complete and comprehensive PMRI standards impairs the basic functions and effectiveness of healthcare information systems and limits our ability to achieve a national health information infrastructure. In particular, not having PMRI standards:

- Limits the ability of different healthcare information systems to communicate with one another (interoperability). This can greatly increase the cost of sharing and integrating data.

- Limits the capability to capture clinically specific information and have it automatically converted into computer readable codes (that retain their accuracy and precision of meaning). This means that healthcare information systems may be able to communicate with each other, but the data that they share is not necessarily complete, accurate, and comparable.

The lack of interoperability and comparability of healthcare data makes it difficult to process discrete data elements to support clinical decision-making, to aggregate data for quality measures, and to improve clinical processes. These constraints continue to relegate many clinical activities to sub-optimal levels of performance and quality.

[6] Buck AS. Joint Commission on Accreditation of Healthcare Organizations, Testimony to NCVHS CPRWG on Data Quality, September 16-17, 1999.

From a vendor and user perspective, the lack of complete and comprehensive PMRI standards has resulted in impaired ability to:

- Develop information systems that are more cost effective (standardized and mass-produced).
- Integrate these systems in a timely and low-cost manner (avoiding customization of interfaces and the need for translation and mapping of data).
- Capture clinically specific information that enhances quality of care, promotes evidence-based medicine, utilizes clinical decision support, and permits continuous quality improvement.
- Share comparable patient care data among multiple sites of care, and therefore enable continuity of care.

This lack of PMRI standards has served to discourage investments by those vendors and providers who attempt to develop healthcare information systems.

7. Why is it taking so long to develop and implement complete and comprehensive standards for PMRI?

The standards and processes necessary to communicate clinical information are vastly more complex than those in other industries. Standards for exchanging healthcare data must be extremely comprehensive. Healthcare language requires precision, but is also dynamic. New illnesses are continuously identified and new treatments created. However, in order to retain consistent meaning over a period of time sufficient to conduct longitudinal healthcare studies, the meaning of terms must be retained while creating new terms to address new issues. Therefore, developing PMRI standards is costly and time-consuming.

The process of developing healthcare data standards is more difficult than developing standards in other industries. This is because health care is comprised of many diverse entities such as individual and group practices, software developers, domain-specific professional associations, and allied health services. This fragmentation has slowed the dissemination and adoption of standards. It has also made it difficult to convene all of the relevant stakeholders and subject matter experts in standards development meetings, and to reach consensus within a reasonable period of time.

Many observers have noted that the healthcare delivery system appears to have placed a higher priority on acquiring information systems for reimbursement than on developing systems that support quality of care. There are several reasons for this. First, the standardization of information required for the claims process was easier to automate than the standardization of information for clinical processes. Secondly, standards for supporting clinical processes have not been universally developed or applied.

Lack of investment in healthcare information systems is further impacted by the fact that many of those who benefit by these systems do not share in the cost of implementing and using them. Many of the benefits that result from these systems are enjoyed by payers, such as insurers (both private and public) and employers, and are not shared with providers. Additionally, payers do not often compensate for the provider's burden of the time and cost of implementing these systems. The point is that savings throughout the healthcare system should be shared with those who pay for and use standardized PMRI. Otherwise, the incentive to take on the extra burden of standardization is reduced.

8. What other issues relative to PMRI should be considered?

Uniform data standards for PMRI are essential to the establishment of a health information infrastructure. The role of the government is to promote and support the public and private development and use of these standards. As these PMRI standards facilitate the development of a health information infrastructure, vendor solutions are likely to be developed to utilize this infrastructure. However, it is the marketplace and not the government that will determine the extent to which it will invest in solutions that use these standards. These solutions include clinical data warehouses and advanced data mining tools, clinical decision support systems, computer-based patient record systems, natural language processors, systems-based ontological principles, etc.

It is also important that the PMRI standards support a health information infrastructure that addresses the needs of all PMRI users, including providers, payers, public health officials, researchers, and consumers.

Another factor is the lack of uniform privacy protections for PMRI, and the lack of widely-implemented security mechanisms. The Administrative Simplification provisions of HIPAA in these two areas are good, though incomplete, steps in the right direction to correct this deficiency.

9. What benefits can we expect when standards for PMRI facilitate a health information infrastructure?

When complete and comprehensive standards for PMRI are available, vendors and users will be able to develop information systems that will:

- Capture clinically specific information more accurately, more quickly, and less expensively.
- Enable authorized caregivers to access this information from many different locations in a manner that can improve continuity of care.
- Provide clinical guidelines and protocols to clinicians to use concurrently with the patient care process.
- Prevent adverse events and other potential problems by providing warnings to the clinician concurrent with the process of patient care.
- Provide more complete and comprehensive clinical data for outcomes analysis to facilitate continuous quality improvement of clinical processes.
- Monitor the health status of elderly and homebound patients via real time or store-and-forward telecommunications to caregivers.
- Extend the knowledge and expertise of healthcare professionals at leading-edge medical facilities to underserved populations via telehealth.
- Facilitate low-cost information exchange between patients and providers via the Internet.
- Improve the ability of public health to recognize and react quickly to problems affecting the health of the public, especially in national health emergencies, by providing more accurate, complete and timely information.
- Increase the scope, efficiency, and effectiveness of clinical and health services research.

- Improve the ability to monitor and protect the confidentiality of healthcare information.

- Improve the ability to use automated, intelligent systems to identify and even correct certain problems with data quality including those associated with data capture, coding, and transmission.

- Facilitate the ability to construct and maintain a comprehensive, lifelong healthcare record that enables continuity of care.

Measuring the full benefit of the above functions and capabilities is not possible until a threshold level of PMRI standards implementations within the health information infrastructure is achieved. However, there are examples of pioneering efforts that have produced impressive results:

- At Kaiser-Permanente of Ohio, smoking cessation reminders automatically provided to the caregivers at the time of visit reduced smoking prevalence in the region by 12%.[7]

- Brigham & Women's Hospital in Boston found that a system displaying charges for lab tests being ordered prompted physicians to choose less expensive tests. In one year, a 5% reduction in ordering saved the hospital approximately $1,000,000.[8]

- LDS Hospital in Salt Lake City employs computerized adverse drug event monitoring. In 1992, 569 adverse drug events were prevented, which eliminated an average of 1,104 inpatient days at a savings of $1,103,291.[9]

- At Queen's Medical Center, Hawaii, automating the guideline for ordering restraints improved compliance with the restraint guideline from 9% to 98% within weeks.[10]

- At Regenstrief Institute, Indianapolis, a two-year study of 1,491 decision support rules executed for 12,000 patients demonstrated a 20% increase in compliance with reminders for all classes of providers.[11]

These and other examples in peer-reviewed medical literature lead us to the conclusion that information systems have the potential to both improve the quality and lower the cost of health care. These examples are isolated in large part, however, because of the lack of standards for seamless exchange of data and standards to achieve data comparability and quality.

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[7] Khoury .A et al. "The Medical Automated Record System," *Third Annual Nicholas E. Davies CPR Recognition Symposium Proceedings,* Bethesda, MD: Computer-based Patient Record Institute, 1997, p. 66.

[8] Teich JM, et al. "Toward Cost-Effective, Quality Care: The Brigham Integrated Computing System," *Second Annual Nicholas E. Davies CPR Recognition Symposium Proceedings,* Bethesda, MD: Computer-based Patient Record Institute, 1996, p. 28.

[9] Grandia LD, et al. "Building a Computer-based Patient Record System in an Evolving Integrated Health System," *First Annual Nicholas E. Davies CPR Recognition Symposium Proceedings,* Bethesda, MD: Computer-based Patient Record Institute, 1995, p. 29.

[10] Davis DC, et al. "Clinical Performance Improvement with an Advanced Clinical Information System at The Queen's Medical Center," *Fifth Annual Nicholas E. Davies CPR Recognition Symposium Proceedings,* Bethesda, MD: Computer-based Patient Record Institute, 1999, p. 113.

[11] McDonald CJ, et al. "The Three Legged Stool: Regenstrief Institute for Health Care," *Third Annual Nicholas E. Davies CPR Recognition Symposium Proceedings,* Bethesda, MD: Computer-based Patient Record Institute, 1997, p. 116.

10. Summary of general rationale

The ability of our healthcare delivery system to manage costs, improve productivity, enhance quality of care, and safeguard patient data is severely constrained by the lack of complete and comprehensive PMRI standards. This Report discusses the issues and offers recommendations that address the development and use of these standards.

D. Process of Studying Issues and Making Recommendations

To study the issues and make recommendations associated with uniform data standards for the electronic exchange of PMRI, NCVHS created the Computer-based Patient Record Work Group as part of its Subcommittee on Standards and Security (see Appendix A). The Work Group was charged to solicit information, guidance, and recommendations from experts in the field (see Appendix B for work plan). A total of 92 individuals in 11 days of hearings over a period of 10 months provided testimony. Appendix C provides a list of testifiers by category. Testifiers were asked to comment on their definition of PMRI, discuss the need for comparability of PMRI, and address specific issues relative to focus areas. These focus areas included message format standards, medical terminologies, data quality, privacy, diverse state laws, business case for standards, and relationship to a national health information infrastructure. They were also asked to identify problems within these focus areas and recommend what the role of the government should be in addressing these problems.

Reflecting the consensus of testimony, NCVHS identified key issues, observations, and assumptions relative to PMRI standards and their electronic exchange. These findings led the Committee to develop recommendations that address the selection of PMRI standards, the acceleration of the development of PMRI standards, the early adoption of PMRI standards, and the relationship of PMRI standards to other issues. The Committee also solicited feedback on these recommendations from external reviewers.

The NCVHS also developed a set of guiding principles for the selection of PMRI standards. This was done to ensure consistency with those guiding principles already established for selecting the financial and administrative transaction standards, and to ensure that they were applicable to the selection of PMRI standards. Therefore, some important additions and modifications to the existing guiding principles were needed. The resulting principles are recommended to become the Guiding Principles for Selecting PMRI Standards. (See Section IV, page 38.)

III. OVERVIEW OF STANDARDS FOR PATIENT MEDICAL RECORD INFORMATION

In order to establish the context for recommending uniform data standards for PMRI and the electronic exchange of such information, it is important to review some basic concepts and terms, identify the overarching issues, and describe the current status of PMRI standards.

A. PMRI Standards Concepts

1. Patient medical record information (PMRI)

Patient medical record information (PMRI) is information about a single patient generated by healthcare professionals as a direct result of interaction with the patient, or with individuals who have personal knowledge of the patient, or both. This information includes demographics, health history, details of present illness or injury, orders for care and treatment, observations, records of medication administration, diagnoses/problems, allergies, and other health information.

2. Electronic exchange of PMRI

Electronic exchange of PMRI is the electronic communication of data, audio, and/or images between healthcare information systems. It does not imply a specific type of information system or repository of data. In other words, if a hospital has administrative, patient billing, laboratory, pharmacy, and patient medical record information systems, they all should exchange data seamlessly, with the ability for the data to be interpreted consistently and accurately, and with privacy and security measures in place to safeguard confidentiality, data integrity, and availability.

3. Uniform data standards for PMRI

Uniform data standards are methods, protocols, and terminologies agreed on by the industry to allow disparate information systems to operate successfully with one another. NCVHS has identified these standards as including: those required to identify individuals, populations, and events; data elements and definitions required to produce PMRI; sources for the data elements; ways of classifying and coding the data elements to achieve comparability of data; and data transmission formats and standards to achieve interoperability.[12]

4. Health information infrastructure

A health information infrastructure is a set of standards, laws, regulations, business practices, and technologies that facilitate exchange of PMRI by authorized users for legitimate uses. For example, a hospital may need to exchange patient-identifiable data with a physician's office practice management system in order to capture hospital charges. Patients may complete a health risk assessment that contributes data to a physician's electronic medical record system. A hospital may receive a patient's test results from a reference laboratory. A radiologist may conduct a teleradiology consultation with another radiologist in another country. Other systems that exchange PMRI could include those supporting quality improvement, public health surveillance, research, and other authorized uses that may be local, regional, national, or even international in scope.

[12] The National Committee on Vital and Health Statistics, 1996-98, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, Hyattsville, MD, December 1999, p. 32.

5. Health information vs. PMRI

A broader context of health information, beyond patient medical record information, is emerging today. This context includes not only data about the illness or injury of a patient, but also about wellness, disease prevention, and health promotion for an individual. Such health information is collected and stored not only by traditional members of the healthcare delivery system but also directly by individuals themselves and by others. This information may be communicated across the Internet and housed in a Web-based data repository.

6. HIPAA Administrative Simplification requirements for PMRI

The HIPAA Administrative Simplification legislation directed NCVHS to focus specifically on uniform data standards for patient medical record information and its electronic exchange. Accordingly, this Report is limited primarily to the issues of interoperability, comparability, and data quality. It also references the broader issues of privacy, diverse state laws, the business case for standards development, and the national health information infrastructure, but does not address them in depth.

B. Evolution of Healthcare Informatics Standards

1. Healthcare informatics standards history

The field of healthcare informatics standards started in the late 1960s. One of the earliest efforts took place under the jurisdiction of ASTM (American Society for Testing and Materials). Standards for laboratory message exchange, properties for electronic health record systems, data content, and health information system security were among the first healthcare informatics standards that ASTM developed. The College of American Pathologists started developing a nomenclature for pathology in 1965, which has now become the internationally recognized Systematized Nomenclature of Human and Veterinary Medicine[13] In 1974, the first Uniform Hospital Discharge Data Set (UHDDS) was promulgated by the Secretary of the HHS, based on advice from NCVHS.[14] In 1987 Health Level Seven (HL7) began to develop a wide range of message format standards for patient registration, orders, and observations reporting and published its first version in October of that year.[15] In 1991, the Accredited Standards Committee (ASC) X12N Insurance subcommittee started developing standards for interactive communication of health claims and other financial and administrative transactions.[16]

Initially, a need for a standard in a specific area was often identified by a clinical specialty group or by a professional or trade association. For example, the American College of Radiology and National Electrical Manufacturers Association identified a need in 1985 for a non-proprietary data interchange protocol, digital image format, and file structure for biomedical images and image-related information, now the Digital Imaging and Communications in Medicine (DICOM) standard. The National Council for Prescription Drug Programs (NCPDP) is another group that created a successful standard focused on a very specific niche area of health care – transactions between community pharmacies, payers, and pharmacy benefits managers. The Logical Observations Identifier, Names and Codes (LOINC)

[13] Kudla K, College of American Pathologists
[14] U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Health Statistics, *The National Committee on Vital and Health Statistics, 1992*
[15] Hammond, W. Ed. "Health Level 7: An Application Standard for Electronic Medical Data Exchange," *Topics in Health Record Management,* 1991, 11(4), 59-66
[16] Data Interchange Standards Association (DISA) web site (www.disa.org)

database is used widely by commercial labs and government agencies and has been provided at no cost on the Worldwide Web since 1995.[17]

Standards in other industries often arise from a dominant vendor (e.g., Microsoft Disk Operating System) or industry action group of vendors willing to converge on a standard in order to enable widespread use of a technology (e.g., ATM banking transactions). In contrast, healthcare standards developed by specific vendors often do not rise to dominance because there are no truly dominant vendors in the industry, nor are there industry action groups powerful enough to achieve voluntary convergence.

2. Standards development organizations

As a result of the diverse needs and fragmentation in health care, many different standards development organizations have emerged. Many of these groups are highly focused and fill a very specific need. When a standards development organization recognizes a need, which may also be related to another focus area, this creates the potential for coordinated standard development. For example, many of the nursing terminologies focus on a specific aspect of nursing, but by necessity must incorporate some common data elements. In the absence of a coordination point for healthcare informatics standards, the potential for overlaps or gaps occurs, where no organization is addressing a standards need.

3. Accreditation and coordination of standards development organizations

The American National Standards Institute (ANSI) has been the "accreditor and coordinator of the U.S. private sector voluntary standardization system" since 1918, "ensuring that its guiding principles – consensus, due process, and openness – are followed by the entities accredited under one of its three methods of accreditation (organization, committee, or canvass)." ANSI "promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where these meet the needs of the user community." "A Standards Board is a standing organization within ANSI having planning and coordination responsibilities on a continuing basis for a defined scope of activity."[18] In 1991, the predecessor organization to the ANSI Healthcare Informatics Standards Board (HISB) was created, initially to respond to European efforts in healthcare informatics standards. It exists currently to coordinate national healthcare informatics standards. ANSI HISB has conducted an extensive inventory of standards that contributed to the selection process for the proposed transaction and code set standards under HIPAA Administrative Simplification. ANSI HISB is voluntary in nature, and it focuses primarily on establishing communications among standards development organizations. As a result of this communication focus, several bilateral and multi-lateral agreements among standards groups have developed. Still, the state of healthcare informatics standards remains complex and underdeveloped, as explained in the following two sections.

C. Overview of Issues Relating to Data Standards for PMRI

1. Interoperability

Interoperability refers to the ability of one computer system to exchange data with another computer system. There are three levels of interoperability.

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[17] Forrey AW, McDonald CJ, DeMoor G, et al. The Logical Observation Identifier Names and Codes (LOINC) Database: A Public Use Set of Codes and Names for Electronic Reporting of Clinical Laboratory Test Results," *Clinical Chemistry,* 1996, 42, 81-90.

[18] American National Standards Institute, Questions & Answers

"Basic" interoperability allows a message from one computer to be received by another but does not require the ability for the receiving computer to interpret the data.

"Functional" interoperability is an intermediate level that defines the structure, or format, of messages (hence the term message format standards). Functional interoperability defines the syntax of the message. It ensures that messages between computers can be interpreted at the level of data fields. For example, when one computer has a structured data field for Ear Exam, that computer should be able to pass data from that structured data field on to another computer and have it appropriately stored in a comparably structured field for Ear Exam in the receiving computer. Neither system has understanding, however, of the meaning of the data within the fields.

"Semantic" interoperability provides common interpretability, i.e., information in the fields within the message can be used in an intelligent manner. At the highest level, semantic interoperability takes advantage of both the structuring of the message and the codification of the data so that the receiving computer can interpret the data. That is, the object Ear Exam may have an attribute "inflammation" with a value "positive," and this could be used to trigger knowledge tools (e.g., guidelines, protocols, and alerts) in the receiving computer. This would help the caregiver make the best possible choice of medication, follow best practices for subsequent care, and offer tailored instructions to the patient.

The healthcare delivery system today employs many different information systems from different vendors, both within a single organization and across multiple organizations. For example, a hospital may have a laboratory system from one vendor, a pharmacy system from another vendor, and a patient care documentation system from a third vendor. Physicians affiliated with the hospital also have different systems in their offices, yet need access to data from the hospital on their patients. These different systems are often not interoperable.

Existing message format standards intended to achieve interoperability between different information systems have a high degree of optionality and are often not implemented in a standard manner. Options were incorporated into these standards in order for vendors to accommodate the variability of workflow and the availability of information in different healthcare settings. This optionality can require costly and time-consuming custom programming. Even larger issues relate to non-standard implementations of the standards and the enormous variability of vocabulary.

Developing customized solutions to exchange data contributes to high costs of healthcare information systems. The high cost of systems development inhibits vendors from researching and developing new and better ways to capture and process data. The high cost of customized solutions also restricts the broadest possible adoption of information systems by providers. If, by accelerating PMRI standards development and implementation, we can lower the cost of these healthcare information systems, their market acceptance would increase. This would contribute directly to improvements in quality of care and encourage quality improvement studies that will improve provider productivity and reduce service costs.

Standard Implementation Guides to Improve Interoperability

For many reasons, institutions and vendors develop their own implementation guides that may contradict or avoid requirements that are very specifically defined in the standard. Further, some implementations may differ from the standard, including being more specific than the standard, without indicating these differences or providing an implementation guide at all. It is important to have a very specific but standard implementation guide that is employed by all vendors for each kind of PMRI message and to have conformance tests that can verify a vendor's conformance to the standard. In the long run this will provide significant savings to the industry.

Conformance Testing to Improve Interoperability

There currently is little or no conformance testing of message format standards. As administrative simplification begins to require standard transactions and trading partners must assure that their data exchange is compliant, conformance testing of standards will be essential. Conformance testing performed by an independent organization assures that a standard has been implemented according to its implementation guidelines and that it performs its functions as intended.

Greater Semantic Precision to Improve Interoperability

Until recently, message format standards have operated at the level of functional interoperability—passing messages between computers and ensuring their appropriate structure, but not ensuring that the content of the messages is interpretable. Message format standards developers are beginning to coordinate their activities with healthcare terminology standards developers to specify the content of the message and make the message format standards interoperable at the semantic level. Further coordination among message format standards developers and healthcare terminology standards developers is needed to promote harmonization, which is the process of incorporating medical terminologies into message formats in a consistent and agreed-upon manner so that the messages can be appropriately interpreted.

Addressing Gaps and Inconsistencies and the Need for Acceleration to Improve Interoperability

The healthcare market is highly fragmented and new technologies are continually being introduced. As a result, gaps and inconsistencies in message format standards occur. Also, standards development processes are by nature slow in order to permit due process. These factors make it difficult to address all market needs in a timely fashion. Enhanced coordination and acceleration of standards development are needed to fill gaps and address emerging technologies in a timely manner.

2. Comparability

Comparability requires that the meaning of data is consistent when shared among different parties. The healthcare terminology used by one clinician in one context must mean the same to another clinician in a similar context. For example, a pain scale used by a physical therapist must either utilize the same measurements or automatically map to a pain scale used by a nurse. A pain level of 3 as described by a physical therapist on a scale of 1 to 4 is quite different than a pain level of 3 as described by a nurse on a scale of 1 to 10. In this example, semantic comparability requires that the matching terms have their context supplied. However, simply supplying context to a linguistic match, does not necessarily provide semantic comparability. For example, if the abbreviation “BPH” is determined to always mean benign prostatic hypertrophy, then it should never be used in any context as shorthand for “blood pressure is high.” Comparability of data also allows clinical findings, trends, population measures, and clinical operations to be validated and contrasted.

Semantic comparability of data, however, does not necessarily ensure that the data are accurate. For example, diagnosing a patient with BPH when he actually has prostatic cancer is inaccurate.

Neither healthcare information systems vendors nor healthcare organizations have adopted a standard set of data elements necessary to supply basic PMRI content, nor a medical vocabulary to assure that data shared across systems are comparable at the most detailed level. Many organizations adopt their vendor’s proprietary data dictionary and code sets or develop one of their own. The result is that these data elements may be incomplete for patient care and may not be

comparable when aggregated for clinical research or public health initiatives. Not only do they not use standard terminologies, these data dictionaries often are limited in scope to administrative data and/or certain clinical domains. Lack of a highly detailed, standardized data set and data definitions can lead to misunderstandings and interpretation problems when used for direct patient care. Lack of comparable data can also directly impact patient care, for example, when different data elements are used to convey the same meaning. Lack of comparable data also makes it difficult to study best practices and to develop widespread quality of care guidance. When statistical classification systems are used, varying rules associated with different reimbursement schemes often compromise the quality of data. Data that have been classified into large groupings also may not have sufficient clinical detail to trigger clinical decision support alerts or to satisfy scientific evidence-based requirements for presenting knowledge that feeds into the development of clinical decision support tools.

Terminology Concepts

In order to be precise in our own use of language with reference to the concept of healthcare terminology, we describe several associated concepts and how they are being used in this Report:

- "Terminology" is considered to be "a collective term used to describe the continuum of code set, classification, and nomenclature [or vocabulary]." [19]

- A "code" is a representation assigned to a term so that it may more readily be processed. In general, most terminologies incorporate a coding system for computer processing. A simple listing of codes and the terms with which they are associated is a code set.

- A "classification" arranges or organizes like or related terms for easy retrieval.[20] For example, a classification system might organize terms by major categories, alphabetically, chronologically, or numerically.

- A "nomenclature, " or "vocabulary," is a set of specialized terms that facilitates precise communication by minimizing or eliminating ambiguity. The term "controlled vocabulary" indicates only the set of individual terms in the vocabulary. A "structured vocabulary," or "reference terminology," relates terms to one another (with a set of relationships) and qualifies them (with a set of attributes)[21] to promote precise and accurate interpretation. These relationships and attributes may be represented in some type of an information model.

Vocabulary Characteristics and Attributes

Comparability of PMRI is achieved through use of vocabularies that incorporate all the characteristics and attributes that are necessary for clinicians to use them as standards for clinical information. There have been several scholarly papers that have set forth such characteristics and attributes[22, 23, 24, 25, 26]

[19] "Action Plan for Development of Health Data Standards," Computer-based Patient Record Institute, September 1996.
[20] "Clarification of Clinical Data Sets, Vocabularies, Terminologies, and Classification," *Journal of AHIMA*/February 1999 – 70/2, 72-73.
[21] Kannry JL, et al. "Portability Issues for a Structured Clinical Vocabulary: Mapping From Yale to the Columbia Medical Entities Dictionary," *Journal of the American Medical Informatics Association*, Jan/Feb 1996, 3/1, 66-78.
[22] Chute CG, et al. "A Framework for Comprehensive Health Healthcare terminology Systems in the United States: Development Guidelines, Criteria for Selection, and Public Policy Implications," *Journal of the American Medical Informatics Association,* Nov/Dec 1998, 5/6, 503-510.
[23] Spillers R., Written Testimony to NCVHS on Standard Reference Ontology
[24]Cimino JJ. "Desiderata for Controlled Medical Vocabularies in the Twenty-First Century," *Methods of Information in Medicine,* 1998, 37(4-5), 394-403.

The ASTM Standard of Quality Indicators for Controlled Health Vocabularies discusses these characteristics within four topics: general characteristics, structure, maintenance, and evaluation[27]

- General characteristics relate to utility and appropriateness in clinical applications, including that concepts are not vague, ambiguous, or redundant; purpose and scope are clear; coverage is in-depth, explicit, and comprehensive; there are systematic and formal definitions of all concepts; and the concepts are built into a reference vocabulary.

- Structure of the vocabulary model determines the ease with which practical and useful interfaces for term navigation, entry, or retrieval can be supported.

- Maintenance characteristics provide the technical choices which impact the capacity of a vocabulary to evolve, change, and remain usable over time, including context-free identifiers, persistence of identifiers, and version control.

- Evaluation criteria address how a vocabulary should be evaluated, and include a clear statement of purpose and scope, availability of tools for mapping, and usability.

Data Capture Challenges

Ideally, data should be captured once for patient care purposes at the most granular or precise level. All information required for other purposes, such as that required for reimbursement, public health, research, and other uses of data should be derived therefrom.[28] Few healthcare information systems today, however, are capable of supporting the practitioner in capturing clinically specific data. Methods that currently exist to capture data include keyboard entry, mouse clicks, bar codes, light pens, touch screens, document imaging, dictation (and associated transcription), and speech recognition technology. A major requirement to encourage clinician use of information systems is the existence of a critical mass of information in the system, so that the clinician can access the computer as the sole source of required information. Additional requirements include that the data capture process be fast and simple and that value to the individual user be clearly demonstrable.

The biggest challenge in using a healthcare vocabulary is to balance usability of the system with the necessity to capture information in a structured form that permits encoding of the data by the system. For example, many physicians order vital signs to be taken at specific intervals, but each physician may have a different concept of what is included in vital signs. To achieve precision, it would be necessary to have the physician check off explicitly what vital signs are to be taken – temperature, pulse, respiration, blood pressure (standing, sitting, or supine), etc. Yet, entering data at this level of detail is very time-consuming.

One solution to the challenge of capturing codable data would be to automatically encode narrative text. Several "text processing" methods are currently in development to parse text from both traditional transcriptions and those created through speech recognition technology, or from documents scanned with optical character recognition. The ability of the system to translate this data into encoded form is a promising method to achieve comparability of data. However, the parsing methodologies that are

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[25] Elkin PL, et al. "The Role of Compositionality in Standardized Problem List Generation," in: Cesnik B, McCray AT, and Scherrer JR, eds. *Ninth World Congress on Medical Informatics*, IOS Press: 1998, pp. 660-664.
[26] Rossi-Mori A, et al. "Semantic Standards for the Representation of Medical Records," *Medical Decision Making,* 1991; 4(Suppl): S76-80. (See also ToMelo Project, www.ehm.kun.nl/tomelo)
[27] ASTM, Standard Specification for Controlled Health Vocabularies, 2000
[28] McDonald CJ. "Quality Measures and Electronic Medical Systems," *Journal of the American Medical Association,* Vol. 282 No. 12, September 22/29, 1999, p. 1181-1182.

dependent upon a reference vocabulary are in early development and are limited because there is no standard healthcare reference terminology yet existing. [29] Furthermore, not all clinicians in all settings will want to perform narrative documentation. In fact, clinicians in some settings may prefer using data entry technologies such as touch-screen or pick-lists that are supported by a structured vocabulary.

3. Data quality, data accountability, and data integrity

The first function of PMRI is communication. PMRI is necessary for communication among the patient's multiple caregivers and to overcome the fallibility of human memory between episodes of care. A second critical function of PMRI is to provide the basis for assessing and continuously improving the performance (effectiveness and efficiency) and thereby improving quality of the healthcare system. A third function is to facilitate adverse event reporting and contribute to producing and analyzing population measures, such as those found in public health surveillance, public health indicators, and so forth.

All of these functions require that healthcare information must possess standard features and characteristics of data quality, data accountability, and data integrity. These concepts are closely related. Data quality refers to the functions and characteristics that must be incorporated into PMRI standards to ensure that data are without error. Data accountability requires that the design of PMRI standards incorporate the identification of the entity associated with the data. Data integrity is a security feature that ensures data have not been altered.

Data Quality

It is very difficult to measure the quality of healthcare data. Every user of healthcare data can point to examples where data quality is suspect and/or cannot be validated for one of the following reasons:

- Erroneous data and variation in the rigor of data editing: The level of sophistication and rigor of processes to edit and audit data varies considerably among institutions and results in variation of data accuracy.

- Missing data: Data that could be potentially entered but are missing or are entered incompletely. This may be the result of lack of training, lack of data entry devices, lack of time, or lack of accommodation by the system. There may be no adherence to standard data content requirements and thus no place in the information system for entering certain data.

- Unstructured data: While narrative data are often essential, abstracted data from free text are often inaccurate, inconsistent, and incomplete.

- Lack of standardized data definitions: Despite some commonality of data dictionaries, different provider settings and different healthcare professions continue to use different definitions for terms within these dictionaries.

- Lack of uniformity in units of measure: Different healthcare professions often adopt different scales for the same measure, including English vs. metric units of measure. For example, the pain scale used by physical therapists and nurses differs such that a high rating by a physical therapist may be interpreted by a nurse as only a moderate rating.

[29] Eisenberg F, SMS, Testimony to the NCVHS CPRWG on Data Quality, Accountability, and Integrity, October 14, 1999.

- Use of nonstandard codes: Some health plans do not use the current version of standard diagnosis or procedure code systems or coding guidelines. Some require providers to use health plan- or payer-developed diagnosis or procedure codes (in place of or as a supplement to ICD-9-CM or CPT-4). Use of such nonstandard code systems hampers comparable performance measurement and requires tracking of multiple coding schemes for providers working for multiple health plans.

- Modification of standard codes: Some health plans that use only standard codes sometimes modify the definitions to accommodate billing and payment needs, thereby impeding the ability to compare performance of health plans.

- Limitations of current classification systems: Current proprietary and standard classification systems, particularly those designed specifically for billing purposes, do not always capture healthcare data as needed for performance measurement or quality improvement processes.[30, 31]

- Lack of ability to uniquely identify patients: Because each provider creates its own patient medical record identifier system and maintains its own patient index, patients have different identifiers at each location where they have received care. This makes it very difficult to seamlessly exchange data, when authorized, among providers. Additionally, different systems that assign identifiers often collect different information, making it difficult to map identifiers. For instance, one system may capture patient name, address, telephone number, and date of birth. Another system may substitute social security number for date of birth, not capture telephone number but capture mother's maiden name. Sometimes patients get assigned several different numbers by one provider, such as when a patient has a name change or uses a nickname on a subsequent visit. This can result in loss of data for patient care purposes. It constrains the ability to exchange data across providers for continuity of care. As providers merge and consolidate, there is a huge cost to merging patient indexes into an enterprise-wide master patient index.

Data Accountability

Data accountability refers to the identification of the healthcare party (e.g., individuals, organizations, business units) or agent (e.g., software, device, instrument, monitor) that is responsible for data origination, amendment, verification, translation, stewardship, access and use, disclosure, and transmission and receipt.[32] Information on who, what, when, where, how, under what conditions, and in what context is often incompletely captured. A unique provider identifier, as provided for under the Administrative Simplification provisions of HIPAA, assigned to each caregiver is essential for ensuring complete capture of information about who had access to what data. Finally, evidence of accountability often does not persist throughout the life of the data, making auditing difficult or impossible.

Data Integrity

Data integrity means that data have not been altered or destroyed in an unauthorized manner. Data integrity is both a security and quality principle that prevents information from being modified or otherwise corrupted, either maliciously or accidentally.

[30] Jenich, H, IPRO, Testimony to NCVHS CPRWG on Data Quality, September 16, 1999
[31] Griffith, SP, Indian Health Service, Testimony to NCVHS CPRWG on Data Quality, September 16, 1999.
[32] Dickinson, GL, Per Se Technologies, Inc. Testimony to NCVHS CPRWG on Data Quality, Accountability, and Integrity, October 14, 1999.

In addition to addressing data integrity here under data quality, data integrity is also addressed in the HIPAA Security Notice of Proposed Rulemaking.

4. Other issues

From hearing testimony associated with interoperability, comparability, and data quality, the NCVHS identified other issues relevant to PMRI standards. Some of these issues are already being addressed by proposed regulations under HIPAA Administrative Simplification or through other reports from NCVHS. However, these issues remain relevant to PMRI standards.

Privacy, Confidentiality, and Security

Privacy, confidentiality, and security issues must be addressed in order for the public to trust having their PMRI exchanged in electronic form. Virtually every testifier cited these issues when addressing uniform data standards for PMRI and the electronic exchange of such data.

There is public concern that PMRI in electronic form may compromise an individual's privacy by reducing the confidentiality of the information; this public concern has not been alleviated by the limited scope of the privacy protections under HIPAA.[33] Many healthcare professionals share this concern. On the other hand, many believe that the existence of electronic security tools will protect the confidentiality of PMRI even better than in their current paper form. In the absence of national legislation to protect the privacy of PMRI, however, public distrust is likely to continue to be the most important barrier to the acceptance of a national health information infrastructure that can help us to improve quality and control costs.

Another problem is that businesses providing Web sites to collect health information from consumers to provide lifetime health record repository services, consumer health education, and consumer-oriented e-commerce (e.g., sites filing prescriptions and selling health-related products) are often not covered entities as defined by HIPAA regulations. In many cases they do not have business partner relationships with covered entities. As a result, the healthcare information these businesses collect is not protected health information subject to HIPAA regulation.

In addition to these general concerns and those already addressed by NCVHS in its comments on the proposed rule for Standards for Privacy of Individually Identifiable Health Information, several other specific issues also surfaced. Several testifiers reported that use of offshore transcription and other information services for healthcare operations for which they contract is a significant privacy concern with respect to electronic PMRI. Some foreign countries may not follow the same principles with respect to protecting private health information as exist in the United States. Privacy and confidentiality must be addressed in contractual agreements, generally covered through international treaties.

A significant privacy concern is the potential for unauthorized disclosure of data by business partners that provide services to the healthcare organization. These businesses have received the data initially under contract to perform specific healthcare operational services. The concern is that these businesses may mine these data for information of value to them, without the knowledge or consent of their clients or the patients whose data are being mined, and may make unauthorized disclosures. This may occur when the businesses store transcriptions, maintain pharmaceutical databanks, provide remote connectivity options, or serve as application service providers.

[33] Testimony to NCVHS Subcommittee on Privacy and Confidentiality, Chicago, June 1998.

The establishment of uniform standards for PMRI raises a wide range of issues related to privacy, confidentiality, and security. A complete discussion of all these issues is beyond the scope of this Report. The NCVHS has addressed these issues in prior documents and will continue to further study and report separately.

Diverse State Laws

Diverse state laws impact the ability to achieve uniformity and to exchange medical record information efficiently.[34]

Achieving widespread use of electronic PMRI is a necessary component of building a national health information infrastructure that can make possible the provision of integrated healthcare services across multiple settings and providers of care. Diverse state laws, however, force vendors to alter their systems for different states, which dramatically increases the time and cost to develop PMRI systems. Some of these diverse state laws mean that different states have different rules for patients to access their records, different periods of retention for records, and different requirements for authentication of records.

States also vary widely in rights of patients to receive a copy and/or view their own medical records. At the present time, 33 states grant access by patients to their records held by hospitals and healthcare facilities; 13 states grant access to records held by health maintenance organizations; 16 states grant access to records held by insurance companies; and 29 states grant patients access to records held by some provider, but each state defines the access differently.

There is also diversity with respect to record retention. The Medicare Conditions of Participation for Hospitals state that "medical records must be retained in their original or legally reproduced form for a period of at least 5 years". Individual state statutes vary. For example, California hospitals must maintain medical records for a minimum of 7 years following patient discharge, except for minors' records, which must be maintained for at least 1 year after a minor has reached age 18, but in no event for less than 7 years. In New York, medical records must be retained for a period of at least 6 years from the date of discharge or 3 years after the patient's age of majority (18 years), whichever is longer, or at least 6 years after death.

Authentication requirements also vary significantly and as a result may render electronic signatures invalid. Authentication requirements are often embedded in state statutes that do not necessarily pertain directly to medical records or health care but address business records in general. The Medicare Conditions of Participation for Hospitals state "all entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished. The author of each entry must be identified and must authenticate his or her entry. Authentication may include signatures, written initials or computer entry." The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires that hospitals have only discharge summaries, history and physical examinations, consultation reports, and operative reports authenticated. There must be a medical staff policy regarding authentication of entries in the medical record. Many states require that entries in the medical record be dated and signed. Few states have recognized the use of electronic authentication. Currently, both Illinois and New York permit electronic authentication.

In summary, diverse state laws are barriers to the electronic exchange of PMRI because different states have different requirements for maintenance or retention of patient records on paper or other

[34] Frawley K. American Health Information Management Association, Written Testimony to NCVHS CPRWG, 1999.

media that are incompatible with full computerization of PMRI. Diverse state statutes and regulations result in discrepancies concerning authentication, retention, permanence, and other data features that increase costs and delay availability of electronic PMRI solutions.

Business Case for Standards Development

Another issue that was identified is the need to support industry investments in the development of PMRI standards. Standardization increases productivity by reducing the need for customization, decreasing errors through applying single meanings, and simplifying steps in procedures. Yet, it is difficult for any individual provider or vendor to obtain value from its contributions to the standards development process when these benefits accrue primarily to the healthcare system as a whole and not directly to any one particular provider or vendor.

Neither the hearings conducted by the NCVHS nor a review of the literature has revealed a formal written business case to justify the investment in the development of PMRI standards. However, many references exist that endorse investment in the development and implementation of standards in general and support the concept that standards remove impediments to addressing broader issues of controlling healthcare costs and improving quality.[35, 36, 37, 38] Although a conclusive business case does not exist, many vendors, users, and professional associations have chosen to invest in the development of PMRI standards. They believe in the crucial role these standards will play to enhance their products and improve their information systems. Standards will, thus, improve the effectiveness and efficiency of their services, and improve the performance of our national healthcare delivery system.

The level of participation in the standards development process by patient advocacy organizations, minority groups, privacy advocacy organizations, certain healthcare professionals and vendors, and others is insufficient to assure broad-based PMRI standards. Message format standards development organizations have a particular need for broader and more active participation by clinicians. Clinician participation is required for verifying the appropriateness of PMRI standards against clinical processes, work flow, data capture, and data content and structure; and for prioritizing areas for standards efforts (such as problem lists, reasons for visit, indications for orders, diagnoses, procedures, and treatments).

In addition to inconsistent representation in U.S. standards development activities, U.S. representation in the international standards PMRI development process is impaired by a lack of official representation by U.S. subject matter experts at international standards meetings. This situation may result in putting U.S. healthcare information systems vendors in a position of being unable to compete effectively in the international marketplace.

National Health Information Infrastructure

PMRI standards are one component of the broader national health information infrastructure. (See also the forthcoming NCVHS report on National Health Information Infrastructure.) A health information infrastructure includes the use of PMRI not only in patient care but also in disease prevention, wellness promotion, and health policy decision-making. Systems, policies, and people

[35] Institute of Medicine. *The Computer-based Patient Record: An Essential Technology for Health Care*, National Academy Press, Washington, DC, 1991
[36] Unter BD. "The Importance of Standards to Hewlett-Packard's Competitive Business Strategy," *ASTM Standardization News,* December 1996.
[37] Blair J. "Standards Bearers," *Healthcare Informatics,* February 1998.
[38] Board of Directors of the American Medical Informatics Association, "Standards for Medical Identifiers, Codes, and Messages Needed to Create an Efficient Computer-stored Medical Record," Position Paper

with specialized training are also needed to process PMRI, to aggregate PMRI for public health use, and to analyze outcomes. As our healthcare delivery system moves into the information age, it becomes clear that uniform data standards for PMRI are essential for all sectors of our healthcare delivery system.

Caregivers, including providers and clinicians, need comparable PMRI seamlessly integrated from all sources to treat patients, ensure continuity of care, measure performance, and improve quality and productivity. Advances in technology have expanded information management options to such an extent that they are propelling the healthcare industry to rethink the patient record paradigm. The healthcare industry is moving from the provider's traditional linear paper record of patient care events to the concept of a virtual health record. In this paradigm, PMRI is gathered from multiple existing systems and made available on an as-needed basis around-the-clock to authorized caregivers with proper access credentials and through secure transmission media.

Public health needs PMRI to monitor the health status of the population, create public health programs to improve health status, and to manage threats to the health status of our communities. PMRI in its new virtual form will provide a longitudinal view of anonymized data to identify factors that affect population health at all life cycle stages. Data extraction will not require manual intervention, so that significantly more data, targeted to specific health risks, social characteristics, or environmental conditions will be available for improved public health surveillance and population health research. Data elements encoded in a structured vocabulary will better support comparative analyses for responding to new, emerging, and ongoing health problems. Data in electronic form may be more easily de-identified, or made anonymous, further protecting the identity of the people receiving community health services.

Individuals will need access to their own PMRI as they assume more responsibility for managing their health and wellness. Technology is providing new capabilities at a time when consumers are taking more active control of their health. Although consumers and healthcare professionals are concerned about the validity of some of the health educational material on the Internet, consumers have a strong desire to educate themselves and take a more active role in sharing medical decision-making with their caregivers.

An overlap and interdependence are clearly developing between the traditional caregivers' view of PMRI and personal and community health views to improve health decision-making, patient-clinician communication, management of health and wellness, medication regimens and care plan compliance, and personal health risk assessment and preventive services.

All of these users of PMRI must be confident that the data are accurate, complete, current, and confidential. To accomplish this, the nation will require a health information infrastructure that employs uniform data standards for PMRI.

Standards for PMRI address a major portion of the requirements necessary to support a national health information infrastructure, but they do not address all of the requirements for standards. There is a need for information to support the underlying functions of all components of health care—not only patient medical care but also prevention of illness and injury, health and wellness promotion, performance improvement—and to support the growing trend toward consumerism in health care.

Data Elements to Produce PMRI Content

The NCVHS discussed the role and relationship of data elements to produce PMRI content. There are several levels of granularity at which such content and structure may be defined. At the lowest level of granularity, data elements required for direct patient care management are best defined by the

professional medical societies in medical vocabularies and implemented in clinical protocols. In order to reflect best practices, such data elements must be continuously updated. At the other end of the spectrum, broadly defined data elements, such as are found in “minimum data sets” may limit documentation, which could result in diminishing effective healthcare communications.

However, a mid-level of content definition is useful for vendors and users to ensure that systems encompass all major components of PMRI. Data elements within this mid-level content area have begun to be defined in the financial and administrative transaction standards, and will continue to be defined as claims attachment standards are developed. Definitions of data elements for clinical data and their sources are being defined within message format and healthcare terminology development activities. The standards for PMRI that will result from the recommendations in this Report will be consistent and compatible with the financial and administrative transaction standards. In addition, these standards should accelerate the further development of the claims attachment standards.

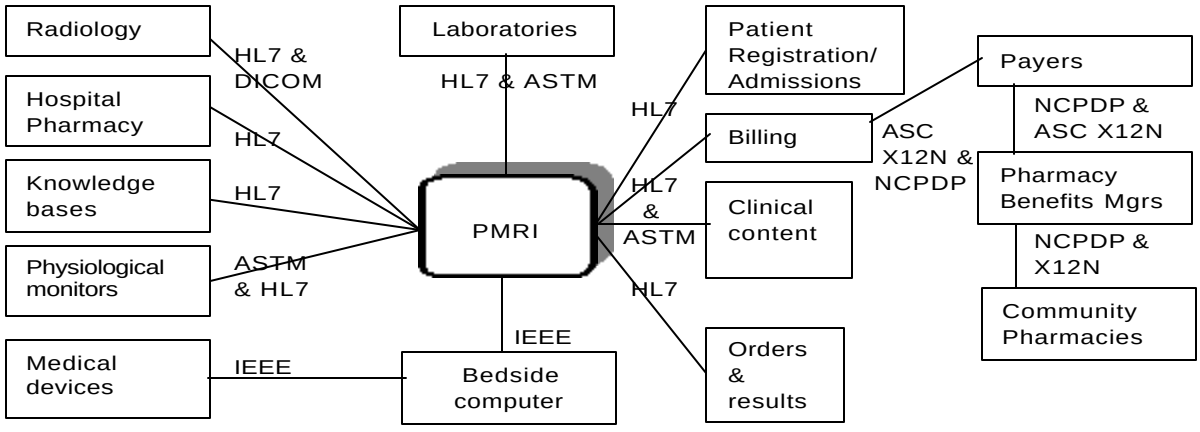
D. Current Status of Data Standards

The healthcare informatics community has made considerable progress in addressing the issues of interoperability, comparability, data quality, and other issues associated with uniform data standards. However, there is widespread agreement that much more needs to be done.

1. Message format standards

Today, message format standards have been developed in the private sector to address interoperability, and many have considerable market acceptance in their respective fields. An Inventory of Clinical Information Standards, which compiles comprehensive profiles contributed by each standards development organization and healthcare terminology developer, was created in 1998 by ANSI HISB.[39] Figure 1 summarizes the message format domain areas as they apply to PMRI. There are some areas where multiple message format standards from different domains are required to achieve interoperability; and other areas where multiple standards may exist, but one standard has a greater market acceptance than the others.

Figure 1. Message Format Domain Areas



(Adapted from Electronic Health Records: Changing the Vision, Eds. GF Murphy, MA Hanken, and KA Waters. Philadelphia: W. B. Saunders Company, 1999)

[39] Inventory of Clinical Information Standards: Clinical Message Format Standards, American National Standards Institute, Healthcare informatics Standards Board, HISB 79-1 through 4, June 1998. (http://aspe.hhs.gov/admnsimp/hisbinv0.htm)

Message format standards developers (and their Web site locations) referenced in Figure 1 include:

ASC X12N: Accredited Standards Committee X12N (www.disa.org/x12)
ASTM: American Society for Testing and Materials (www.astm.org)
DICOM: Digital Imaging and Communications in Medicine (www.dicom.org)
HL7: Health Level Seven (www.hl7.org)
IEEE: Institute of Electrical and Electronic Engineers (www.IEEE.org)
NCPDP: National Council for Prescription Drug Programs (www.ncpdp.org)

As message format standards evolve, they are beginning to address interoperability among different healthcare facilities by including clinically specific terminologies within the messages. Coordination among standards development organizations addressing message formats has grown both overall and bilaterally. Information and reference models are being developed to facilitate the generation of standards in a more comprehensive and efficient manner and to facilitate coordination among standards. New standards, such as object-oriented request broker architectures and document mark-up language standards (e.g., XML, SGML) are being incorporated into message format syntax development activities, and are gaining interest among vendors, users, and the federal government. User needs continue to drive the development, improvement, and coordination of message format standards.

2. Medical terminologies

Comparability of PMRI data may be greatly enhanced through the use of standard medical terminologies. The state of adoption of medical terminologies is generally not as mature as that for message format standards. Recognizing that medical terminologies need more development and testing before they can be widely implemented, NCVHS believes that there is an urgent need for the acceleration of the development, maintenance, and use of clinically specific terminologies that provide a suitable basis for standardization. Caution must be applied, however, not to impose premature national implementation of these terminologies.

Code sets, classifications, and vocabularies to encode, classify, and represent some clinical data exist, but the use of vocabularies to capture clinically specific data is not widespread. For example, classification systems (ICD-9-CM and CPT-4) are widely used to categorize selected data for reimbursement and statistical purposes. There will continue to be a need for clinically specific data to be aggregated and mapped properly to classifications and codes sets for these purposes. However, classifications and code sets do not support the capture of clinically specific data at a level granular enough to provide comparability of data to support evidence-based medicine.

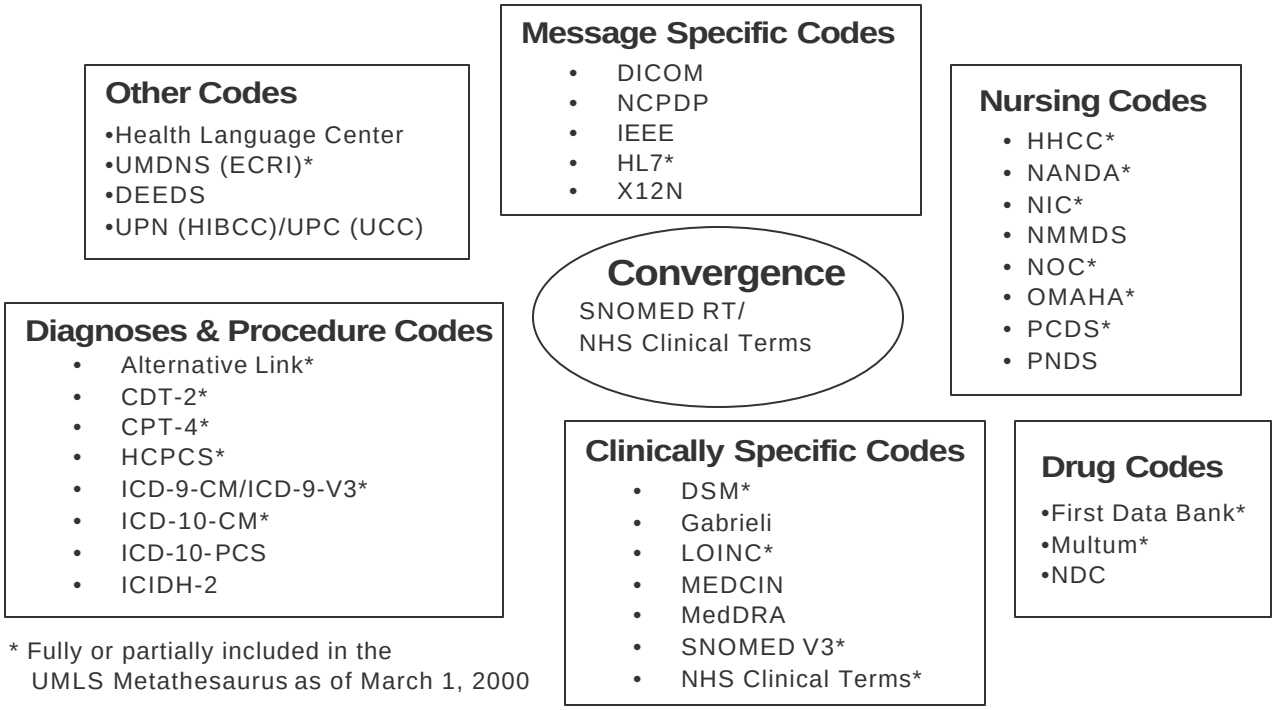
Figure 2 summarizes the healthcare terminology domain areas. (See Appendix D for the definitions of the acronyms. Also note that there is some overlap between the message format standards and healthcare terminologies, as some message format standards embody unique healthcare terminology.) The intent of this graphic is to show that there are multiple domains covered by medical terminologies. However, it should be noted that there is a need for coverage of multiple domains, but that all terminologies need to converge.

What may not be apparent from the diagram is the variation in specificity or gaps that need to be addressed. Also, there are some areas of content coverage where the need for greater specificity and harmonization are more acute than other areas. For example, the need for harmonization of terminologies in the drug area is very acute. The National Drug Codes (NDC) was developed for identification of drug registration and listing. The NDC number identifies each commercially available drug product marketed in the U.S. and can be linked directly to the labeling for the product. The NDC, however, was not designed to support more specific requirements for patient care (e.g., a patient's

actual dose, route, frequency, and strength). It is not accessible in a readily available electronic form, nor categorized in a hierarchical classification system for reference purposes. As a result, other drug coding systems are evolving to address these needs. These drug-coding systems are not fully compatible with one another nor with NDC. As a further result, incompatibility of drug terminologies impairs the ability to perform drug utilization studies, to monitor enterprisewide drug formulary usage, to control the cost of drug usage, and most importantly, impairs the ability to protect patient safety.

Most healthcare terminology developers and users believe that a combination of multiple medical terminologies will be needed to cover all requirements of PMRI. The terminologies selected as standards should form an interlocking set of clinically specific terminologies that affords comprehensive coverage while avoiding duplications.

Figure 2. Healthcare Terminology Domain Areas



Finally, the expense of continual development, evolution, and maintenance of medical terminologies that meet the characteristics and attributes for clinical specificity, comparability, and usability is high. There is a need for a solution that covers the costs of maintaining robust medical terminologies and also facilitates their use by message format standards developers, vendors, creators, and other users of PMRI.

3. Data quality, data accountability, and data integrity

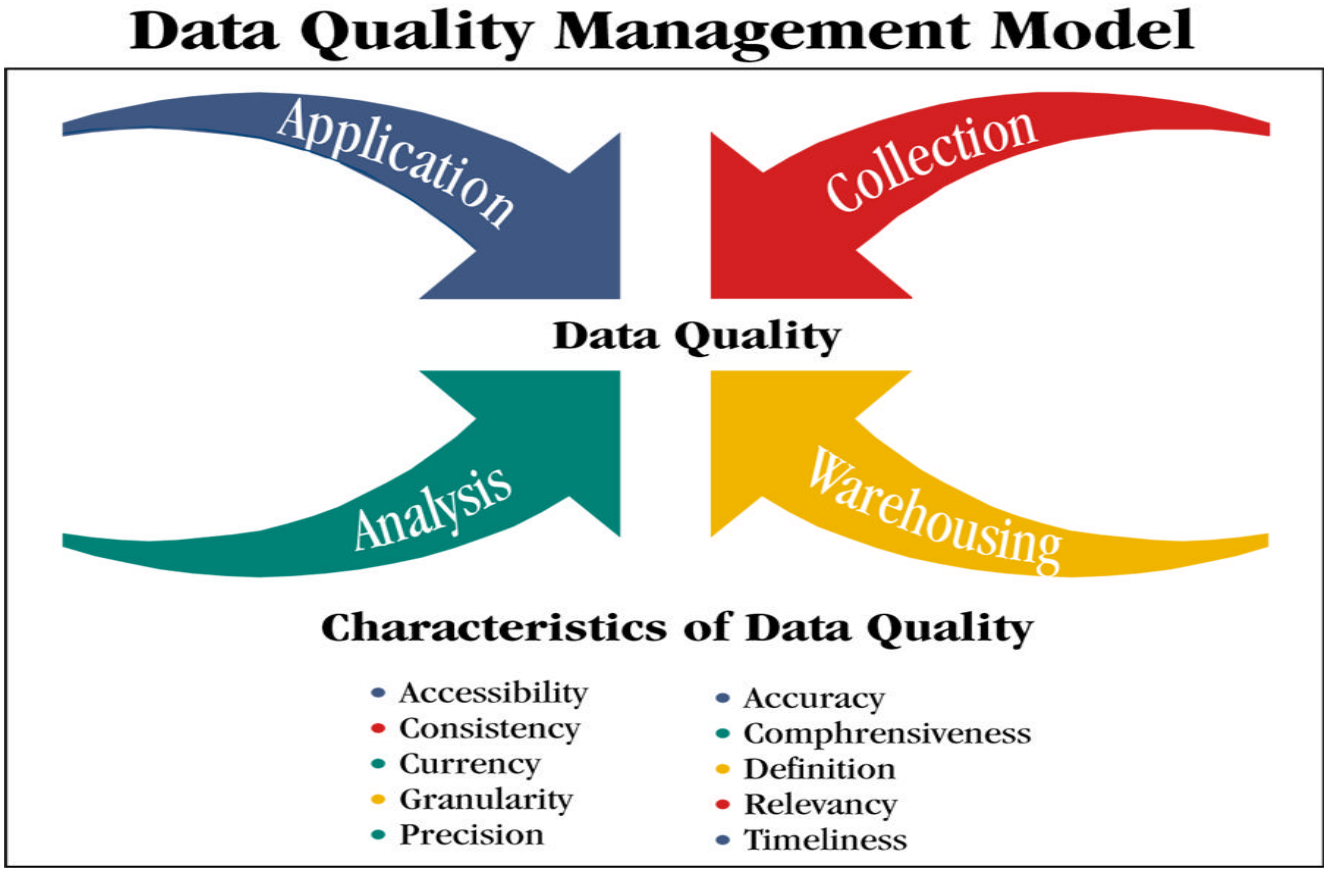
The healthcare industry has few measures of the quality of its data and relies upon security mechanisms to address data accountability and data integrity. Information systems today do not incorporate sufficient data editing, uniformity in units of measure, or other controls. Requirements for data quality, accountability, and integrity need to be incorporated into PMRI standards.
Principles of data quality exist in research institutions and some professional associations. The American Health Information Management Association (AHIMA) has developed a Data Quality Management Model (see Figure 3) that describes ten characteristics of data quality. These characteristics address the quality of data elements. It must be noted that data quality also refers to

the context of the data elements as well as the overall completeness of all data elements. The features and characteristics of quality data elements include:

- Accessibility – data items should be easily obtainable and legal to collect.
- Accuracy – data are the correct values and are valid.
- Comprehensiveness – all required data items are included.
- Consistency – the value of the data should be reliable and the same across applications.
- Currency – the data should be up-to-date, i.e., current for a specific point in time.
- Definition – each data element should have clear meaning and acceptable values.
- Granularity – the attributes and values of data should be defined at the correct level of detail.
- Precision – data values should be just large enough to support the application or process.
- Relevancy – the data are meaningful to the performance of the process or application for which they are collected.
- Timeliness – determined by how the data are being used and their context.

Standards to address interoperability and comparability should incorporate the principles of data quality, accountability, and integrity to ensure that the content and semantic characteristics of the data are properly exchanged and that the data can be consistently and uniformly interpreted. Quality is not a stand-alone process or an afterthought. Features and characteristics to ensure quality must be integrated into healthcare standards, processes, and systems.

Figure 3. Data Quality Model



(American Health Information Management Association. Practice Brief – Data Quality Management Model. Chicago: AHIMA, June 1998)

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IV. RECOMMENDATIONS

A. Introduction

The National Committee on Vital and Health Statistics (NCVHS) has identified several major impediments to improving healthcare quality and cost and achieving administrative simplification, including:

- limited interoperability between information systems
- lack of comparability in healthcare data
- concerns with the quality of healthcare data
- need to protect the privacy of health information
- inconsistencies among state laws relative to medical record information
- need for a national health information infrastructure

The NCVHS also recognizes the dynamic nature of patient medical record information (PMRI). NCVHS believes that it is important to improve the interoperability and comparability of PMRI in a manner that will allow sufficient flexibility in the content and structure of health records to adapt to new medical knowledge, procedures, technologies (such as Web-based personal health records), and public policies.

The recommendations in this Report reflect the belief that significant quality and cost benefits can be achieved in health care if clinically specific data are captured once at the point of care and derivatives of these data are made available for all legitimate purposes. The recommendations address standards to exchange comparable PMRI seamlessly within a healthcare enterprise as well as to share data in a secure manner with those outside the enterprise who have legitimate need for such information. The PMRI standards that result from these recommendations must be consistent and compatible with the current financial and administrative transaction standards, including the claims attachment standards.

This Report does not support the promulgation or adoption of any standard providing for the assignment of a unique identifier for patients until legislation is enacted specifically approving the standard.

Therefore, in accordance with the directives in Section 263 of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and in consideration of broad industry testimony, the NCVHS sets forth the guiding principles for the selection of PMRI standards on page 38, and the recommendations to the Secretary of HHS on page 39.

Guiding Principles for Selecting PMRI Standards

The NCVHS will use the criteria in these Guiding Principles to make recommendations for PMRI standards that:

1. Improve the efficiency and effectiveness of the health system for delivering high quality care.

2. Meet the data needs of the health community, particularly providers, patients, health plans, clearinghouses, and public health organizations.

3. Will support making patient data available in the least personally-identifiable form practical when used or disclosed for intended purposes.

4. Will include strong protections for privacy of patients where applicable.

5. Will be consistent with the other HIPAA standards.

6. Have low additional standards development and implementation costs relative to the benefits of using PMRI standards.

7. Will be supported by an ANSI-accredited standards development organization, or other private or public organization that will assure continuity and efficient update of the standard over time.

8. Have timely developmental, testing, implementation, and updating procedures to achieve benefits faster.

9. Are vendor-neutral and technologically independent of the computer platforms and transmission protocols used in the electronic exchange of PMRI.

10. Are precise and unambiguous but as simple as possible.

11. Keep additional data collection burdens on users as low as is feasible.

12. Incorporate flexibility to more easily adapt to changes in the healthcare infrastructure (such as new services, organizations, and provider types) and changes in information technologies (such as new forms of data capture, knowledge representation, and information presentation).

13. Are consistent with the characteristics and attributes for clinically specific PMRI terminologies. Examples of these characteristics include in-depth and comprehensive coverage of a clinical area, the ability to map to broader statistical and reimbursement classifications, formal and systematic definitions, internal consistency and non-redundancy, and the capacity to evolve, change, and remain usable over time.

14. Are consistent with features and characteristics of data quality, including accessibility, accuracy, comprehensiveness, consistency, currency, definition, granularity, precision, relevancy, and timeliness.

15. Consider the degree to which the market has accepted each candidate PMRI standard.

B. Recommendations

1. Adopt the Guiding Principles for Selecting PMRI Standards (see box on page 38) as the criteria for selecting uniform data standards for patient medical record information (PMRI).

2. Consider acceptance of forthcoming NCVHS recommendations for specific PMRI standards. The first set of these recommendations will be delivered to the Secretary eighteen months following submission of this Report. The recommendations will:

   a. identify on an ongoing basis PMRI standards using the criteria in the Guiding Principles for Selecting PMRI Standards.

   b. include implementation timeframes that consider industry readiness for the PMRI standards.

   For each recommendation for PMRI standards, NCVHS encourages the Secretary to provide an open process to give the public an opportunity to comment on the PMRI standards proposals before final rules are adopted.

3. Provide immediate funding to accelerate the development and promote early adoption of PMRI standards. This should take the form of support for:

   a. government participation in standards development as:

      (1.) members of healthcare informatics standards development organizations.

      (2.) a Departmental member of the American National Standards Institute Healthcare Informatics Standards Board.

   b. broader participation of expert representation in standards development through:

      (1.) outreach projects to those groups who may be underrepresented in the standards development process.

      (2.) encouraging standards development organizations to make greater use of the Internet to solicit comments and conduct balloting.

      (3.) making existing government facilities, including teleconferencing, available to standards development organizations.

   c. enhancement, distribution, and maintenance of clinical terminologies that have the potential to be PMRI standards through:

      (1.) government-wide licensure or comparable arrangements so that these terminologies are available for use at little or no cost.

      (2.) augmentation of the National Library of Medicine's Unified Medical Language System (UMLS) to embody enhanced mapping capabilities among and between medical vocabularies, and between medical vocabularies and statistical classifications and reimbursement code sets designated in the HIPAA standards for financial and administrative transactions.

(3.) development and testing of quality measures and clinical practice guidelines, such as are published in the Agency for Healthcare Research and Quality (AHRQ) clearinghouses, and patient safety measures for their compatibility with existing and developing clinical terminologies.

(4.) development and testing in appropriate multi-agency projects, such as the GCPR (Government Computer-based Patient Record) framework project.

d. coordination of data elements among all standards selected for adoption under HIPAA through funding:

(1.) the development and maintenance of an open meta-data registry.

(2.) working conferences to harmonize message format and vocabulary standards.

e. improvement of drug data capture and use through:

(1.) requiring the Food and Drug Administration (FDA) to make publicly available in an easily accessible format its National Drug Codes (NDC) database registry information

(2.) requiring the FDA to develop a drug classification system based on active ingredients so that all drugs that fall into a given category can be identified by the name of that category.

(3.) encouraging the FDA to participate in private sector development and ongoing maintenance of a reference terminology for drugs and biologics that promotes the ability to share clinically specific information.

f. early adoption of PMRI standards within government programs to provide broadened feedback to the standards development community. HHS should support use of PMRI standards according to the following priority:

- Within government projects, such as the GCPR framework project.
- Within government agency programs that directly deliver healthcare services.
- Within federally funded research and evaluation, where applicable.

Government agencies that may be candidates for early adoption activities include but are not limited to the National Library of Medicine, National Cancer Institute, Centers for Disease Control and Prevention, Agency for Healthcare Research and Quality, the Indian Health Service (as the HHS participant in the GCPR framework project), Health Care Financing Administration, and the Food and Drug Administration.

4. For each standard recommended by NCVHS, commit funding for:

a. development of a uniform implementation guide.

b. development of conformance testing procedures and selection of conformance testing organization(s).

c. ongoing government licensure or comparable arrangements of those terminologies selected for adoption as PMRI standards so that these codes sets, classifications, and vocabularies are available for use within the public and private sectors at little or no cost.

5. Support demonstration of the benefits and measurement of the costs of using uniform data standards for PMRI that provide for interoperability, data comparability, and data quality. Areas in which value should be demonstrated include ability of clinicians to care for patients, clinical performance measurement, use of practice guidelines, reduction in medical adverse events, and public health surveillance and intervention.

6. Support increases in funding for research, demonstration, and evaluation studies to:

    a. promote data capture systems that can make it faster, more economical, and more accurate to collect clinically specific information at the point of care and enable use of these data for multiple purposes such as for payment, quality improvement, public health, and research.

    b. undertake basic healthcare informatics research on health data representation, data mining methods, workflow efficiency, change management, and human-computer interfaces.

7. Accelerate the development and implementation of a national health information infrastructure. HHS should work in collaboration with other federal components, state governments, and the private sector on demonstration and evaluation projects, test beds, and/or networks, such as the GCPR framework project.

8. Promote United States' interest in international health data standards development:

    a. through HHS participation in international healthcare informatics standards development organizations.

    b. in cooperation with the Secretary of the Department of Commerce, through monitoring the activity of U.S. healthcare information system vendors abroad.

9. Promote the equitable distribution of the costs for using PMRI standards among all major beneficiaries of PMRI. This may take the form of incentives for submission of data using the PMRI standards that can support a variety of purposes, including quality improvement.

10. Encourage enabling legislation for use and exchange of electronic PMRI, including the following:

    a. comprehensive federal privacy and confidentiality legislation. This should ensure that all health information in any medium, used for any purpose, and disclosed to any entity receives equal privacy protection under law.

    b. uniform recognition by all states of electronic health record keeping; and national standards for PMRI retention and electronic authentication (digital signatures).

C. Conclusions

The lack of complete and comprehensive PMRI standards is a major constraint on the ability of our healthcare delivery system to enhance quality, improve productivity, manage costs, and safeguard data. NCVHS believes the government has a significant role to play in facilitating the acceleration of standards development, coordination, and adoption. Government leadership is essential to effectively address the issues of interoperability, comparability, and data quality, as well as the related issues of protecting the confidentiality of PMRI, reducing ineffective diversity in state laws, and building a national health information infrastructure.

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Appendix A. NCVHS Work Group on Computer-based Patient Records

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Appendix B. NCVHS CPR Work Group Work Plan

CPR Work Group Work Plan (Version XI)
October 13, 1999

I. Introduction

II. The Vision of Computer-based Patient Records (CPRs) and the Requirements for Comparable Patient Medical Record Information (PMRI)

III. Identification of the Major Areas of Focus Within the Work Plan

IV. Descriptions of Activities to Address the Areas of Focus

V. Description of Supporting Activities

VI. Time Frame for NCVHS Work Plan Activities for the CPR Work Group (Matrix)

I. Introduction

The objective of this Work Plan is to assist the National Committee on Vital and Health Statistics (NCVHS) in developing "recommendations and legislative proposals" for data standards on patient medical record information to the Secretary of the Department of Health and Human Services (HHS) by August 2000. The subjects of these recommendations and legislative proposals are set forth in Section 263 of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

These provisions state NCVHS:

"(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

(C) shall report to the Secretary not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange;"

The Work Group has agreed to prepare a preliminary report to the Secretary of the HHS outlining the objectives and Work Plan of this Work Group. This preliminary report will be delivered to the Secretary in September 1999.

The final report to the Secretary will include an introduction. The introduction will include the objectives of the Work Group, definitions of the phrases "uniform data standards", "patient medical record information", and the "electronic exchange" of this information. The body of the report will describe the issues related to these topics and our recommendations to address them. These recommendations will have both a near-term and long-term perspective. The need to provide and align incentives is also recognized. This may apply to all areas of focus identified below but is noted as especially needed to advance accountability for quality in health care.

Additionally, the Work Group will consider or build upon those data standards already adopted by the HHS as part of its responsibilities defined by HIPAA.

II. The Vision of Computer-based Patient Records and the Requirements for Comparable Patient Medical Record Information

A. The Vision of Computer-based Patient Records

The Administrative Simplification Provisions of HIPPA states that NCVHS "shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information." Many members of the CPR Work Group interpret this phrase as an activity that will address one of the major barriers to widespread acceptance of CPRs.

The vision of computer-based patient record systems was defined during an 18-month study conducted by the Institute of Medicine (IOM). The results of the IOM study were published by National Academy Press in 1991 in a work entitled *The Computer-based Patient Record, An Essential Technology for Health Care*. This vision may be summarized by the following three quotations from the book.

"A computer-based patient record (CPR) is an electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems, links to medical knowledge, and other aids."

"CPRs are a key infrastructural requirement to support the information management needs of physicians, other health professionals, and a variety of other legitimate users of aggregated patient information."

"The [IOM] committee identified five objectives for future patient record systems. First, future patient records should support patient care and improve its quality. Second, they should enhance the productivity of healthcare professionals and reduce the administrative costs associated with healthcare delivery and financing. Third, they should support clinical and health services research. Fourth, they should be able to accommodate future developments in healthcare technology, policy, management, and finance. Fifth, they must have mechanisms in place to ensure patient data confidentiality at all times."

B. The Requirements for Comparable Patient Medical Record Information

The CPR Work Group conducted hearings on December 8 and 9, 1998, to better understand the requirements for comparable patient medical record information and validate whether the work group's work plan had the right areas of focus. These hearings resulted in a modification of the four initial areas of focus into seven areas of focus. On September 27, 1999, the Subcommittee on Standards and Security of the NCVHS asked the CPR Work Group to restore data security as a focus area for the final report to the Secretary of the HHS. These new areas of focus are described in following section.

III. Identification of the Major Areas of Focus within the Work Plan

This section of the Work Plan sets forth the seven areas of focus. These areas were identified by the CPR Work Group because they are potential impediments to the widespread acceptance of "data standards for patient medical record information" and computer-based patient record systems.

1. Identify issues and make recommendations regarding message format standards that contain patient medical record information. This area of focus will include message format syntaxes,

document format standards, the role of information models in enabling the development of message format standards, and the need to coordinate standards.

2. Identify issues and make recommendations regarding standards for healthcare terminology related to patient medical record information including data element definitions, data models, code sets, and the development of an overall framework into which existing and developing healthcare terminology efforts can be integrated and coordinated. This area of focus will include issues related to the convergence of medical terminologies, coordination and maintenance of vocabularies, coordination of drug knowledge bases, and other issues related to medical terminologies.

3. Identify issues and make recommendations regarding the business case issues related to the development and implementation of uniform data standards for patient medical record information. This area of focus will include return on investment issues and the cost burden of vendors, standards development organizations (SDOs), code set developers, and users to participate in the standards development processes.

4. Identify issues and make recommendations regarding standards necessary to support the national health information infrastructure (NHII). The vision of NHII and identification of issues related to it are being defined within the NHII Subcommittee of the NCVHS. The CPR Work Group will identify the standards issues necessary to support this vision.

5. Identify issues and make recommendations regarding standards for data quality, accountability, and integrity related to patient medical record information. This area of focus will include data quality issues beginning with the initial capture or recording of data, the communication of data, the translation and encoding of data, and the decoding or presentation of data. It will also include the guidelines or standards for accountability and data integrity (e.g., accuracy, consistency, continuity, completeness, context, and comparability).

6. Identify the inconsistencies and contradictions among state laws that discourage or prevent the creation, storage, or communication of patient medical record information in a consistent manner nationwide. Inconsistencies include laws for record retention, document authentication, access to records, etc.

7. Monitor privacy, confidentiality, and security issues with the Subcommittee on Standards and Security within the NCVHS. This area of focus will not require separate data gathering and analysis activities by the CPR Work Group.

The above list does not include issues related to privacy and confidentiality of health records because it assumes that Congress will pass such legislation by August 1999 or the HHS will promulgate regulations to address this subject by February 2000. This list also does not include issues related to patient identifiers because it assumes that the HHS and Congress will address this issue prior to February 2000.

IV. Descriptions of Activities to Address the Areas of Focus

Each area of focus will be addressed by three activities. The first activity will be information gathering. The second activity will be an analysis phase, which may include some additional information gathering, testing, or validation. The third activity will be the development of recommendations for each focus area.

V. Description of Supporting Activities

In addition to the activities to address the seven areas of focus, there are three supporting activities that should be reflected in the Work Plan. They are:

1. The preliminary hearings in December 1998 to obtain feedback on the areas of focus and to better understand comparable patient medical record information.

2. The preliminary report to the Secretary of the HHS will be prepared and delivered by September 1999.

3. The activities to pull together the preliminary recommendations from the focus areas into the final recommendations to the Secretary of the HHS. These will include:

    a. Creation of the preliminary recommendations by the CPR Work Group,

    b. Review of the preliminary recommendations by full NCVHS Committee,

    c. Updates and additions to the preliminary recommendations,

    d. Feedback on the preliminary recommendations from the HHS Data Council and HHS agency leaders,

    e. Approval of the final recommendations by the full NCVHS Committee.

    f. Presentation of the final report and recommendations to the Secretary of the HHS.

June 20-21, 2000

VII. Areas to Address for Subsequent Work

The NCVHS plans to continue to hear testimony in order to help formulate specific recommendations for PMRI standards. Among the topics to be included for additional hearings are:

1. Medical Device Terminology – there is a need for systems to support information exchange for device utilization/maintenance, risk management, adverse events involving patient/user safety, and reimbursement and procurement. Suggested testifiers may include healthcare providers (including the Veterans Health Administration and Department of Defense); device manufacturers, distributors, and associations; standards development organizations (e.g., HIBCC, UCC, HL7, SNOMED); regulatory agencies (FDA and HCFA); and ECRI.

2. Web-based Interoperability Solutions – Web-based solutions are being developed that may serve as alternatives to traditional message format standards. There is a need to evaluate the implications of such evolving solutions. Suggested testifiers may include vendors serving as application service providers (ASPs), standards development organizations (e.g., ASTM, HL7), and users (e.g., small physician practices, consumer users).

CPR Work Group Work Plan by Date

Date	Area of Focus	Major Issues	Testifiers
12/8/98	Feedback on Work Plan	Are the areas of focus correct? What is the definition of PMRI?	SDOs Vendors Providers Clinicians
12/8/98	Feedback on Work Plan	Are the areas of focus correct? What is the definition of PMRI?	SDOs Vendors Providers Clinicians
3/29/99	Message Format Standards (Day 1 of 2)	Message Format Syntaxes Data Format Standards Information Models as Enablers Need for SDO Coordination	HIS Vendors SDOs Syntax Experts Users
3/30/99	Data Quality, Accountability, and Integrity (Day 1 of 3)	Data Capture Data Encoding/ Translation/Transformation Data Communication Data Decoding/Presentation Data Accountability Issues Data Integrity Issues	Encoding Vendors HIS Vendors Performance Measurement Services Users
5/17/99	Medical Terminologies and Message Format Standards (Day 1 of 4)	Coordination Among Code Set Developers Coordination Among Drug Knowledge Bases	Developers of Medical Terminologies
5/18/99	Medical Terminologies and Message Format Standards (Day 2 of 4)	Issues Related To Convergent Medical Terminologies such as availability, maintenance, costs, etc. Need for Crosswalks and Thesaurus Functions	Developers of Medical Terminologies

Date	Area of Focus	Major Issues	Testifiers
6/22/99	Work Group Planning	Update of the Work Plan Update of the Calendar Plans for Progress Letter to the Secretary Additional Testimony	GCPR Project AAMT/ASTM Representative
8/31/99	Identify preliminary issues to be reflected in progress letter to the Secretary targeted for September 1999		
9/16/99	Medical Terminologies and Message Format Standards (Day 3 of 4) Data Quality, Accountability, and Integrity (Day 2 of 3)	User experience with medical terminologies and message format standards Data Capture Data Encoding/ Translation/Transformation Data Communication Data Decoding/Presentation Data Accountability Issues Data Integrity Issues	User Perspectives from Providers, Vendors, SDOs Encoding Vendors HIS Vendors Perf. Measurement Services Users
9/17/99	Progress letter to the Secretary of HHS Select date for January/February Administrative items		
9/27/99	Approval of progress letter to the Secretary by the full NCVHS Committee		

Date	Area of Focus	Major Issues	Testifiers
10/14/99	Medical Terminologies and Message Format Standards (Day 4 of 4)	User experience with medical terminologies and message format standards	User Perspectives from Providers, Vendors, SDOs
	Inconsistencies Among State Laws for PMRI	Laws Regulating Retention of Records Laws Regulating Document Authentication Laws Regulating Access to Records	Report provided by AHIMA
	Data Quality, Accountability, and Integrity (Day 3 of 3)	Data Capture Data Encoding/Translation/Transformation Data Communication Data Decoding/Presentation Data Accountability Issues Data Integrity Issues	Encoding Vendors HIS Vendors Perf. Measurement Services Users
	International Standards	How do we consider coordination with international standards organizations?	Chair of US TAG ISO TC215
	Standardized Methodology for Representing Knowledge	Develop a basic understanding of ontological principles.	ANSI Ontology SDO
10/15/99	Business Case Issues	ROI for Standards Development Cost Burden To Participate in Standards Development	Users HIS Vendors SDOs
10/31/99	WKGP consensus on the issues to be reflected in the Final Report to the Secretary		
12/9/99	Create preliminary recommendations		
12/10/99	Reserved for the Subcommittee on Standards		

Date	Area of Focus	Major Issues	Testifiers
1/31/00- 2/01/00	Agree on preliminary recommendations by the CPR Work Group		
2/24/00- 2/25/00	Review preliminary recommendations with the full NCVHS Committee		
March/April 2000	Update the preliminary recommendations		
May 2000	Obtain feedback on recommendations from the Data Council and others		
June 2000	Final Approval of the Report and recommendations from the full NCVHS Committee		
August 2000	Presentation of the Report and recommendations to the Secretary of the HHS		

Compiled by: Jeff Blair
October 13, 1999 Draft 10

Appendix C. List of Testifiers

December 8-9, 1998 – PMRI Standards

Opening Panel
- Peter Waegemann, Chair, ANSI HISB and Medical Records Institute
- Ralph Korpman, MD, Per-se Technologies
- William Stead, MD, Vanderbilt University Medical Center
- John Quinn, Ernst & Young, HL7 message format standards developer

Value & Quality
- Paul Schyve, MD, JCAHO
- David Schutt, MD, The MEDSTAT Group
- Dorothy Webman, Health and Human Services Systems Co.

Managed Care and Physician Users
- Homer Chin, MD, Kaiser Permanente
- John Mattison, MD, Kaiser Permanente
- Jean Narcisi, American Medical Association
- Jane Orient, MD, Association of American Physicians and Surgeons
- Kent Spackman, MD, College of American Pathologists, developer of SNOMED healthcare terminology

Hospital Users
- Reed Gardner, LDS Hospital and American Medical Informatics Association
- George Arges, American Hospital Association
- Tommy Bozeman, North Mississippi Medical Center

Health Information Systems Vendors
- Dan Russler, MD, HBOC
- Paul Tang, MD, Epic Systems Corp.
- Jesse Tonks, 3M Health Information Systems
- Blackford Middleton, MD, MedicaLogic, Inc.
- John Morris, MD, Oceania, Inc.
- Rick Peters, MD, iTrust
- Timothy McNamara, MD, Cerner Corp.
- Gary Radtke, Ford Motor Co.

March 29-30, 1999 – Message Format Standards

Health Level Seven (HL7)
- George "Woody" Beeler, Jr, PhD, Mayo Foundation and Chair, HL7
- Abdul-Malik Shakir, The Huntington Group
- Robert H. Dolin, MD, Kaiser Permanente
- Wes Rishel, Wes Rishel Consulting

Standards Developers
- Gary Beatty, Mayo Foundation and ASC X12N
- Rachel Sokolowski, Magnolia Technologies, XML specialist
- Harold Solbrig, 3M Health Care

Vendors
- Jack Harrington, Hewlett-Packard Medical Products Group
- Mark J. Shafarman, OACIS Healthcare Systems
- Doug Pratt, SMS
- Charles Meyer, McKesson/HBOC

Data Quality, Accountability, and Integrity
- Joseph Bormel, MD, Cerner Corporation
- Jeff Sutherland, PhD, IDX

May 17-18, 1999 – Vocabularies, Terminologies, Classifications, and Code Sets

Overview of Clinical Vocabularies and Issues
- James Cimino, MD, Columbia Presbyterian Medical Center
- Christopher G. Chute, MD, DrPH Mayo Foundation

Overview of Terminologies and Issues
- Keith Campbell, MD, PhD, Kaiser Permanente
- Mark Tuttle, Lexical Technologies, Inc.

Statistical Classifications and Code Sets
- Melinna Giannini, Alternative Link developer of code sets for alternative practitioners
- Dan Pollock, Centers for Disease Control and Prevention, Data Elements for Emergency Department Systems (DEEDS)
- Sue Prophet, RHIA, American Health Information Management Association, ICD-10-PCS (filling in for Pat Brooks, RHIA, HCFA)
- David Berglund, National Center for Health Statistics, ICD-9-CM and ICD-10-CM
- Tracy R. Gordy, MD, Interim Chair, American Medical Association, CPT-4 Editorial Panel
- Robert E. Lapp, DDS, American Dental Association, CDT-2 and SNODENT

Clinical Specific Code Sets
- Dean Bidgood, MD, DICOM
- Kent Spackman, MD, Oregon Health Sciences University and Chair, SNOMED Editorial Board
- Peter Goltra, Medicomp Systems, Medcin healthcare terminology developer
- David LaRoche, Medicomp Systems, Medcin healthcare terminology developer
- Stan Huff, MD, Intermountain Health Care, and Co-chair, with Clem McDonald, MD, of LOINC, and Chair-elect of HL7
- Karen Martin, RN, MSN, FAAN, ANA Omaha System of nursing terminology
- Virginia Saba, EdD, RN, FAAN, FACMI, Home Health Care Classification of nursing diagnosis

Medical Code Sets
- Bob Kennelly, Medical Device Communications Industry Group of IEEE
- Elmer Gabrieli, MD, Computer-based Medicine, Inc.
- Ronald A. Jordan, RPh, American Pharmaceutical Association and NCPDP

Nursing Code Sets
- Dorothy Jones, RN, Boston College, and President, North American Nursing Diagnosis Association (NANDA)
- Joanne McCloskey, University of Iowa, Nursing Interventions Classification (NIC) and Nursing Outcomes Classification (NOC)
- Sue Moorehead, University of Iowa, Nursing Outcomes Classification (NOC)
- Judy Ozbolt, PhD, RN, FAAN Vanderbilt University, American Medical Informatics Association and American Nurses' Association, Council on Nursing Systems and Informatics

Drug and Device Code Sets
- David Rothwell, MD, Health Language Center, developer of structured health mark-up language (SHML)
- Andrea Neal, FDA, MedDRA terminology
- Bill Hess, FDA, National Drug Code (NDC)

Vivian Coates, ECRI (formerly Emergency Care Research Institute) medical device terminology developer
Terri Meredith, RPh, Multum Information Services, subsidiary of Cerner Corporation developer of clinical drug information systems

Patient Medical Record Information
Claudia Tessier, CAE, CMT, RHIA, American Association for Medical Transcription and ASTM

Government-based Patient Record (G-CPR)
Peter Groen, Department of Veterans Affairs
Lt. Col. Janet Martino, MD, Department of Defense
David Kentsmith, MD, Department of Veterans Affairs
Cmdr. James McCain, RPh, Indian Health Service

September 16-17, 1999 – PMRI

Health Data Quality
William Jessee, MD, MGMA
Alfred Buck, MD, JCAHO
Stephen Lamb, JD, NCQA

Health Data Quality and Users
Herman Jenich, IPRO of NY
Stanley Griffith, MD, Indian Health Service

Users of PMRI
Gary J. Arvary, MD, Skylands Medical Group
Jeffrey Rose, MD, Kaiser Permanente
Janet Dillione, SMS

National Library of Medicine
Betsy Humphreys, NLM

October 14-15, 1999 – PMRI

Users of PMRI Standards and/or Health Data Quality
Blackford Middleton, MD, MedicaLogic
John Kelly, MD, Aetna
Gary Dickinson, Mediphis/Per Se
Barbara Demster, Healtheon Corp.

National and International Health Information Environment and Nursing Terminology Consolidation
David Kibbe, MD, Future HealthCare Inc.
Peter Waegemann, Medical Records Institute
Rick Peters, MD, iTrust
Judy Ozbolt, PhD, RN, FAAN, Vanderbilt University

Drug Knowledge Base Developers and Users
Joan Kapusnik-Unser, PharmD, First Data Bank

Users of PMRI Standards and Ontology for Health
Floyd Eisenberg, MD, SMS
Robert Spillers, Spillers' Consulting (written testimony only)

PMRI Standards Developers and Users
Helene M. Guilfoy, ASTM
Lee Min Lau, MD, PhD, 3M Health Care, terminology developer
Lt. Col. Mark Rubertone, US Army

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Appendix D. Glossary of Terms and Acronyms

Accountability refers to identifying the healthcare party (i.e., individuals, organizations, business units) or agent (e.g., software, device, instrument, monitor) that is responsible for data origination, amendment, verification, translation, stewardship, access and use, disclosure, and transmission and receipt.

Aggregate data are those data elements assembled into a logical format to facilitate comparisons or to elicit evidence of patterns.

AHRQ (Agency for Healthcare Research and Quality) of the U.S. Department of Health and Human Services is the lead agency charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services. AHRQ's broad programs of research bring practical, science-based information to medical practitioners and to consumers and other healthcare purchasers.

Alternative Link is a developer of Alternative Billing Codes (ABC) which provides a description of the patient encounter with alternative medicine providers in terms of the procedures, treatments, and services provided.

ANSI (American National Standards Institute) is the organization that accredits U.S. standards development organizations (SDOs) to ensure they are following due process in promulgating standards. The organization does not create standards itself.

ANSI Healthcare Informatics Standards Board (HISB) is a group within ANSI that coordinates the development of standards for exchange of healthcare information.

ASC X12N (Accredited Standards Committee X12N) is the standards development organization charted by ANSI to develop uniform standards for inter-industry electronic interchange of business transactions – electronic data interchange (EDI), insurance subcommittee that develops standards for claims and other administrative transactions.

ASTM is an ANSI-accredited standards development organization and is approved as an ANSI self-designator of American National Standards. Committee E31 pertains to Healthcare Informatics and develops standards for health record content, structure, functionality, privacy, security, vocabularies, and selected healthcare information message formats.

Classification - *see healthcare terminology.*

Clinical decision support is the use of automated rules based on clinical evidence to provide alerts, reminders, clinical guidelines, and other knowledge to assist in healthcare delivery.

Code – *see healthcare terminology.*

Comparability refers to the ability of different parties to share precisely the same meaning for data.

Computer-based patient record (CPR) is the term coined by the Institute of Medicine in its work T*he Computer-based Patient Record: An Essential Technology for Health Care* (Washington, DC: National Academy Press, 1991, rev. 1997). It may be used synonymously with **electronic medical record (EMR)** or **electronic health record (EHR)**. It is electronic patient medical record information that resides in a system specifically designed to support users by providing accessibility to complete and

accurate data, alerts, reminders, clinical decision support systems, links to medical knowledge, and other aids.[40]

CDT-2 (Current Dental Terminology) is the official coding system for dentists to report their professional services and procedures to third parties for payment. It is produced by the American Dental Association.

CPT-4 (Current Procedural Terminology) is the official coding system for physicians to report their professional services and procedures to third parties for payment. It is produced by the American Medical Association.

Data integrity is the property that data have not been altered or destroyed in an unauthorized manner or by unauthorized users; it is a security principle that protects information from being modified or otherwise corrupted either maliciously or accidentally.

Data quality refers to the features and characteristics that ensure data are accurate and complete and that they convey the intended meaning.

Data registry is an information resource kept by a registration authority that describes the meaning and representational form (meta-data) of data units, including data element identifiers, definitions, units, allowed value domains, etc. HIPAA's proposed standards for electronic transactions call for a master data dictionary to be developed and maintained to ensure common data definitions across the standards selected for implementation.

Data set usually describes a minimum group of data elements to be collected in a standardized manner for a specific purpose. Examples not referenced elsewhere in this Glossary include the Uniform Hospital Discharge Data Set (UHDDS) developed by the National Committee on Vital and Health Statistics (NCVHS), Uniform Ambulatory Care Data Set also developed by NCVHS, Minimum Data Set (MDS) for Long-term Care and Resident Assessment Protocols created by HCFA, the Outcomes and Assessment Information Set (OASIS) created by HCFA for home health data, the Health Plan Employer Data and Information Set (HEDIS) established for managed care accreditation by the National Committee for Quality Assurance (NCQA), and ORYX, which is a program of outcomes measurement systems established for accreditation purposes by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

DEEDS (Data Elements for Emergency Department Systems) is the recommended data set for use in emergency departments; it is published by the Centers for Disease Control and Prevention (CDC).

DICOM (Digital Imaging and Communications in Medicine) is an ANSI-accredited standards development organization that has created a standard protocol for exchanging medical images among computer systems.

Domain refers to a field of action, thought, or influence. In health care, domain is often used to describe a one of many different clinical areas.

Drug reference terminology is a collection of drug concepts and information such as definitions, hierarchies, and other kinds of knowledge and relationships related to the drug concepts.

[40] Institute of Medicine. *The Computer-based Patient Record: An Essential Technology for Health Care*. National Academy Press, Washington, DC, 1991, p. 11

DSM (Diagnostic and Statistical Manual of Mental Disorders) is produced by the American Psychiatric Association to facilitate communication among mental health clinicians, researchers, and administrators; to improve patient care by facilitating reliable and valid diagnosis and differential diagnosis; to facilitate education and training in psychopathology; and to facilitate collection of statistical data about mental disorders.

ECRI (formerly Emergency Care Research Institute) is an independent, nonprofit institution that provides the healthcare community with information about the safe and efficacious use of medical technology. It produces the Universal Medical Device Nomenclature System (UMDNS).

Electronic exchange of PMRI is the electronic communication of data, audio, and/or images between healthcare information systems. It does not imply any data repository or necessarily any functionality of data capture, storage, processing, presentation, or security.[41]

Evidence-based medicine is the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions.[42]

First Data Bank is a supplier of knowledge bases and software concerning drug, medical, and nutrition information.

Gabrieli is a developer of an automated medical text analyzer.

GCPR Framework Project is a government computer-based patient record framework project of the Department of Defense, Department of Veterans Affairs, and Indian Health Service to build the infrastructure and standards to allow the sharing of information among existing systems to achieve a comprehensive life-long medical record.

Granular refers to a high degree of detail. In particular, a vocabulary that is highly granular provides names and definitions for the individual data elements within the context of a broader concept.

Harmonization is the coordination process used by standards development organizations to make standards work together. Processes to achieve harmonization include convergence, modeling, mapping, translation, and other techniques.

HCPCS (HCFA Common Procedure Coding System) currently incorporates CPT-4, national codes for reporting certain healthcare supplies, durable medical equipment and other services not listed in CPT-4, and local codes for Medicaid reporting.

Health refers to the general condition of the body or mind. When referencing the health system in general, the reference is to all actions contributing to health, including public health, health care, preventive care, health maintenance, and consumer health.

Health care generally refers specifically to the treatment of illness or injury to the body or mind in order to restore good health or mitigate the effects of chronic disease or disability.

Healthcare information systems are computer systems that capture, store, process, store, communicate, and present any healthcare information, including PMRI.

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[41] Computer-based Patient Record Institute. *Computer-based Patient Record System Description of Functionality*. Bethesda, MD: CPRI, September 1996.

[42] Rosenberg W and Donald A. "Evidence-based Medicine: An Approach to Clinical Problem-Solving." *British Medical Journal* Vol. 310, April 29, 1995, pp. 1122-1126.

Healthcare terminology is considered "a collective term used to describe the continuum of code set, classification, and nomenclature [or vocabulary]." A **code** is a representation assigned to a term so that it may more readily be processed. A **classification** arranges or organizes like or related terms for easy retrieval. A **nomenclature**, or vocabulary, is a set of specialized terms that facilitates precise communication by eliminating ambiguity. The term "**controlled vocabulary**" suggests only the set of individual terms in the vocabulary. A "**structured vocabulary**," or "**reference terminology**," relates terms to one another (with a set of relationships) and qualifies them (with a set of attributes) to promote precise and accurate interpretation.

HHCC (Home Health Care Classifications) consists of the HHCC of Nursing Diagnoses, which is a code set/vocabulary representing nursing diagnoses and/or patient problems in home health care and the HHCC of Nursing Interventions code set/vocabulary that represents interventions, procedures, activities, and/or service performed in home health care.

HIBCC (Health Industry Business Communications Council) is an ANSI-accredited, industry-sponsored organization that facilitates electronic communications by developing standards for information exchange, including electronic data interchange message formats, bar code labeling data standards, and universal numbering systems. The Universal Product Number (UPN) provides an identifier for medical/surgical product labels.

HL7 (Health Level Seven) is an ANSI-accredited standards development organization that creates message format standards. Version 2.3 provides a protocol that enables the flow of data between systems. Version 3.0 is being developed through the use of a formalized methodology involving the creation of a Reference Information Model (RIM) to encompass not only the ability to move data but to use data once it is moved

ICD (International Classification of Diseases) is produced by the World Health Organization. ICD-9-CM is a clinical modification of the 9th edition of ICD prepared by the U.S., which incorporates a procedure coding system. The U.S. is also preparing a clinical modification of the 10th edition of ICD (ICD-10-CM) and a procedure coding system (ICD-10-PCS).

ICIDH (International Classification of Functioning and Disability) is a classification system first issued by the World Health Organization in 1980 that provides a scientific model of disability and the basis for a common language for clinical use, data collection, and research.

Interface is computer hardware or software that is designed to communicate information between devices, between programs, or between a computer and a user.

Interoperability refers to the ability of one computer system to exchange data with another computer system such that, at a minimum, the message from the sending system can be placed in the appropriate place in the receiving system. At the highest level, the data content of the message should be comparable, i.e., the data embedded in the message should convey the same meaning in both systems.

IEEE (Institute of Electrical and Electronics Engineers) Medical Data Interchange (MEDIX) committee is working on a standard set of hospital system interface transactions based on the International Standard Organization (ISO) standards; another IEEE committee has developed a standard for a medical information bus (MIB) to link instruments in critical care.

Information infrastructure includes the standards, laws, regulations, business practices, and technologies needed to facilitate authorized sharing of comparable data in a safe and secure manner.

Information model is a set of rules for describing, combining, and relating the units of a knowledge representation structure.[43]

IOM (Institute of Medicine) is one of The National Academies. Its mission is to advance and disseminate scientific knowledge to improve human health. It provides objective, timely, authoritative information and advice concerning health and science policy to government, the corporate sector, the professions, and the public.

Knowledge bases are data tables, databases, and other tools designed to assist the process of care.

LOINC (Logical Observation Identifiers, Names and Codes) provides a set of universal names and identifier codes for laboratory and clinical observations.

Medcin is a medical vocabulary incorporating natural language processing developed by Medicomp systems, Inc.

MedDRA (Medical Dictionary for Regulatory Activities) is a terminology developed under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. MedDRA is a standard international terminology for regulatory communication in the registration, documentation, and safety monitoring of medical products throughout all phases of their regulatory cycle. As a standard, MedDRA is expected to promote harmonization of regulatory requirements and documentation for medical products in the U.S., Japan, and European Union.

Message format standards are protocols that make communication between disparate computer systems possible. These message format standards should be universal enough that they do not require negotiation of an interface agreement between the two systems in order to make the two systems communicate.

Metathesaurus – is intellectual middleware; The National Library of Medicine's Unified Medical Language System (UMLS) Metathesaurus cross-references national and international medical vocabularies.

Multum Information Services is a subsidiary of Cerner Corporation and a developer of clinical drug information systems and a drug knowledge base.

National health information infrastructure (NHII) includes standards, laws, regulations, business practices, and technologies. For example, information systems standards are needed to facilitate the sharing of comparable data. State and federal laws are needed to protect the privacy of healthcare information and remove barriers to sharing data between states. Federal regulations are needed that define consistent policies and practices to protect the integrity of and provide security for healthcare information. Cost effective systems and technologies are needed to utilize the infrastructure and translate its efficiency and effectiveness into value for the user.

NCPDP (National Council for Prescription Drug Programs) is the ANSI-accredited standards development organization in the pharmacy services sector of the health care industry. It creates standards for exchange of financial and clinical claim data between pharmacies, switches, and payers.

[43] Huff SM and Carter JS. "A Characterization of Healthcare terminology Models, Clinical Templates, Message Models, and other kinds of Clinical Information Models," pp. 74-82.

NANDA (North American Nursing Diagnosis Association) is a set of nursing diagnoses that describes patient reactions to disease. It is maintained by the North American Nursing Diagnosis Association.

NDC (National Drug Codes) is a 10 digit number that is developed and maintained by the U.S. Food and Drug Administration (FDA) to identify drug products marketed in the United States. NDC numbers are not assigned to drug products not marketed in the United States, blood products, medical devices, in vitro diagnostic products, dietary supplements, or drug products used only in pre-market approval investigations.

NIC (Nursing Interventions Classifications) is a comprehensive classification that names and describes treatments performed by nurses.

NIST (National Institute of Standards and Technology) in the Department of Commerce's Technology Administration was established by Congress to assist industry in the development of technology needed to improve product quality, modernize manufacturing processes, ensure product reliability, and facilitate rapid commercialization of products based on new scientific discoveries. It carries out its mission through Measurement and Standards Laboratories, the Advanced Technology Program, a Manufacturing Extension Partnership, and the Malcolm Baldrige National Quality Award.

NOC (Nursing Outcomes Classification) provides a standard language with measures for patient outcomes influenced by nursing practice.

NMMDS (Nursing Management Minimum Data Set) is a minimum data set developed by the University of Iowa for reporting nursing services.

Omaha System is comprised of a problem classification scheme, an intervention scheme, and a problem rating scale for outcomes. It was developed by the Visiting Nurse Association of Omaha to provide a multidisciplinary model for describing and quantifying the practice of nurses and other healthcare professionals.

Ontology is an information model that provides the structure to enable all forms of available knowledge to be used in integrated applications with semantic understanding. A reference terminology is a form of ontology.

Patient medical record information (PMRI) is information about a single patient. Healthcare professionals generate this information as a direct result of interaction with the patient, or with individuals who have personal knowledge of the patient, or with both. PMRI documents the course of a patient's illness and treatment, communicates between care providers, assists in evaluating the adequacy and appropriateness of care, substantiates claims for payment, protects the legal interests of all concerned parties to the information, and provides case studies for education and data to expand the body of medical knowledge. PMRI includes patient demographics, health history, details of present illness or injury, orders for care and treatment, observations, records of medication administration, diagnoses/problems, allergies, and other healthcare information. PMRI facilitates the creation of a lifetime health record for individuals. PMRI of many individuals may be aggregated to provide the basis for continuous quality improvement, outcomes analysis, and population-based care management.

Patient safety is described in the Institute of Medicine report, *To Err is Human: Building a Safer Health System* (Washington, DC: National Academy Press, 1999), as "freedom from accidental

injury."[44] The report describes that the human cost of medical errors – the majority of which do not result from individual recklessness but from basic flaws in the way the health system is organized – is immense, and recommends a four-part plan to create both financial and regulatory incentives that will lead to a safer healthcare system.

PCDS (Patient Care Data Set) is a compilation of pre-coordinated terms actually used in patient records to record patients' problems, therapeutic goals, and care actions. These terms are recognized by the Nursing Information & Data Set Evaluation Center of the American Nurses Association and are being used as source material for building searchable structure text that closely approximates clinical vernacular.

PNDS (Perioperative Nursing Data Set) was developed by the Association of Perioperative Registered Nurses, Inc. as a minimum data set for nursing services in the perioperative area.

Provider is any practitioner, including a **caregiver** such as a physician, nurse, pharmacist, therapist, or other, as well as any healthcare institution, such as a hospital, clinic, nursing home, home health agency, physician office, or other, that provides patient care.

Semantics pertains to the meaning, or interpretation, of a word, sign, or other representation. It is the content of a concept.

SNOMED (Systematized Nomenclature of Human and V**eterinary Medicine)** is terminology for indexing medical record information. It is produced by the College of American Pathologists.

Standard is a prescribed set of rules, conditions, or requirements describing the following information for products, systems, services, or practices: classification of components; specification of materials, performance, or operations; or delineation of procedures.

Syntax pertains to the patterns, or rules, for forming sentences, phrases, or fields from words, abbreviations, codes, and other elements. It is the context of a concept. Syntax is the basic structure of a message format standard.

Terminology – *see healthcare terminology.*

UCC (Uniform Code Council) is an administrative and educational organization whose mission is to promote multi-industry standards for product identification and related electronic communications. The Universal Product Code (UPC) is a bar code symbol used by companies in North America to uniquely identify themselves and their products worldwide.

UMLS (Unified Medical Language System) is a system designed by the National Library of Medicine (NLM) to help health professionals and researchers retrieve and integrate electronic biomedical information from a variety of bibliographic databases, factual databases, and expert systems.

Uniform data standards are methods, protocols, or terminologies agreed to by an industry to allow disparate information systems to operate successfully with one another.[45] Uniform data standards for PMRI include data definitions, message format protocols, medical terminologies, and data quality methods that are adopted across the healthcare delivery system.

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[44] Institute of Medicine. *To Err is Human: Building a Safer Health System.* Washington, DC: National Academy Press, 1999, p. 16.

[45] Amatayakul M. *The Role of Health Information Managers in CPR Projects.* Chicago: American Health Information Management Association, 1999, p. 263.