United States General Accounting Office

GAO

Report to the Chairman, Committee on Governmental Affairs, U.S. Senate

April 1993

AUTOMATED MEDICAL RECORDS

Leadership Needed to Expedite Standards Development

149267

GAO/IMTEC-93-17

GAO

United States
General Accounting Office
Washington, D.C. 20548

Information Management and
Technology Division

B-248716

April 30, 1993

The Honorable John Glenn
Chairman
Committee on Governmental Affairs
United States Senate

Dear Mr. Chairman:

Despite dramatic advances in medical technology, U.S. health care practitioners rely on a cumbersome, paper-based clinical record system that has remained largely unchanged for decades. The inability to share medical information electronically, through automated records, has contributed to unnecessary patient health risks and increased costs in a health care system already hobbled by burgeoning medical costs.

In a January 1991 report, we concluded that automated medical records offer great potential for improving patient care, increasing efficiency, and reducing costs.[1] However, we identified a number of barriers that impede their development. This report discusses a major barrier—the lack of standards to ensure uniform electronic recording and transmission of medical information. Such standards are a prerequisite to developing effective automated medical record systems. As agreed with your office, we focused on determining the (1) standards needed to develop and share automated medical records, (2) status of standards development, and (3) federal role in developing standards. Appendix I details our scope and methodology.

Results in Brief

The federal government, while expected to pay 31 percent of the $808 billion 1992 cost of health care, often lacks the information needed to evaluate the effectiveness and benefits of the health care it is paying for. The automated medical record is key to this information. However, after over a decade of effort, the comprehensive set of standards needed to make an automated medical record system a reality still do not exist. While we found some agreement that four broad categories of standards—vocabulary, structure and content, messaging, and security—need to be developed, consensus on the actual standards has not yet emerged.

[1]Medical ADP Systems: Automated Medical Records Hold Promise to Improve Patient Care (GAO/IMTEC-91-5, Jan. 22, 1991).

Efforts to develop automated medical record standards have been impeded by a lack of leadership. Several voluntary organizations have been most active in developing standards. However, the complex nature of medical care, large number of standards needed, and variety of special interests involved in standards development have made this a daunting task. Without the leadership to set priorities, marshal resources, coordinate activities, and facilitate consensus-building, standards development efforts have yielded meager results. To date, the federal role in developing automated medical record standards has been limited. However, more active federal involvement could help accelerate standards development.

Background

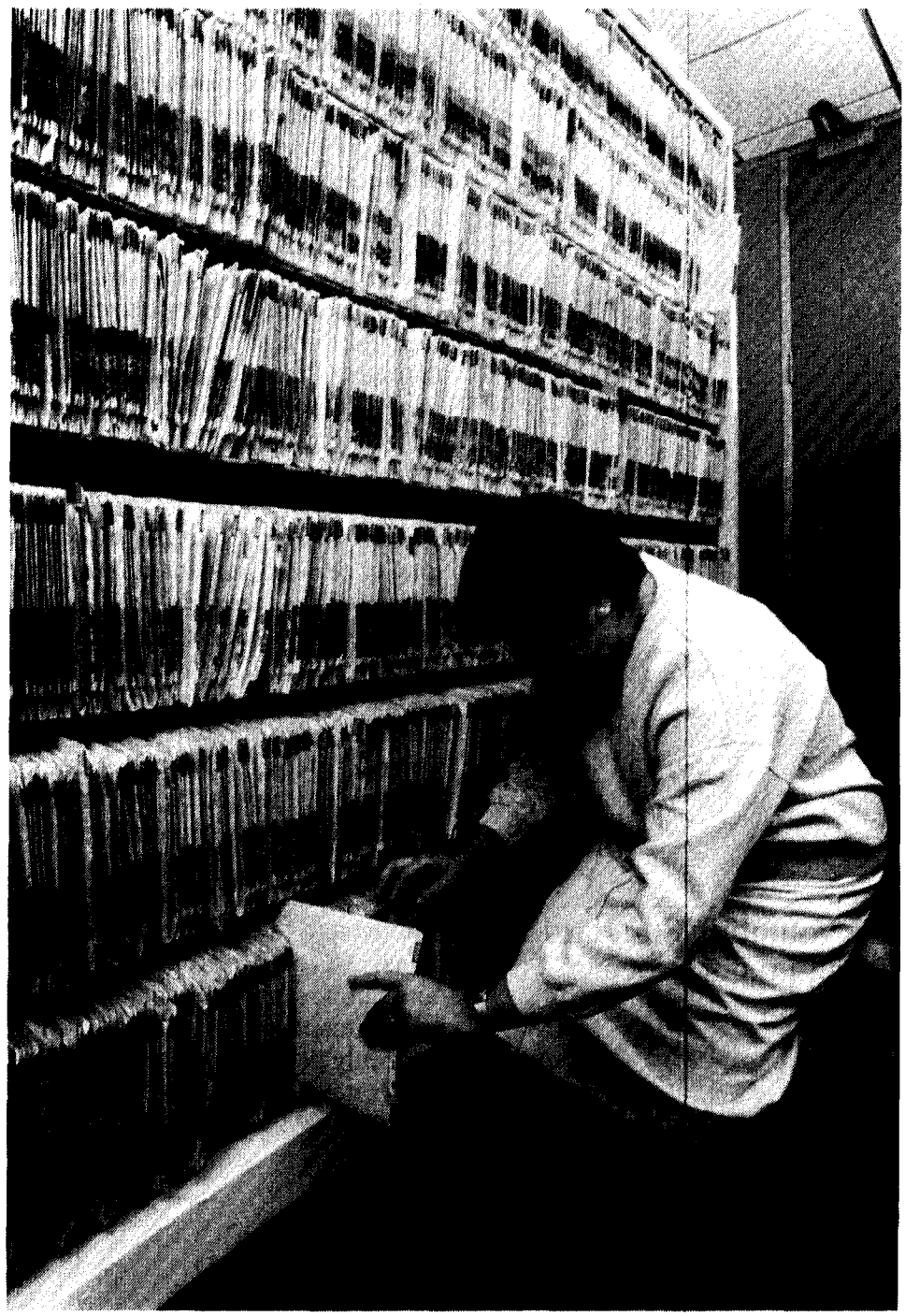
Standards Are Crucial to Sharing Information Electronically

To provide quality health care, medical practitioners require complete, accurate, and timely data. Practitioners need to know their patients' medical histories to avoid prescribing treatments that may have adverse effects. They need quick access to the results of laboratory tests and other diagnostic procedures to determine the best treatments. In emergency situations, critical information can mean the difference between life and death.

Yet most medical records are kept in voluminous paper files,[2] typically located in doctors' offices or other provider sites. These files are often not available when most needed. Even hospitals and medical facilities now using automated systems cannot easily access patient data maintained by other providers.

[2]We estimate that the 34 million annual U.S. hospital admissions and 1.2 billion physician visits could generate the equivalent of 10 billion pages of medical records.

Figure 1: Typical Medical Record Storage



Source: Uniphoto, Inc.

Electronic sharing of medical data offers great potential for improving health care delivery by (1) providing doctors with full knowledge of patients' medical histories, (2) permitting many practitioners to share a patient's data simultaneously, and (3) reducing the need for costly duplicate diagnostic tests. Similarly, insurers will be able to increase their efficiency and productivity through electronic claims submission and payment.

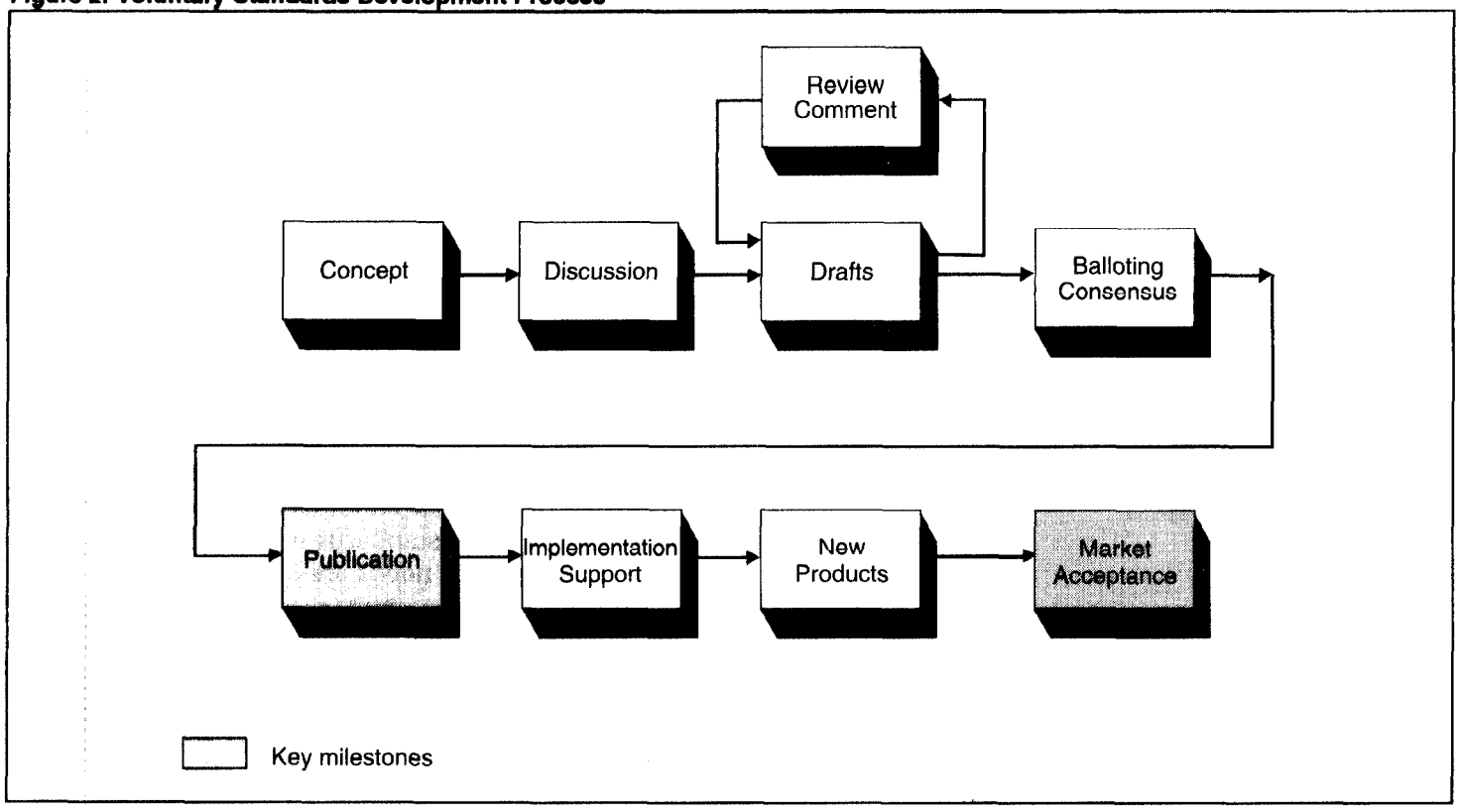
The current inability to share medical information electronically stems largely from the lack of comprehensive standards for automated medical records. Such standards provide the foundation needed to support automated medical records and electronic data-sharing. These standards would allow hospitals to streamline operations by facilitating data transfer both among departments within a hospital and among different hospitals. In addition, standards would facilitate data transmission between outpatient and inpatient facilities. They would also permit data transmission to insurers who pay patients' bills; organizations that perform quality reviews; and institutions that perform health outcomes and effectiveness research, such as the tracking of health outcomes associated with new drugs and medical devices.

As the nation's largest health care insurer, the federal government has a basic need for standardized automated medical information to carry out its diverse responsibilities. Such information would provide essential data needed for formulating and implementing policies to contain expenditures and reform health care delivery.

The Voluntary Standards Development Process

Almost half of all U.S. standards are developed through a voluntary consensus process that includes interested participants from the private and public sectors. Standards are also developed by the federal government, with the Department of Defense accounting for most federally developed standards. The voluntary consensus process is illustrated in general in figure 2 and described in the discussion that follows.

Figure 2: Voluntary Standards Development Process



Note: Time frame to publication: up to 10 years.
Time frame to market acceptance: unpredictable.

Once it is decided that a standard is needed, volunteers from industry, professional associations, consumer groups, and other interested parties, such as government agencies, form working groups under one of several standards development organizations. In this setting, the volunteers develop a concept, discuss issues, and draft proposed standards. When consensus is reached on a standard's content, usually through a process of review by the organization's members, the standards development organization publishes the standard.

The process of developing a complex standard through publication usually takes 5 to 7 years, but can take 10 years or longer. Moreover, a standard cannot be considered completed until it has gained acceptance and

validation in the marketplace. Market acceptance can take longer than publication, and the time frame for this final phase is unpredictable.

Development of standards is expensive. Substantial costs are incurred in procuring meeting places and in transcribing, printing, and disseminating information to interested parties. Salary and travel costs of volunteer standards developers also affect participation in and commitment to the process. Additional costs result from establishing a certification process for testing products for conformance to standards and interoperability with other systems, and from sponsoring standards implementation workshops to help manufacturers interpret standards and bring products to market.

Federal Policy Is to Rely on Voluntary Process

The federal government prefers to rely on the voluntary standards development process as long as this approach serves the public interest. Federal agencies participate in volunteer standards development organizations to ensure that their specific needs are taken into account in the development process. However, when voluntary standards bodies do not or cannot develop needed standards in a timely manner, federal agencies with statutory responsibility can develop their own standards. Government agencies have developed over 52,000 standards, including 8,500 standards in such areas as environmental protection, consumer product safety, occupational safety, and medical devices.

The Department of Commerce, through its National Institute of Standards and Technology (NIST), has assisted both the public and private sectors in developing standards. NIST prefers to work with established standards development organizations and follow the traditional consensus process. However, it has developed standards on its own when asked to do so by a federal agency. In general, the agency reimburses NIST for this service. For example, NIST developed a data encryption standard, now widely used in banking systems, by convening groups of experts. NIST has also conducted implementation workshops on such technical topics as packet switching, open systems interconnection, and integrated services digital networks.

Automated Medical Records Require Many Standards

The standards required to develop automated medical records are numerous and reflect the complex nature of modern health care. Adding to this complexity is the need for a high degree of security and confidentiality to protect medical records from unauthorized disclosure.

Once developed, the standards will govern the systems communicating and sharing data among the many users in the U.S. health care system.

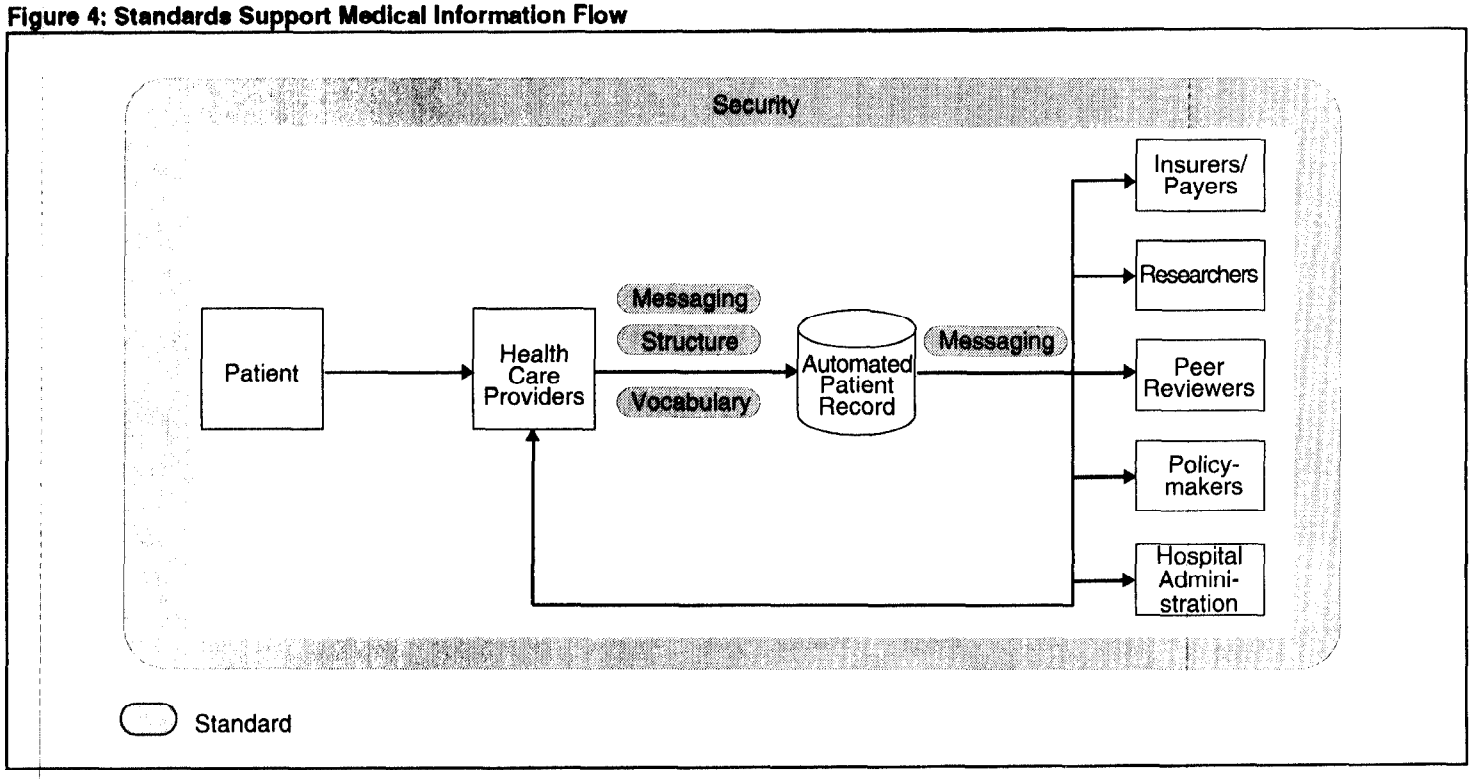
Figure 3: Emergency Medical Care Requires Rapid Access to Information

Source: Uniphoto, Inc.

The medical information flow begins when a patient visits a health care provider (hospital, clinic, or physician's office) and continues through

diagnosis, treatment, and billing. This process generates information relating to the patient's history and treatment, as well as laboratory results, pharmacy prescriptions, and treatment fees. We have divided the set of standards needed to exchange this information into the four general categories discussed below—vocabulary, structure and content, messaging, and security. Figure 4 illustrates how these standards support the medical information flow.

Figure 4: Standards Support Medical Information Flow



Vocabulary Standards

Vocabulary standards establish common definitions for medical terms and determine how information will be represented in medical records. These standards are intended to lead to consistent descriptions of a patient's medical condition by all practitioners. Currently, the terms used to describe the same diagnoses and procedures sometimes vary. For example, the condition known as hepatitis may also be described as liver inflammation.

The use of different terms and codes (abbreviated representations of medical terms) to indicate the same condition or treatment complicates retrieval and reduces data reliability and consistency. The development of vocabulary standards is a formidable task because of the complexity of medical terminology, the unresolved issues such as the extent to which coding will be required, and the difficulty of choosing a single set of codes from the many that are available.

Structure and Content Standards

Standards for structure and content are needed to provide a definitive description of the data elements that will be included in automated medical records. This involves identifying essential data elements, such as blood pressure and temperature, and standardizing the organization and location of those data elements within the records. To be acceptable, the amount of data included must be minimized to avoid placing an undue burden on the health care provider, yet be sufficiently comprehensive to meet the needs of a variety of users. The objective of these standards is to ensure that uniform records will be produced no matter where or in what type of health care setting the patient is treated.

Messaging Standards

Messaging standards provide for the uniform and predictable electronic exchange of data by establishing the order and sequence of data during transmission. The electronic transmission of patient record data will be almost impossible without these standards.

A comprehensive set of standards includes both medical and more general computer messaging standards. Medical messaging standards dictate the segments in a specific medical transmission. For example, they might require the first segment to include the patient's name, hospital number, and birth date. A series of subsequent segments might transmit the results of a complete blood count, one result (e.g., iron content) per segment. More general computer messaging standards help ensure error-free communications among computers.

When comprehensive messaging standards are implemented, messages will be intelligible and automated systems will be able to interconnect. The inability to interconnect has been a major obstacle to sharing medical data. Most hospitals and providers purchase systems that meet their specialized needs. These systems are often built by different manufacturers, use diverse software packages, and are installed without plans for interconnecting to other systems. For example, according to

industry data collected by Sheldon I. Dorenfest & Associates, Ltd.—a well-known industry analyst—the number of hospitals using six or more software vendors more than quadrupled between 1986 and 1990. As a result, many hospitals cannot share electronic data within their own institution, let alone among others. Some have attempted to solve this problem by creating custom interfaces; however, these can be difficult to develop and maintain, and expensive to implement.

Security Standards

Comprehensive security standards (e.g., audit trails, passwords, encryption) are needed to ensure that patient data remain confidential and protected from unauthorized or inadvertent disclosure, modification, or destruction. Such standards are essential because automated records will expand accessibility to multiple users who will be able to access records from multiple locations with relative ease. Access to health care information is a sensitive issue requiring standards that balance patients' rights to privacy with the benefits of carefully monitored use for research, planning, and other publicly beneficial functions. Significant open discussion will be needed as these standards are being developed in order to achieve an appropriate balance.

Health care providers, hospital administrators, researchers, policymakers, and insurers must agree on common levels of data protection before they can benefit from the widespread use of automated patient information. Such agreement will require the development of standards for determining who should have access to specific portions of a patient's record and under what circumstances. Additional standards will also be needed, such as unique codes to identify patients, providers, and care sites. Standards for access procedures, encryption approaches, identification of invalid or inaccurate data, and verification of user access privileges must also be developed.

Progress in Standards Development Has Been Limited

Although efforts to develop automated medical record standards have been underway for over a decade, a comprehensive set of standards does not yet exist. Over 40 different parts or versions of standards are being developed by at least four standards development organizations, whose membership reflects the diverse health care community. One group comprises radiologists and electrical equipment manufacturers; another draws its membership primarily from vendors, medical practitioners, and information technology professionals. A third group was formed by the Institute of Electrical and Electronic Engineers, and the fourth is a

heterogeneous standards development organization with six subcommittees working on standards for computer applications in medicine. In addition, a planning panel, including representatives from each of these organizations, has recently been formed to coordinate standards development activities. (App. III provides a listing of these organizations and the standards categories they are working on.) A discussion of the progress to date in the four standards categories follows.

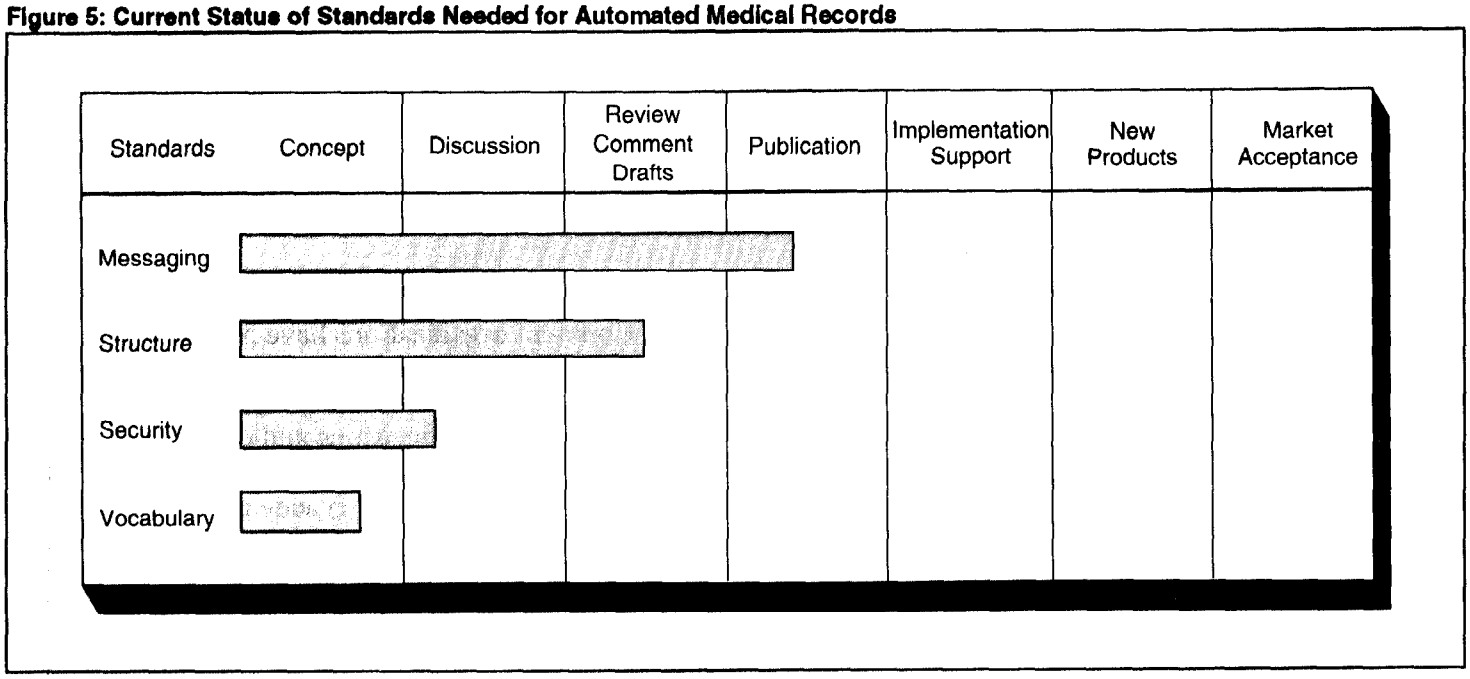
The greatest progress in standards development has been in messaging. Most of the standards development organizations have published messaging standards. These standards address individual activities, such as the transfer of data between classes of laboratory equipment, as well as activities with a wider scope, including admissions and order entry messages. While some of these standards are being used by a number of hospitals and vendors, none has achieved industrywide acceptance, without which widespread sharing of data cannot occur.

Three of the organizations are addressing structure and content issues—one is focusing on radiological image records, while the others are addressing broader topics such as the primary care record. Several standards have been published, but are not widely used. A lack of consensus on basic issues, including what information practitioners need to have in automated medical records and how a longitudinal record should be constructed, has hindered progress in this category.

Efforts to develop security and confidentiality standards are in their early stages. Although there is general agreement that this issue is critical, only one of the four organizations is addressing this topic. Its work began in November 1991, and it is currently working on an early draft of the standards.

Minimal progress has been made in developing industrywide vocabulary standards. The major activity in this category has been the planning panel's efforts to identify the numerous vocabulary and coding systems that have been published over the years by professional groups such as the World Health Organization and the American Medical Association. In addition, one standards development organization is working on standards for medical terminology. However, key issues remain to be addressed, including the amount of narrative versus coding that should be used in medical records, and physician and industry agreement on a set of vocabulary and coding standards. Figure 5 depicts the progress made in the four standards categories.

Figure 5: Current Status of Standards Needed for Automated Medical Records



Lack of Leadership Has Hindered Progress

The lack of leadership to establish priorities, marshal resources, coordinate activities, and facilitate consensus-building has been a major obstacle in developing a comprehensive set of standards. The organizations involved in standards development include many volunteers, whose interests sometimes conflict. These include competing information system vendors, hospitals with costly information systems in place, physicians and professional groups that may be reluctant to change their practices, and government agencies with oversight responsibilities that are sometimes viewed as intrusive. Although agreement exists that standards are needed, organizations have preferred to pursue standards development independently, with no one group taking the lead.

An initial attempt to coordinate activities led to the formation of the Health Information Standards Coordinating Committee in 1988. This informal group of individuals from several standards organizations did not attract the organizational and financial support needed to accomplish their objectives, and they have decided to suspend their meetings.

More recently, in December 1991, the American National Standards Institute (ANSI),[3] the national coordinating body for U.S. standards development organizations, approved the formation of the Health Care Informatics Standards Planning Panel (HISPP). The panel's membership, which includes representatives from the major standards development organizations, has formed working groups to address issues relating to three of the four standards categories.

HISPP's objectives are to coordinate the work of the standards development groups and provide a focal point for U.S. interaction with the European Committee for Standardization. The European Committee, which is funded by member European nations, has a technical committee for medical information technology that has had seven working groups involved in standards development activities since February 1991. Many of the 51 items the working groups are addressing are similar to issues being addressed by U.S. standards development organizations.

ANSI officials believe that HISPP can accomplish its objectives and contribute to the development of a comprehensive set of standards. There has been continued interest among standards development organizations, industry, government agencies, and other interested parties in achieving compatible standards. However, although the panel's first meeting in March 1992 attracted many interested participants, its second, third, and fourth meetings, in June 1992, October 1992, and January 1993, failed to attract a quorum. We believe this lack of participation raises concerns about the panel's ability to achieve its goals.

Federal Role in Developing Medical Record Standards Has Been Minimal

As discussed, federal policy is to rely on voluntary standards development organizations where feasible and participate in their activities.[4] Federal agencies with statutory authority can develop their own standards if the voluntary process fails to develop standards, judged to be in the public interest, in a timely fashion.

The Omnibus Budget Reconciliation Act of 1989 assigned responsibility for developing automated medical record standards to the Agency for Health Care Policy and Research (AHCPR), a component of the Department of

[3]ANSI is a private, nonprofit organization that coordinates the U.S. voluntary consensus standards system and approves American national standards. ANSI has approved procedures that provide criteria, requirements, and guidelines for coordinating and developing consensus for American national standards.

[4]Office of Management and Budget Circular No. A-119.

Health and Human Services (HHS). At that time, AHCPR was made responsible for conducting and supporting outcomes research, developing practice guidelines, educating the health care community, and developing a database to meet its mandate. The standards to be developed include uniform definitions of data and common reporting formats and linkages, as well as standards to ensure security, confidentiality, accuracy, and appropriate maintenance of data describing a patient's clinical status. The legislation did not establish timetables for completing the standards.

AHCPR has been reluctant to take a leadership role in standards development, preferring to allow standards development organizations to proceed at their own pace. According to AHCPR officials, the agency's priority is the development of practice guidelines for physicians based on outcomes research. AHCPR has sponsored meetings on linking public and private medical data, funded research, and published a report to the Congress as required by the act. In addition, AHCPR is serving as liaison with the Technical Committee on Medical Informatics of the European Committee for Standardization and the Advanced Informatics Program of the Commission of the European Communities. It has also funded meetings and provided other organizational support for HISPP.

Groups other than AHCPR also deal with issues related to automated medical record standards. The Computerized Patient Record Council, formed in October 1992, coordinates HHS' efforts in the area of computerized patient records and monitors progress in this area. In addition, three private-sector workgroups were established after former Secretary Sullivan's Forum on Administrative Costs, held in November 1991. The work of these three groups, the Workgroup for Electronic Data Interchange, the Task Force on Patient Information, and the Workgroup on Administrative Costs and Benefits, addresses health care administrative issues.

Other federal involvement in medical record standards development has been primarily through participation in voluntary organization meetings. Agencies that use medical records to carry out their missions have attended these meetings to provide input on their specific needs. Participating agencies have included the Health Care Financing Administration (HCFA); the Social Security Administration; the Department of Veterans Affairs; the Public Health Service (specifically AHCPR, Indian Health Service, National Institutes of Health, and the Food and Drug Administration); the National Highway Traffic Safety Administration; and the Consumer Product Safety Commission.

Recent Legislation Proposed a More Active Federal Role

HCFA, a component of HHS, recognizes that standardized automated medical information is critical to its ability to reduce costs and increase the efficiency of its programs. As a result, HCFA helped draft the Medical and Health Insurance Information and Reform Act of 1992. According to HCFA officials, this initiative was intended to raise the level of urgency for standards development organizations and create incentives for faster standards development.

The bill provided clear federal direction and established a timetable for standards development. Sections of the bill (1) addressed HCFA's future needs for billing, utilization review, and peer review data; (2) set standards development priorities by emphasizing hospital systems first, followed by other health care provider systems; (3) required certain standards to be in place by certain dates and, if they were not, authorized the Secretary of HHS to promulgate them; and (4) required hospitals to begin transmitting information to HCFA electronically as a requirement for Medicare participation. The bill, however, was not enacted by the 102nd Congress.

Conclusions

Developing standards for automated medical records has been a long and arduous task, with no end in sight. For the past decade, in line with government policy, development has focused on voluntary standards organizations. However, the voluntary process has been unable to produce the comprehensive set of standards necessary to support automated records.

The lack of standards has been a fundamental barrier in efforts to improve the delivery of health care services. In particular, the lack of standardized medical information has been a barrier in improving patient care and safety, controlling costs, enhancing practitioner productivity, facilitating outcomes research, and developing more efficient and accurate claims billing systems.

The government and the private sector have a great deal at stake in the success of these actions. American manufacturers need standards for automated medical records before they can successfully market the interoperable and interchangeable medical information systems and components needed to support health care providers in domestic and international markets. For the government, the federal share of U.S. health care expenditures is growing and exceeded $250 billion annually in 1992. To develop and implement effective policies to contain expenditures and ensure quality health care services, the government has a fundamental

need for accurate, comprehensive data from standardized automated medical records.

In view of these critical needs, we believe it is no longer in the public interest for medical standards development to continue at the same pace. Action is needed to break the impasse and provide the leadership necessary to expedite the development process.

Matters for Congressional Consideration

The Congress should consider taking action to enhance federal involvement in the development of automated medical record standards. In particular, leadership is needed to set development priorities, marshal resources to implement the priorities in a timely fashion, coordinate activities, and facilitate consensus-building among the diverse interests that comprise the U.S. health care community.

The key issue for the Congress to decide is how to best provide the leadership necessary to expedite medical record standards development. This can be accomplished in several ways. We believe the decision on which alternative to choose can best be made following congressional deliberations on the following options:

1. Keep leadership in the private sector by providing resources to a private organization, such as HISPP, that is already attempting to coordinate standards development activities. Assistance could include directing NIST to provide technical and administrative support to bolster ongoing work.

2. Give standards development a more prominent role in the federal government. This could be achieved by (a) directing AHCPR to exercise its authority and make standards development a top priority as envisioned in its enabling legislation or (b) elevating the level of federal authority in medical record standards development from AHCPR to the Secretary of HHS.

Once a clearly defined leadership role has been assigned, the following actions could be considered:

- Establish time frames for the organizations developing automated medical record standards.
- Create a range of incentives for timely completion of standards development, such as (1) tying the use of standardized medical records to Medicare reimbursement and (2) funding pilot projects demonstrating the

technology required to implement standards and share information in the complex health care setting.

- Work with standards development organizations and involved federal agencies to determine private and federal information needs and, on the basis of these needs, set standards development priorities.

Agency Comments and Our Evaluation

Overall, HHS agreed with our conclusion that more active federal involvement could help accelerate standards development. In other comments, HHS said that the report may overstate the impact of standardized automated medical records on the nation's efforts to control rising health care costs because companion investments would also be needed to (1) develop and evaluate clinical decision support systems and (2) conduct research on the most effective uses of automated patient care data. Further, HHS said that additional information was needed on the economic benefits of exchanging automated patient data among providers and on necessary confidentiality and privacy protections.

The Department also noted that AHCPR has been a leading advocate for the benefits of health care information-related standards at many meetings, has actively promoted the work of ANSI and HISPP, and has undertaken international liaison with several European standards development committees and programs.

We recognize that significant costs will be associated with implementing an automated medical record system and agree that more information is needed to better understand the costs and benefits associated with automated medical records. Since this issue was not central to our report and because of the paucity of available data, our discussion on this matter was general in nature. Specifically, we observed that (1) the lack of standardized medical information has been a barrier to progress in a number of areas, including cost control; and (2) in developing policies to contain expenditures and ensure quality health care, the government has a fundamental need for accurate, comprehensive data from standardized automated medical records. We do not believe these observations overstate the impact of automated medical records on containing costs.

Regarding AHCPR, our report discusses its role in sponsoring and attending meetings on medical record standards development, providing organizational support for HISPP, and serving as a liaison with several European standards development activities. However, while these activities provide necessary support, they do not comprise the active

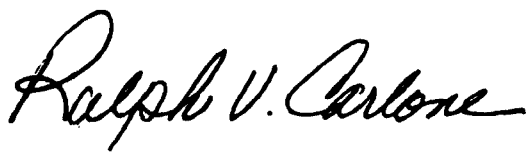
leadership that we believe is needed to expedite the standards development process. For that reason, we listed as one alternative for providing the necessary leadership that AHCPR be directed to make standards development one of its top priorities and assume a more active leadership role.

HHS also provided a number of technical comments that have been incorporated throughout the report as appropriate. HHS' comments are presented in their entirety in appendix IV. In addition, a draft of our report was reviewed for accuracy by representatives from the major standards development organizations and HISPP, and their technical comments have been incorporated where appropriate.

We conducted our review from September 1991 to March 1993, in accordance with generally accepted government auditing standards.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time we will send copies to interested congressional committees; the Secretary of Health and Human Services; the White House Task Force on Health Care Reform; and the Director, Office of Management and Budget. We will also make copies available to others upon request. This report was prepared under the direction of Frank W. Reilly, Director, Human Resources Information Systems, who can be reached at (202) 512-6408. Other major contributors are listed in appendix V.

Sincerely yours,



Ralph V. Carlone
Assistant Comptroller General

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Abbreviations

AHCPR	Agency for Health Care Policy and Research
ANSI	American National Standards Institute
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HISPP	Health Care Informatics Standards Planning Panel
IMTEC	Information Management and Technology Division
NIST	National Institute of Standards and Technology

Objectives, Scope, and Methodology

In response to a request from the Chairman, Senate Committee on Governmental Affairs, we focused this review on a major barrier to the development of automated medical records—the lack of comprehensive standards. Specifically, our objectives were to determine the (1) standards needed to develop and share automated medical records, (2) status of standards development efforts, and (3) federal role in developing standards.

To obtain information on the types of standards needed, we reviewed reports by federal agencies, health care organizations, and standards development organizations. We also reviewed copies of standards and draft standards; articles in technical journals and medical informatics periodicals; and other documents from government agencies, private industry, and professional groups. We contacted experts and key officials from these groups and attended a number of conferences sponsored by medical informatics groups and standards development organizations.

To determine the status of standards under development, we contacted the chairpersons of the committees involved in developing automated medical record standards at several American standards development organizations. We obtained information from them on the history of their efforts, the composition of their committees, their published and draft standards, and their estimates of when the standards would be completed. We attended all meetings of ANSI's Healthcare Informatics Standards Planning Panel, and interviewed the chairman of HISPP, ANSI officials, and officials at AHCPR—the federal agency with statutory responsibility for developing automated medical standards—about the status of standards development.

To determine the federal role in developing standards, we reviewed federal policy, laws, and regulations on the federal role in standards development in general and automated medical record standards in particular. We interviewed a representative of the Office of Management and Budget about provisions in Circular A-119 concerning federal policy in standards development and its enforcement of these provisions. We also interviewed AHCPR officials regarding their activities in carrying out their mandate to develop standards, as well as officials at HCFA and NIST. Appendix II contains a complete listing of the organizations and agencies contacted during the course of this review.

Organizations and Agencies Contacted

Standards Development Organizations

American College of Radiology, National Electrical Manufacturers Association
American National Standards Institute (ANSI)
American Society for Testing and Materials
Health Level Seven
Institute of Electrical and Electronic Engineers

Trade and Professional Associations

American Healthcare Information Management Association
American Hospital Association
American Medical Association
Health Industry Manufacturers Association

Hospitals and Other Health Care Providers

Beth Israel Hospital, Boston, Massachusetts
Columbia Presbyterian Medical Center, New York City
Emory University Hospitals, Atlanta, Georgia
Harvard Community Health Plan, Burlington, Massachusetts
Harvard Medical School, Boston
Massachusetts General Hospital, Boston
Medical College of Wisconsin, Milwaukee
Strong Memorial Hospital, Rochester, New York
University of Virginia Hospitals, Charlottesville
William Beaumont Hospital, Troy, Michigan

Government Agencies

Congressional Research Service
Consumer Product Safety Commission
Department of Commerce:
- National Institute of Standards and Technology (NIST)

Department of Health and Human Services:
- Agency for Health Care Policy and Research (AHCPR)
- Food and Drug Administration
- Health Care Financing Administration (HCFA)
- National Library of Medicine
- Social Security Administration

Department of Transportation:
- National Highway Traffic Safety Administration

Office of Management and Budget
Office of Technology Assessment

Consultants/Vendors/ Others

Commonwealth of Massachusetts
Sheldon I. Dorenfest & Associates, Ltd.
Enterprise Systems, Inc.
Inter Practice Systems
Joint Commission for Accreditation of Healthcare Organizations
Kurzweil Applied Intelligence, Inc.

Most Active Standards Organizations and Medical Standards Areas Being Addressed

Organization	Vocabulary	Structure	Messaging	Security
American College of Radiologists/National Electric Manufacturers Association		●	●	
American National Standards Institute				
• Accredited Standards Committee X3			●	
• Accredited Standards Committee X12N			●	
• Healthcare Informatics Standards Planning Panel	○		○	○
American Society for Testing and Materials				
• Committee E31	●	●	●	●
Health Level Seven		●	●	
Institute of Electrical and Electronics Engineers		●	●	

● Developing standards
○ Coordinating standards development

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAR 29 1993

Mr. Ralph V. Carlone
Assistant Comptroller General
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Carlone:

Enclosed are the Department's comments on your draft report, "Automated Medical Records: Leadership Needed to Expedite Standards Development." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely yours,

Bryan Mitchell

Bryan B. Mitchell
Principal Deputy Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT "AUTOMATED MEDICAL RECORDS: LEADERSHIP NEEDED TO EXPEDITE STANDARDS DEVELOPMENT" GAO/IMTEC-93-17, FEBRUARY 1993

GENERAL COMMENTS

There is general agreement with the basic conclusion of the General Accounting Office (GAO) draft audit report: "... more active federal involvement could help accelerate standards development." The report identifies standards barriers as significant obstacles to the rapid development of computer information decision support systems for health care. There are, of course, other barriers that influence the cost and complexity of achieving truly transportable electronic medical records.

Without noting the companion investments needed (1) to develop and evaluate clinical decision support systems and (2) conduct evaluative research on the most effective uses of automated patient care data, the report may overstate the impact of standardized automated medical records on the nation's efforts to control rising health care expenditures while assuring high quality health care services. In addition, more information is needed on the economic benefits of exchanging automated patient data among providers, and the confidentiality and privacy protections that are necessary.

The Agency for Health Care Policy and Research (AHCPR) and the Health Care Financing Administration (HCFA) collaborated with other Department of Health and Human Services (HHS) agencies in the formation of the HHS Computerized Patient Record Council on October 23, 1992. The Council provides advice to the Secretary on asserting national leadership in the promotion, use and evaluation of computerized health care decision support systems, especially computer-based patient records. The Council coordinates the Department's efforts in the area of computerized patient records, coordinates activities with outside groups including standards setting groups, and generally monitors progress on the development of computerized patient records. The Council is co-chaired by the Assistant Secretary for Health and the Administrator of HCFA.

The AHCPR has been a leading spokesperson for the benefits of health care information standards at many meetings of professional associations and standards developing organizations. AHCPR has also actively promoted the work of the American National Standards Institute (ANSI), the Health Care Informatics Standards Planning Panel (HISPP) and the HHS Computerized Patient Record Council. In addition, AHCPR has undertaken significant international liaison with the Technical Committee [for developing standards] on Medical

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Informatics of the European Committee for Standardization and with the Advanced Informatics Program of the Commission of the European Communities.

The AHCPR has undertaken these activities in close collaboration with other Public Health Service (PHS) agencies, especially the Food and Drug Administration (FDA). AHCPR and FDA have shared much of the planning for medical informatics coordination within PHS and the Department, and have been fully supportive of medical information standards with leadership roles in professional meetings, HISPP, and exchanges with the European Community. The Centers for Disease Control and Prevention has been active in the development of uniform health data sets. The Social Security Administration (electronic exchange of medical record supporting the disability claims process) and the National Cancer Institute (standards for image transfers) have also participated. In addition, the National Library of Medicine, the Clinical Center at the National Institutes of Health (NIH), and the Indian Health Service (IHS) have developed the systems and infrastructure to support the use of standardized patient care information.

The recent creation and charge of the Health Care Reform Task Force and the confirmation of a new Secretary of HHS may result in new direction for the automated medical records system objective. This potential new direction is necessary to any further discussion on GAO's matters for Congressional consideration.

TECHNICAL COMMENTS

We believe that GAO should consider the following comments before finalizing its report.

Page 4: Regarding the statement on page 4 that "The current inability to share medical information electronically stems largely from the lack of comprehensive standards for automated medical records." The lack of standards may be the largest technical barrier, but physicians must also agree on the utility of automating this data. This is another barrier that may be just as large.

Page 4, second paragraph: Standards for safeguarding confidentiality and privacy must also be addressed.

Page 6: Regarding the statement that the National Institute of Standards and Technology (NIST) "... has developed standards on its own when asked to do so by a federal agency." Our understanding is that NIST requires payment to develop

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standards, as well as to test them. A general lack of resources devoted to medical informatics standards has an impact here, too.

Page 10: At the top of page 10, the draft report identifies two alternate phrases that might be used to describe findings in an asthmatic patient. We also note that the same abbreviation or diagnosis can mean different things at different times. This kind of problem has occurred and will continue to occur because both medical science and the English language continuously evolve.

Page 11: The last paragraph on page 11 on Security Standards merges two concepts: policy choices about who is authorized to see records (confidentiality) and the technical mechanisms for assuring that only those authorized actually see them (security). This distinction is blurred in the report.

Page 12: Suggested wording for the sentence ending in the top line on page 12 is "...privacy with the benefits [of use], under careful conditions, for research, planning, and similar important publicly beneficial functions."

Page 12: The report does not mention the major confidentiality policy effort of the Department, the HHS Task Force on Privacy of Private Sector Health Records.

Page 15: The HISPP was approved by the ANSI Executive Standards Committee on December 19, 1991. It may, however, have been announced later, as GAO indicates.

Page 15: The European Standardization Committee is funded by European Countries and its standards developers are paid to develop standards.

Pages 15 and 16: The description of the formation of HISPP and the next section on the federal role being minimal ignores the leadership for support of health care information standards by the collaboration among AHCPR, FDA, ANSI, the standards developing organizations, and the European Committee on Standardization.

Page 16, first paragraph: The lack of a quorum at HISPP may be a function of the initial sign-up procedure and the lack of a follow-up procedure for determining membership (which is now being addressed) rather than a lack of interest in standards. We are encouraged by the continued interest and cooperation among the standards developing organizations to achieve compatible standards, and to move in the direction of official ANSI national standards. We suggest the following paragraph

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be substituted for the first full paragraph on page 16 of the draft report.

> "ANSI officials believe that HISPP can accomplish its objectives and contribute to the development of a comprehensive set of standards. There has been continued interest and cooperation among standards developing organizations, industry, government agencies, and other interested parties, in achieving compatible standards as envisioned by HISPP and in moving in the direction of official ANSI standards."

Page 16, second paragraph: We suggest deletion of 2 commas and insertion as follows: "... fails to develop standards [that are] judged to be in the public interest [and developed] in a timely manner."

Page 17: In view of the description of AHCPR's activities in the General Comments, we suggest that the following paragraph be substituted for the first paragraph on page 17.

> "Within available resources, AHCPR has pursued an approach consistent with federal policy in standards development, i.e., promoting voluntary, consensus development of standards while prodding standards developing organizations to pick up their pace. AHCPR has sponsored meetings on linking public and private medical data, funded research, and published a report to the Congress that was required by the Act. AHCPR has also funded meetings of HISPP. In addition, AHCPR has, together with FDA, provided organizational support to HISPP and undertaken liaison with the European Committee for Standardization and the Commission of the European Communities' Advanced Informatics in Medicine Program."

Page 17, second paragraph: We suggest the last sentence be changed to "Participating agencies have included HCFA, the Department of Veterans Affairs, [PHS (i.e., AHCPR, IHS, NIH, FDA)], the National Highway Traffic Safety Administration, and the Consumer Product Safety Commission."

Page 19: HISPP should have more resources available to it. Even though the John A. Hartford Foundation has awarded a grant to Dr. Clem McDonald to support the work of the Message Developers Subcommittee there are other subcommittees and more that are needed, e.g., for data modeling. NIST could develop a working model (test bed) for testing medical informatics standards that are developed.

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Page 20: The following language is suggested for inclusion after the discussion of "option 3":

> "However, the Congress should recognize that complete and comprehensive standards will not be developed quickly, easily, or inexpensively. The diversity of information and language associated with medical care, disease descriptions, medical history and physical examination data, and the evolving medical sciences indicate the inherent complexity of medical standards development. For a standard to achieve its full potential, changes in training, behavior, and technology use will be required, as well as ongoing support for the evolution of the standard itself. A sustained, pragmatic, consistent effort that achieves regular periodic successes while keeping the long-term goals in mind is most likely to be successful."

Finally, the GAO draft report does not discuss the efforts of the Workgroup for Electronic Data Interchange, the Workgroup on Administrative Costs and Benefits, and the Task Force on Patient Information. These three workgroups were established in the private sector after former Secretary Sullivan's Forum on Administrative Costs, which brought together health care leaders to discuss ways of reducing administrative costs in the health care delivery system, including the automation of patient information. All three of these groups are in various stages of evaluation on health care administrative issues. We suggest that GAO at least refer to the efforts of these groups in the final report.

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