

A REPORT RECOMMENDATION
FROM THE NATIONAL COMMITTEE
ON VITAL AND HEALTH STATISTICS

Personal Health Records and Personal Health Record Systems

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
National Institutes of Health
National Cancer Institute

National Center for Health Statistics
Centers for Disease Control and Prevention



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**A Report and Recommendations from
the National Committee on Vital and Health Statistics**

U.S. Department of Health and Human Services

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National Committee on Vital and Health Statistics October 2005

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EXECUTIVE SUMMARY

President Bush and Secretary Leavitt have put forward a vision that, in the Secretary's words, "would create a personal health record that patients, doctors and other health care providers could securely access through the Internet no matter where a patient is seeking medical care." The National Health Information Infrastructure Workgroup of the National Committee on Vital and Health Statistics (NCVHS)¹ held six hearings on personal health records (PHRs) and PHR systems in 2002-2005. On the basis of those hearings, the Workgroup developed a letter report with twenty recommendations that it sent to the Secretary in September 2005.² Citing the role PHR systems could play in improving health and healthcare and furthering the broad health information technology agenda, the letter report urges the Secretary to exercise leadership and give priority to developing PHRs and PHR systems, consistent with the Committee's recommendations. The present report is a slightly expanded version of the letter report sent to the Secretary. Although substantively unchanged, it adds clarifying information for a broader audience.

Currently, PHRs and their associated health management tools are heterogeneous and evolving. There is no uniform definition of "personal health record" in industry or government. The following attributes can vary:

- the scope or nature of the information/ contents
- the source of the information
- the features and functions offered
- the custodian of the record
- the storage location of the contents
- the technical approach
- the party who authorizes access to the information

The Committee concluded that while this variety reflects the current stage of innovation, it makes collaboration and policy-making difficult. The Committee recommended development of a descriptive framework to facilitate nuanced discussion and policy-making in this area, and proposed the attributes listed above as a starting point (see page 11).

Although the consumer/patient is the primary beneficiary and user of PHRs, other stakeholders stand to benefit from their use, as well. The table below summarizes potential benefits from the perspective of various roles. (These perceived benefits may not align with any specific PHR or PHR system, and the same users may play different roles at different times.)

1 NCVHS is the statutory public advisory Committee on health information policy to the Secretary of Health and Human Services.

2 <http://www.ncvhs.hhs.gov/050909lt.htm>

KEY POTENTIAL BENEFITS OF PHRS AND PHR SYSTEMS

ROLES	BENEFITS
Consumers, Patients and their Caregivers	<ul style="list-style-type: none"> <input type="checkbox"/> Support wellness activities <input type="checkbox"/> Improve understanding of health issues <input type="checkbox"/> Increase sense of control over health <input type="checkbox"/> Increase control over access to personal health information <input type="checkbox"/> Support timely, appropriate preventive services <input type="checkbox"/> Support healthcare decisions and responsibility for care <input type="checkbox"/> Strengthen communication with providers <input type="checkbox"/> Verify accuracy of information in provider records <input type="checkbox"/> Support home monitoring for chronic diseases <input type="checkbox"/> Support understanding and appropriate use of medications <input type="checkbox"/> Support continuity of care across time and providers <input type="checkbox"/> Manage insurance benefits and claims <input type="checkbox"/> Avoid duplicate tests <input type="checkbox"/> Reduce adverse drug interactions and allergic reactions <input type="checkbox"/> Reduce hassle through online appointment scheduling and prescription refills <input type="checkbox"/> Increase access to providers via e-visits
Healthcare Providers	<ul style="list-style-type: none"> <input type="checkbox"/> Improve access to data from other providers and the patients themselves <input type="checkbox"/> Increase knowledge of potential drug interactions and allergies <input type="checkbox"/> Avoid duplicate tests <input type="checkbox"/> Improve medication compliance <input type="checkbox"/> Provide information to patients for both healthcare and patient services purposes <input type="checkbox"/> Provide patients with convenient access to specific information or services (e.g., lab results, Rx refills, e-visits) <input type="checkbox"/> Improve documentation of communication with patients
Payers	<ul style="list-style-type: none"> <input type="checkbox"/> Improve customer service (transactions and information) <input type="checkbox"/> Promote portability of patient information across plan <input type="checkbox"/> Support wellness and preventive care <input type="checkbox"/> Provide information and education to beneficiaries
Employers	<ul style="list-style-type: none"> <input type="checkbox"/> Support wellness and preventive care <input type="checkbox"/> Provide convenient service <input type="checkbox"/> Improve workforce productivity <input type="checkbox"/> Promote empowered healthcare consumers <input type="checkbox"/> Use aggregate data to manage employee health
Societal/Population Health Benefits	<ul style="list-style-type: none"> <input type="checkbox"/> Strengthen health promotion and disease prevention <input type="checkbox"/> Improve the health of populations <input type="checkbox"/> Expand health education opportunities

These and other benefits are not assured, however. To realize the potential of PHRs and PHR systems to improve health and healthcare, significant steps are needed in the areas of privacy, security, and interoperability, in particular, as recommended in this report. The Committee's key findings include the following:

- It is important to clarify the respective rights, obligations, and potential liabilities of consumers, patients, providers, and other stakeholders in PHR systems.
- Consumers should have the right to make an informed choice concerning the uses of their personal information when signing up to use any personal health record products or services.
- Security is a critical component of a PHR system, especially if it is accessible via the Internet.
- The full potential of PHR systems will not be realized until they are capable of widespread exchange of information with Electronic Health Records (EHRs) and other sources of personal and other health data.

The Committee also identified broad areas for research and evaluation for PHR systems. They include consumer, health services, and technical research and the development of metrics to assess the implementation and impact of PHR systems on multiple dimensions of health and healthcare.

Most of the National Committee's recommendations (which are listed below and discussed further in the full report) are directed to the U.S. Department of Health and Human Services (HHS). Some also call for action by other federal agencies, standards development organizations, PHR vendors, health care organizations, and pilot project contractors. All the recommended steps require coordination among stakeholders and between the public and private sectors. They also require federal leadership. The Committee recommends that, similar to its role in stimulating EHR adoption, the Department encourage and actively participate in a public/private partnership that facilitates standards-based approaches to PHR systems in a harmonized legal and regulatory environment across geopolitical boundaries.

NCVHS Recommendations on PHRs and PHR Systems

RECOMMENDATIONS ON EVOLVING TERMS AND PRACTICES

1: Consensus framework. NCVHS recommends that HHS support the development of and promote public-private consensus on a framework for characterizing personal health record systems, building on this initial framework (see p.11).

2: Education. HHS and others should use the agreed-upon framework as a basis for education efforts highlighting the benefits and risks of various types of PHRs, aimed not only at consumers and patients but also at healthcare providers (e.g., physicians and nurses) and other stakeholders.

Recommendations on Privacy

3: Education about privacy. In any public education program about PHR systems, HHS and other parties should inform consumers about the importance of understanding the privacy policies and practices of PHR system vendors, including the enumeration of potential secondary uses and disclosures of personally identifiable health information.

4: Best practices. HHS should identify and promote best practices with respect to privacy policies and practices for PHR systems, and models for plain language wording of notices describing these policies and practices. These best practices and models should also address translations into other languages.

5: Privacy in HHS-sponsored activities. For any HHS-sponsored pilot projects, and any contractual relationship that CMS undertakes with entities intending to utilize CMS data in PHRs, HHS should require that those PHR systems provide advance notice to consumers of any uses or disclosures of personally identifiable health information. In those situations where HIPAA does not apply, uses or disclosures of information in PHRs should not be allowed without the express consent of the consumer.

6: Privacy in activities by entities not covered by HIPAA. Entities not covered by HIPAA that offer PHR systems should voluntarily adopt strict privacy policies and practices and should provide clear advance notice to consumers of

these policies and practices. This notice should specifically include a full description of all uses of PHR data. In addition, NCVHS recommends that no health information in a PHR be used without the express consent of the consumer, which may be obtained in conjunction with the notice.

7: Assessment. HHS should collaborate with other Federal agencies as appropriate to review and assess issues related to privacy and other consumer protections for PHR systems. Such a review should evaluate existing authorities and mechanisms for addressing potential problems; it should also identify gaps and recommend appropriate action.

Recommendations on Security

8: Security standards framework. HHS should work with relevant stakeholders to develop and promote a standards framework for authentication, access control, authorization, and auditability based on the following principals:

- All PHR systems should provide consumers with terms and conditions of use.
- All PHR systems should provide functionality that enables a consumer to audit who has accessed the consumer's information within the PHR.
- All PHR systems should be based on industry-standard security and authentication schemes. This should not preclude vendors from making additional security protections available at the option of the consumer. The decision to adopt additional security technologies should take into consideration portability, supportability and cost of such solutions.
- PHR systems should include functionality that provides a consumer with the ability to control who accesses the consumer's information within the PHR. This would include the ability for the consumer to restrict access to specific subsets of information within the PHR.

9: Security in HHS activities. For any HHS-sponsored pilot projects and any HHS contracts to produce PHR systems, HHS should require that security protections consistent with the HIPAA Security Rule be implemented.

Recommendations on Interoperability

10: Addressing standards gaps. Standards development efforts should be expanded to address issues related to authentication, identification of the data source, non-repudiation, communication to/from PHR systems, mapping to consumer-oriented concepts and terms, and the enabling of consumer-controlled access.

11: Consistency of EHR and PHR standards. HHS should encourage standards development organizations, wherever possible, to adopt for the PHR those standards that are used to promote interoperability of EHRs.

12: PHR data sets. HHS should encourage standards development organizations, wherever possible, to identify data sets for PHR systems that are consistent with those used for EHRs.

13: Standards for HHS-sponsored activities. For any HHS-sponsored pilot projects and any contractual relationship that CMS undertakes with entities intending to utilize CMS data in PHR systems, HHS should require that PHR vendors and health care organizations adopt data content and exchange standards that are based upon standards accepted for EHRs, as a way of improving the interoperability of the systems.

14: Standards for private-sector activities. Private sector PHR vendors and health care organizations should voluntarily adopt data content and exchange standards that are based upon standards accepted for EHRs, as a way of improving the interoperability of the systems.

Recommendations on the Federal Role

15: Federal roles. Federal agencies should assess how they can more fully explore and appropriately promote the benefits of PHR systems across their respective roles.

16: Considerations for underserved populations. The Federal government should identify and address the information technology access and use barriers that limit the dissemination of PHR systems, particularly to underserved populations. HHS also should address health literacy issues that could limit the use of PHR systems by the most vulnerable populations.

Recommendations on Research and Evaluation

17: HHS research. The Secretary should request that all agencies review their research portfolios and program operations and report to the Secretary the ways they could contribute to the research and evaluation of PHR systems.

18: OPM pilots. HHS should collaborate with the Office of Personnel Management to help implement pilot studies of PHR systems with payers and beneficiaries of the Federal Employees Health Benefits Plan.

19: AHRQ research. The Agency for Healthcare Research and Quality (AHRQ) should expand its evolving health information technology research portfolio to support health services research and the development of metrics to assess the impact of PHR systems on quality of care, patient safety, and patient outcomes.

20: CMS pilots. The Centers for Medicare and Medicaid Services (CMS) should conduct pilot studies of PHR usage for chronic diseases to evaluate utility and cost effectiveness for beneficiaries, providers and payers.

NEXT STEPS FOR NCVHS

NCVHS will continue to gather information on this dynamic field. It plans to release additional recommendations on privacy, confidentiality and the NHIN. In addition, it will provide a forum for exploring several issues that arose from the initial hearings:

- The role of CMS
- Ownership and control of data within PHR systems
- The ability of PHR systems to obtain data from external sources such as provider systems, claims clearinghouses, health plans and similar sources
- Non-repudiation (authenticating the integrity of the contents and exchange of information)
- Potential liability for providers associated with the use of incomplete or inaccurate data within a PHR
- Privacy policy practices, including notice

BACKGROUND

President Bush and Secretary Leavitt have put forward a vision that, in the Secretary's words, "would create a personal health record that patients, doctors and other health care providers could securely access through the Internet no matter where a patient is seeking medical care." Responding to this vision, the National Committee on Vital and Health Statistics (NCVHS) submitted a letter report on Personal Health Record (PHR) systems in September, 2005. The letter report describes initial findings from national hearings covering the many types of systems referred to as "Personal Health Records," suggests areas for further exploration, and offers twenty recommendations. It urges the Secretary to exercise leadership and to give this area the priority it deserves, in view of the role PHR systems could play in improving health and healthcare and furthering the broad health information technology agenda. The present report is a slightly expanded version of the letter report sent to the Secretary. Although substantively unchanged, it adds clarifying information for a broader audience.

In its 2001 report, *Information for Health: A Strategy for Building the National Health Information Infrastructure*, NCVHS identified three primary areas or dimensions that comprise a national health information infrastructure (NHII): information to support the needs of patient care, population health, and personal health. The healthcare provider (patient care) area promotes quality patient care by providing access to more complete and accurate patient data on the spot, around the clock. It includes provider notes, clinical orders, decision-support programs, electronic prescribing programs, and practice guidelines. The second area, population health, makes it possible for public health officials and other data users at local, State, and national levels to identify and track health threats, assess population health, and create and monitor programs and services. This area includes information on both the health of the population and influences on it. Finally, the personal health area of the NHII supports individuals in managing their own

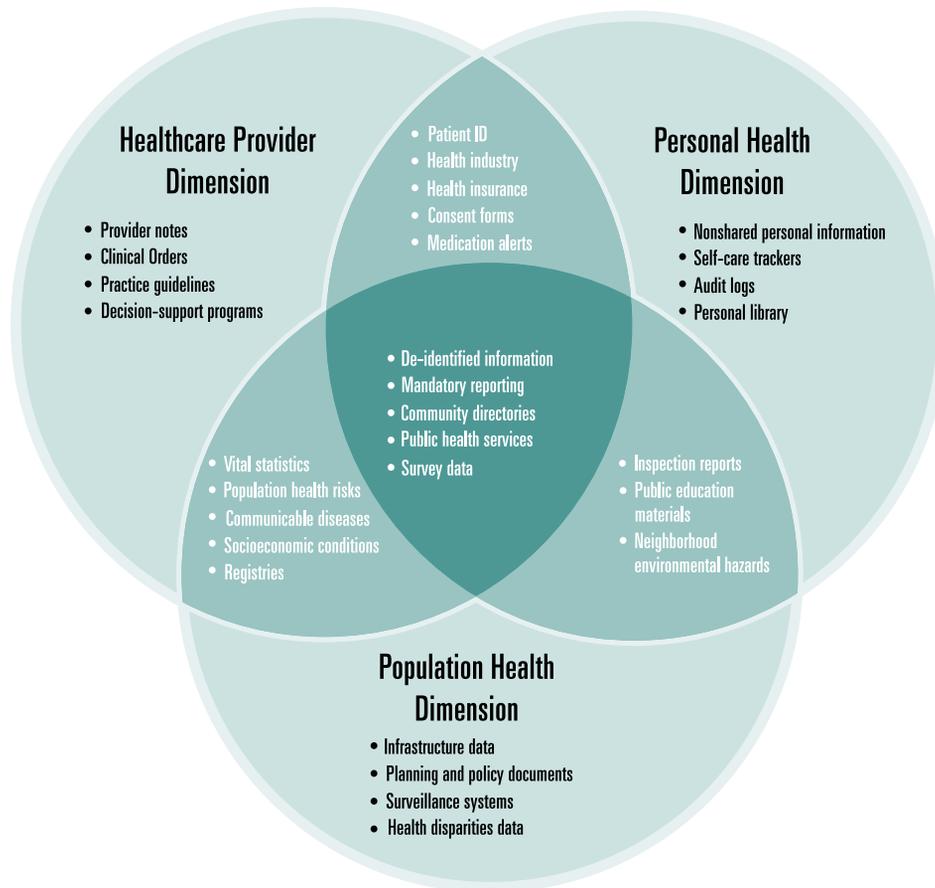
wellness and healthcare decision making. It includes a personal health record that is created and controlled by the individual or family, plus information and tools such as health status reports, self-care trackers and directories of healthcare and public health service providers.

In this vision of the NHII, the three primary areas are equally important, and the goal for the infrastructure as a whole is to promote optimum information exchange among them. The heart of the vision is sharing information and knowledge as appropriate so it is available to people when they need it to make the best possible health decisions. Ready access to relevant, reliable information and secure modes of communication will enable consumers, patients, healthcare and public health professionals, public agencies, and others to address personal and community health concerns far more effectively.

The diagram below, from the 2001 NCVHS report, shows how some information needs are unique to one dimension of activity and users, some are shared by two, and some are

shared by all three. The list of information types below is intended to be illustrative and is not exhaustive.

Examples of content for the three dimensions and their overlap



Source: National Committee on Vital and Health Statistics, *Information for Health: A Strategy for Building the National Health Information Infrastructure*, Washington, D.C., 2001.

Following publication of the 2001 NCHVS report, considerable work got underway on many fronts to develop the provider and population health dimensions of the NHII, much of it spurred by federal policy. In these two areas, infrastructure development has been paired with progress toward standards and privacy protection. However, there was less federal attention to the development of technologies, content, connections and protections for the personal dimension of the NHII. The NCVHS Workgroup on the National Health Information Infrastructure (NHII) decided to hold a series of hearings to learn more about PHRs and PHR systems (described below) because of their importance for

Ready access to relevant, reliable information and secure modes of communication will enable consumers, patients, healthcare and public health professionals, public agencies, and others to address personal and community health concerns far more effectively.

empowering consumers and patients to manage their health and partner with their healthcare providers.

By April 2005, the Workgroup had held six open hearings on information needs and activities related to personal health, and personal health records in particular. The hearings covered PHR models, data sets, standards, identification, authentication, barriers to adoption, privacy, policy issues and business issues. The invited presenters included consumers, government, health care organizations, nonprofit and commercial sponsors, Federal staff, standards and policy experts, healthcare providers, payers, and economists. The Workgroup was also informed about the work done on personal health records/personal health management tools by the HHS Office of Disease Prevention and Health Promotion and the Markle Foundation's Connecting for Health Collaborative,³ as well as about the Veterans Health Administration experience with MyHealtheVet, a personal health record already deployed for veterans.

The Workgroup identified seven issues where specific measures, collaboration and leadership are needed to assure that stakeholders' investments yield the desired benefits. These issues, discussed below, include evolving conceptions of PHRs; varying perspectives on their benefits; privacy; security requirements; interoperability requirements; the federal role; and research evaluation needs.

3 See Lansky, D., Kanaan, S., Lemieux, J. April 15, 2005. *Identifying Appropriate Federal Roles in the Development of Electronic Personal Health Records. Results of a Key Informant Process.* Submitted to the Office of Disease Prevention and Health Promotion, OPHS, U.S. Department of Health and Human Services; and Connecting for Health, July 2004. *Connecting Americans to their Healthcare. Final Report. Working Group on Policies for Electronic Information Sharing Between Doctors and Patients.* Markle Foundation and Robert Wood Johnson Foundation. http://www.connectingforhealth.org/resources/wg_eis_final_report_0704.pdf

PERSONAL HEALTH RECORDS ARE EVOLVING IN CONCEPT AND PRACTICE

Personal health records are broadly considered as means by which an individual's personal health information can be collected, stored, and used for diverse health management purposes. However, NCVHS found that there is no uniform definition of "personal health record" in industry or government, and the concept continues to evolve. In some concepts, the PHR includes the patient's interface to a healthcare provider's electronic health record (EHR). In others, PHRs are any consumer/patient-managed health record. This lack of consensus makes collaboration, coordination and policymaking difficult. It is quite possible now for people to talk about PHRs without realizing that their respective notions of them may be quite different. Recognizing the variety of attributes and possibilities and being very specific about what is being discussed would enable those engaged in collaboration and policymaking to conduct more nuanced discussions of PHRs and to collaborate more effectively.

There is no uniform definition of "personal health record" in industry or government, and the concept continues to evolve. This lack of consensus makes collaboration, coordination and policymaking difficult.

The first step in this direction is to catalog the variety of types of PHRs and PHR systems in existence and the varied uses of the terminology. This section summarizes the different perspectives of PHRs that the Workgroup observed throughout

The Committee proposes adopting the term "personal health record" to refer to the health or medical record that includes clinical data, and the term "personal health record systems" to refer to the multi-function tools that include PHRs among a battery of functions.

its process and recommends a way HHS could promote greater clarity.

The term "record" in "personal health record" may itself be limiting, as it suggests a singular static repository of personal data. The Committee found that a critical success factor for PHRs is the provision of software tools that help consumers and patients participate in the management of their own health conditions. A "personal health record system" provides these additional software tools. The Committee proposes adopting the term "personal health record" to refer to the collection of information about an individual's health and health care, stored in electronic format. The term "personal health record system" refers to the addition of computerized tools that help an individual understand and manage

the information contained in a PHR. These terms are analogous to the terms “electronic health record” and “electronic health record systems” that have been adopted by the standards development organization HL7, which is leading the standards activity in this area. The PHR and the PHR system are intended for use by consumers, patients or their informal caregivers, in contrast with EHR systems that are intended for use by healthcare providers.

Despite the heterogeneity of PHRs and PHR systems at present, NCVHS concluded that it is not possible, or even desirable, to attempt a unitary definition at this time. However, the Committee believes it is possible as well as useful to characterize them by their attributes: specifically, the scope or nature of their information/contents, the source of their information, the features and functions they offer, the custodian of the record, the storage location of the content, the technical approach to security, and the party who authorizes access to the information.

NCVHS believes that establishing a framework for characterizing and describing the attributes of PHRs and PHR systems would be extremely helpful in promoting a better understanding and appropriate use of any given PHR system. A consensus framework would also provide a foundation for public education efforts.

NCVHS believes that establishing a framework for characterizing and describing the attributes of PHRs and PHR systems would be extremely helpful in promoting a better understanding and appropriate use of any given PHR system. Some of the approaches to each of the attributes, as heard by the Committee, are listed below in a framework that the Committee offers as a starting point for such an effort. The consensus-building process around such a framework should take into consideration the work that standards development organizations are doing to define the functional attributes of PHR systems. A consensus framework would also provide a foundation for public education efforts, which many speakers

called for, to highlight the benefits and risks of various types of PHRs, aimed not only at consumers and patients but also at healthcare providers and other stakeholders.

Initial framework of PHR and PHR systems attributes

- Scope and nature of content
 - Some PHR systems just have consumer health information, personal health journals, or information about benefits and/or providers, but no clinical data about the individual.
 - Some PHR systems have clinical information. Of these, some are disease specific, some include subsets of information such as lab reports, and some are comprehensive.
- Source of information
 - Data in PHR systems may come from the consumer, patient, caregiver, healthcare provider, payer, or all of these.
 - Some PHR systems are populated with data by EHRs.
- Features and functions
 - PHR systems offer a wide variety of features, including the ability to view personal health data, exchange secure messages with providers, schedule appointments, renew prescriptions, and enter personal health data; decision support (such as medication interaction alerts or reminders about needed preventive services); the ability to transfer data to or from an electronic health record; and the ability to track and manage health plan benefits and services.
- Custodian of the record
 - The physical record may be operated by a number of parties, including the consumer or patient, an independent third party, a healthcare provider, an insurance company, or an employer.

- Data storage
 - Data may be stored in a variety of locations, including an Internet-accessible database, a provider’s EHR, the consumer/patient’s home computer, a portable device such as a smart card or thumb drive, or a privately maintained database.
- Technical approaches
 - Current PHRs and PHR systems are generally not interoperable (with the exception of the PHRs that are “views” into the EHR, and they vary in how they handle security, authentication, and other technical issues.
- Party controlling access to the data
 - While consumers or patients always have access to their own data, they do not always determine who else may access it. For example, PHRs that are “views” into a provider’s EHR follow the access rules set up by the provider. In some cases, consumers do have exclusive control.

Recommendation 2:

Education.

HHS and others should use the agreed-upon framework as a basis for education efforts highlighting the benefits and risks of various types of PHRs, aimed not only at consumers and patients but also at healthcare providers (e.g., physicians and nurses) and other stakeholders.

Recommendations on Evolving Terminology and Functions:

1. Consensus Framework
2. Education

Recommendation 1:

Consensus framework.

NCVHS recommends that HHS support the development of and promote public-private consensus on a framework for characterizing personal health record systems, building on this initial framework.

PERSONAL HEALTH RECORD SYSTEMS' VALUE DEPENDS ON USERS, SPONSORS, AND FUNCTIONALITY

PHR systems create different kinds of value for a range of individual, institutional and societal stakeholders.

Testimony to NCVHS indicated that PHR systems create different kinds of value for a range of individual, institutional and societal stakeholders. The table below summarizes potential benefits from the perspective of various roles. Given the heterogeneity of concepts of PHRs and PHR systems, these perceived benefits may not align with any specific PHR or PHR system. Also, it is worth pointing out that the same users may play different roles at different times.

Key Potential Benefits of PHRs and PHR Systems

Roles	Benefits
Consumers, Patients and their Caregivers	<ul style="list-style-type: none"> <input type="checkbox"/> Support wellness activities <input type="checkbox"/> Improve understanding of health issues <input type="checkbox"/> Increase sense of control over health <input type="checkbox"/> Increase control over access to personal health information <input type="checkbox"/> Support timely, appropriate preventive services <input type="checkbox"/> Support healthcare decisions and responsibility for care <input type="checkbox"/> Strengthen communication with providers <input type="checkbox"/> Verify accuracy of information in provider records <input type="checkbox"/> Support home monitoring for chronic diseases <input type="checkbox"/> Support understanding and appropriate use of medications <input type="checkbox"/> Support continuity of care across time and providers <input type="checkbox"/> Manage insurance benefits and claims <input type="checkbox"/> Avoid duplicate tests <input type="checkbox"/> Reduce adverse drug interactions and allergic reactions <input type="checkbox"/> Reduce hassle through online appointment scheduling and prescription refills <input type="checkbox"/> Increase access to providers via e-visits <input type="checkbox"/> Improve documentation of communication with patients
Healthcare Providers	<ul style="list-style-type: none"> <input type="checkbox"/> Improve access to data from other providers and the patients themselves <input type="checkbox"/> Increase knowledge of potential drug interactions and allergies <input type="checkbox"/> Avoid duplicate tests <input type="checkbox"/> Improve medication compliance <input type="checkbox"/> Provide information to patients for both healthcare and patient services purposes <input type="checkbox"/> Provide patients with convenient access to specific information or services (e.g., lab results, Rx refills, e-visits) <input type="checkbox"/> Improve documentation of communication with patients
Payers	<ul style="list-style-type: none"> <input type="checkbox"/> Improve customer service (transactions and information) <input type="checkbox"/> Promote portability of patient information across plan <input type="checkbox"/> Support wellness and preventive care <input type="checkbox"/> Provide information and education to beneficiaries
Employers	<ul style="list-style-type: none"> <input type="checkbox"/> Support wellness and preventive care <input type="checkbox"/> Provide convenient service <input type="checkbox"/> Improve workforce productivity <input type="checkbox"/> Promote empowered healthcare consumers <input type="checkbox"/> Use aggregate data to manage employee health
Societal/Population Health Benefits	<ul style="list-style-type: none"> <input type="checkbox"/> Strengthen health promotion and disease prevention <input type="checkbox"/> Improve the health of populations <input type="checkbox"/> Expand health education opportunities

Consumers and patients who use PHR systems express strong support for them. Even those who are not familiar with them are interested in their potential benefits.

Consumers and patients who use PHR systems express strong support for them. They appreciate having access to their personal health information to manage their own health and health care and to share information with their providers. While surveys confirm that most of the general population is unaware of PHR systems, they also show that even those who are not familiar with them are interested in their potential benefits. Specific areas of interest include access to their health information (e.g., diagnoses, medications, test results), communicating with their physicians, scheduling appointments, renewing prescriptions, tracking immunizations, noting mistakes in the medical record, transferring information to new doctors, and getting test results.

The Committee heard testimony that people with chronic conditions are more likely to use PHR systems, including disease-specific PHR systems. It also heard of growing interest from payers, providers, and employers to sponsor PHR systems for their members, patients, or employees.

Many presenters (consumers, policy analysts, economists, health system executives) observed that PHR systems bring health care in line with electronic and automated services in other consumer sectors. Several raised the possibility that Health Savings Accounts and other “consumer-driven health plans” may provide a stimulus for PHR systems. However, these insurance approaches are too new to draw conclusions from them.

NCVHS heard testimony that the market for stand-alone PHRs offered for sale or subscription as commercial products or through non-healthcare third party entities is fairly new. While the number of products is growing, sales and usage statistics are limited.

Among the potential market drivers of PHR systems are the following: chronic disease management; improved access to personal health data; improved customer service and convenience; strengthened market position through increased loyalty (to the sponsoring entity); promotion of wellness, prevention and self-care; and improved care delivery and coordination through timely access to information.

The Committee believes that the emerging market for PHR systems needs to be monitored.

On a cautionary note, the Committee believes that relying entirely on market forces to determine the nature and direction of PHR systems could cause personal health information to be exploited for its economic value without adequate consumer controls. While this is addressed more fully in the section below on Privacy, the Committee believes that the emerging market for PHR systems needs to be monitored. As the market evolves, there may be occasions when the government needs to set standards or limits that formally recognize certain consumer rights. Otherwise, a breach of confidence in PHRs and PHR systems could harm the consumer and undermine consumers’ trust in electronic health records and the National Health Information Network.

PRIVACY

The Committee views privacy and security as closely entwined, with technical security measures being designed to implement privacy policies and practices. The Committee's findings on security follow this section on privacy.

The privacy considerations of PHR systems are complex, yet addressing them adequately is essential if PHR systems are to become widely accepted and used. Consumers want to be able to control access to their personal health information. As noted above, all PHR systems are based on consumers having access to their health information, and some are based on consumers having exclusive control of the information in their PHR. Some presenters raised the issue of consumers' ownership of their personal health information. Some identified a difference between legal control and ownership of the institutional medical record, on one hand, and consumer control and ownership of personal information and of a PHR, on the other. NCVHS observed that although the issues of health record ownership and access control are not new, they take on added dimensions with the emergence of PHR systems. Moreover, while *ownership* per se may not be as relevant as *control*, it will nevertheless be important to clarify the respective rights, obligations, and potential liabilities of consumers, patients, providers, and other stakeholders in PHR systems.

All PHR systems are based on consumers having access to their health information, and some are based on consumers having exclusive control of the information in their PHR. It will be important to clarify the respective rights, obligations, and potential liabilities of consumers, patients, providers, and other stakeholders in PHR systems.

Consumers should have the right to make an informed choice concerning the uses of their personal information when signing up to use any personal health record products or services.

The Committee notes that unique privacy issues arise in relation to PHR systems offered by third parties, including some emerging systems that warehouse and mine personal health data for secondary uses. The Committee is concerned that some business models involving third-party data warehouses could be predicated on the secondary use (including sale or barter) of consumer data. Consumers using these PHR systems may have little control over secondary uses by the PHR vendor. Although there are

beneficial secondary uses of data, such as post-marketing surveillance of adverse events from prescription drugs or population health monitoring, other secondary uses (e.g., targeted marketing) may not be desired by the consumer. Consumers should have the right to make an informed choice concerning the uses of their personal information when signing up to use any of these personal health record products or services.

Privacy measures at least equal to those in HIPAA should apply to all PHR systems, whether or not they are managed by covered entities.

While HIPAA compels covered entities to provide notice of their privacy practices to consumers, not all PHR vendors are “covered entities” as defined under HIPAA. The Committee is unaware of any requirement that compels PHR vendors not covered by HIPAA to provide to consumers the terms and conditions governing the privacy of their personal data. While the Committee does not suggest that HIPAA or a HIPAA-like framework is necessarily the most appropriate for safeguarding privacy in PHR systems, it does believe that privacy measures at least equal to those in HIPAA should apply to all PHR systems, whether or not they are managed by covered entities. The Committee also believes that it is vital for PHR systems vendors to provide clearly stated, easily understood, up-front privacy notices to consumers of their privacy policies and practices, and that these notices should be translated into other languages.

The recommendations below indicate some initial steps that should be undertaken to address these concerns. However, the Committee believes that these issues are entwined with, though not necessarily identical to, the privacy and confidentiality issues that must be addressed within the context of the National Health Information Network (NHIN). The NCVHS Subcommittee on Privacy and Confidentiality has been conducting hearings on privacy and confidentiality and the NHIN, and additional recommendations will be forthcoming.

Recommendations

on Privacy:

3. Education about privacy
4. Best practices
5. Privacy in HHS-sponsored activities
6. Privacy in activities by entities not covered by HIPAA
7. Assessment

Recommendation 3:

Education about privacy. In any public education program about PHR systems, HHS and other parties should inform consumers about the importance of understanding the privacy policies and practices of PHR system vendors, including the enumeration of potential secondary uses and disclosures of personally identifiable health information. (See Recommendation 2.)

Recommendation 4:

Best practices. HHS should identify and promote best practices with respect to privacy policies and practices for PHR systems, and models for plain language wording of notices describing these policies and practices. These best practices and models should also address translations into other languages.

Recommendation 5:

Privacy in HHS-sponsored activities. For any HHS-sponsored pilot projects, and any contractual relationship that CMS undertakes with entities intending to utilize CMS data in PHRs, HHS should require that those PHR systems provide advance notice to consumers of any uses or disclosures of personally identifiable health information. In those situations where HIPAA does not apply, uses or disclosures of information in PHRs should not be allowed without the express consent of the consumer.

Recommendation 6:

Privacy in activities by entities not covered

by HIPAA. Entities not covered by HIPAA that offer PHR systems should voluntarily adopt strict privacy policies and practices and should provide clear advance notice to consumers of these policies and practices. This notice should specifically include a full description of all uses of PHR data. In addition, NCVHS recommends that no health information in a PHR be used without the express consent of the consumer, which may be obtained in conjunction with the notice.

Recommendation 7:

Assessment. HHS should collaborate with other Federal agencies as appropriate to review and assess issues related to privacy and other consumer protections for PHR systems. Such a review should evaluate existing authorities and mechanisms for addressing potential problems; it should also identify gaps and recommend appropriate action.

SECURITY REQUIREMENTS

NCVHS noted that security is a critical component of a PHR system, especially if it is accessible via the Internet. Appropriate security measures must be employed to minimize the risk that an unauthorized person could gain access to an individual's information contained within a PHR. Survey and focus group research presented to the Workgroup indicates that widespread adoption of PHRs is not likely to happen until consumers are confident that they have adequate security protections. This confidence seems to depend on having the ability to control access to personal information and to audit who has seen it. As noted, the Committee found that PHR systems may exist in a variety of forms. Some of these may be within the exclusive control of the individual, such as a smart-card or thumb-drive based system. The large majority are currently Internet-based, such as those sponsored by healthcare providers, health insurers, or commercial ventures. New technical approaches may be needed to promote and achieve personal control over the creation, management, and exchange of personal health information contained within PHRs. The HIPAA Security Rule, as noted, has limited application. However, there is broad validity to its observation that specific security requirements will vary over time based both on threats, available security technologies and requirements inherent to a particular PHR. As noted above, the HIPAA Security Rule only applies to covered entities.

Security is a critical component of a PHR system, especially if it is accessible via the Internet.

With an Internet-based PHR system, multiple individuals, such as family members and caregivers, may view and contribute patient information. Ensuring authentication and access control in this context represents a major challenge.

In a healthcare setting, the provider can control the access of employees and affiliated staff to a patient's information in an EHR. With an Internet-based PHR system, in contrast, multiple individuals, such as family members and caregivers, may

view and contribute patient information. Ensuring authentication and access control in this context thus represents a major challenge. Further, while healthcare providers can use a variety of advanced technologies to secure an EHR, there is some question as to whether consumers generally are willing to accept the burdens or costs associated with the use of enhanced security technologies. The wide-scale adoption of such technologies for PHR systems will therefore be problematic, and security for PHR systems will probably be limited to technologies that are generally available for desktop operating systems. Further complexity is added by the multiple sources for information on the individual, including provider EHRs and external laboratory systems providing test results. Ensuring that the source of the information and the contents are authenticated and can not subsequently be changed (i.e., can not

be repudiated) is part of the challenge. The Committee plans to explore the issue of non-repudiation (i.e., authenticating the integrity of the contents and exchange of information) as it relates to PHR systems. Here it offers recommendations pertinent to the other issues raised above.

Recommendations

on Security:

8. Security standards framework

9. Security in HHS activities

Recommendation 8:

Security standards framework. HHS should work with relevant stakeholders to develop and promote a standards framework for authentication, access control, authorization, and auditability based on the following principals:

- All PHR systems should provide consumers with terms and conditions of use.
- All PHR systems should provide functionality that enables a consumer to audit who has accessed the consumer's information within the PHR.
- All PHR systems should be based on industry-standard security and authentication schemes. This should not preclude vendors from making additional security protections available at the option of the consumer. The decision to adopt additional security technologies should take into consideration portability, supportability and cost of such solutions.
- PHR systems should include functionality that provides a consumer with the ability to control who accesses the consumer's information within the PHR. This would include the ability for the consumer to restrict access to specific subsets of information within the PHR.

Recommendation 9:

Security in HHS activities. For any HHS-sponsored pilot projects and any HHS contracts to produce PHR systems, HHS should require that security protections consistent with the HIPAA Security Rule be implemented.

INTEROPERABILITY

As observed at the beginning of this report, the greatest opportunities for improving health and health care lie in enabling information exchange between the three dimensions (areas) of the national health information infrastructure. Consumers, providers, and those responsible for population health use much of the same information, but they do so for different purposes: respectively, to manage personal and family health, to care for patients, and to protect and promote the health of the community and the nation. The overlapping areas shown in the diagram on page 12 illustrate the types of information that will be shared and the need for interoperability. *Interoperability* is the term used to describe the technical capacity for this exchange of data between different information systems. The full potential of PHR systems will not be realized until they are capable of widespread exchange of information with EHRs and other sources of personal and other health data.

The greatest opportunities for improving health and health care lie in enabling information exchange between the three dimensions (areas) of the national health information infrastructure. The full potential of PHR systems will not be realized until they are capable of widespread exchange of information with EHRs and other sources of personal and other health data.

Interoperability is limited in a number of ways.

Currently, interoperability is limited in a number of ways. First, most PHR systems in use today are integrated with one provider's EHR system, in effect serving as a portal view into the EHR. This provides tight integration between what the patient sees and what the provider sees. However, if EHR systems are not interoperable, the content would be primarily limited to what is stored in that provider's EHR. In all likelihood, the data from other providers or other data sources would not be accessible to the patient's PHR. Hence under those conditions, the value to consumers exists only in the narrow context

of their treatment relationship to that provider. Interoperability is even more limited at present for most stand-alone PHR systems, which require consumers to manually enter their health data. None currently exchanges information with EHRs electronically, although some pilot projects to do so are underway in both the Federal and private sectors. While stand-alone PHR systems could potentially contain data from multiple EHRs, the current lack of interoperability standards impedes the flow of information between any one EHR and a stand-alone PHR.

Standards development efforts to date have not focused on certain key areas that would be necessary for optimum PHR implementation.

Standards development efforts to date have not focused on certain key areas that would be necessary for optimum PHR implementation. Significant work is needed on the following issues: user authentication, identification of the data source (consumer, family member, caregiver, provider, other), non-repudiation, communication to and from PHR systems, mapping of medical jargon to consumer-oriented information and terms, and enabling consumer-controlled access. The Committee heard broad agreement that a core or limited set of personal health data is important for PHR utility, although there was no consensus on a particular data set. Agreement on a specific minimum or core data set could help promote interoperability.

Recommendations on Interoperability:

10. Addressing standards gaps
11. Consistency of EHR and PHR standards
12. PHR data sets
13. Standards for HHS-sponsored activities
14. Standards for private-sector activities

Recommendation 10:

Addressing standards gaps. Standards development efforts should be expanded to address issues related to authentication, identification of the data source, non-repudiation, communication to/from PHR systems, mapping to consumer-oriented concepts and terms, and the enabling of consumer-controlled access.

Recommendation 11:

Consistency of EHR and PHR standards. HHS should encourage standards development organizations, wherever possible, to adopt for the PHR those standards that are used to promote interoperability of EHRs.

Recommendation 12:

PHR data sets. HHS should encourage standards development organizations, wherever possible, to identify data sets for PHR systems that are consistent with those used for EHRs.

Recommendation 13:

Standards for HHS-sponsored activities. For any HHS-sponsored pilot projects and any contractual relationship that CMS undertakes with entities intending to utilize CMS data in PHR systems, HHS should require that PHR vendors and health care organizations adopt data content and exchange standards that are based upon standards accepted for EHRs, as a way of improving the interoperability of the systems.

Recommendation 14:

Standards for private-sector activities. Private sector PHR vendors and health care organizations should voluntarily adopt data content and exchange standards that are based upon standards accepted for EHRs, as a way of improving the interoperability of the systems.

FEDERAL ROLES IN PHR SYSTEMS, INTERNAL AND EXTERNAL

The Committee heard testimony that the Federal government can offer vision and strategic leadership for PHR development and dissemination across its many roles in the health sector—that is, its roles as policy maker, healthcare provider, payer, employer, and sponsor of research and public education. The Committee notes that a number of documents already exist that can help identify specific opportunities, including the report cited on page 12 of this Report. Several Federal agencies are already pursuing the use of or interaction with PHR systems to support their own missions (e.g., CDC and CMS, DoD and VA). Development of harmonized definitions for PHR systems and EHR systems will help coordinate these efforts with other Federal agencies, thereby preventing unwanted duplication and confusion among users and promoting needed interoperability. NCVHS believes that HHS can model its role on the one it plays with respect to EHR adoption. That is, it can encourage and actively participate in a public/private partnership that facilitates standards-based approaches in a harmonized legal and regulatory environment across geopolitical boundaries. The Committee heard that the Federal Employee Health Benefits Plan could provide a vehicle for encouraging PHR system use and assessment. An additional federal role is to provide for experimentation and research to facilitate the evolution of PHR systems, as described below.

The Federal government can offer vision and strategic leadership for PHR development and dissemination across its many roles in the health sector. NCVHS believes that HHS can encourage and actively participate in a public/private partnership that facilitates standards-based approaches in a harmonized legal and regulatory environment across geopolitical boundaries.

NCVHS observed that the ability of people to easily connect to their health information source, either by the Internet or other means, will be a determining factor in the widespread success of PHR systems. There are limited examples of PHR systems supporting underserved populations in rural and urban areas.

Recommendations

on the Federal Role:

15. Assess Federal roles

16. Considerations for underserved populations

Recommendation 15:

Federal roles. Federal agencies should assess how they can more fully explore and appropriately promote the benefits of PHR systems across their respective roles.

Recommendation 16:

Considerations for underserved populations.

The Federal government should identify and address the information technology access and use barriers that limit the dissemination of PHR systems, particularly to underserved populations. HHS also should address health literacy issues that could limit the use of PHR systems by the most vulnerable populations.

ADVANCING RESEARCH AND EVALUATION ON PHR SYSTEMS

The hearings identified numerous issues regarding PHR systems that require further research and evaluation—for example, who uses them and how, interactions with health services, and impacts. NCVHS found that much of the currently available information about PHR systems is based on expert opinion and focus groups. It concludes that a variety of research, evaluation, and pilot studies are necessary to answer key questions and allow comparison of PHR system types and approaches. Findings from rigorous research and evaluation studies will increase the evidence base for the effective implementation and use of PHR systems. At least some of the needed research may be conducted as an extension of current and planned research into EHR systems. The Committee estimates that the amount of funding

required for PHR systems research would be a modest percentage of ongoing and future health IT and EHR research efforts.

The Committee identified broad areas for research and evaluation for PHR systems. These areas include consumer, health services, and technical research and the development of metrics to assess the implementation and impact of PHR systems on multiple dimensions of health and healthcare.

The Committee identified broad areas for research and evaluation for PHR systems. These areas include consumer, health services, and technical research and the development of metrics to assess the implementation and impact of PHR systems on multiple dimensions of health and healthcare.

Consumer Research

Consumer research should identify who is adopting PHR systems; how individuals use the systems; barriers to adoption and successful use; and access, pricing and usability issues, among other things. Identification of these factors can inform decisions about the functions and drivers for PHR systems adoption. When overlaid with the different types of PHR systems that the Committee has identified, the health care and technology industries can design successful products that will match consumers' needs and preferences, and the Federal government can more easily identify the best purposes for any Federally-sponsored or Federally-promoted PHR system.

Health Services Research

Health services research should address issues related to PHR systems' impact on workflow, particularly its effects on efficiency and utilization. While there are presumptive positive relationships between PHR systems and patient safety, healthcare quality, costs, and individual and population health, the actual impact is unknown. Some areas for further research with respect to patient management include whether and how PHR systems change the way individuals relate to healthcare providers and the healthcare system; whether PHR systems lead to better self-management of chronic conditions;

whether PHR systems improve the availability of clinically relevant information before, during and after encounters; and whether PHR systems contribute to modifying unhealthy life-style behaviors such as smoking, lack of exercise, and poor diet.

Technical Research

Technical research would examine methods to optimize the interface between PHR and EHR systems; the optimization of standards for interoperability; approaches to authentication, identification, and role-based permissions; and the ability to execute data-source annotation.

Metrics

NCVHS concludes that a series of metrics around PHR system usage, processes, outcomes, and impacts should be identified and tested. Metrics should also monitor the quality, validity and reliability of records management of PHR system data, including the concordance of consumer/patient-entered and provider-entered data.

Recommendations on Advancing Research and Evaluation:

- 17. HHS research
- 18. OPM pilots
- 19. AHRQ research
- 20. CMS pilots

Recommendation 17:

HHS research. The Secretary should request that all agencies review their research portfolios and program operations and report to the Secretary the ways they could contribute to the research and evaluation of PHR systems.

Recommendation 18:

OPM pilots. HHS should collaborate with the Office of Personnel Management to help implement pilot studies of PHR systems with payers and beneficiaries of the Federal Employees Health Benefits Plan.

Recommendation 19:

AHRQ research. The Agency for Healthcare Research and Quality (AHRQ) should expand its evolving health information technology research portfolio to support health services research and the development of metrics to assess the impact of PHR systems on quality of care, patient safety, and patient outcomes.

Recommendation 20:

CMS pilots. The Centers for Medicare and Medicaid Services (CMS) should conduct pilot studies of PHR usage for chronic diseases to evaluate utility and cost effectiveness for beneficiaries, providers and payers.

NEXT STEPS FOR NCVHS

The National Committee will continue to gather information on this dynamic field. In particular, it plans to release additional recommendations on privacy, confidentiality and the NHIN. In addition, it will provide a forum for exploring the following issues that arose from the initial hearings:

- The role of CMS
- Ownership and control of data within PHR systems
- The ability of PHR systems to obtain data from external sources such as provider systems, claims clearinghouses, health plans and similar sources
- Non-repudiation (authenticating the integrity of the contents and exchange of information)
- Potential liability for providers associated with the use of incomplete or inaccurate data within a PHR
- Privacy policy practices, including notice

