

Individuals should have the right to understand how their health data may be used, and to provide consent where appropriate. Often, consent is difficult, as not all uses are known at the time the health data are collected. Further, standards do not yet exist to track an individual's consent as data are exchanged. Although many of the population health uses described in this concept paper involve aggregated or de-identified health data, legitimate concerns exist about group harms and possible re-identification. In addition, the possibility of using health data from emerging information sources, such as personal health record systems, raises unique privacy concerns.

NCVHS has discussed many of these privacy challenges in numerous reports and letters to the Secretary. Most notably, NCVHS published two reports, a *Primer* on health data stewardship⁷ and *Recommendations on Privacy and Confidentiality, 2006-2008*. Both are available on the NCVHS website.⁸

Further work is necessary to develop the privacy, confidentiality, and security standards that should apply as these data uses continue to evolve. In addition, work is needed to establish governance structures to provide the proper oversight of entities that exchange and use health data. In essence, governance is the accountability for ensuring that proper data stewardship (as described in the NCVHS *Primer* cited above) is practiced. To differentiate between governance and data stewardship, data stewardship is focused on the internal practices of the entity that uses health data, whereas governance is focused on the oversight of such entities to ensure that their data stewardship practices are adequate. Such oversight includes initially approving entities that have access to data, ensuring that such entities appropriately use and protect data, and ensuring that entities that misuse data are appropriately sanctioned.

THE WAY FORWARD

Taken together, today's emerging policy opportunities and the nation's longstanding health challenges create a situation of considerable urgency for the United States. The openness to bold new approaches offered by recent legislation will disappear quickly. Given that the U.S. lags behind most other industrialized countries in the health status of its citizens, we must seize the opportunities to maximize the health benefits and begin to assess whether the huge investments are indeed having the desired impact.

This paper has noted the critical federal role in devising health information policy to support national health goals. Federal leadership is more needed than ever to create the comprehensive approaches that will guide the development of information capacities and coordinate efforts by actors in the public and private sectors. Whatever progress is made in the critical transition to electronic health records, clinical data alone will not suffice; broad information capacities that

⁷ An NCVHS *Primer: Health Data Stewardship—What, Why, Who, How*, December 2009.

⁸ <http://www.ncvhs.hhs.gov/>

draw on all the sources and serve all the purposes discussed in this paper will be necessary. This will require shoring up the data resources for public functions such as surveys, safety surveillance, and vital records, along with strategic thinking to determine what capacities will be needed in the future and how to guide their development. Many issues require research and demonstration as part of a prioritized, adequately funded research agenda. In addition, further investments in a trained workforce are needed, to ensure the availability of professionals and leaders who can properly use information resources for analysis and decision-making.

As it develops policies and strategies, the Department has always invited input from experts and stakeholders; and NCVHS has long helped to facilitate this dialogue and distill the key messages and lessons. NCVHS will continue to use its consultative and deliberative processes, working collaboratively with other HHS advisory committees, to help the Department meet the current opportunities and challenges. As noted, all NCVHS subcommittees plan to be involved in this effort; this report is an early installment on subcommittee and full Committee work plans for the coming 18 months or more. NCVHS expects to develop recommendations on a research agenda, which may be the focus of one or more hearings. Each of the subcommittees is identifying the key issues in its domain, to be pursued through workshops, hearings, and internal deliberations as NCVHS develops recommendations for the Secretary. The subcommittees' preliminary thinking is outlined below.

SUBCOMMITTEE ON QUALITY

Over the next two years, the NCVHS Subcommittee on Quality will focus on supporting the development of meaningful measures, leveraging both existing and emerging data sources (e.g., patient-generated data, remote monitoring, personal health records), and in particular identifying significant opportunities and gaps. Critical to meaningful measurement is the availability of relevant data elements that could be easily captured using certified EHR technology and functionality, among other tools. The Subcommittee on Quality will identify emerging health data needs for a health system where the individual engages in his or her health and health care. As a near-term priority, the Subcommittee will address the data needs of person-centered health and health care, emphasizing coordination and continuity of care across a continuum of services. A longer term goal is to develop a national strategy to leverage clinically rich health data to address important national questions about determinants of health and disease.

SUBCOMMITTEE ON PRIVACY, CONFIDENTIALITY AND SECURITY

The NCVHS Subcommittee on Privacy, Confidentiality and Security will focus its efforts on providing recommendations that support national priorities, in coordination with such groups as the ONC HIT Policy Committee's Privacy and Security Workgroup. In the next year, the

Subcommittee plans to develop recommendations regarding governance as well as a framework for the identification and appropriate management of sensitive data. The Subcommittee will also consider transparency and the role of patient consent. In addition, it will continue to review and make recommendations regarding new privacy, confidentiality, and security regulations; compliance with these regulations; and strategies for effective enforcement.

SUBCOMMITTEE ON STANDARDS

Health care reform legislation now provides a new opportunity to continue the administrative simplification that began under HIPAA—a process in which NCVHS will remain heavily involved. The NCVHS Subcommittee on Standards will continue to meet its responsibilities related to HIPAA; will implement the many administrative simplification responsibilities assigned by the Health Reform Act of 2010; and will meet new requests for recommendations on the use of standards to enhance interoperability of the transmission and semantics of health data as they arise. As we look to the future, several goals stand out with respect to standards. The Subcommittee will seek to ensure a comprehensive framework and roadmap for health information standards that support the national health IT strategic framework, vision and policy priorities; the public health policy agenda; the NCVHS proposed data stewardship framework; a national research agenda that includes comparative effectiveness; and the needs of all data users.

SUBCOMMITTEE ON POPULATION HEALTH

Understanding the population's health and its determinants relies on multiple data sources, including population surveys, clinical data, administrative data (notably, birth and death records and billing data on use of health services), and public health and environmental reporting systems. At the national level, Federal agencies such as the National Center for Health Statistics are charged with developing methods, assessing validity, and reporting national population health information. As we envision building a comparable capacity for communities and states across America, the quality of information and its timeliness will be central to success. The Subcommittee on Population Health will focus on facilitators and barriers to data linkage at state and local levels as a critical part of health information infrastructure, specifically linking EHR data with existing administrative and local survey data. Fundamental to understanding population health is describing the underlying population, which also comprises those who have not seen a doctor recently or have refused to respond to a survey. The work of the Subcommittee will focus on methods to ensure that linked data sources provide valid health information, including methods to adjust for missing data and methods to protect privacy.