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NHII 04 Conference
Background Material for Topic:
Confidentiality, Ethics, Privacy and Access

Although there are many issues related to confidentiality, ethics, privacy and access for the national health information infrastructure, many issues are in four categories: uniformity of privacy laws; access to and control over patient medical information; secondary uses of medical information; and, miscellaneous. The NHII 04 conference breakout sessions for confidentiality will focus its discussions on these areas.

Area One - Uniformity of Privacy Laws

First Issue: HIPAA established a statutory policy that stronger state privacy laws prevail over the baseline federal standards. That policy potentially creates uncertainty about the law applicable in any state to any entity covered by HIPAA. The NHII will likely increase the interstate flow of identifiable health information and exacerbate existing uncertainties.

Point: More uniformity in privacy law and standards could resolve existing legal federal and state questions, reduce costs, simplify the practice of medicine across state borders, and lessen the background legal confusion and complexity surrounding the use of health information for treatment and payment activities.

Counterpoint: In order to achieve more uniformity, existing privacy protections currently in place in some states would necessarily have to be reduced. Further, legislation to require more uniformity might be complex because state laws on health information can be found in numerous places.

Questions:

- How can these interests be reconciled, especially when Congress has already established a statutory policy that favors stronger state health care privacy laws?

- How can the NHII be protected against the concerns of some that NHII will reduce existing privacy protections for some patients?

Area Two - Access and Control of Patient Medical Information

First Issue: The NHII has the potential to magnify the tension that exists between the "duty to warn" patients of medical risks versus the right to privacy.

Questions:

- If a genetic trait is discovered in one or more patients, or contagion is found, should the patient(s), relatives or physicians or the patient(s), quickly be notified through the NHII?

- How can the NHII be appropriately used to warn the public about possible public health risks or bioterrorism?

Second Issue: The NHII promises both greater availability of patient information for treatment purposes and greater patient control over information. These might be either conflicting or complimentary goals.

Point: The NHII can support the sharing of information among all providers treating a patient, including internists, cardiologists, laboratories, pharmacists, dentists, and others. Greater availability of treatment information will lead to improved outcomes and reduced costs.

Counterpoint: Today, one way that a patient can try to control the availability of information is to try to keep the patient's relationship with providers confidential from everyone, including other providers. For example, a patient does not necessarily have to tell the patient's internist, dentist, or employer's on-site nurse that the patient is seeing a psychiatrist. If the NHII removes a patient's current ability to control aspects of the patient's health information, then some members of the public may not accept the NHII. It should not be assumed that it is always helpful for an individual to know information about that individual. And sometimes providing an individual's information without context can be detrimental to that individual. Procedures should be established to address circumstances in which it is unacceptable to give individuals unsolicited health (eg. HIV) or genetic information before a physician or genetic counselor has provided the individual with appropriate background information and support

Questions:

- Does the conflict between greater treatment availability and improved patient control have to be resolved at either extreme? Are there areas in which disagreements can be resolved or alternative solutions?

- Can the NHII support individual patient privacy preferences without undue complexity and cost?

Third Issue: Electronic health records can have the potential to provide greater security protections than paper medical records.

Point: The electronic health record has the potential to give patients more control over physical access to their medical information, because electronic medical records can be secured

through strict electronic security mechanisms that are far better than simple controls that can be placed on paper records.

Counterpoint: If there is a security breach in a system that holds electronic medical records, then potentially many more unauthorized people can wrongfully view a patient's medical information than would be the case if the physical security of paper records is compromised.

Questions:

- Will health care organizations be able to afford the necessary electronic security mechanisms and security limitations that are necessary to support and use the NHII?

Area Three - Secondary Uses of Medical Information

First Issue: The HIPAA privacy rule applies directly to covered entities (providers who communicate electronically in standard format transactions), payers, clearinghouses, and drug card vendors). Secondary users who obtain health information from covered entities might not be covered by the rule.

Point: Privacy rules applicable to NHII users should cover all users, including those who are not now covered by HIPAA. This includes researchers, public health agencies, law enforcement agencies, health oversight agencies, coroners, national security agencies, the media, and other institutions. Compliance with privacy rules should be a prerequisite to obtaining direct access.

Counterpoint: The expansion of privacy rules to numerous other organizations will present many challenges. HIPAA's need to strike a fair balance between the interest of patients and the requirements of covered entities was difficult. Because there are many other users, a broader federal privacy rule modeled after HIPAA would be more complex.

Questions:

- If secondary users obtain direct access to the NHII to meet major goals of improving research and public health, how can the need for greater privacy protections be met without great complexity?

- Should all secondary users be permitted to have direct access or can distinctions among secondary users be justified?

?Will the NHII include a substitute for the gate keeping activities now performed by providers and payers?

Second Issue: There is a significant potential for information derived through the NHII to be used in any number of arenas, including public health,

bioterrorism surveillance, quality improvement, and research. There are different sets of information that may be required for performing these activities - from access to individually identifiable personal health information (PHI), to aggregated population information.

Point: Any future Privacy Rules affecting the NHII should differentiate among PHI, de-identified PHI and aggregate population data and differentiate the various rights and responsibilities of patients and data keepers (such as providers) in these various forms.

Counterpoint: Research has shown the potential for "re-identifying" de-identified PHI using publicly available data, therefore the information should all be given the same level of protection.

* How should we balance the need for access and the threat of its misuse?
* Are there technical and legal solutions to these conflicting issues?
* Do patients have a right to restrict or control the use of their data that has been de-identified or collected in the aggregate?

Area Four - Miscellaneous Issues/Questions

- Who owns, and who has rights in and to, the information contained in the NHII?
- Is the NHII a conduit or a custodian or an architecture?
- Should the information in the NHII be subjected to carefully controlled data mining for the greater good of medical research or public health?
- Should the Food and Drug Administration regulate parts of the NHII given that the FDA currently regulates certain electronic medical devices?