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Improve Privacy in Research by Eliminating Informed Consent? IOM Report Misses the Mark

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In February 2009, the Institute of Medicine released its report on privacy in health research, *Beyond the Privacy Rule: Enhancing Privacy, Improving Health Through Research*.[1] The report is based on formal presentations, commissioned and invited surveys and papers, a literature review, and deliberations by the Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule. The Committee was charged with addressing the often-expressed concern of researchers that the Privacy Rule burdens research without adequately protecting the privacy interests of patients and subjects.

There is much to commend in the report. Among other things, it recommends the following: (1) privacy protections should apply to all research regardless of the funding source; (2) the Department of Health and Human Services (HHS) should take steps to harmonize the requirements of the Federal Policy for the Protection of Research Subjects (Common Rule)[2] and the Standards for Privacy of Individually Identifiable Health Information under the Health Insurance Portability and Accountability Act (HIPAA Privacy Rule);[3] (3) HHS should reduce the variability in interpretations of the Privacy Rule by Institutional Review Boards (IRBs) through expanded guidance; (4) HHS should revise provisions of the Privacy Rule that impose burdens on researchers without a commensurate improvement in patient privacy; and (5) HHS should simplify the criteria for IRBs and Privacy Boards to use in evaluating proposed waivers of authorization for research. Many of these recommendations have been made in the past by various other bodies.[4]

The most unique — and controversial — proposal in the IOM Report is the recommendation to eliminate informed consent for research other than for "interventional" or clinical research. The report presents an extreme version of the argument that obtaining permission from patients to use their health information and specimens is too burdensome for researchers and therefore should be eliminated entirely. The IOM Report distinguishes between interventional research and information-based research. As to the former, it recommends that the Common Rule should apply to all research regardless of the funding source and "all researchers who gain access to personally identifiable health information as part of the interventional research should be required to protect that information with strong security measures."[5] The IOM Report also recommends that all research should be exempt from the requirements of the Privacy Rule.

Information-Based Research

Information-based research is not defined in the report, but it explicitly includes the use of human specimens stored in biobanks.[6] The IOM Report recommends that "a new approach to uniform, goal-oriented oversight [rather than prescriptive measures]...should be developed by HHS and other relevant federal agencies."[7] Programs or institutions certified by HHS or some other designated body would qualify for "safe harbor" protection from regulation. Certified entities would be permitted to "collect and analyze personally identifiable health information for clearly defined and approved purposes, without individual consent."[8] The report states that because of unspecified "administrative requirements in becoming certified, this option is most appropriate for disease registries and other very large scale research databases."[9] Because of the lack of specificity in the IOM Report, it is difficult to as-

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sess how such a certification system would work, the number of entities likely to apply for certification, or even whether certification would take the form of self-regulation by an organization established by the research institutions. Besides the myriad ethical and policy issues raised by this proposal, discussed below, it is impossible to support replacing the current regulatory regime, notwithstanding its flaws, with such a vaguely described successor.

Under the proposed scheme, certified entities could aggregate personally identifiable data from multiple sources and then provide data to researchers with direct identifiers removed.[10] In instances where researchers cannot use data with direct identifiers removed, and personally identified health information is needed for research, approval by an "ethics oversight board" would be needed.[11] The IOM Report does not describe the composition or duties of the ethics oversight board, and it is unclear how such a board would differ from an institutional review board (IRB) or Privacy Board. In deciding whether to approve a research protocol using personally identifiable health information, the ethics oversight board would consider the scientific merit and potential benefit of the research to the public, along with the potential harms to research subjects. To summarize, for information-based research, if direct identifiers are removed, certified entities and their collaborators could conduct research without consent or authorization; for research with individually-identifiable health information, no consent or authorization is required, but an ethics oversight board would have to approve the action after weighing the scientific merit of the research against the potential harm to individual privacy.

The IOM Report recognizes that "public opinion polls suggest that a significant portion of the American public would like to control all access to their medical records for research via an individual consent mechanism."[12] Nevertheless, the IOM Report completely rejects this overwhelming public opinion for the following three reasons.

First, the IOM Report asserts that "a universal requirement for informed consent can lead to invalid results because of significant differences between patients who do or do not grant consent." This assertion is not well supported by studies objectively documenting or quantifying self-selection bias attributable to informed consent. As in other parts of the report, the IOM Committee cites a few studies, but relies heavily on surveys of researchers who believe that informed consent interferes with their research.[13] It is not known what percentage of potential research subjects decline to participate, for what types of research, and under what consent mechanisms; nor is there evidence of what the effects are on sample accrual or on the statistical power of the research. Furthermore, the IOM Report makes no effort to address the argument that, as a society, it is essential to tolerate a slight degree of imprecision in research to advance other important societal interests.

By asserting that self-selection bias leads to invalid research, the IOM Report could be read as questioning the validity of much contemporary research. It is not clear whether the report intended such a broad criticism of current research or whether the report's criticism of informed consent is limited to future research, especially research using large datasets. Ironically, in a report extolling the value of research, there are no recommendations to undertake ongoing, systematic research on the effects of various options for obtaining consent to participate in research.

Second, the IOM Report asserts that obtaining consent can be "prohibitively costly and difficult to obtain" for studies requiring analysis of large datasets. This argument is extremely important, and it receives insufficient attention in the report.[14] As with many issues, the IOM Report addresses the matter from the perspective of researchers and relies greatly on surveys of researchers. Nevertheless, a compelling argument could be made that delay and increased cost should be regarded less as a matter of inconvenience and expense to researchers than as impeding some meritorious and potentially promising research that would benefit society. The report also fails to consider alternatives to reduce expenses and delays other than abandoning informed consent.

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Third, the IOM Report recommends its new approach because of utilitarian concerns for facilitating research. "If society seeks to derive the benefits of medical research in the form of improved health and health care, information should be shared for the greater good, and governing regulations should support the use of such information, with appropriate oversight."[15] In other words, the benefits of the research override the privacy interests of the subjects. The merits of this value judgment are further addressed below.

Before presenting the main critique of the IOM Report's central proposal, it is important to clarify some aspects of the deidentification issue. If health information is anonymous (never contained identifiers) or deidentified (identifiers have been removed), then it is not subject to the Common Rule[16] or the Privacy Rule.[17] Unfortunately, the two rules differ on what constitutes deidentification, with the

Privacy Rule containing more stringent requirements.[18] Removal of only "direct identifiers," as contemplated by the IOM Report, would not satisfy either standard. As noted earlier, however, the report also recommends that all research should be exempt from the Privacy Rule and that only interventional research should be subject to the Common Rule.

Major Flaws in the IOM Report's Key Proposal

There are four main problems with the IOM Report's recommendations on information-based research.

1. Underestimating the Risk to Individuals

The IOM Report's recommendation to exclude information-based research from the Common Rule is based on the assumption that such research presents less of a risk to informational privacy than does interventional research.[19] There is no basis for such an assumption. Depending on the type of research involved, interventional research can pose a broad array of physical, psychological, and social risks to research subjects. Accordingly, the Common Rule attempts to protect the welfare of research subjects, including protecting their privacy. Although information-based research does not present physical risks, many of the other risks are the same. Information-based research includes the analysis of stored biological specimens, individual medical records containing a wide range of sensitive information, and the results of diagnostic and predictive genetic and other tests performed in the clinical setting. In terms of privacy risks, there is little to suggest a clear, qualitative difference between these categories of research that would justify vastly different levels of privacy protection.

The IOM Report also fails to recognize that information-based research raises other important interests besides privacy, notably autonomy. Indeed, the IOM Report is a repudiation of autonomy in health research. Autonomy "encompasses at a minimum, self-rule that is free from both controlling interference by others and from certain limitations such as an inadequate understanding that prevents meaningful choice."[20] Autonomy would be completely overridden by the proposal to permit information-based research by certified entities without consent using information with direct patient identifiers removed, and to permit research on identifiable information without consent if a vaguely described ethics oversight board approves. "To respect autonomous agents is to acknowledge their right to hold views, to make choices, and to take actions based on their personal values and beliefs."[21] The proposed rule would dispense with individual consent and establish an irrebuttable presumption that all individuals agree to use of their health information and biological specimens for any research. Such a rule not only denigrates autonomy, but it runs counter to the norms and experience of a pluralistic society. Individuals sometimes refuse to permit biobank or records-based research for a range of religious, cultural, and personal reasons.[22] The essence of autonomy is respect for the decisions of individuals with which those in positions of authority may disagree. The IOM Report's central proposal demonstrates a lack of respect for individuals as autonomous agents and assumes that all individuals have the same values and interests with regard to research.

The decision whether to grant any individual or entity access to one's health record or biological specimen is personal and subjective, just as the decision whether to enroll in a clinical trial or consent to treatment is personal and subjective. Clinicians, researchers, and their institutions do not have the moral authority to override the wishes of autonomous agents. Individuals seeking treatment at a medical facility are not expressly or impliedly waiving their right to be informed before their health information and biological specimens are used for research. The recommendation of the IOM Report would automatically convert all patients into research subjects without their knowledge or consent. Such abrogation of individual rights is not saved by simply removing direct patient identifiers. Even deidentification meeting HIPAA requirements presents risks, including the potential for reidentification, group-based harms, objectionable uses, commercial exploitation, and loss of trust. Removing only "direct" identifiers is even less likely to protect the identity of the individual.[23]

2. Failing to Justify Abandonment of Informed Consent

The first international code drafted to address the ethical conduct of research was the Nuremberg Code, drafted in 1947 after the trial of the Nazi doctors for atrocities committed in the name of medical research during the Holocaust.[24] The first principle of that first code begins unequivocally: "The voluntary consent of the human subject is absolutely essential."[25] The Nuremberg Code did not distinguish between interventional and information-based research, and the IOM Report drafters would assert, no doubt, that it was not intended to cover the latter situation. There is no evidence to suggest one way or the other. Nevertheless, a broadly considered notion of informed consent has been the cardinal principle of research ethics around the world for over half a century.[26] Therefore, any recommendation to dispense with the existing requirement that researchers obtain informed consent from research subjects must carry an extremely heavy burden. The IOM Report fails to recognize the magnitude of the change it suggests and fails to carry its burden of making the case for eliminating the current obligations.

The IOM Report also fails to give appropriate attention to waivers of consent under the Common Rule. Under appropriate circumstances, an IRB may approve a consent mechanism that alters some or all of the elements of informed consent. The IRB may even waive informed consent altogether if the following elements are satisfied: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect

the rights and welfare of the subjects; (3) the research could not be practicably carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.[27] To the extent that the waiver criteria are too narrow or waivers are inappropriately denied, the IOM Report fails to provide additional recommendations about how to remedy the problem.[28] Although the IOM Report addresses the issue of waivers, as with other important elements, the discussion is overwhelmed by the boldness of the central recommendations.

3. Overvaluing Researchers' Interests

Many members of the research community long have expressed concerns about the additional burdens (beyond the Common Rule) imposed on researchers by the HIPAA Privacy Rule. Several of these elements, such as requiring authorizations (in addition to informed consent documents) for the use and disclosure of protected health information in research and prohibiting authorizations for unspecified future uses of protected health information in biobanks, undoubtedly hinders research. Other provisions also are excessive, duplicative, unnecessary, inconsistent, and burdensome. Various public and private groups have urged HHS to harmonize the two sets of rules. All such attempts have been unsuccessful. The IOM Committee was charged with revisiting these oft-expressed concerns and assessing the degree to which the Privacy Rule affects or impedes research.

The title of the report is *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research.* It is obvious, however, that the report is not about enhancing privacy; relatively few of the recommendations address the issue. Rather, the report is about the Committee's view of improving health research by relaxing privacy protections. Unquestionably, biomedical research is a societal good. It needs to be encouraged, funded, supported, nurtured, and free of excessive regulation. Notwithstanding its importance, health research does not trump all other values and interests. Privacy, autonomy, justice, beneficence, and other interests are essential considerations for the research enterprise. Because the welfare of research subjects is of utmost importance, the interests of individuals in deciding whether they want to become research subjects must be respected.

Any protection for research subjects, from explaining the nature of a protocol to protecting the confidentiality of records, imposes some burden on researchers. It is an unavoidable part of research. Individuals who take part in interventional research have an absolute right to withdraw from research at any time,[29] even though doing so could jeopardize the success of the research. The inability to enroll an adequate number of subjects can derail a research protocol before it gets started. These are facts of life for researchers. It is legitimate for researchers to want to reduce needless, duplicative, or excessive regulation. It is not legitimate for researchers to seek to eliminate the fundamental right of individuals to decide whether to permit their health records and specimens to be used in research.

4. Overlooking the Betrayal of Trust

If the proposals in the IOM Report or similar ones were adopted, the potential harm would extend beyond the research setting. Many patients whose records and samples were used without their knowledge or consent would feel betrayed by the health care system and their individual health care providers. For many individuals, there is no difference between health care providers and researchers. Many individuals would feel a sacred trust was violated by health care providers and institutions. It is unclear whether or to what degree some individuals would delay treatment, forego treatment altogether, utilize nontraditional health care providers, or refuse to participate in clinical trials. Proposed public policies should be subject to strict scrutiny if they have the potential to result in more harm than good.

The IOM Committee commissioned health privacy expert Dr. Alan F. Westin to conduct a national survey on "How the Public Views Privacy and Health Research." One question in the survey directly tracks the key recommendations in the IOM Report and discussed in this article. Because of its importance, the entire question (and answers) is included.

> When conducting health studies, researchers often want to select patients whose personally-identified medical or health information is contained in patient records. Sometimes, the patients will be invited to give general approval to have their records used in future health research. Or, the researchers may seek patient consent to join a specific study. For some studies, researchers seek to include the patient information automatically in the research, without seeking any consent.
>
> The researchers promise, as required by federal and/or state health privacy laws, that no personally-identified health information of research subjects will be disclosed outside the research group and that security measures will be applied to protect the data.
>
> Researchers must also have the project approved by a Human Subject Protection or Privacy Board. These groups decide whether the importance of the research and the safeguards promised outweigh potential risks to privacy or data security, or other risks to research participants.
>
> Some say that patient interests in privacy and data security are not protected well by such procedures, and there is little policing of researcher practices. It is argued that patients must be asked for consents — either specific or general — for all health research.
>
> Health researchers say many patients would not respond or agree to requests for permission,

creating a sample that would not accurately reflect the group whose health condition or status are being studied. They also say obtaining permission for each health study would be very costly and time-consuming, and there is no pattern of health researchers disclosing the personal medical information of research subjects.

In these situations [which of the following answers] is closer to your opinion?[30]

The answers confirm the degree to which the public objects to the nonconsensual use of their health privacy information, even if measures were taken to deidentify the information.

Researchers would be free to use my personal health information without my consent at all
1%

I would be willing to give a general consent in advance to have my personally-identified medical or health information used in future research projects without the researchers having to contact me
8%

My consent to use my personal medical and health information would not be needed as long as the study never revealed my personal identity and it was supervised by an institutional review board
19%

I would want each research study seeking to use my personally-identified medical or health information to first describe the study to me and get my specific consent for such use
38%

I would not want the researchers to contact me or to use my personal or health information under any circumstances
13%

Not sure
20%[31]

According to the survey, only 1% of respondents would approve of a system of researcher access to and use of health information without consent. Another interesting finding is that only 13% of respondents would object to access or use of their personal or health information under any circumstances. To generalize, respondents were willing to have their health information used in research, but they want to be asked for permission and they want some controls on the researchers.

Beyond the aggregate data in the survey, an even more troubling picture emerges. Among the demographic groups reporting the greatest concern about the nonconsensual use of their health information are racial and ethnic minorities as well as persons with potentially-stigmatizing and serious health conditions.[32] Thus, members of vulnerable groups with a history of exploitation by researchers and those at risk from disclosure of their health information strongly disapprove of abandoning informed consent in information-based research.

The survey also asked a follow-up question to determine the reasons why individuals would object to use of their health information for research without their consent. The number one reason — 77% — was: "I would feel violated and my trust in the researchers betrayed."[33] This reason, outranking concerns about possible discrimination or embarrassment, underscores the notion that privacy is not the sole concern of individuals. Respect for persons and autonomy were of even greater importance. This key finding of the Westin survey is consistent with the findings of several other surveys.[34]

Finally, in contemplating the consequences of abandoning consent for information-based research, it must be remembered that a substantial part of health research in the United States is publicly funded. This means that research is funded, collectively, by the people whose health records and biological specimens the IOM Report says that researchers should be able to use without obtaining informed consent. Such a position is overwhelmingly rejected by the public whose tax dollars fund research. Thus, irrespective of ethical concerns, one must wonder whether advocating for such a dramatic and unpopular change in current policy is politically astute.

Health Information Technology and Privacy

The timing of the IOM Report is also extremely problematic. Title XIII of the American Recovery and Reinvestment Act of 2009 (ARRA or Stimulus Bill)[35] enacts the Health Information Technology for Economic and Clinical Health Act (HITECH Act). This provision makes a major federal financial commitment to electronic health records and networks. Besides provisions for promoting health information technology (HIT), adopting HIT standards, and funding grant and loan programs, Subtitle D of Title XIII contains detailed privacy provisions.[36] Congress recognized that the transition to electronic health records and networks would not be supported by the public without expanded privacy protections. Therefore, among other things, the ARRA extends the HIPAA Privacy Rule to cover business associates,[37] requires prompt notification of security breaches,[38] restricts the sale of electronic health information,[39] and increases enforcement.[40] A new HIT Policy Committee also was established to recommend strengthening privacy protections, including allowing for the segmentation and protection from disclosure of sensitive health information.[41]

The IOM Report runs directly counter to the emerging federal policy of affording increased protection to health records and providing individuals with greater control over the uses and disclosures of their health information. In addition, some leading private sector vendors of personal health records, employers, and insurers have adopted extensive, voluntary privacy rules for their newly-developed electronic health record systems. By suggesting that, at least as to research uses, individuals should not have control over their health records, the IOM Report could undermine the

credibility of these voluntary initiatives as well.

Conclusion

The IOM Report is a missed opportunity. The research privacy requirements under the Privacy Rule and the Common Rule are uncoordinated and contain gaps, overlaps, and inconsistencies. It is difficult to discern the necessity or effectiveness of elements of each rule with regard to health privacy. Prior proposals to resolve the predicament, including those from the National Committee on Vital and Health Statistics,[42] have not persuaded HHS to correct the problem. Against this backdrop, the appointment of the IOM Committee led to optimism that an authoritative report from the highly respected IOM would create the impetus for action by the federal government.

Now, the disappointing product is in hand. The IOM could have produced a report emphasizing the inadequacies and needless burdens imposed by the current regulatory requirements. The IOM could have highlighted a series of recommendations to correct the problems, starting with a forceful call to harmonize the Privacy Rule and Common Rule. Lamentably, the generally excellent recommendations about revising the Privacy Rule are merely part of the report's "fallback" position. The IOM could have strongly endorsed the enactment of comprehensive health privacy legislation to protect health information beyond the three classes of covered entities subject to the Privacy Rule (health care providers, health plans, health clearinghouses).[43] The IOM could have recommended a rigorous system of research to measure the effects of modifying the Privacy Rule and Common Rule on individuals and researchers to determine whether additional steps would still be needed.

Instead of advocating for these constructive and achievable goals, the IOM Report adopted as its centerpiece a set of implausible measures supporting the anti-regulatory agenda of some researchers and organizations. Unfortunately, the result of producing such an unpersuasive and easily dismissed document is the increased likelihood of perpetuating a regulatory system that fails to serve the interests of researchers, research subjects, or the public.

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