THE COSTS OF HIPAA:
TO PATIENTS, TO PROGRESS, AND TO THE NATION’S HEALTH

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About C-Change: The mission of C-Change is to eliminate cancer as a major public health problem at the earliest possible time by leveraging the expertise and resources of our members. A 501(c) 3 organization, C-Change is comprised of approximately 150 of the Nation's cancer leaders from the private, public, and non-profit sectors. These leaders collaborate on issues spanning the continuum of research, prevention, and care - that cannot be solved by one organization or even one sector alone.

Abstract
Recent studies including a 2009 Institute of Medicine report have highlighted how the HIPAA Privacy Rule fails to protect privacy and has created significant barriers to research. The purpose of this article is to outline the impact of the HIPAA Privacy Rule on patients and its cost to the research enterprise in terms of time, dollars, and lost opportunities. During this review, we found that HIPAA burdens the research process by deterring patients from participating in research, creating an enrollment bias and translating into research that is not applicable to all populations, perpetuating treatment disparities. Biospecimen data is difficult to re-use, limiting personalized medicine, which directly impacts cancer patients’ and their ability to quickly find a treatment that will benefit them and minimize side effects. The limited utility of de-identified data and perceived restrictions on data mining also limit other forms of research including comparative effectiveness research. Further, the protocols required to meet HIPAA privacy standards have subjected clinical trial enrollees to burdensome paperwork and added thousands of hours and hundreds of thousands of dollars to the time and costs of individual studies, taking limited resources away from clinical cancer research. In some trials, insufficient resources to manage these protocols have led to the abandonment of studies all together, undermining the trust that clinical researchers have worked to establish with clinical trial participants. We conclude that actions must be taken to exempt research from the HIPAA Privacy Rule to improve patient privacy protection and improve the economy and efficiency of lifesaving research.
INTRODUCTION
Research is guided by many laws and regulations to ensure the safety, efficacy, and protection of patients and their health information. However, the Health Information Portability and Accountability Act (HIPAA) Privacy Rule makes medical research inefficient, costly, and slow. Its complexity can lead researchers to abandon studies. It also impedes researchers from using “personalized medicine” to craft therapies uniquely beneficial for particular patients, and its contribution to enrollment bias, perpetuates health disparities. From a public health perspective, HIPAA creates barriers to the comparative effectiveness and epidemiologic research continually needed to improve medical care.

The Institute of Medicine (IOM) appraisal of the Privacy Rule concluded that it does not adequately protect patient privacy and significantly impedes research. This report updates and builds on the IOM report by summarizing the impact of HIPAA on health research and on patients through a more in-depth illustration of the dollar, time, and opportunity costs HIPAA imposes.

HIPAA EFFECTS ON HEALTH RESEARCH

HIPAA impacts the research process and as a result directly impacts patients. HIPAA has hampered health research and patients’ ability to participate in research mainly by its effects on the informed consent and authorization process, and the IRB review process. These effects include deterring patients from participating in research, fostering research findings with limited relevance to broad groups of patients, hampering personalized medicine research dependent on biospecimens and stored clinical data, fostering rejection or abandonment of clinical studies, and increasing the time and cost of conducting large, clinical studies. See Table 1.

A. Deters patients from participating in research

The additional consent forms required to authorize personal health information for research lengthens and complicates the research consent process, and can deter patients from participating in research. With forms as long as 30-35 pages in the post-HIPAA era, reviewers have concluded that many are too long for patients to read. One study found the main reason for not participating in clinical research was poor understanding of the authorization form. Respondents to a survey of cancer researchers indicated that the HIPAA authorization language made patients “confused” and “frustrated,” and that the long forms were “very off-putting.” These forms are written at a college level, even though half of the U.S. adult population reads at or below and 8th grade reading level.

B. Fosters research findings with limited relevance to broad groups of patients: Enrollment bias

Researchers try to enroll the broadest spectrum of patients to ensure that their conclusions are applicable to patients across economic, ethnic, and educational groups. However, studies indicate that patients who sign their authorization forms and agree to participate in clinical studies are different from those who decline, creating a “selection bias.” One study found that authorization
requirement deterred African-Americans from participating in health research.\textsuperscript{5} Other studies have found that people who sign authorization forms were more likely to be Caucasian, older, and sicker than those who chose not to sign.\textsuperscript{10,11,12} In one survey, 74 percent of researchers that responded reported they had experienced problems with selection bias, with the most commonly cited reason being that fewer patients have agreed to participate in research since the Privacy Rule was implemented. In addition, 42 percent of the respondents reported that health clinics serving disadvantaged populations are not participating in research because of being unable to meet all of the Privacy Rule requirements. The end result has been an underrepresentation of minority populations in many research studies.\textsuperscript{13} In another survey of cancer registries, 36 percent of respondents reported that the Privacy Rule had introduced selection bias into a research project.\textsuperscript{14} This skewed representation of certain population groups in clinical studies is likely to invalidate or limit the application of the findings to a broader group of patients, especially those from traditionally underserved populations.\textsuperscript{11}

C. Hampers personalized medicine research dependent on biospecimens

One way for research participants to derive broader impact from their medical data and biospecimens is to have those resources available for other future studies. Currently, the Privacy Rule does not allow for reuse of patient data and specimens unless trial participants authorize the use for specifically defined future studies. By limiting future uses of data, scientists are unable to access a wealth of information contained in stored records. This data is particularly useful when searching for cancer causes or “biomarkers” of cancer aggressiveness or responsiveness to specific treatments. Such “personalized medicine” research is a major thrust in oncology and other health research. With growing awareness of more cancer subtypes, each of which may have different causes or response to treatment, doctors want to apply targeted therapies to increase response rates and decrease toxicity.

For example, using tumor biospecimens, researchers can identify cancer patients most likely to benefit by particular therapies. The cancer drug Herceptin is effective in treating breast cancer in patients that have several copies of the gene HER-2 in their tumors.\textsuperscript{2} The lung cancer drug Iressa only appears to be effective in patients with an EGFR mutation.\textsuperscript{15} In colon cancers with a particular mutation in the gene KRAS, patients receive no benefit from certain drugs and experience only toxicity.\textsuperscript{16} In patients with heart disease undergoing cardiac evaluation, certain gene mutations determine the risk of potential coronary thrombosis even with optimal therapy. Biomarker research depends on the use of archived samples and medical records.

Three Institute of Medicine reports have cited the problems created by HIPAA with respect to biomarker development using existing specimens for developing tools for cancer screening, diagnosis, and treatment. They found barriers to accessing identifiable patient health information to conduct meaningful research, and found delays and inefficiency created by HIPAA which hindered the use of existing data and tissue resources.\textsuperscript{1,2,3} A survey of members of the American Society of Clinical Oncology also identified the authorization process as the most significant challenge to complying with the Privacy Rule, especially for future research projects relying on stored tissue and databases.\textsuperscript{17}
D. Hampers research dependent on stored clinical data

The Privacy Rule’s de-identification and authorization requirements to use stored clinical data, and the limited value of de-identified or limited datasets has significantly reduced the quantity and quality of health research.

Many researchers cannot use de-identified data because it lacks the complete information they need to conduct their studies. One study found that a HIPAA-compliant de-identified dataset had 31 percent fewer data elements and the lost data was the type most beneficial to researchers. The study concluded that de-identified data removes too much information to enable good research.\(^{18}\)

The HIPAA Privacy Rule especially impacts epidemiology, comparative effectiveness, and health services research because of their dependence on stored medical records. Discoveries from these studies are important for improving patient care in real-world settings, as distinct from the more controlled clinical trials. These types of research are also critical to a “rapid learning healthcare system” that uses the large amounts of data collected in healthcare systems and disease registries to quickly match the most appropriate treatments to specific types of patients. Unfortunately researchers cannot do this research unless the datasets are complete and rapidly available, both of which HIPAA impedes.

A survey of cancer registries found that 68 percent of respondents reported that HIPAA delayed or lengthened research projects.\(^{14}\) Another study of three health services research projects aimed at improving healthcare for minorities found that HIPAA requirements made health organizations more hesitant to let researchers access previously collected patient data, while at the same time making it more challenging to recruit patients to original studies. “Overall HIPAA complicates the research process and requires more resources and longer time to conduct [health services] research,” the investigators concluded.\(^{19}\)

Comparative effectiveness research often requires data mining, using previously collected data to conduct new studies, to reveal superior efficacy and safety of different medical interventions for the same disorder. Currently, as conservatively interpreted, the Privacy Rule inhibits attempts to expand comparative effectiveness research, thereby limiting the knowledge needed for treatment decisions.\(^{20}\)

E. Increases the time and expense of clinical trial development

Prior to conducting a clinical trial, researchers expend a significant amount of time preparing protocols for IRBs review to ensure the study will be conducted properly and ethically, and will conform to regulations regarding patient safety. HIPAA Privacy Rule requirements for authorization or waiver of authorization by an IRB have burdened research through increasing the number of projects requiring initial and repeated full committee IRB review.\(^{22}\) The added time required to comply with HIPAA also slows down the pace of discovery and increases costs. Of the 1,527 epidemiologists who responded to a survey on how the Privacy Rule had affected their research, 87 percent (1,328) reported an increase in the time required for preparing a
research proposal for IRB review. Preparation includes modifying and resubmitting protocols for another IRB review after a previous review requested changes.

The initial HHS estimate that the research provisions of the Privacy Rule would cost $10 million to implement the first year and $146 million over 10 years has already been realized. Johns Hopkins University estimated that their cost of complying with HIPAA for research and health care operations was about $2 million annually, for the first two years after the legislation was implemented. Another study found that the implementation of HIPAA midstream in a clinical trial led to a 70 percent increase in staff hours.

F. Fosters abandonment of clinical studies and deters initiation.

Studies already in progress have been abandoned due to HIPAA requirements. A survey by the Agency for Healthcare and Research Quality found that 45 percent of respondents had a study that had been stopped or changed because the protocol could not comply with HIPAA. Studies that were ended included follow-up studies of patients tracked through several different health facilities, studies involving community health centers and rural sites, and research evaluating government programs and clinical interventions in order to improve patient population health. After HIPAA was implemented, researchers had to abandon one large, 25-year old longitudinal study of how ethnicity, various procedures, and medications affect heart disease and stroke survival because they were unable to obtain a waiver of authorization to use patients’ medical records.

The HIPAA Privacy Rule also deters many clinicians from starting clinical research. A survey of investigators at a large Health Maintenance Organization (HMO) research network in Seattle found that 65 percent of respondents agreed they were hesitant to pursue new study ideas for drug safety, cancer care delivery, and cancer screening due to the Privacy Rule.

The abandonment of clinical studies due to HIPAA restrictions limits patients’ opportunities to participate in health research, discourages clinicians from conducting future studies, makes research less efficient, and slows down the pace of discovery. Discontinuing clinical studies also wastes the contributions of those patients who had already agreed to participate.

G. Increases the time and cost of large, multi-site studies

The vague Privacy Rule also hampers multi-site research by fostering varying IRB interpretations which produces inconsistent patient protections, and increases time and expense of these studies while reducing their validity.

Several studies demonstrate that varying IRB interpretations impede multi-site studies, including a survey of health services researchers where three percent reported they were unable to proceed with a multi-site study because they were unable to resolve disagreement among IRBs at different sites. In another survey, half of the respondents that participated in multi-center research reported that the concerns IRBs raised about the same study protocol varied considerably, which led to different modifications at different centers. Inconsistent study methods can invalidate results or limit their application.
Multi-site studies are necessary to identify the causes and treatments for rare cancers as few clinical research centers have enough patients with these rare diseases. Pharmaceutical companies also rely on large, multi-center research to test new cancer treatments for more common cancers. Delays in the completion of these studies increases the time it takes for patients to receive new, more effective treatments.

CONCLUSION
The HIPAA Privacy Rule has not significantly improved patient privacy protections, and instead has needlessly hampered health research. The barriers imposed by HIPAA are typically expressed in terms that are meaningful to researchers including selection bias, inefficiency, procedural burdens, increased costs, and abandoned studies. When researchers abandon studies, results are not realized. When research is hampered by the use of de-identified data, results are not as meaningful or useful. When accrual is hampered by bureaucratic hurdles, the strength and broad applicability of findings is limited. When previously acquired data are inaccessible, research is not initiated and an investment is rendered useless. Translating these barriers into a patient perspective, the selection bias driven by HIPAA creates challenges to finding treatments applicable to all types of patients, thereby perpetuating health disparities. HIPAA also delays comparative effectiveness studies, which can identify the most effective therapies more rapidly for patients. The additional burdens to the patient consent process makes the patient experience more complicated, confusing, and unpredictable. In addition, HIPAA dishonors the trust that patients have in researchers when studies are abandoned and experimental protocols are no longer available. The resulting cost burden of these barriers weighs heavily on the healthcare and research system in terms of time and dollars.

Health research should be exempted from the HIPAA Privacy Rule and effective security protections should be implemented to improve privacy protection and accelerate research. As the IOM report on HIPAA notes “…if society seeks to derive the benefits of medical research in the form of improved health and health care, information should be shared to achieve that greater good, and governing regulations should support the use of such information, with appropriate oversight.”
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