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Ethics of Chart Review Research

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Patients presume their medical records are private. They think their records are not seen by anyone other than their physicians and that this privacy is guaranteed under the Health Insurance Portability and Accountability Act, commonly known as the HIPAA law. Patients are surprised that many other people have access to their medical records and their private health information (PHI). In addition to people in the extended physician team (nurses, medical assistants, registration, billing, coding, and health information management), insurers, regulators, and accreditation personnel might also see a patient's chart in the course of performing their duties. Quality improvement activities in an institution may involve staff members who have no clinical connection with patients seeing the details of medical records as they look for quality problems with the care given at the institution.

Chart review research is also done by people with no involvement in the healthcare operations described above. The use of medical records for research is common and in many cases important to society. For example, a surgical resident may review the last 100 cases of a procedure performed with 2 different techniques and then run a statistical analysis to determine if 1 technique results in better outcomes than the other. In the process, the resident sees a great deal of PHI about 100 people. Chart review research can also be computerized. An example is data mining 20,000 diabetic records using algorithms to evaluate which drug combinations have the best impact on hemoglobin A1c values. Data mining research often distances the details of a specific patient's PHI from the researcher.

Is it okay for chart review researchers to routinely see a patient's PHI without the patient's specific authorization, permission, or consent? Is it legal? Is it ethical?

Can Researchers Legally Look at Patients' Medical Records Without Their Consent?

Chart review research without patient consent is legal under federal laws in the United States under certain conditions; state laws vary. Louisiana law does not address this question, so the default is the federal law. Federal research regulations on chart review research apply to federally funded or Food and Drug Administration (FDA)-regulated research, although most healthcare institutions that own the medical records apply the same ethical rules to all research regardless of funding.

Federal research regulations allow an institutional review board (IRB) to approve research with a waiver of informed consent if 4 conditions are met (does not apply to FDA-regulated studies)[1]:

(1) The research is minimal risk; that is, the probability and magnitude of harm or discomfort anticipated in the research are not greater than the harm or discomfort ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
(2) The waiver will not adversely affect the rights and welfare of subjects.
(3) The research could not practicably be carried out without the waiver or alteration. For example, because of the numbers of records being accessed without any patient contact or the difficulty of locating some or all of the patients, it would not be realistically possible to conduct the research without such a waiver.
(4) Whenever appropriate or feasible, subjects will be provided with additional pertinent information after participation. (This condition does not generally apply to chart review research.)

The HIPAA regulations have a similar section for waiver of authorization by an IRB or privacy board.[2]

Can Researchers Ethically Look at Patients' Medical Records Without Their Consent?

To ensure the scientific validity of the results, most chart review research involves large numbers of records, typically hundreds or thousands. Chart review research is often done on a shoestring budget during after-hours time or during limited administrative time. A requirement to obtain informed consent from each patient would most often mean the research could not happen. Even if obtaining consent were possible, a small number of patients with bad outcomes who declined consent could bias the results and make them scientifically invalid. Society needs the benefits from chart review research to evaluate the evidence of what appears to work better and to develop hypotheses for further research in prospective randomized clinical trials. Societies weigh the benefits and risks of chart review research, and at least in the United States, our conclusion is that such research is ethical if certain conditions specified in the regulations are met.

What Safeguards Should Be Used to Protect PHI in Chart Review Research?

The regulations are limited in regard to safeguarding PHI. The regulatory focus is on the approval process to do such research, rather than on the details of how the research should be conducted after its approval by an IRB. The HIPAA regulations use the "minimum necessary" standard, requiring researchers to have the minimum amount of access to PHI that will still allow them to achieve their approved research goal.[3]

The Institute of Medicine has studied this issue and noted that retrospective chart reviews can involve risks to patients. Harms that can be done by accessing secondary data are the psychological and financial risks that can result from improper disclosure of PHI: potential denial of health insurance coverage, difficulty obtaining employment, embarrassment, loss of reputation, legal liability, or anxiety about what the recipient of an unauthorized disclosure of information might do with the information.[4]

Because of these risks, confidentiality is important. While opinions vary, many think confidentiality in the use of data requires at a minimum (1) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security numbers except when essential for an approved study protocol; (2) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (3) encrypting personal identifiers if they must remain to combine with future data instead of using the plain clinic or hospital numbers (a statistician can help with this process); and (4) keeping the data files in a secure environment such as a locked cabinet, a properly secured computer file with password protection, or a secure server drive.[4]

Another approach to PHI protection is to deidentify all data before it reaches a researcher. Some institutions have invested in chart review-savvy data miners within a health information management department. When a researcher wants to study a problem, he or she determines with the statistician how many records and what types of records are needed and then sits down with a health information management specialist to agree on the type of spreadsheet data from the records that will be needed for the research. The health information management specialist on the operations side of the firewall extracts the needed data, deidentifies it according to HIPAA standards, and gives the researcher a deidentified spreadsheet with the requested data. Because the researcher sees no PHI, the federal regulations conclude that no human subject research is occurring; hence no IRB approval is needed. This approach has the ethical advantage of chart review researchers never being exposed to PHI. However, funding data miner positions is expensive and is not the norm at most institutions.

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