Patient Privacy and Using Medical Records in Research

Balancing Confidentiality and the Need for Public Health Data

By Andrea Dumbrell

"Whatever, in connection with my professional practice or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret."

--Excerpt from The Hippocratic Oath

Since the time of the ancient Greek physician Hippocrates, respecting patients' privacy has been considered imperative to the ethical practice of medicine. The reasons for such a stipulation are many but, most generally, it has been reasoned that ensuring patient privacy has favourable consequences for the patient-doctor relationship (Lo 2000). For example, the assurance of privacy encourages patients to seek medical help for all kinds of illnesses and to openly discuss their condition with a physician. As a result, both the patient's and public's health benefit when conditions like sexually transmitted diseases, psychological disorders or other stigmatized illnesses are reported (Dodek 1997, Lo 2000).

Patient privacy is related to the ethical concept of autonomy, that is, one's capacity for "self-rule" (Beauchamp 1994). Furthermore, one of the major notions inherent in the concept of autonomy is informed consent: the idea that a patient has the right to make self-ruling decisions based on relevant information provided about such a decision (English 1994, Beauchamp 1999). However, these central concepts are precisely those at stake in some modern medical research settings. Of course, occasionally there are reasonable (and indeed, compelling) grounds for overriding a patient's privacy: the mandatory reporting of gunshot wounds, domestic violence and impaired drivers are just a few examples (Lo 2000). But the need for epidemiological (public health) research has the potential to challenge the conception of patient privacy in a way that greatly concerns many ethicists, physicians and researchers.

Doubtless, the value and justification for public health research is "self evident" (Black 1994). By studying epidemiological trends, the public benefits from improved health care and carefully targeted health interventions (Beauchamp 1991, Black 1994). Hospitals are permitted to disclose identifiable health care information to researchers, provided that an institutional review board (IRB) has given approval for the study. As a result, much epidemiological research could not be conducted if obtaining consent from each patient was a mandatory requirement. Moreover, such a loss of research would effectively contravene the assumptions of the Geneva Convention, which state that medicine and research bear responsibility not only to the individual but also to humanity at large (Knox 1992). Accordingly, Beauchamp (1991) explains that the "use of records without consent is not necessarily an ethical violation. [Epidemiological research]...may be the first stage of an investigation that determines whether there is a need to trace and contact particular individuals and obtain their permission for further participation in a study." Indeed, if patients' medical records were not available for public health research, the ability to identify and remedy illnesses in a population would be severely limited. Clearly, strong cases exist for the necessity of both patient privacy and the need for reliable, accessible health data. However, these two concepts can be – and often are – put into conflict in the biomedical setting. By examining the issues at stake in balancing patient privacy and the use of medical records in research, possible changes or solutions to this tenuous relationship can be considered.

One of the issues at the core of the debate between patient privacy and the need for research is the notion of informed consent. Informed consent dictates that an individual has the right to choose whether or not to join an epidemiological study based on a full disclosure of its methods, treatments, possible side effects and so on (English 1994, Beauchamp 1999). As common sense would suggest, informed consent is an essential ethical aspect of the patient's right to autonomy and self-determination when participating in a clinical study. However, it has been noted "that informed consent to research is generally viewed as something very different from informed consent to medical practice" (Levine 1986). Consequently, this difference between what constitutes informed consent in either setting provides a ripe opportunity for the concept of patient privacy to falter. In many cases in the research field, medical records are considered to have "legitimate extended uses" beyond the private documentation of a patient's medical history (Knox 1992). Indeed, hospitals often disclose identifiable health information to qualified researchers in order to perform retrospective analyses, following approval by an IRB or similar committee (Dodek 1997).

Subsequently, there are two main visions of how patient privacy can be secured while allowing epidemiological research to progress. The first and most extreme position is that any access to medical records for the purposes of research must follow the explicit informed consent of the patient to do so (Black 1994). The other view is that medical records used for research purposes must be provided in a way that reveals no identifiable features of a patient, including name, age, address, postal code, sexual orientation and so on. Complete preservation of autonomy, as endorsed in the first position, initially appears to be ideal but is impossible to reconcile with the needs of biomedical research (Dodek 1997, Beauchamp 1994, Black 1994). For example, retrospective studies that examine temporal trends in diseases like cancer often need health data on tens of thousands of individuals in order to have sufficient statistical power behind their conclusions (English 1994, Beauchamp 1991); gathering informed consent for the use of each patient's confidential medical data would be a hopelessly time-consuming task. In addition to the hundreds of work hours needed to do so, a researcher put in charge of obtaining explicit consent would likely be unable to trace patients who had moved or died in the time between the study and the date of their medical records.

Unfortunately, the apparent compromise evident in the second view of balancing patient privacy and the need for health data also has detrimental implications for biomedical research. Many studies rely on personal information like addresses or postal codes to investigate the association between residential areas and certain diseases (for example, the UK Childhood Cancer Study Investigators' study of exposure to power frequency magnetic fields and the risk of childhood cancer). Consequently, eliminating access to this type of data would prevent studies that relate the occurrence of disease to personal details such as place of residence. Likewise, much valuable epidemiological research is based on information provided by death certificates (such as the Ontario Cancer Registry's studies of correlative factors in cancer development). Clearly, banning researchers' access to the identifying details of personal information would most certainly come at a great cost to these types of epidemiological studies. Furthermore, other types of data, particularly genomic information, may be impossible to keep

"anonymous" in that it is intrinsically associated with, and identifiable to, only one individual (Gostin 1995).

The solution to the problem of balancing the needs for patient privacy and accessible health data is hardly straightforward. Various suggestions have been made, including the possibility of separating the contents of medical records into confidential and non-confidential portions in order to allow researchers and other third parties (such as insurance companies) access to the valuable information within (Dodek 1997, Black 1994, Seigler 1982). Other ideas include promoting a renewed prudence and awareness of the many methods by which patient confidentiality can be breached, with particular attention directed towards the hazards posed by modern technology. The growing computerization of medical records, while a convenient feature for clinicians and researchers alike, has produced yet another domain in which the confidentiality of medical records can be compromised (English 1994, Beauchamp 1991).

Although Siegler (1982) famously asserts that confidentiality in medicine has become "a decrepit concept," such a pessimistic opinion need not be the last word on this subject. Without question, physicians, researchers and patients alike must address the changing reality of patient privacy. As a result, due to the ever-increasing demand for updated, accurate health research, patients should be aware of the fact that their personal information may be shared with others for the good intentions of research. What this requires of physicians, however, is the responsibility to discuss frankly this reality with their patients, in order to ensure that they are aware of the limits of patient confidentiality. Although the reality of accessibility to medical records may be unsettling for some, ultimately patients must understand what the operating concept of patient privacy does and does not entail in the clinical and research realms of medicine. ■

Anthrax and the Three Amigos

by Ajit Thakur

Bioterrorism involves the deliberate use of microorganisms to cause infection and long-term destruction and destabilization of the human population.

The notion of Bioterrororism was conceived during World War I and II by the Germans, Japanese, Americans, Russians and the English. Only recently has Iraq developed the powder form of this microorganism. Even Canada had once actively participated in the development of weapons grade Anthrax spores for Britain. At the end of WWII, hundreds of pounds of Anthrax spores were barrelled and cast away into the depths of the St. Lawrence River in Canada.

There are thirty different pathogenic microbes used in Biological warfare. They include viruses, bacteria, toxins, and animal venom eg: Anthrax, *Clostridium botulinum*, Plague, Smallpox virus, and Tularaemia.

The anthrax bacillus, *Bacillus anthracis*, was the first bacterium shown to be the cause of a disease. In 1877, Robert Koch incubated pure cultures of the organism and demonstrated its ability to form endospores. He was the first to experimentally induce anthrax by injecting it into animals. It was later found that *Bacillus anthracis* is a gram-positive bacterium. It is non-motile and multiplies as vegetative rods capable of spore formation that enable it to resist extreme environmental conditions.

The Anthrax bacteria and the spores are present in the soil in all developing and developed countries. It is endemic, most commonly present in the soil of Asia, Middle East, Africa and even some places in the United States, like Texas, Oklahoma, Minnesota, Dakota and Nevada.

Grazing animals commonly acquire this disease. When the animal ingests the bacterium, the poison of the anthrax kills the animal cells. Once the animal is dead, the spores and the vegetative rods multiply and spread from the carcass into the soil and then are spread by the wind and soil into the environment. This is the only way through which the bacterium propagates itself.

It might be surprising to note that Anthrax bacteria are actually harmless themselves, if not for a few mutations that sets them apart from the others. An individual bacterium can be