Spousal Abuse

CASE STUDY

An elderly woman is seen in clinic and appears to have injuries consistent with spousal abuse. In that her husband is her primary caregiver, she feels very dependent on him. When you question her, she begs you not to say anything to him.

1. Google and review the function of "Adult Protective Services."
2. How would you handle this situation?

Confidentiality is an expectation of the patient-provider relationship and has a long history in the practice of health care. Early Greek physicians not only pledged to respect confidentiality, but they were known to inscribe patients' histories and treatments on columns within the temple and, to assure this privacy, access to the temple was limited.[1]

Privacy and confidentiality are no less significant in Western health care today, and contemporary codes of ethics echo the Hippocratic principle of respect for confidentiality. The World Medical Association's Declaration of Geneva, for example, contains the statement "I will respect the secrets which are confided in me, even after the patient has died."[2]

A patient's basic right to expect the information he or she gives a health care practitioner to be held in confidence can be arrived at and defended using any of the four systematic approaches to ethical decision making. Whether the reasoning is from a utilitarian, duty-oriented, virtue ethics, or divine command standpoint, confidentiality seems to be a settled issue.

From a utilitarian point of view, the long-term consequences of making public any personal information gained as a result of the practitioner-patient relationship would have a chilling effect on the truth telling in that relationship. Because health care practice is normally conducted under a tacit agreement of confidentiality, practitioners who breach this trust are in violation of an agreed-on expectation. This is especially critical in psychotherapy, in which the patient is encouraged to take the risks involved in personal disclosure. If the patient has lost confidence in the process and fails to discuss personal issues with the practitioner, the quality of care provided will be severely limited.

From a duty-oriented perspective, personal privacy is a basic right, with its foundations firmly based not only in long-standing codes of professional practice but also in common law. The unwarranted disclosure of a patient's private affairs, the unauthorized use of a person's photograph, or exploitation of a person's name have traditionally been considered acts that might give rise to legal action on the grounds of invasion of an individual's right to privacy. The medical duty to protect the confidentiality of patients could be argued on the basis of our general rights as citizens to be free from invasion of privacy. Individuals in our society have the autonomous right to the control of personal information and the protection of personal privacy. In some sense, privacy can be viewed as a person's right, while confidentiality is the professional's duty.

From the vantage point of virtue ethics, the practice of patient confidentiality has been a mainstay of health care practice and forms one of the virtues one would expect from the "good practitioner."

Confidentiality is a critical principle, and, regardless of the specialty, the good practitioner cannot be viewed as cavalier in regard to protecting patients' confidences and privacy. While it is obvious that confidential information must be shared among practitioners in order to provide the best care for the patient or to extend the body of knowledge within health care, it is equally obvious that this does not take the form of conversations in elevators, in cafeterias, or with friends at a party.

The real question, then, is not whether confidentiality is a good—regardless of what reasoning you use—but whether it is a moral absolute, or might be overridden by other considerations. In the classic *Tarasoff* case, a young man by the name of Prosenjit Poddar confided to his clinical psychologist that he intended to kill a young woman he readily identified as Tatiana. The psychologist, understanding that his patient presented a real danger to the young woman, decided Prosenjit should be committed for 72 hours to allow further evaluation, and he notified security to assist in securing the patient's confinement. The patient, however, convinced the security officers that he was rational, and he was released following his promise to stay away from the young woman. The health care providers rescinded the orders to place Prosenjit in confinement for evaluation, and no efforts were made to warn Tatiana or her family of potential danger. Within weeks of these events, Prosenjit murdered the young woman.[3]

The health care practitioners later defended their decision to maintain patient confidentiality on the basis that they had a duty only to their patient, and in the absence of duty they were not required to protect the life and safety of others. To whom did the caregivers owe duty: to their real patient or to the potential victim? They had chosen to serve the one and ignore the other. Arguments used in their defense were that effective treatment required the patient's full disclosure of his innermost thoughts and that, without the promise of confidentiality, patients needing treatment would fail to seek care.

In its decision, the court recognized the difficulty that a practitioner might have in attempting to predict whether statements made by a patient would actually be carried out. However, the court ruled that the specialist would be held to the standard of reasonable practice, and where that standard indicated a foreseeable danger to another, a duty to warn was created. The protective privilege of confidentiality is limited where the health and safety of others is involved. This breaching of the trust of confidentiality is recognized and allowed by the Code of Medical Ethics: Current Opinions of the American Medical Association, which states:

> the obligation to safeguard patient confidences is subject to certain exceptions, which are ethically and legally justified because of overriding social considerations. Where a patient threatens to inflict bodily harm to another person or to himself or herself and there is a reasonable probability that the

patient may carry out the threat, the physician should take reasonable precautions for the protection of the intended victim, including notification of law enforcement.[4]

In her book *Secrets: On the Ethics of Concealment and Revelation*, Sissela Bok cites several instances in which confidentiality is overridden by more compelling obligations.[5] Many of these instances have found their way into legal statutes, and practitioners are generally required to report cases involving child abuse, contagious diseases, sexually transmitted diseases, wounds caused by guns or knives, and other cases in which identifiable third parties would be placed at risk by failure to disclose the information. Bok feels that the personal protective privilege of confidentiality is limited by the **harm principle.** This principle requires that health care providers refrain from acts or omissions that would foreseeably result in harm to others, especially in cases in which the individuals are particularly vulnerable to the risk.

The harm principle is modified by the level of vulnerability. Consider the case of a married man who tests HIV positive. In that the risk to the community at large is rather minimal, whereas the risk to the man in regard to discrimination, deprivation of rights, and occupational and social harm are great, the practitioner would have an obligation to be very discrete in regard to confidentiality, and to do little more than that which is legally required in reporting the test results. However, in the case of the wife, who is far more vulnerable than the community at large, the practitioner must either be assured that the situation is modified in order to lessen the woman's vulnerability or disclose the information to the woman. It would seem, then, that the practitioner's observance of the principle of confidentiality must always be balanced by the need to protect others from foreseeable harm, especially if the other individual is particularly vulnerable to that harm.

LEGAL FOUNDATION OF PRIVACY

The right to be left alone, free from unwanted publicity, is considered an important freedom in American society and has found its way into both state and federal statutes. The phrase **right to privacy** is a generic concept encompassing a variety of rights thought to be necessary for an ordered democracy. American law has sought to prevent governmental interference into intimate personal relationships, activities, and decision making. In 1965, the U.S. Supreme Court struck down a Connecticut ban on the sale of contraceptives in the landmark *Griswold* v. *Connecticut* case. Justice Douglas described a "zone of privacy" created by several constitutional guarantees, which forbade governmental intrusion into the homes and lives of citizens. This constitutional recognition of a right to privacy and self-determination formed the basis of the *Roe* v. *Wade* (1973) decision on abortion. The Supreme Court determined that a woman's right to make this personal choice rested first, on the avoidance of disclosing personal matters and, second, on the need to provide for an arena where independent decision making could take place.

In general, we have a right to make fundamental choices involving ourselves, our families, and our relationships with others free from scrutiny, so long as our assertion of these rights is consistent with law or public policy. We have a right to maintain our private lives and to restrict the collection, processing, use, and dissemination of information about our personal attributes and activities. The law provides legal redress against those who would infringe on our legitimate right to privacy from motives of malice, greed, curiosity, or gain. The standard to determine whether an invasion of privacy has taken place is that of a hypothetical "person of ordinary sensibilities." If such a person would find the appropriation, or exploitation, of one's personality, the publicizing of one's private affairs, or wrongful intrusion into one's private activities was unwarranted and brought mental suffering, shame, or humiliation, then there would be grounds for legal action on the basis of invasion of privacy. Tort actions involving invasion of privacy issues generally involve one or more of the following four classes:[6]

- Misappropriation—usually deals with the unpermitted use of a person's name or likeness for another's benefit or advantage.
- Intrusion—involves the intrusion upon another's solitude or seclusion; a clinical example might be the allowance of unessential, or lay personnel to be present during a surgical procedure or examination.
- Public disclosure of private facts—involves publicity of an objectionable nature of private information.
- Presenting someone in a false light to the public—usually involves the publication of information that leads to the public regarding the plaintiff falsely. An example would be the use of a stock photo of a surgical team in an article about Medicare fraud. The intent was to show a generic picture of practitioners; however, the implication of associating them with the article would place them in a false light.

LEGAL CASE STUDY

Wrong Person, Wrong Place, Wrong Time!

In this early (1881) classic case,[7] a physician was called to the home of a female patient in labor. The physician was accompanied by a non-physician friend who remained in the delivery area and held the woman's hand providing her comfort during the birth. When the woman became aware that the individual was not a health care provider, she sued the physician for a breach of individual privacy. The court held that having a nonessential person present during the labor violated the woman's legal right to privacy at the time of her child's birth.

1. Which class of tort action associated with privacy fits this case?
2. Do you agree with the court that the standard of *a hypothetical "person of ordinary sensibilities" would be offended* is met in this case?

Many state statutes and a few federal regulations require the reporting of certain types of information from the medical record, to appropriate agencies with or without the patient's authorization. Common legal reporting requirements found in most American jurisdictions include:[8]

- Child abuse
- Drug abuse
- Communicable disease
- Births and deaths
- Injuries with guns or knives
- Blood transfusion reactions
- Poison and industrial accidents
- Misadministration of radioactive materials

These reporting requirements deal with issues thought to be vital to community health and welfare. The child abuse statutes in most states require that hospitals and practitioners report incidents of suspected abuse. In these cases, the practitioners are protected from liability if they are making the report in good faith even if the reported abuse proves to be false. Failure to make a report in regard to child abuse by those required to do so can leave them legally liable for any additional injuries the child may suffer upon return to the hostile home environment.

Some states maintain a registry of the names and addresses of all patients who obtain drugs that are subject to abuse. These reporting regulations have been upheld as a reasonable exercise of an individual state's broad police powers. In the absence of a legal regulation to provide patient information, a police agency has no authority to examine a medical record without the patient's authorization.

MODERN HEALTH CARE AND CONFIDENTIALITY

At the turn of the last century, maintaining confidentiality and privacy of the medical record was a relatively easy task as 85 percent of the direct medical care services were delivered by physicians. Access to and the obligation to maintain confidentiality in regard to medical records was limited to the physician and a small direct care staff. The records kept were maintained as paper charts, usually poorly indexed, with poor handwriting, with little opportunity for access outside of the particular clinic or hospital. In a real sense, the private nature of the medical record was generally maintained by the simplicity and inefficiency of our processes.

Today, with the emergence of massive electronic health care record databases, the principle of confidentiality and legal right to privacy is no longer protected by simplicity and inefficiency, but is threatened by our ability to store and share data that has opened up an almost unlimited opportunity for health information to be stolen and misused.

Today over 80 percent of direct patient care is provided by allied health and nursing professionals. In the hospital, only about a third of the patient's record is maintained by physicians, with the rest being recorded by other members of the health care team. As reported in *Time* magazine: The patient's record is not only accessible to physicians but also readily available to technical and administrative staff who generate and handle patient data. During an average five days of inpatient care within a teaching hospital as many as 150 staff—from nursing, respiratory care, radiology, and billing clerks—have legitimate access to a patient's record to provide both direct and/or supportive services.[9]

Moreover, the problem of access to patient information has been exacerbated by the growing use of computerized information systems. The large scale on which information can be stored and the ease of access to this data has made distribution of the information outside the arena of the patient–health care practitioner interface a daily routine, as patient data is used for administration, payment, **utilization review**, teaching, and research. In addition to the health care providers, patient files may be available to the following: insurance companies (because they pay the bills); public health agencies (to assist in monitoring and investigating disease outbreak patterns); employers (to assess job-related injuries); federal, state, and local government (to develop health care plans and allocate resources); attorneys and law enforcement agencies (as evidence to settle civil or criminal matters); media (to report health hazards and help report medical research development); and accreditation, licensing, and certification agencies (to assess compliance with various criteria and standards).

The concerns of these **third-party payers** with access to medical information may or may not coincide with the patient's best interests, inasmuch as confidentiality and privacy are not necessarily a high priority for groups such as governmental regulators, third-party payers, insurers, or utilization reviewers. Given the tasks they perform, they may favor safety, truth, and knowledge far more than they value the personal privacy of a single patient. The computerized accumulation, analysis, and storage of unlimited quantities of medical information have overwhelmed the medical record professionals who are entrusted with protecting patient privacy and confidentiality.

By the early 1990s it was clear that the use of computers and complex database retrieval systems was making confidentiality of patient information difficult to maintain. Periodic stories involving computers put up for sale as surplus from medical schools or other agencies that were later found to contain confidential files providing case details of thousands of patients, or marketing companies that advertised databases with literally millions of names and addresses of people with conditions such as bladder cancer, allergies, and clinical depression, underscored the scope of the problem. It was obvious that the patchwork of state laws governing the area left gaps in the protection of patients' privacy and confidentiality. Prior to the enactment of HIPAA and the **Privacy Rule** there was no unifying federal privacy act for medical records.

IN THE NEWS

Massive Hack of Hospital Network Files—4.5 Million Records

UCLA Hospital System's president, Dr. James Atkinson, apologized to the public for the potential loss of millions of records. Information lost included patients' names, medical information, Social Security numbers, Medicare numbers, health plan IDs, birthdays, and physical addresses. The hospital group is now notifying staff and patients, offering them one year of identity theft recovery.

The UCLA system is just one of many health systems who have lost control of millions of records. These systems are under near constant attack by hackers, some of which are operating in foreign countries. Hospitals, health insurance companies, and universities have all become a frequent target for hackers seeking massive databases of personal information. Profile data, Social Security numbers, and health records sell on the black market. Illegal data brokers amass large databases of this stolen information and then sell access to identity thieves.[10]

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

Recognizing the growing confidentiality problem associated with electronic databases, Congress enacted the **Health Insurance Portability and Accountability Act (HIPAA)** in 1996 to encourage the use of electronic transmission of health information (to assist in cost containment) and provide new safeguards to protect the security and confidentiality of the information. HIPAA has three self-declared major purposes:

- To protect and enhance the rights of consumers by providing them access to their health information and controlling the inappropriate use of that information.
- To improve the quality of health care in the United States by restoring trust in the health care system among consumers, health care practitioners, and the multitude of organizations and individuals committed to the delivery of care.
- To improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on efforts by states, health systems, individual organizations, and individuals.

HIPAA rules affect virtually all health care records. Entities covered under the law are health care plans, health care clearinghouses, hospitals, nursing homes, physicians, managed care organizations, and payers. All medical records and other electronically identifiable health information used or disclosed in any form are protected. Figure 5-1 provides the key elements of the Privacy Rule including who is covered, information protected, and how information can be used and disclosed. The Rule established for the first time a set of standards for the protection of certain health information.[11]

Those required to follow HIPAA Privacy Rule:

- Doctors, nurses, allied health professionals, pharmacies, hospitals, clinics, nursing homes, and many other health care providers
- Most employer health plans, HMOs, and health insurance companies
- Certain government programs that pay for health care, such as Medicare and Medicaid

Protected information:

- Information your doctor, nurses, and other health care providers put in your medical record
- Conversations your doctor had about your care or treatment with nurses and other health care professionals
- Information about you in your health insurer's computer system
- Billing information about you from your clinic/health care provider
- Most other health information about you, held by those who must follow this law

To make sure health care information is protected in a way that does not interfere with the patient's health care, information can be used and shared:

- For treatment and care coordination
- To pay physicians and hospitals for the patient's health care
- With family, relatives, friends, and others the patient identifies as being involved with their health care or health care bills, unless the patient objects

Without the patient's authorization health care providers generally cannot:

- Give information to the patient's employer
- Use or share the patient's information for marketing or advertising purposes
- Share private notes about the patient's mental health counseling sessions

Patient's rights:

- Right to see and get a copy of your health records
- Right to have corrections added to your medical records
- Right to receive a notice as to how your health information may be used and shared
- Right to decide if you want to give permission before your health information can be used or shared for certain purposes, such as marketing
- Right to a report on how and why your health information was shared
- Right to due process if your rights are denied

FIGURE 5-1 Summary of the HIPAA Privacy Rule

Adapted from CaringInfo, National Hospice and Palliative Care Organization (NHPCO), "Summary of the HIPAA Privacy Rule"

IN THE NEWS

Why Doctors Are Demoralized

According to an article in the *Washington Post* (June 2015), physicians are becoming demoralized by the loss of traditional professional autonomy as they are forced to attend to ever-increasing demands and interference from insurers, lawyers, and government. A major point of grievance is the federal electronic health record (EHR), which mandates that all medical offices go paperless by the end of 2015. While it is thought that this change will save lives by reducing medical errors, and result in cost savings of billions of dollars, it is also having the effect of turning physicians into typists rather than healers. If doctors are spending their time tapping data into computers, this comes at the expense of listening to patients, eye contact with patients, and time with patients. One study found physicians spending 44 percent of their time completing what might be considered secretarial duties.[12]

1. Do you feel this is governmental overreach into health care practice?
2. Are the benefits of electronic health care records in cost savings and reductions in medical errors important enough to alter traditional medical practice?
3. If we assume both sides are correct here—how can we make the transition easier?

LEGITIMATE INTEREST

The medical record goes far beyond just medical information and contains personal data of a financial and social nature. It is the property of the hospital or clinic, but the patient has a legal interest and right to the information.

It is generally considered that the record is confidential and that access to it should be limited to the patient, authorized representatives of the patient, the attending physician, and hospital staff members who have a legitimate interest. The exact specification of who has a legitimate interest is a great concern to health care practitioners, but some general guidelines are accepted where the need is for patient care, professional education, administrative functions, auditing functions, research, public health reporting, and criminal law requirements. In regard to patient care, any information may be shared among health care providers who are responsible for the patient within the treating facility. Modern medicine is a team practice, and adequate exchange of information is necessary for patient care. Table 5-1 provides an indication of the large numbers of individuals with possible legitimate access to health care information.

TABLE 5-1

Health Records and Legitimate Access	
LEVEL ONE—DIRECT PATIENT CARE	
Physicians	Institutional Services
Nurses	Therapists/technologists
LEVEL TWO—SUPPORTIVE SERVICES	
Service Payers	Quality Care Reviews
Risk Management	
LEVEL THREE—SOCIAL SERVICES	
Insurance	Research
Licensing	Education
Employment Decisions	Media
Civil/Criminal Judicial Review	Law Enforcement
Public Health Reporting	Rehabilitation

LEGAL CASE STUDY

Estate of Behringer v. Medical Center at Princeton, 1991

In *Estate of Behringer* v. *Medical Center at Princeton*, the court was confronted with a charge of discrimination by an otolaryngologist/plastic surgeon whose surgical privileges were initially restricted and then revoked after he tested positive for HIV. From the date of diagnosis until his death two years later, he did not perform any further surgeries at the medical center.

One of the many problems associated with the Behringer case was the loss of personal privacy suffered by the infected practitioner as news of his infection spread rapidly across the hospital. Within hours he began receiving messages of concern and consolation as the matter became public knowledge. The plaintiff was entitled to recover damages from the hospital and its laboratory director for the unauthorized disclosure of his condition. The hospital and director breached their duty to maintain confidentiality of his medical records by allowing placement of the patient's test results without limiting access to the chart, even though they knew it would be available to the entire hospital community.[13]

Although we think of confidentiality in terms of patients, we have the same responsibility to protect the privacy of coworkers.

The need for professional education usually permits information in regard to in-house patients to be exchanged for these purposes. This generally includes medicine, nursing, allied health, psychology, social services, or any other professional group involved in patient care. If the information is to be disseminated outside the treating facility (as in a patient case study), this may not be done without prior patient consent or unless the information is in a form that precludes all possible patient identification.

Limited amounts of information as needed for the administrative functions of appointments, admissions, discharges, billing, compiling census data, and the like are necessarily shared among clerical and administrative staff.

Data in regard to the conducting of research can generally be shared with all the researchers involved, provided that the patient is not identified directly or indirectly in the process or subsequently in any other report or presentation. Hospitals that permit their staff to engage in research generally have research committees set up to screen the protocols. These **institutional review boards** (IRBs) attempt to balance the potential risk to the patient against the potential benefits of the research. In the absence of more stringent standards, the research committees should require the following as minimum standards.[14]

1. The research results should be presented in such a fashion as to protect the anonymity of the patients.
2. Only those involved in the study will have access to the raw data.
3. Safeguards to protect the patient's privacy will be part of the research protocol.
4. The same level of obligation to maintain patient confidentiality in the practice of health care is expected in the conduct of medical research.

Health care providers often record far more than is needed for documentation or to convey the necessary information required for patient care. It generally is not necessary for confidences to be recorded in explicit detail. A note in the record that a young patient "has a close relationship" with her boyfriend would generally be adequate to jog the practitioner's memory in regard to the need for counseling of a sexually active teenager. The less confidential information written explicitly into the record, the fewer opportunities there are for harmful disclosures involving patient privacy. Only material necessary for documentation and therapeutic care should be recorded; for example, in the case of a stab wound, the practitioner would not necessarily confide to the record other privileged information in regard to the attack, prior crimes or involvement in gang warfare.

It is essential and required by law that hospitals establish effective procedures to protect the content of medical records, not only from the standpoint of patient confidentiality, but also against the possibility of intentional falsification or alteration of the record. Unfortunately, records have been doctored by patients and practitioners alike who wished to improve their chances in pending legal actions.

LEGAL CASE STUDY

Altered Medical Records

A middle-aged man presented himself to a community clinic in California complaining of bone pain from multiple myeloma and asked for something to control the pain. He was seen by a physician assistant (PA) and hydrocodone bitartrate and acetaminophen were prescribed.

Over the next year the patient presented himself on multiple occasions requesting refills for the opioids. During this time period his examinations showed no clinical deterioration, weight loss, anemia, or lesions on X-ray. Becoming suspicious, the PA confronted the patient, who confessed that he did not suffer from multiple myeloma but needed the refills to control withdrawal symptoms.

The PA brought the matter to her supervising physician, and they determined that the opioids should be stopped and he should be referred to an addiction medical specialist for continued care.

The patient consulted an attorney who asked for the medical records to review the case. Risk management at the clinic's affiliated hospital was informed of the potential lawsuit but concluded that there were no legal merits to the case and that the PA had acted in good faith and could not have initially known that the patient was fabricating his medical history.

A year later the plaintiff's attorney asked to review the medical records again and, following the review, requested a settlement conference with the hospital's attorneys. What the plaintiff's attorney had found was that in the interim the PA had altered the records without dating the changes and had used a similar pen to the one used in the original notes.

Unfortunately, following the initial intent to sue, the PA became concerned that she should have included more details within the record describing key aspects of the history and physical exam. She remembered that she had questioned him about any history of substance abuse but had not included this in her notes. She did not date or sign the addendum, which made it look as if they were originally included in the record.

Although risk management had determined that there was no legal merit to the case even with the incomplete record, once the additions were discovered, it fell within California Penal Code 471.5 (*Any person who alters or modifies the medical record of any person, with fraudulent intent, or who, with fraudulent intent, creates any false medical record, is guilty of a misdemeanor.*) The case was settled for $1.5 million because of the falsification of the medical record.[15]

Humans make errors, so it's inevitable that medical record entry errors will occur. In the absence of specific state statutory or regulatory rules concerning the amending of medical records, health care facilities should provide a clear process for making corrections. If the needed correction is of a significant nature, someone designated in the facility's policy should review the correction to determine that it meets policy requirements. Spelling errors,

or miswritten dates are generally considered minor and do not require review. Health care practitioners should make changes only within the scope of practice for their specialty. As an example, an allied health practitioner or nurse would not normally amend a physician's medication error. When amending a record, the person correcting a charting error will normally draw a single line to cross out the incorrect entry, then enter the correction. The error should be initialed and dated.[16] It is important that mistakes are not erased or made unreadable, as that might give rise to questions as to the original record.

If a legal suit is threatened, no changes should be made in the medical record without consulting risk management. If the plaintiff can show that a record was altered without justification, the credibility of the whole record may be undermined. When charting or amending a record it is important to keep a potential jury in mind. In some states (e.g., Kentucky), a practitioner who is found to have falsified a medical record (an act considered to constitute dishonorable, unethical, or unprofessional conduct) can be subject to license revocation.[17]

HUMAN SUBJECT RESEARCH

Did She Give Informed Consent?

CASE STUDY

An elderly female patient hospitalized for dementia is asked to participate in a clinical study testing a new drug designed to slow progress of the condition. She has periods of time when she is quite lucid. It is during such a period that the trial was explained to her and she signed the informed consent form. However, when the investigator meets with her again to begin the study, she stares at him blankly, seemingly not remembering anything about it.

1. What should he do?
   a. In that she signed the consent when she appeared to understand, and given that she might benefit from the clinical trial, he should go forward with the study.
   b. Perhaps there is a surrogate who could give a valid consent for her participation?
   c. Given her level of vulnerability, he should cancel the previously signed document.

One of the more interesting and rewarding aspects of health care education and practice is the opportunity for clinicians and students to participate in research. Research projects generally are described in a protocol that sets forth the explicit objectives and formal procedures designed to reach these objectives. The objectives themselves may involve everything from gaining an understanding of normal and abnormal physiological, psychological, and sociological phenomena, to evaluating the efficacy of diagnostic, therapeutic, or preventive

interventions and variations in service or practice. To reach these objectives, researchers may conduct both invasive and noninvasive procedures, the collection of body tissues and fluids, the administration of chemical substances, randomization of subjects, modification of diet or daily routine, orchestration of strenuous physical exercise, alteration of environment, administration of questionnaires, reviews of records, and a host of other activities.

The basic ethical principles that need to be considered in planning a research protocol involving human subjects are autonomy, beneficence, nonmaleficence, confidentiality, and justice.[18] Autonomy in these cases flows from two important considerations. The first is that subjects are individual autonomous agents and have the right to expect that the researcher will support their opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. One basic application of this principle is informed consent. The researcher has an obligation to ensure that the individual has adequate information on which to base an autonomous choice. The second consideration deals with the fact that not all individuals are capable of self-determination. For individuals who have either not gained the capacity for self-determination or have lost this capacity due to illness, mental disability, or circumstances that severely restrict liberty, special considerations need to be put in place to ensure their protection, even if this means excluding them from participation in the research.

Patient benefit and risk calculations should always be considered in human research under the principles of beneficence and nonmaleficence. Every effort should be made to secure for all participants their well-being. Two general rules that have been formulated to extend to these activities are (1) do no harm, and (2) maximize possible benefits and minimize possible harm. Obviously the process of learning what will in fact provide benefit may involve exposing research subjects to some risk. In all cases of human subject research, this cost-benefit analysis must be done to decide when it is justifiable to seek benefits despite risks and when the benefits should be forgone because of the risks.

The principle of justice involves questions such as who benefits from the research and who bears the burden. Often in the nineteenth and early twentieth centuries, the burdens of serving as research subjects fell disproportionately on groups such as the poor ward patients, and the benefits of improved medical care flowed primarily to private patients.

History is unfortunately replete with the exploitation of unwilling prisoners as research subjects, such as in the Japanese and Nazi concentration camps, and in the exploitation of disadvantaged groups such as in the Tuskegee syphilis study. It is against this historical background of abuse that the consideration of justice within human research takes place. It is critically important that the selection of research subjects be scrutinized to ensure that vulnerable groups (e.g., welfare patients, racial and ethnic minorities, or persons confined in institutions) are not being selected simply because of their easy availability, their compromised position, or their manipulability, but rather for reasons directly related to the purpose of the study.

Finally, a consideration of justice requires that research supported by public funds that leads to improvement of technologies or therapies should benefit more than those who can afford them and that the research should not depend unduly on populations unlikely to be among the beneficiaries of the applications of research findings.

Whenever human subjects are part of the research protocol, great care must be used to ensure professional and ethical standards are followed. Generally the use of human subjects requires that the following are satisfied:[19]

1. Risks to subjects are minimized by using procedures consistent with sound research design that do not unnecessarily expose subjects to risk. Whenever appropriate, the research will use procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to them, and the importance of the knowledge that may reasonably be expected to result. Researchers should consider only risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive if they were not participating in the research). Researchers should not consider the long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of their responsibilities.
3. Selection of subjects is equitable. In making this assessment, the researcher should take into account the purposes of the research and the setting in which the research will be conducted. The researcher also should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought and appropriately documented from the subject or the subject's legal representative, in accordance with the requirements of law and ethical practice.
5. There will be appropriate provision for monitoring the data collected to ensure the safety of subjects.
6. There will be adequate provision for the protection of privacy and the maintenance of confidentiality of collected data.

INSTITUTIONAL REVIEW BOARDS

To ensure satisfactory compliance with appropriate research standards, institutions create institutional review boards to review the research protocols prior to implementation. One of the many important activities gathered under the aegis of role duty is service on an IRB. These boards are established to protect the rights and welfare of human subjects recruited

to participate in research activities under the auspices of the institution with which a board is affiliated.

For the purpose of this discussion regarding the activities of an IRB, *research* is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. *Human subjects* are defined as living individuals about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

Since the end of World War II and the general knowledge of the horrors associated with the concentration camp practices regarding human experimentation, several documents and codes dealing with the proper and reasonable conduct of research using human subjects have been developed. Included in these codes and documents are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (with later revisions), the Belmont Report of 1979, U.S. Department of Health and Human Services Title 45 of 2001, and the American Psychological Association Code for the conduct of social and behavioral research. Students and clinicians considering participating in research involving human subjects or on an IRB will find these documents a valuable starting place.

Tainted Data

CASE STUDY

Your secretary is a person of Jewish descent who recently read a book about medical experiments conducted in the Nazi concentration camps. In that you teach bioethics as part of your course work, she asks you whether you think it is appropriate for scientists to use the data collected from these experiments. In the conversation, you learn that a recent scientific paper references the material. It also becomes clear that your secretary feels that it is an outrage for the information gained in these experiments to be used.

1. Is she correct? Is the information gathered in the experiments tainted beyond use by the process?
2. Is the information gathered morally neutral?
3. If this information was used, should it be referenced differently from other data?

CONCLUSION

Personal privacy appears to be under siege in all aspects of our lives. The use of computers has greatly increased this concern, as it is common knowledge that all of us have dossiers in several major data banks. These governmental and commercial data sources provide information to

others in regard to credit ratings, marital status, and even hobbies and interests. It seems at times that one need only provide a small donation to a favorite charity (perhaps to save the woodlands) before being inundated by an avalanche of offers for the type of person who might want to save woodlands, or at least look woodsy.

The general patient population still places a great deal of faith in the manner in which health care providers maintain the principle of confidentiality. Confidentiality seems to serve two basic purposes. First, the principle acknowledges a respect for the individual's right to privacy as guaranteed by our legal system and enshrined in our cultural values. Second, and perhaps more important to the health of the patient, the promise of confidentiality provides a bond between the practitioner and patient that allows for a full and honest disclosure of information.

Confidentiality is arguably the most common basic principle found in codes of health care ethics. However, some now argue that the vastness of our database systems, the complexity of governmental requirements, the large numbers of personnel who have access to the information and the perfunctory way that we carry out the required rules makes confidentiality as it is currently practiced in health care a "Decrepit Concept"[20] worn out and useless.

Regardless of our current problems, it is difficult to imagine a healthy patient/provider relationship or health care system where confidentiality as a principle is not honored. It is the duty of all health care practitioners to work to create an underlying cultural environment that supports this important principle.

KEY CONCEPTS

- The principle of confidentiality can be defended as a positive duty from any of the accepted ethical frameworks (duty orientation, virtue, or utilitarian).
- The "harm principle" provides a rationale for overcoming the duty to maintain confidentiality to protect vulnerable individuals. Confidentiality is a principle with qualifications, as there are important considerations that at times force a practitioner to reveal confidences.
- In cases in which there is an important societal need, legal duties to report information have been developed (child abuse is an example).
- Modern health care is a team practice. Not only clinicians and patients have a need to view the records, but also those who function in an administrative, clerical, research, or monitoring capacity.
- The general goals of the Health Insurance Portability and Accountability Act (HIPAA) were to encourage the use of electronic transmission of health care information to assist in cost containment as well as to provide new safeguards to protect the security and confidentiality of the information.

- HIPAA Privacy Rule provides new rights to patient access and new requirements for providing enhanced security for medical records.
- Human subject research and the institutional review board are important and rewarding duties that require constant diligence in regard to the principles of autonomy, confidentiality, beneficence and nonmaleficence, and justice.
- Legal standard for invasion of privacy is that of a hypothetical "person of ordinary sensibilities." If such a person would find the appropriation, or exploitation, of one's personality, the publicizing of one's private affairs, or wrongful intrusion into one's private activities was unwarranted and brought mental suffering, shame or humiliation, then there would be grounds for legal action.

REVIEW EXERCISES

A. Unauthorized versus authorized disclosure: In this exercise, state whether you think the disclosure of information was appropriate or inappropriate and defend your position.

1. A young woman who states she has just been raped comes into the emergency room requesting a pelvic examination and a morning-after pill but insists that the staff not call the police. The staff reports the incident.
2. A young father brings his child into the emergency room for treatment of an arm injury. The family has brought the child in several times for similar injuries with the excuse that she is somewhat clumsy and is having difficulty learning to ride her bike. The child shows no fear of the parent and, upon questioning, confirms the parent's version of the events. The staff reports the injury as a possible child abuse case.
3. You are a physical therapy student on a pediatrics rotation within the hospital, and you notice that the neighbor of your parents has been admitted to the surgery unit. During your lunch break, you review her record before you drop in to see her.
4. You are a technical nurse just completing post-op care of a young woman who is a fellow church member and who has just had an abortion. You are very concerned for the young woman and decide to confide this information to your minister.
5. A young man who lives in the same housing complex that you do comes into the hospital's clinical laboratory for tests and is confirmed as being HIV positive. As the manager of that laboratory, you feel it a duty to tell the manager of the housing complex that the person in Unit Five has an infectious disease.
6. You are a respiratory therapist, and your patient states that she would like to tell you something but only if you would hold it in strictest confidence. She then relates to

you that she is very depressed and is thinking about taking her own life once she is discharged from the hospital. You relate this information to the attending physician.

7. You are a medical records technician and are in the department when two men come in and flash badges indicating that they are from the FBI and need to see the Hiram Jones record as a matter of national security. You cooperate and allow them access to the files.
8. In the course of caring for a patient, a school bus driver, the physician notes that she is at risk for having a heart attack and recommends that she cease driving, since she may be placing the children at risk. The driver asks that the physician not notify the school district because it would put her at risk of losing her job. The physician notifies the district.
9. During the course of a patient evaluation, you find that the family has incest problems. You recommend the notification of the police.
10. You have been invited to present at the monthly meeting of your health specialty's local chapter. One of your patients is a very interesting case, which you use as a case study for your presentation.

B. Under the HIPAA legislation, each covered health care institution is required to provide patients with a clear, written explanation of the conditions of use and disclosure of health information. If possible, collect several of these from your local area hospitals and clinics. Evaluate the provided information for clarity of understanding and for compliance with the intent of the HIPAA legislation. Several sites on the Internet will provide you with a review of the exact legislation requirements.

C. You are a student radiographer and are assigned to the surgery suite to assist another technician performing an X-ray during a surgical procedure. You gown up, assist, and are present during much of the surgery that was being performed on Mrs. Jones by Dr. Perez.

The next day you are in Mrs. Jones's room, and you comment that her choice of Dr. Perez was excellent in that he is a fine surgeon. "Dr. Perez?" she replies, "My physician was Dr. Robinson! Call my lawyer!"

Have you breached confidentiality? In that it caused the hospital and physicians to be involved in a lawsuit, were you in error?

D. A couple comes into the emergency room, she complaining of vaginal discharge and pelvic pain and the husband of a urethral discharge. The tests done on the husband prove positive for gonorrhea, and he adamantly demands that you keep this information from his wife. Her tests will not become available for two days. Should you tell the wife, or maintain the confidentiality of the husband?

E. As the pharmacist of the local community pharmacy, you have been filling prescriptions for Mrs. Arthur for several years. She has an extensive medication profile that suggests that

she has several chronic illnesses, including a psychiatric disorder. In her dealings with you, there has been nothing that indicated an inability to make competent decisions or to authorize appropriate treatment decisions. One day her husband, Bob, comes into the pharmacy and requests that you give him a copy of his wife's medication profile. He indicates that he wants to be sure that his wife is receiving the correct medications and was being compliant in taking the drugs as prescribed.

For this problem we will use the RESOLVEDD method of problem solving developed by Dr. Raymond Pfeiffer. The steps of the process are:[21]

(R) Review facts involved.
What are the relevant facts of the case?
Who, if anyone, is at fault?
How did the situation come about?
Who is charged with making the decision?

(E) Estimate of the problem or conflict involved in the case.
What options do you have?
What difficulties are presented by the case?
What is the major ethical dilemma involved?

(S) State the solutions with initial credibility.
Group the options into a small number of potential choices.

(O) Examine the outcomes of the solutions.
What are the significant possible outcomes that will result from following each of the potential solutions?

(L) Likely impact on those involved.
In what way are those involved hurt or helped by the solutions?

(V) Values upheld/compromised.
Which of the basic values are upheld or sacrificed by the solutions?

(E) Evaluation and refining of solution and weighing values.
Which solution seems to have the best consequences for the individuals involved and sacrifices the least principles?

(D) Decision arrived at, clarified, and shown to implement equal consideration of interest.
Decide how the decision will be carried out, and explain why this was the best of the possible solutions.

(D) Defense of that decision against objections to its main weaknesses.
What are the major weaknesses of the decision?
What are the best answers to objections based on the weaknesses?

Take each step as a separate exercise, and work the problem through.