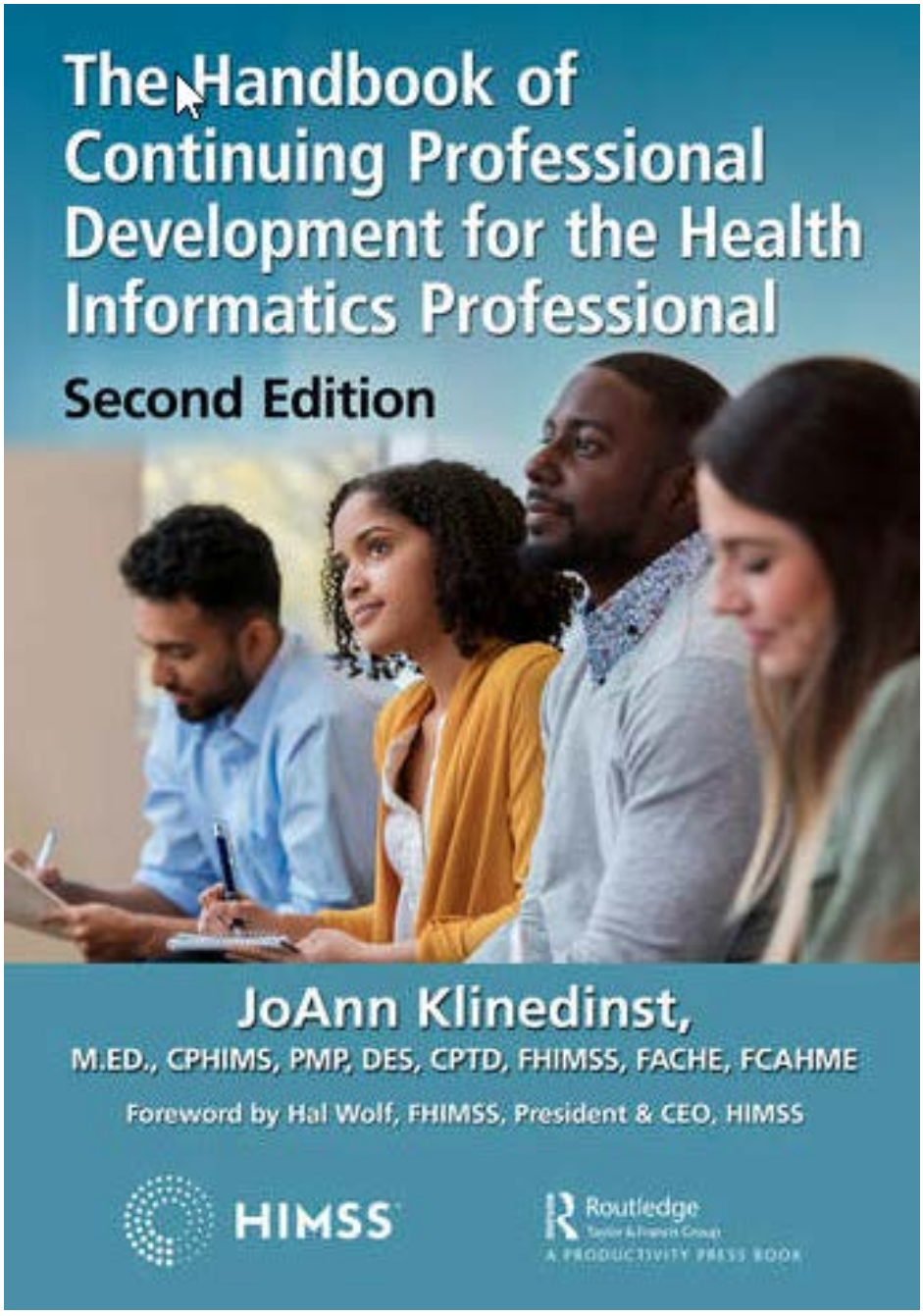
Chapter 35: Establishing and Practicing Ethical Standards: Both a Professional and Personal Responsibility. *Craig M. Klugman*



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35 Establishing and Practicing Ethical Standards: Both a Professional and Personal Responsibility

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INTRODUCTION

Siena Health Care Systems is a large midwestern hospital corporation with 4,000 healthcare workers, 12 hospitals, and 200 outpatient clinics that has entered a partnership with Bailey Informatics, a startup company in precision health. Under the terms of the agreement, Bailey makes an annual payment to Siena Health for full access to its patient records. Bailey will use the data to train its proprietary algorithms to better diagnose disease and to make more precise treatment recommendations. Siena hopes to be able to use any resulting artificial intelligence to improve patient outcomes in the future.

This scenario describes collaborations between healthcare institutions and health data companies that have become common over the last decade (Kayyali, Knott, and Kuiken 2013). Patient records include valuable information that can feed the growth of big data initiatives, precision medicine, and artificial intelligence in healthcare. For the healthcare system, the opportunity represents potential revenue as well as the possibility of improving patient outcomes and satisfaction. For informatics companies, the size and depth of the record repository would be impossible to get any other way. While working together would seem to be a win-win from a financial standpoint, these collaborations raise a host of ethical, moral, and legal issues that can affect patient privacy, trust, and autonomy.

Consider that when entering the clinic Siena's patients sign consent forms that say their health information can be used to diagnose and treat them. Did the patients know that their information would also be used for research and product development? Does a broad consent form cover sending personal health information to an outside company? Siena's patients share their private information because the hospital and physicians have a fiduciary responsibility of confidentiality. Bailey is not a covered health entity and therefore has no such legal requirement. If a discovery is made from a patient's record, does that patient get a share of any profits?

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This chapter explores ethical issues that arise in health informatics including definitions, explaining why protections in research and patient care exist, and examining codes of ethics and what values they embody. Lastly, this chapter will offer guideposts for holding people in the health informatics field to the highest professional standards.

DEFINITIONS

Good ethics begins with (a) good facts and (b) shared definitions. This chapter begins by defining common terms that are important when working in healthcare: ethics, morality, and law.

Ethics is a branch of moral philosophy that explores how people make decisions regarding right and wrong. Ethics is both (a) the science of morality and (b) the principles and values that guide the behavior of a group of people. More specifically, *bioethics* is the study of moral issues in the life sciences (Reich 1978).

One problem with the term ethics is that even when applied to issues of right behavior, it is used differently in different settings. For example, in government, "ethics" refers to a set of laws that guide action. A lawyer or a politician who violates ethics has actually committed a criminal act because the ethics of that group is ensconced in the civil law. For example, a pharmaceutical company provides a gift of a $15 burrito meal to a judge who is hearing a case to which the company is a party. This is a violation of law (bribery), and the company as well as a judge accepting such an offer may face criminal prosecution.

A physician who violates ethics has violated a standard norm for a group to which they have chosen to belong. Thus, in medicine and health, ethics is not necessarily a legal requirement but a question of what this group of professionals has decided is proper conduct for its members. This standard is often encapsulated in an aspirational set of principles, the code of ethics. A physician who accepts the same burrito from a pharmaceutical company is not violating a law but may be violating ethics. Professional organizations have determined a dollar amount of what is an acceptable gift from companies to doctors that is unlikely to influence their prescribing habits. Some medical schools and hospitals have policies that their faculty, staff, and students cannot accept pharmaceutical company gifts because any amount could compromise their objectivity. The burrito is not a legal matter, but rather an ethical one as determined by the standards of their professional peers.

Morality, on the other hand, is one's personal belief about what is right and what is wrong. This belief system is shared and learned among a group of people. One's notion of right and wrong might be learned from one's family, school, religious leaders, sacred texts, pop culture, and formal study. Morality may not be based in logic and may be part of a larger belief system (e.g., Catholicism, Hinduism, or Islam). Some believe that morality is culturally bound (applies only to a select group of people who share historical beliefs in common), and others hold that morality is universal (what I believe is right applies to everyone, even if they believe differently).

Law is the set of rules that a society establishes for itself to determine what behaviors are permissible and what are not. For almost any possible behavior or action there are people who would find it moral and immoral. In a pluralistic society, it is necessary to develop rules of permissible behavior that recognize varied moral beliefs but provide guidance for all people who live under that government. Some groups and nations believe that law should reflect morality (in the form of say religious belief). Islamic countries that follow Sharia law have agreed to allow their religious morality to form the basis of their laws. Heterogeneous societies, however, often value individual choice and try to allow a wider set of laws as long as they do not harm others. In terms of health, the law represents the minimum that one is required to do.

Consider that some people find HIPAA (a law) to be ethical (in that it meets a professional standard of protecting health information) but others find it morally problematic (many clergy like to visit their congregants in the hospital but HIPAA means that they cannot see who is a patient in a hospital unless that particular patient gives information for that specific clergy to know of their admission). Laws are compromises between the various morals of the citizens.

HISTORY OF ETHICS IN MEDICINE AND RESEARCH

The history of medicine and medical research is replete with violations of patient and subject trust. Bioethics, medical ethics, and research ethics were born out of this abusive history and have led to the regulations and ethical standards that exist today. In 1946, the world witnessed the first trial for crimes against humanity in Nuremberg, Germany. In the Doctor's Trials, 23 German physicians and administrators were accused of performing medical experiments on prisoners without their consent as well as for torturing and abusing them, and of committing mass murder of those the state found "unworthy of life". Sixteen of the doctors were found guilty and sentenced to imprisonment. Seven of them were executed (Leaning 1996). The defendants were charged under the Nuremberg Code, a set of ten principles drawn up by the United States (Shuster 1997).

The first principle says "the voluntary consent of the human subject is absolutely essential" (Shuster 1997). The other nine principles say that the experiment should have an expectation of producing useful results, there should be no other ways of gathering the information, subjects should be protected from physical and mental harm, the benefit should outweigh the risk, staff should be properly trained and credentialed, and the experiment can be ended at any time if the subject withdraws or the researcher believes continuing could harm the subject. These principles have become the worldwide basis of both human subjects research and delivering medical treatment, leading to the development of professional codes of ethics under the World Medical Association's Declaration Of Helsinki (1964) that governs medical research (WMA 2013).

Even though authorship of the Nuremberg Code is American, U.S. researchers have not always abided by them. In 1932, the U.S. Public Health Service began the Tuskegee Study of Untreated Syphilis in the African American Male (a.k.a. Tuskegee Study). This experiment sought to observe the natural progression of syphilis in Tuskegee, Alabama—a poor, mostly Black community. Over 600 men were enrolled in the study (399 with syphilis; 201 without the disease). The men were told that they had "bad blood"—a local folk category of blood-born illnesses that included a number of conditions and infections. The men received a modest death benefit for participation to pay for their burial and received regular check-ups that included spinal taps, which they were told was "treatment". Syphilis is cured by penicillin, which was discovered in 1928 and was standard treatment for this infection by 1947. The subjects were not told about this cure and were actively prevented from getting access to it (Jones 1981). The study ended in 1972 when it was splashed on the front page of most major newspapers after Jean Heller, an Associated Press writer, broke the story (Heller 1972).

The story of Tuskegee led to a Congressional investigation and establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission's 1978 report—known as the Belmont Report after the name of the conference center in Maryland where members met—established three ethical principles for the conduct of human subjects research in the United States:

- *Respect for persons*—Research subjects have autonomy (the power of self-governance) that must be protected by securing their informed consent. Such agreement requires that potential subjects be told the risks, benefits, alternatives, and the procedures they will undergo. The researcher must be honest and transparent in this informational process. A potential subject/patient must have the volition to make a choice free of coercion. They must be able to say no without any repercussions to their ability to get or receive healthcare.
- *Beneficence*—Experiments should be designed to minimize harm to subjects and to maximize benefits. Projects should function to provide a benefit to society and individuals. This altruistic perspective means that a project solely focused on profit is ethically problematic. Protecting the potential subject/patient from mental, physical, and data harm is also essential. The health informatics specialist has a positive obligation to take steps to ensure the protection of records and record holders.

- *Justice*—fair distribution of benefits and burdens within a research protocol. This includes not using a population simply because it is convenient. In later interpretations, the idea has come to mean being inclusive in recruiting research subjects (U.S. Department of Health Education and Welfare 1979).

Consider the opening scenario to this chapter that lays out a bioinformatics study using patient medical records. How would Belmont view such a study?

- *Respect for persons*—Have the subject-patients given informed consent to participate in the research? Were they told the risks, benefits, alternatives, what procedures their data would undergo, and been given the opportunity to withdraw from participation? The answer, of course, is no. The subject pool are all patients of Siena Health System and if this fictional study follows the real-life examples on which it was based, the patients were never even informed that their data was being used. Under the federal Common Rule (45 CFR part 46) that regulates human subjects protection, such a study would have had to undergo an institutional review board (IRB or human subjects review committee) to collect new data. However, recent edits to this law allow for the secondary use of anonymized data without getting consent and undergoing IRB review. The revisions also permit the use of broad consent where a patient signs an agreement at the hospital giving permission not only for diagnosis and treatment but often to have any records or specimens used in research (and they likely will not be told about such studies). While the law allows broad consent, such action violates the ethics and standards that patients and subjects expect. Namely, data collected for purposes of diagnosis and treatment is expected to be kept confidential (only shared with people involved in the patient's care).
- The hospital system has a legal and ethical obligation to maintain confidentiality of patient data, but Bailey Informatics is not a "covered entity" (i.e., not a healthcare provider) and thus does not have a legal duty of confidentiality. However, this author holds that they have an ethical duty in order preserve trust with the community and as a partner in the research enterprise. Thus, ethically, using patient data for research purposes should require re-consenting all potential subjects for the use of their data, though such an act could be burdensome. The least that Siena and Bailey can do is to inform their patient-subject population of the project and establish a method for people to withdraw their data from the study.
- *Beneficence*—Can patients be harmed by the transfer of their data to Bailey Informatics? Technically, the data transmitted should be anonymized, but accidents can happen where unintended information is shared. Also hacking is a real possibility when information exists in electronic form. The ethics of beneficence asks what protocols and procedures exist to protect patient identity and information from falling into the wrong hands or being used in untoward ways. Medical information is sensitive information, and many patients do not want others to know of their health conditions. Beneficence also holds that the project needs to have a likelihood of benefit to the community. Thus, a project that merely seeks to produce a marketable product and profit. The goal must be to improve patient outcomes because that may also include a potential benefit to the subjects.
- *Justice*—As originally conceived, justice as an attempt to ensure a sharing of benefits and burdens. For example, if a drug was tested on an impoverished population but the drug will only be affordable by the wealthy, then all of the risk is being taken by a group that will not benefit. More modern interpretations hold that the subject population must be diverse in terms of sex, age, ethnicity, and socioeconomic status. One of the problems that has haunted most informatic projects is that the work is based on limited datasets that do not represent the population at large (O'Neil 2016). In terms of informatics, data is often taken from the people who are easily available (i.e., those who work in tech). That workforce is

overwhelmingly male and Caucasian or Asian (Harrison 2019). An unjust dataset will lead to conclusions and algorithms that are not generally accurate. The data from Siena Health is partially a corrective to this problem since its information is likely broader and more diverse than a convenience sample. But such diversity is not guaranteed since communities of color and impoverished neighborhoods can be near the hospital (Gaskin et al. 2012). Thus, only gaining the records from a single hospital system or even in a single geographic location will not necessarily eliminate bias. The informatics professional needs to be aware of the bias in selecting data sources.

PROFESSIONALISM AND CODES OF CONDUCT

In the sphere of medicine and health, ethics may seem more stringent than in other areas of human endeavor. The reasons are twofold: (1) The potential for harm (morbidity and mortality) is high and (2) healthcare workers are professionals who have extraordinary moral obligations. A profession is "an occupation that regulates itself through systematic, required training and collegial discipline; that has a base in technical, specialized knowledge; and that has a service rather than profit orientation enshrined in its code of ethics" (Starr 1982, 15) The original professions (medicine, law, and clergy) grew out of the medieval guilds whose purpose was to protect their practitioners and their livelihood. Professions have a monopoly on working in a specific area or providing certain services. For example, only a lawyer who has passed the bar and holds a license may practice law. Only a physician who has passed a series of exams and holds a medical license may cut into a human being (if someone else did this they would be arrested for committing a battery or a murder if things did not go well). The state offers this monopoly in exchange for the profession setting standards of excellence and self-policing its members.

Professions exist to benefit patients and clients, not the practitioner. Thus, professions are often considered to be a calling (rather than a job) and require a substantial amount of adult education, passing exams, and licensure that is controlled by the profession (e.g., a state board of medicine that grants licenses is staffed by doctors) and has a code of ethics. The reason for this high level of accountability and responsibility is the necessity of gaining and keeping the public's trust. In 1847, the very first act of the newly founded American Medical Association was to pass an ethics code. Since then, other trades that have aspired to be professions have passed similar codes of ethical conduct for its members. Such codes bind members to particular conduct and to accept investigation and punishment by their peers if the code is violated.

In the field of health informatics, two professional organizations have crafted codes of ethics to guide behavior. The goal of both of these codes is (a) to establish the profession of health informatics and (b) to engender trust with the public. The American Health Informatics Management Association code of ethics begins:

> *The ethical obligations of the health information management (HIM) professional include the safeguarding of privacy and security of health information; appropriate disclosure of health information; development, use, and maintenance of health information systems and health information; and ensuring the accessibility and integrity of health information (AHIMA 2019).*

The specific principles of the code include putting the customer first, putting the interest of others first, preserving confidentiality, mentoring, using technology and information wisely, and honesty. One of the goals is to work for the good reputation of the profession, ensuring trust and that health informatics is seen as a benefit rather than as a danger.

The International Medical Informatics Association also has a code of ethics which focuses on the field's obligations to society. The IMIA code includes principles of ethics such as autonomy, equality/justice, beneficence, non-malfeasance, impossibility, integrity, privacy, openness, security, access, accountability, and the least intrusive alternative principle (Kluge 2016). This code

protects the record holders and healthcare workers by ensuring that they know how, where, and by whom their information is being used. The emphasis is on protecting the data and furthering social interests.

Is Bailey Informatics following these codes of ethics? Is the point of this project to provide a benefit to the community and patients or is it solely to make money for the company and the hospital? Have all safeguards been taken to protect privacy and security? Have patients been informed about the use of their records, and what actions have been taken to ensure data security? Is there built-in accountability such as a plan to inform patients if the system is hacked, or to let them know if new information that affects their health is found? Have patients been informed about who owns the records and the data? Have patients been asked for informed consent or is that covered under any broad consent they previously signed? Do patients have opportunity to withdraw their record from participation? Have the credentials and history of Bailey Informatics been shared with patients? Considering that not all companies succeed, what is the plan for the records if Bailey Informatics goes out of business? The brief scenario does not allow us to answer these questions, but the codes of ethics require they be answered before the project commences.

PROFESSIONAL VIRTUES

Beyond a code of ethics, professions are guided by virtues—traits or characteristics associated with being a good person, or in this case, with being a good health informatics professional. The virtues are aspirational and as we practice them, they come a habit and part of our character. For instance, *confidentiality* is a fiduciary responsibility to keep a person's secrets private. In medicine, private details are shared to help the healthcare worker to diagnose and treat the patient. In research, private details are shared to contribute to data and someday improve people's lives. In both cases, this virtue requires protecting a person's identity as well as health details that if released could cause negative consequences to their life.

Health informatics professional should uphold *accountability* and *security*. The professional is expected to use the highest standards of data protection to thwart hacking and to prevent accidental releases of private information. These virtues also demand *transparency.* Ideally, there should be a record of where records are stored, how and when they are used, and who has accessed them. The patient or subject should be able to know their record is being used.

Health informatics professionals must be *truthful* and *transparent*. They should be able to show how the data led to conclusions (instead of simply saying the data is crunched in a "black box" and no one know how it works). Although many big data-dependent systems use proprietary algorithms that are not released to the public (or even necessarily understood by the programmers), the profession should aspire to make these processes transparent and understandable to the people whose records contributed to the project.

Health informatics professionals much recognize data justice. *Data justice* is "fairness in the way people are made visible, represented and treated as a result of their production of digital data" (Taylor 2017). This concept is essential to minimize potential biases in conclusions made from health information. Given that health data reflects structural biases in society, science, healthcare institutions, and individual biases held by healthcare workers and health information professions, information systems may inadvertently reflect and further such biases. Health information is always biased—what information is collected, what questions are asked of whom, what recommendations are made, what tests are run can differ with each person or population. Thus, it is important to actively look for and minimize such biases in data.

Health informatics professionals must be *competent* and honest in representing their credentials to create trust. This requires a dedication to continuing education and gaining skills necessary to do needed work. Additionally, it means representing oneself truthfully to potential employers and to clients.

Health informatics depends on people and institutions trusting them with their data. Society has to trust that the information, algorithms, and advise generated by looking at these big data sets. Without *trust*, the enterprise will cease to exist. Principles outlined in codes of ethics and virtues of practice are essential to creating such trust.

CONCLUSION

Virtues and codes of ethics can be aspirations, or they can be part of the professional and personal character of those who choose a profession. Aristotle says that to know the good and the right is not enough, one must practice it until it becomes a habit and part of their character. To achieve this aim requires deliberative action to understand and practice the ethical behaviors of the profession. This can be achieved through education by making ethics a required part of training programs, certificates, and continuing education. Professionals should practice upholding the values—be an asset and model of the profession—including transparency, supporting autonomy, and promoting diversity and justice. In addition, professions self-monitor; thus, professional organizations must establish mechanisms for enforcement—reporting ethical violations and repercussions for violations. And because the future is unknown and technology and needs change, a professional ethics needs to have a system for revision to respond to new opportunities and challenges.

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