A Review of Past and Modern Unethical Medical Practice

Hannah Johnston
John G. Rangos School of Health Sciences
Student, Department of Physician Assistant Studies
Duquesne University
Pittsburgh, PA, USA

Bridget Calhoun, DrPH, PA-C2
Chair and Associate Professor
Department of Physician Assistant Studies
Duquesne University
Pittsburgh, PA, USA

Abstract

Medicine is known for the strong tradition of reviewing outcomes so current and future clinicians can learn from prior mistakes, and continually improve standards of care. The processes of peer chart review, publication of case studies, and detailed presentations during morbidity and mortality conferences allow for ongoing education and improvements in clinical outcomes. Clinicians are strongly encouraged to learn from medical errors and "near-misses," which is a term used to describe potential medical errors that were caught before reaching the patient. The same fundamental principles of learning from previous mistakes or actions of health care providers (HCP) can be applied to examples of unethical medical research and immoral clinical practice. Being informed of previous unethical behavior can help deter current and future practitioners as well as public health researchers from acting in a similar fashion, and may also help explain some of the distrust of the medical community by some subsets of the population.

Key words: Medical Research, Ethics, Clinical Practice

1. Introduction

Regardless of the practice setting, clinicians are likely to encounter patients of different race, gender, ethnic background, religion, etc. whom maintain distrust for HCP. This distrust may be due to a recent or remote history of maltreatment of themselves, family members, or someone with similar demographics. Unfortunately, there are many examples of unethical practices in both research and clinical medicine that clinicians can learn from. The medical literature and historical documents provide many examples of unethical medical research, which include cases of exploitation associated with gender, race, ethnicity, and religion. The general media also depicts recent examples of unethical practices in clinical medicine. Examples such as medical fraud, performing unnecessary invasive procedures, and diluting medications for financial gain are readily found. Whereas egregious unethical behaviors have been seen in clinical research, at least they were founded on true scientific inquiry, as opposed to the modern unethical practices in clinical practice, which are founded on greed.

2. History of Unethical Medical Research

Unfortunately, unethical medical research dates as far back as the 1800's, when doctors first reported a case study on a patient with anorexia nervosa. Sarah Jacob, who became known as the "Welch Fasting Girl," fell subject to an experiment on whether or not "one can live without eating."

Rather than helping the young woman with severe mental illness, doctors instead chose to passively observe her unhealthy habits. She validated their hypothesis when she died of starvation.[1,2] Ultimately, the physicians' unethical lack of intervention, now described as non-maleficence, led to her death.

Another disturbing case of unethical research occurred in the 1890's on women in state mental institutions. At the time clinicians considered the possibility of a relationship between insanity and reproductive functions. In order to test their theory, physicians performed oophorectomies on women in state mental institutions without rationale or informed consent.[3] This study is another case of unethical medical research performed on a vulnerable population that did not lead to significant advancements in health care.

The most well known case of unethical medical research occurred in 1932 in Tuskegee, Alabama. The primary aim of this study was "to document the natural progression of syphilis infection in black men." Researchers recruited African American (AA) men from churches and schools; researchers even collaborated with plantation owners to enroll participants. They offered incentives, transportation, free meals, and burial insurance for enrollees. This coercion made it nearly impossible for prospective subjects to say no to the study recruiter. Doctors told four hundred black men with syphilis that they had "bad blood." This represents the initial unethical action, which involved knowingly withholding a diagnosis from a research subject. A subsequent unethical behavior was withholding treatment when penicillin became available in 1943. Despite the availability of curative treatment for syphilis, researchers employed by the National Health Service Corp prolonged the study another thirty years. Although President Clinton publically apologized for this study at a White House Ceremony in 1997, most of the men included in the study had died decades before.[4,5] These unethical events are of great significance among the AA population. To this day, many AA are suspicious of HCP because of the immorality associated with this study. Such distrust may negatively impact current and future AA representation in clinical research and organ donation. Effective communication with HCP of discordant race may also be hindered in any clinical environment due to ongoing distrust.

Similarly, in 1940 German Nazi experimenters conducted research on unwilling prisoners. Of the many cruel experiments performed, one involved subjecting individuals to extreme pressure to observe at what point the human eardrum would rupture. Researchers also contained prisoners in severe temperatures to test how long someone could survive. The rationale behind these studies was influenced by their correlation to wartime conditions. However, studies were also carried out with no intended purpose, but rather out of curiosity. For instance, researchers tortured one twin to see if the torture would affect the other, even when physically separated.[6] These experiments exemplify international cases of unethical medical research.

Throughout the 1940's, unethical medical research occurred in Guatemala under the direction of an American physician named John C. Cutler. Dr. Cutler intentionally injected a mentally ill Guatemalan woman with syphilis. Concurrently infested with scabies, she suffered for months, and was finally treated for syphilis only because she appeared to be dying. At the time, Cutler claimed to be unsure as to why she was ill. To further his research, he also placed gonorrheal pus from a male subject into her eyes, her urethra, and her rectum. Consequently, her eyes filled with pus and she began bleeding from the urethra. She died while under his "care." This individual patient was one of eighty-three subjects who died over the course of Cutler's experiments, and one of more than five thousand research subjects involved.[7] As disturbing as this case is, it sheds light on the brutal history of unethical medical research and provides evidence that clinical research must be regulated even when performed abroad.

Furthermore, throughout the 1950's, the United States government tested potential biological warfare agents such as Q fever, tularemia, typhoid fever, and equine encephalitis on humans. Researchers targeted enlisted U.S. servicemen, who were 7th Day Adventists (a protestant Christian denomination) in the United States Army. Although scientists briefed the subjects on the experiment, and reportedly informed them of their freedom to terminate involvement in the study at any time, researchers also offered incentives for participation, which included the highly desired honorable discharge.[8] Fundamentally, this is another case of unethical medical research in which a vulnerable population was exploited.

As if the previously mentioned cases are not enough to stress the frightful history of unethical medical research both domestically and abroad, still another example worth addressing involves poor Puerto Rican women. In the 1960's, researchers tested birth control medications on impoverished Puerto Rican women without their consent. It can be hypothesized that researchers selected Puerto Rican women because in their culture, women are encouraged to have a higher than average number of children.[9,10] Regardless of the rationale for patient selection, lack of informed consent and deliberate subject selection emphasizes the unethical natures of this study.

This information may seem redundant and irrelevant because it draws attention to the past; however, it is history that determines the future. It is important to be reminded of the shameful aspects of health care's past. This knowledge can minimize the risk unethical medical research will continue to occur. Also, this knowledge provides clinicians with a more comprehensive understanding of why a patient may be distrusting when interacting with HCP or anyone within the medical establishment.

3. Modern Research Practices

In response to the horrific cases of unethical medical research, the Belmont Report of 1978 was released to guide future research. The Belmont Report outlines boundaries of biomedical, behavioral, and observational research, and defines acceptable routine practice of medical research. The Belmont Report also addresses the role of risk-benefit assessment criteria in determining the appropriateness of and research involving human subjects. Further, it addresses appropriate selection of human subjects for participation. Lastly, the Belmont Report provides the definition of informed consent, which is utilized in both research and clinical settings. Ultimately, the Belmont Report offers three basic ethical principles: respect for persons, beneficence, and justice. These principles are applied to informed consent, assessment of risks and benefits, and selection of subjects, respectively.[11]

As outlined in the Belmont Report, obtaining informed consent involves providing information, answering questions to improve subject or patient comprehension, giving sufficient time to consider decisions, allowing the patient to weigh both the expected benefits and possible complications of procedures, and obtaining the voluntary agreement to participate in the study or treatment. Additional information that must be provided to subjects or patients includes a comprehensible explanation of the purpose and procedures, a description of any foreseeable risks and benefits, information on alternative procedures or treatments, a statement on the confidentiality of subject or patient records, contact information for future questions or concerns, and reiteration that the subject or patient will not be penalized for failure to consent or request to terminate involvement.[11] A comprehensive understanding of all aspects of informed consent is crucial to researchers and clinicians alike.

4. Modern Unethical Clinical Practices

In spite of the Belmont Report, unethical behavior is still seen in clinical settings. Following a nurse's complaint, internal investigators discovered that Hospital Corporation of America (HCA) doctors were performing unnecessary, even dangerous, cardiac procedures for their own financial benefit. These doctors deceptively documented patient charts to make such procedures seem necessary. For instance, investigators found that nearly half the angioplasty surgeries "were outside reasonable and expected medical practice," considering doctors noted in medical records the blockages were 80 to 90 percent, when in fact they were 33 to 53 percent. Investigators also determined that about half the cardiac catheterizations performed were done on patients without significant heart disease. Consequently, some patients suffered avoidable complications as a result of needless catheterizations. Specifically, a 44-year-old man admitted with chest pain, experienced a punctured blood vessel and near-fatal irregular heartbeat. Another women, with no prior diagnosis of heart disease, went into cardiac arrest and thus, was hospitalized for days after her cardiologist perforated a blood vessel while placing a stent. Moreover, investigators cited cases in which patients were treated for multiple lesions when the second (or third) lesion did not appear to be clinically significant. This investigation suggests that unnecessary cardiac procedures were done with intent rather than by mistake.[12] Preoccupied with the fact that Medicare reimburses hospitals about $10,000 for a cardiac stent and approximately $3,000 for a diagnostic catheterization,[12] many HCA physicians behaved unethically.

Equally disturbing, in 2001, a Kansas City pharmacist was accused of diluting Taxol, Gemzar, Paraplatin, and Platinol, which are used to treat pancreatic cancer, lung cancer, advanced ovarian cancer, breast cancer, and AIDS-related Kaposi's sarcoma. Federal investigation discovered that distributed samples of Taxol and Gemzar contained no more than 39 percent of the intended prescription. The diluted infusions likely resulted in the death of many cancer patients. Dr. Fred DeFeo, chairman of council of the Missouri State Medical Association, states, "it is certainly possible that some have had cancers that could have been cured that weren't." It is clear that the pharmacist intentionally altered the composition of the chemotherapy drugs out of gluttony because the price of 1,900 milligrams of Gemzar is $1,021, while 450 milligrams is only $242.[13] With greater desire for financial gain rather than appropriate treatment of patients, the Kansas City pharmacist illustrates yet another instance of unethical behavior in medicine.

Another example of unethical clinical practice motivated by greed involves a Detroit oncologist who pleaded guilty to thirteen counts of Medicare fraud, one count of conspiracy to pay or receive kickbacks, and two counts of money laundering after administering unnecessary cancer treatments to patients, some of whom did not even have cancer. The individuals who did not actually have cancer were left to deal with unnecessary medical expenses, let alone were physically compromised from the side effects of chemotherapy. One patient in particular was prescribed more expensive and more intense chemotherapy when it was not necessary. The same patient also needlessly received an orchiectomy (surgical removal of one or both testicles).[14] It is evident that this oncologist took advantage of his patients' trust, fear of dying, and health insurance.

5. Conclusion

Even though there are strict guidelines relating to current medical research, distrust still remains among some of the general patient population. Minority patients are under-represented in research, perhaps because minorities and other vulnerable populations have been exploited in the past. In addition, some AA believe that physicians decide not to treat their HIV infection because of their skin color, or worse yet, some believe a cure to HIV has been discovered, but it's being withheld for financial gain. Likewise, many minority patients offer insecurities regarding being told of all available treatment options. Also, some individuals are reluctant to become an organ donor due to rumors that first responders will not provide care because the individual's organs could be used to save another patient.[4]

Thus, unethical medical research plagues history; however, comprehension of past unethical cases explains certain misconceptions in heath care today. HCP familiar with the examples of unethical medical research and clinical practice and its consequences are less likely to make poor judgments in similar situations. In the end, both researchers and clinicians should adhere to research standards, as they overlap with clinical standards. Ultimately, a reminder regarding unethical medical research and lessons learned profits all HCP regardless of their particular practice area or specialty.

References

Brumberg. Fasting girls: reflections on writing the history of anorexia nervosa. *Monogr Soc Res Child Dev.* 1995; 50(4-5): 93-104.

Goldstein J. *Console and Classify: The French Psychiatric Profession in the Nineteenth Century.* New York: Cambridge University Press; 1987: 322-377.

Scull A, Favreau D. A chance to cut is a chance to cure. *Research in Law, Deviance, and Social Control.* 1986; 8: 3-39.

Gamble VN. Under the shadow of Tuskegee: African Americans and health care. *Am J Public Health.* 1997; 87: 1773-1778.

Jones J. *Bad Blood: the Tuskegee syphilis experiment.* New York: The Free Press; 1993.

Lifton RJ. *The Nazi doctors: medical killing and the psychology of genocide.* New York: Basic Books; 1986.

Ove T. *Bioethics panel blasts late Pitt professor's 1940s tests in Guatemala.* Pittsburgh Post Gazzette. http://www.post-gazette.com/news/nation/2011/09/14/bioethics-panel-blasts-late-pitt-professor-s-1940s-tests-in-guatemala/201109140137. Published September 14, 2011. Accessed February 3, 2016.

Beech BM, Goodman M. *Race & research: perspectives on minority participation in health studies*. Washington, DC: American Public Health Association. 2004: 144.

Gordon. *Women's Body.* New York: Penguin; 1990: 336-338.

Vaughn P. *The Pill on Trial.* New York: Coward-McCann. 1970: 38-49.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Washington, D.C.: Government Printing Office; 1978.

Abelson R, Creswell J. *Hospital Chain Inquiry Cited Unnecessary Cardiac Work.* The New York Times. http://www.nytimes.com/2012/08/07/business/hospital-chain-internal-reports-found-dubious-cardiac-work.html?_r=0. Published August 6, 2012. Accessed February 3, 2016.

Belluck P. *Prosecutors Say Greed Drove Pharmacist to Dilute Drugs.* The New York Times. http://www.nytimes.com/2001/08/18/us/prosecutors-say-greed-drove-pharmacist-to-dilute-drugs.html?pagewanted=all. Published August 18, 2001. Accessed February 3, 2016.

14. Moghe S. *Patients give horror stories as cancer doctor gets 45 years.* CNN U.S. Edition. http://www.cnn.com/2015/07/10/us/michigan-cancer-doctor-sentenced/. Published July 11, 2015. Accessed February 3, 2016.