

7.2.2 Release of Data from Unethical Experiments

Research that violates the fundamental principle of respect for persons and basic standards of human dignity, such as Nazi experiments during World War II or from the US Public Health Service Tuskegee Syphilis Study, is unethical and of questionable scientific value. Data obtained from such cruel and inhumane experiments should virtually never be published. If data from unethical experiments can be replaced by data from ethically sound research and achieve the same ends, then such must be done. In the rare instances when ethically tainted data have been validated by rigorous scientific analysis, are the only data of such nature available, and human lives would certainly be lost without the knowledge obtained from the data, it may be permissible to use or publish findings from unethical experiments.

Physicians who engage with data from unethical experiments as authors, peer reviewers, or editors of medical publications should:

- (a) Disclose that the data derive from studies that do not meet contemporary standards for the ethical conduct of research.
- (b) Clearly describe and acknowledge the unethical nature of the experiment(s) from which the data are derived.
- (c) Provide ethically compelling reasons for which the data are being released or cited, such as the need to save human lives when no other relevant data are available.
- (d) Pay respect to those who were the victims of the unethical experimentation.

AMA Principles of Medical Ethics: II,V,VII

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report 5-A-98 Information from unethical experiments

7.2.2 Release of Data from Unethical Experiments

Research that violates the fundamental principle of respect for persons and basic standards of human dignity, such as Nazi experiments during World War II or from the US Public Health Service Tuskegee Syphilis Study, is unethical and of questionable scientific value. Data obtained from such cruel and inhumane experiments should virtually never be published. If data from unethical experiments can be replaced by data from ethically sound research and achieve the same ends, then such must be done. In the rare instances when ethically tainted data have been validated by rigorous scientific analysis, are the only data of such nature available, and human lives would certainly be lost without the knowledge obtained from the data, it may be permissible to use or publish findings from unethical experiments. [New content sets out key ethical values and concerns explicitly.]

Physicians who engage with data from unethical experiments as authors, peer reviewers, or editors of medical publications should:

- (a) Disclose that the data derive from studies that do not meet contemporary standards for the ethical conduct of research.
- (b) Clearly describe and acknowledge the unethical nature of the experiment(s) from which the data are derived.
- (c) Provide ethically compelling reasons for which the data are being released or cited, such as the need to save human lives when no other relevant data are available.
- (d) Pay respect to those who were the victims of the unethical experimentation.

AMA Principles of Medical Ethics: II,V,VII

CEJA Report 5 – A-98 Information from Unethical Experiments

INTRODUCTION

At the 1997 Annual Meeting the House of Delegates adopted Substitute Resolution 4, “Medical Ethical Responsibility Act of 1997.” This resolution asks “the AMA to develop policy which forbids the use of any material, whether it be scientific experimentation, books or atlases, that have been generated by methods that violate the Nuremberg Code of Medical Ethics.”

Bad ethics do not necessarily produce unreliable knowledge. Some of the commonly known examples of unethical experimentation, such as the Nazi experiments and the Tuskegee Study, are referred to in comments such as, “It is too late to talk of ignoring or exercising the results of such research already in science’s knowledge base.”¹ The fact that it is possible to produce scientifically sound data from unethical experiments poses the dilemma of how to handle ethically tainted but scientifically solid data. Much of the debate over how to handle material that contains data gathered through unethical experimentation focuses on the activities of Nazi Germany. However, considerable medical knowledge throughout history has been developed through techniques and circumstances that violate current ethical standards. For instance, in the 1960’s Dr. Henry K. Beecher in his article “Ethics and Clinical Research”² pointed out numerous examples of unethical research. Given this history, it is conceivable that, despite ethical codes of clinical research, data from unethical experiments will still be brought to the attention of the biomedical community.

This report will address the use of ethical data from unethical experiments.

THE HISTORY OF ETHICAL CODES OF CONDUCT IN EXPERIMENTATION

The question — “should data gathered through unethical experimentation be used?” — is preceded by the ambiguity in determining what exactly is unethical experimentation. There is a range of standards of ethics used to judge clinical research starting with the Nuremberg Code of Medical Ethics. The fundamental goal of each is essentially the same: to protect the rights of subjects by ensuring the most professional standards of scientific investigation. However, the protections advocated by each are not identical.

Historically, the Nuremberg Code responded to the World War II atrocities committed by physicians and scientists during the war.³ The Nuremberg Code assembled ten requirements for the ethical use of experiments on human subjects.⁴ Two of the ten address the rights of the subjects. The remaining eight address the protection of the subjects’ welfare. The World Medical Association later met to prepare new guidelines for experiments on human subjects. The resulting 1964 Declaration of Helsinki shifted the emphasis from the protection of human rights through informed consent to the protection of human welfare through physician responsibility.⁵ Where the Nuremberg Code placed primacy on the informed consent of the subject, the Declaration of Helsinki focused on the paternalistic values of the patient-physician relationship. Later, the unethical nature of the Tuskegee Study led to the assembly of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The ensuing National Research Act of 1974 and the Belmont Report⁶ laid foundations for the ethical requirements that govern the conduct of research on human subjects in the United States today, namely the mandated institutional review board (IRB) approval of all federally funded proposed research with human subjects.⁷ Several codes of ethical experimentation subsequently followed, including FDA policies⁸ and an AMA position⁹. These latter two allow for the progression of research in clinical circumstances involving the patient’s decision-making incapacity through the adoption of legal proxy guidelines and careful waiver-of-informed-consent protocols.

Some experiments on human subjects fall outside the spectrum of ethical permissibility as outlined by all sets of guidelines. Such experiments would universally be considered egregious. Other experiments may be considered marginal and thereby fall into grey zones of established ethical standards. Experiments that contained minor aberrations or a single bad component would be one example of this sort (e.g., the most recent case of breast cancer trials in which a single investigator in a large multi-investigational trial behaved unethically)¹⁰. Labeling these experiments unethical may be controversial given that the experiments do not in and of themselves generate offenses to humanity or violations of human rights. A distinction should be made between rejecting data on the basis of unreliability as opposed to disapproval of data from experiments which wronged others.

In addition, there are some historical data obtained by methods which do not conform to contemporary ethical standards. The epochal anatomy of Vesalius published in 1543 was the result of dissections of executed criminals, which today we would consider ethically unacceptable.¹¹ Many other experiments have involved self-experimentation, also ethically unacceptable today. These data are often cited without reference to their ethically questionable origins.

Given that, both historically and currently, data of this sort comes up, professionals must address the question of how to deal with data from unethical experiments.

BASIC PRECEPTS

The Council on Ethical and Judicial Affairs identifies the following basic precepts: First, any person utilizing data from human experimentation should attempt to use ethically obtained and scientifically sound data and do so with good intent. Second, scientifically sound data from experiments that fall within grey zones of ethical conduct should be carefully reviewed to identify and affirm ethical standards, thereby reducing any risk of a “slippery slope” of declining moral standards if the data are used. Third, scientifically sound data from egregious experiments should be evaluated in light of necessity. If no essential human need for the data exists, then the data must not be utilized. In the extremely rare case when no other data exist and human lives would certainly be lost without the knowledge obtained from use of such data, publication or citation is permissible. In such a case the disclosure should cite the specific reasons and clearly justify the necessity for citation.

EVALUATING CASES

The Council identified the following ethical principles as providing guidance in evaluating cases of data from unethical experiments and deciding whether or not, and if so how, to use the data.

Advancing Scientific Knowledge

Physicians and others in the medical community should act in pursuit of a moral commitment to help patients and advance science. One of the Principles of Medical Ethics states: “A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public.”¹² It is important for a physician to utilize only accurate material and apply it in the context of best medical judgment.

If data from unethical experiments can be replaced by existing ethically sound data and achieve the same ends, then such must be done. However, it may be the case that data from unethical experiments are the only data available. It may further be true that it is in the best interest of patient care, especially when life-saving potential exists, to utilize the data. Since boycotting data from unethical experiments may be both unrealistic and detrimental to patient care, the remaining ethical considerations provide guidance in the non-use or use of ethically tainted data.

Redemptive Value

“There are some who [...] say that the data *must* be used, for such use has redemptive values.”¹³ “Redemptive” is used here in the sense that utilizing the data to promote good science and medicine gives the human suffering some meaning. However, this argument can be reversed to oppose using the data: data should not be used because doing so would perpetuate the unethical activities from which the data arose. Opponents of using data from unethical experiments take the position that using the data not only increases the “evil” of the experiment as it occurred in the past, but becomes an extension of the “evil” into current and future use. Both views hinge on some theory of causality according to which events in the future can amplify or amend the wrong doings of the past. In other words, they imply that subsequent events have the ability alter the ethical significance of a past event.¹⁴

Statement of Ethical Convictions

The purpose behind non-use of material based on data from unethical experiments is to state that the medical community will not tolerate ethical violations. Those who would like to ban the utilization of data from unethical experimentation favor this argument. However, the non-use of data gathered from unethical experiments could instead be misconstrued as not acknowledging and therefore denying the fact that unethical experiments occurred. “Silence is ambiguous and often amounts to the uncomfortably averted gaze, whether consciously intended or not.”¹⁵ It may be necessary to say something clearly, rather than nothing at all.

Good Conscience

There are those who contend that the inherent immorality of the data taints those who continue to rely on it, implying a connection between the corrupt nature of the experimental data and those who make use of it. Physicians who give the material generated from unethical experimentation a place in current or future medical practice run the risk of being viewed as indicating that the events were not so hideous. Some would argue that physicians jeopardize their own ethical credibility by legitimating unethical experiments. This view assumes that the investigators at the time of the experiment and the professionals who use the data at a later point have the same intentions or sensibilities. An understanding of what was unethical about the experiments is crucial in order to use the data in good conscience. Clarity about the egregious nature of unethical experiments and the purpose of using such ethically tainted data is an essential component of proper utilization.

Data from the Most Egregiously Immoral Experiments

Special attention needs to be paid to data collected from experiments that are incontrovertibly inhumane. Experiments that generate massive offenses to humanity, such as the experiments run by Nazi scientists and physicians and the Tuskegee Study, can be categorized as inhumane. One primary argument against using material obtained from Nazi experiments or the like is that such experiments were not experiments at all, but rather means of torture overseen by scientists and physicians. Results derived from senselessly cruel acts offer little scientific merit and should never be used, just as poor data collected under ethically sanctioned experiments have little value and would never be used.¹⁶ Data from unethical experiments whenever possible, must be replaced with data gathered through acceptable mechanisms. Most data obtained from unethical experiments can be replaced; for example the “Pernkopf Anatomy” atlas, a medical atlas containing photos taken during the Nazi experiments, can be replaced with modern photos and computer models that are not merely equivalent but actually superior teaching tools. However, some data gathered from egregious experiments may have unique scientific value. In such rare cases when no other version of the data is available, and data are absolutely necessary to ensure human lives are not lost, use of data from unethical experiments may be permissible.

CONSIDERATIONS FOR PHYSICIANS

If accurate yet ethically tainted data are the only data of that nature available, and such data are necessary in order to advance scientific knowledge and save lives, then the utilization of such data by physicians and editors should not be considered inappropriate. In the context of ethical implications, utilizing data from unethical experiments should not reflect poorly on those who do so if the proper conditions and intentions are demonstrated. Such demonstrations would include: (1) promoting good science and medicine in order to give the experiment some redemptive value, (2) requiring statements of disclosure that reveal the unethical nature of the activities from which the data was produced and clearly justify the necessity for citation, and (3) confirming a commitment to a good conscience through an understanding of what was unethical about the experiments.

CONSIDERATIONS FOR HUMAN STUDIES REVIEW BOARDS AND EDITORS AND AUTHORS OF MEDICAL PUBLICATIONS

In accordance with the current ethical standards in the Belmont Report, all proposed experiments using human subjects should undergo proper ethical evaluation by a human studies review board before being undertaken.¹⁷ Despite this ideal safeguard, unsanctioned experiments may still arise, leaving significant responsibility for revealing the tainted nature of the data in the hands of editors of medical texts that publish experimental studies. “Editors and authors have a specific ethical duty to follow the principles outlined in [doctrines developed during the mid-20th century: the Nuremberg Code, the World Medical Association’s Declaration of Geneva, and the World Medical Association’s Declaration of Helsinki] when making decisions about publishing studies that involve human experimentation.”¹⁸ All such publications should have in place an ethical standard by which to evaluate clinical research on a consistent basis.¹⁹ For example, the International Committee of Medical Journal Editors (ICMJE)²⁰ has adopted the Declaration of Helsinki in its “Uniform Requirements for Manuscripts Submitted to Biomedical Journals.”

On select occasions medical publications may opt to publish experiments that do not meet their ethical standards. This option becomes morally compelling when data from unethical experiments are the only source of life-saving information. In these cases editors should be aware of the implication for physicians who face the decision to utilize the data. An effort should be required to openly explain the decision to publish such data. Editors and/or authors ought to include an explicit condemnation of the unethical element of the experiment from which the data was generated alongside the published material. This disclosure should also clearly justify the necessity for publishing such data. It is important to note throughout this process that neither the replacement of the data nor the disclaimer serves to rectify unethical conduct or legitimize data gathered from unethical experiments. Certain generally accepted historical data may be cited without such disclosure, though a discussion of the ethical issues would be valuable and desirable.

CONCLUSIONS

The claim cannot be made that material that does not meet all ethical standards ever argued should be banned from use. The reason such a claim would be problematic is that ethical standards may contain controversial nuances that create a grey zone. The determination of which experiments are unethical and not fit for utilization would depend on the established standard. Ethical analysis also demonstrates that with careful deliberation and disclosure of the proper intentions, data from unethical experiments may be applied to some medical practice. In some cases even blatantly unethical experiments’ data can be utilized if there is no other way to help patients in dire need.

RECOMMENDATIONS

The Council recommends approval of the following guidelines in the ethical utilization of unethical experimentation data, and that the remainder of this Report is to be filed:

1. All proposed experiments using human subjects should undergo proper ethical evaluation by a human studies review board before being undertaken.
2. Responsibility for revealing that data are from unethical experiments lies in the hands of authors, peer reviewers, and editors of medical texts that publish results of experimental studies. Each publication should adopt a standard for publication or not of data from unethical experiments.

3. If data from unethical experiments can be replaced by existing ethically sound data and achieve the same ends, then such must be done. If scientifically accurate yet ethically tainted data are the only data of that nature available, and such data are necessary in order to advance scientific knowledge and save lives, then the utilization of such data by physicians and editors may be appropriate.

Should editors and/or authors decide to publish an experiment or data from an experiment that does not reach standards of contemporary ethical conduct, a disclaimer should be included. Such disclosure would by no means rectify unethical conduct or legitimize the methods of collection of data gathered from unethical experimentation.

This disclaimer should:

- a. clearly describe the unethical nature of the origin of any material being published;
- b. clearly state the need for publication of the data;
- c. pay respect to the victims;
- d. avoid trivializing trauma suffered by the participants;
- e. acknowledge the unacceptable nature of the experiments; and
- f. endorse higher ethical standards.

4. Certain generally accepted historical data may be cited without such disclaimer, though a disclosure of the ethical issues would be valuable and desirable.

5. Based on both scientific and moral grounds, data obtained from cruel and inhumane experiments, such as, data collected from the Nazi experiments and data collected from the Tuskegee Study, should virtually never be published or cited. In the extremely rare case when no other data exist and human lives would certainly be lost without the knowledge obtained from use of such data, publication or citation is permissible. In such a case the disclosure should cite the specific reasons and clearly justify the necessity for citation.

REFERENCES

1. Caplan AL. How Should Science Handle Data from Unethical Research? *J NIH Res.* 1993; 5:22-24.
2. Beecher HK. Ethics and Clinical Research. *N Engl J Med.* 1966;274:1354-1360.
3. The Nuremberg Issue. *JAMA.* 1996;276: 657-1683, 1691.
4. *The Nuremburg Code.* *JAMA.* 1996;276:1691.
5. *World Medical Association. Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research involving Human Subjects.* *JAMA.* 1997;227:925-926.
6. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Washington, DC: US Government Printing Office; 1978. OS publication 78-0012.
7. Caplan AL. When Evil Intrudes. *Hastings Center Rep* 1992;6:29-32.
8. Katz J. Blurring the Lines: Research, Therapy, and IRBs. *Hastings Center Rep.* 1997;1: 9-12.
9. Council on Ethical and Judicial Affairs, American Medical Association. Opinion 2.07, "Clinical Investigation." In: *Code of Medical Ethics.* Chicago: American Medical Association; 1996:14-17.
10. Angell M., Kassirer, JP. Setting the Record Straight in the Breast Cancer Trials. *N Engl J Med.* 1994;330:1448-1450.
11. Gillispie CC, ed. *Dictionary of Scientific Biography.* Vol. XIV. New York: Charles Scribner's Sons; 1976:5.
12. Council on Ethical and Judicial Affairs. American Medical Association. Principles of Medical Ethics. In: *Code of Medical Ethics.* Chicago: American Medical Association; 1996:xiv.
13. Freedman B. Moral Analysis and the Use of Nazi Experimental Results. In Caplan AL, ed. *When Medicine Went Mad.* New Jersey: Humana Press Inc. 1992:141-154.
14. Freedman B. Moral Analysis and the Use of Nazi Experimental Results. In Caplan AL, ed. *When Medicine Went Mad.* New Jersey: Humana Press Inc. 1992:141-154.

15. Freedman B. Moral Analysis and the Use of Nazi Experimental Results. In: Caplan AL, ed. *When Medicine Went Mad*. New Jersey: Humana Press Inc; 1992:141-154.
16. Freedman B. Moral Analysis and the Use of Nazi Experimental Results. In: Caplan AL, ed. *When Medicine Went Mad*. New Jersey: Humana Press Inc; 1992:141-154.
17. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC: US Government Printing Office, 1978. OS publication 78-0012.
18. Iverson C, et al. American Medical Association Manual of Style: a guide for authors and editors. 9th ed. Baltimore, MD: William and Wilkins: 1998:140-142.
19. *JAMA* Instructions for Authors. *JAMA*. 1997;278:68-76.
20. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. *JAMA*. 1997;277:929.