The Belmont Report

The Triple Crown of Research Ethics

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The Belmont Report is a critical document for those involved in research. However, the report is also applicable to clinical practice. The primary purpose of the Belmont Report is to protect the rights of all research subjects or participants. The Belmont Report also serves as an ethical framework for research. There are 3 major components: (1) respect for persons, (2) beneficence, and (3) justice. This article will review these principles and show how they can be applied to the clinical as well as the research setting and address some concerns for the 21st century.

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As a Kentucky woman (born and raised), I have a great fondness for horses, particularly thoroughbreds. The Triple Crown of Thoroughbred Racing includes 3 major races: (1) The Kentucky Derby, (2) the Preakness Stakes, and (3) The Belmont Stakes. A horse must win all 3 races during the course of 5 weeks to capture the title of Triple Crown winner. This is a difficult feat, and it has been 37 years since the last winner. American Pharoah (Note: This is the spelling of the horse's name on his registration, although it is not the traditional way to spell pharoah.) broke the losing streak by winning the Triple Crown of Thoroughbred Racing in 2015. Winning the Triple Crown of Thoroughbred Racing has only been accomplished 12 times in the history of the sport.

While watching these amazing horses and jockeys this year and finally seeing another Triple Crown winner, I began to think of the Belmont Report (since the last race of the Triple Crown of Crown of Thoroughbred Racing is the Belmont Stakes). The Belmont Report serves as the guiding ethical document to protect the rights of human subjects and participants involved in research and may be applicable in many areas of health care, not only research.[1] This article will discuss the 3 major principles, which must be followed when conducting clinical research: (1) respect for persons, (2) beneficence, and (3) justice.[1] It must be noted that these 3 tenets overlap and there is some repetitiveness. A brief history of the Belmont Report will also be presented.

HISTORY OF THE BELMONT REPORT

This article is not meant as an in-depth review of the laws and acts enacted before the Belmont Report. Rather, this article will present a brief overview of the acts leading to the development of the Belmont Report, its principles, and how it will be used in the today's ever changing health care system.

The Belmont Report was finalized in 1979 after several years of working on the guiding principles of research.[1] It was developed as a result of ongoing recommendations inspired by other codes, laws, and acts. Although this article will focus on the Belmont Report, it is essential to briefly discuss the acts and codes enacted before the Belmont Report. For a summary of these acts and codes, see Table 1.

To fully understand the purpose of this report, one must remember the atrocities of World War II. The first act to help eradicate ethical abuses came with the development of the Nuremberg Code in 1947 shortly after the end of World War II. The Nuremberg Code established a set of research principles for medical research using human participants. The Nuremberg Code helped form a foundation for ethical codes of research internationally.[2,3]

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TABLE 1 Brief Summary of Ethical Codes/Acts/Laws[1-10]

Date	Title	Purpose/Components
1947	Nuremberg Code	(1) Developed after the atrocities committed by Nazi Germany during World War II
		(2) First effort to define ethical guidelines for research
		(3) Placed restrictions on investigational research
1963	Food and Drug Administration	(1) Instituted by President John F. Kennedy to Administration regulate clinical trials of medications, biological products, and medical devices
		(2) Oversees protection of human participants
		(3) Assures the quality and safety of medical products in humans and animals
1964	Declaration of Helsinki	(1) Developed by the World Medical Association
Revised 1965		(2) Statement of ethical purpose for medical research
		(3) Mostly applied to physicians
		(4) Began to emphasize the importance of clinical research in humans
1974	National Research Act	(1) Became a US law to authorize local institutional review boards
		(2) Charged "a commission to develop ethical guidelines for human subjects"[4(p15)]
		(3) Identification of risk-benefit criteria
		(4) Role of informed consent
		(5) Created the National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research
1979	The Belmont Report	(1) Respect for persons
		(2) Beneficence
		(3) Justice
		(4) Explains the differences between research and clinical practice
1981	Protection of Human Subjects Law	(1) Helped form the basis of clinical research Subjects Law as we know it today
		(2) Began to look at balance of risks and benefits
		(3) Stressed the importance of following strict protocols
1991	Common Rule	(1) Published by the Federal Policy for the Protection of Human Subjects
		(2) Added more protection for pregnant women, fetuses, neonates, children, and prisoners
		(3) Outlines basics for institutional review boards, informed consent, and compliance with research protocols

However, the Nuremberg Code did not completely solve the problem of unethical research as was demonstrated by the Tuskegee Study. This study was conducted to determine the course of syphilis without consent of the human participants. No informed consent was obtained, and these men suffered considerably.[2] This is only 1 example of unethical research after the Nuremberg Code was developed. Other unethical studies included using mentally disabled children in a hepatitis trial, and another involved injecting live cancer cells into patients with chronic diseases.[2] Clearly, something more needed to be done (see Table 2 for more information about unethical studies).

In 1963, President John F. Kennedy developed the Food and Drug Administration (FDA). One purpose of the FDA is to regulate clinical trials of products under its jurisdiction (medications, medical devices, veterinary medicine, biological products).[4-8] Although the Nuremberg Code was a good start, more was needed. Thus, in 1964, the Declaration of Helsinki was adopted by the World Medical Association.[4-6] This document was the first attempt by physicians to establish an ethical code of conduct in research. This act placed even more stringent criteria on informed consent practices and strengthened the ethical basis for research.[4,5] This act provided an even greater foundation for the Belmont Report to include the 3 guiding principles for research with humans and took 3 years to complete.[4]

In 1981, a further step to protect the rights of human participants was made with the passing of the Protection of Human Subjects Law.[5] This law serves in conjunction with the Belmont Report, and these documents provide the ethical standards and protocols in use today. The role of the National Commission for the Protection of Human

TABLE 2 Examples of Unethical Studies[1,2]

Date	Title	Description
1930-1945	Nazi Medical Experiments	(1) Numerous atrocities committed against civilians, Jewish population, and prisoners of war
1930s-1972	Tuskegee Syphilis Study	(1) A longitudinal study to examine the effects of untreated syphilis in disadvantaged black men
		(2) Penicillin was available at the time but not offered to the participants
		(3) No informed consent
1963	Jewish Chronic Disease Hospital	(1) Conducted to examine the effect of hospital injecting live cancer cells into patients hospitalized with chronic diseases
		(2) Wanted to determine the body's ability "to reject cancer cells was due to cancer or the presence of a debilitating disease"[2(p26)]
		(3) No informed consent
1960s	Willowbrook Studies	(1) Several studies to examine the natural course of infectious hepatitis
		(2) Infected children who were mentally disabled with hepatitis
		(3) Conducted in a facility with poor children and the families may have been financially coerced

Subjects of Biomedical and Behavioral Research was essential in the development of the Belmont Report.[3] For more in-depth information or to see copies of these documents, please visit the National Institute of Health at www.NIH.gov and the Collaborative Institutional Training Program at https://www.citiprogram.org. The Collaborative Institutional Training Program can be helpful when training researchers before they start conducting research.

The Belmont Report uses and builds upon the Nuremberg Code, Declaration of Helsinki, and other laws. The Belmont Report uses 3 principles to guide ethical research: (1) respect for persons, (2) beneficence, and (3) justice.[1-3,8-10] These 3 principles will be presented next.

RESPECT FOR PERSONS

The first principle of the Belmont Report is respect for persons. People are autonomous beings and have the right to decide whether they want to participate in a clinical trial. This can also be used in practice where patients have the right to choose certain treatments or medications.[1-5]

Respect for persons actually is based on 2 ethical concepts. The first is autonomy, which was discussed in the previous paragraph. This allows people to make their own choices and decisions. The second ethical concept under respect for persons is to make allowances for vulnerable persons who require even more protection.[2,3,5] Examples of vulnerable populations include but are not limited to children, comatose patients, or those who are mentally challenged. These populations require the utmost protection and require the same autonomy and respect for persons as all others.[1,5,8]

An autonomous person given the correct and enough information has the right to make their own decisions, and these decisions must be honored and respected. For those who are not completely autonomous, additional safeguards must be in place. In some cases, it may be prudent to exclude some patients from certain clinical trials to cause no harm. Respect for all persons is an absolute must.[1-3,5,8]

BENEFICENCE

The second principle of the Belmont Report is beneficence, which incorporates the "principle of doing good."[2(p45)] As with respect for persons, there are 2 rules to guide research and clinical care. They are, first, (1) do no harm and (2) increase potential benefits and decrease possible adverse events or harm.[1-3] People must be made aware of any known and possible unknown adverse events of harm before participating in a clinical trial as well as undergoing any medical or nursing procedure. They need this information to make an informed autonomous decision, which also is included in the principle of respect for persons. All efforts must be taken by researchers and health care providers to protect the patient.[2] Sometimes, the risks are not known, particularly in clinical trials, and participants must be made aware of this before providing informed consent.

One measure to protect the rights of persons and to protect them from harm is the institutional review board (IRB).[1,6,7] The Belmont Report is the framework of all IRBs and works by protecting patients in the most ethical manner possible, particularly when research and clinical practices intersect. This independent board consists of people involved with research as well as laypersons. The IRB's primary purpose is to review research protocols and protect patients from harm and ascertain that measures are

taken to reduce risks.[1,7] The Belmont Report serves as a guide for every research plan and provides important distinctions between research and practice.[7]

Another measure in place to protect patients is a written informed consent form. In some cases, consent may be given verbally such as when asking a patient whether it is all right to perform a venipuncture or to conduct a survey. However, most medical/nursing care and research requires a written signed informed consent from the patient or a delegated person who has the legal right to make decisions for the patient. The informed consent has several components including but not limited to the following[10]:

1. The purpose of the study
2. In-depth description of the research procedure
3. Potential benefits if known
4. Potential risks if known
5. All risks may not already be identified and are unforeseeable
6. Participation is voluntary without fear of reprisal if the patient refuses to participate

Briefly, "first, do no harm" is the main principle of beneficence. In addition, all efforts must be to reduce risks and increase benefits for all patients in clinical trials and practice.[3,7,8] The decisions of the patients must be respected, and all efforts must be made to keep them from harm.[1,3,8]

JUSTICE

The third principle of the Belmont Report is justice, which demands equal treatment and fairness for all people.[1,2,6] As health care providers, we must ascertain that fairness is applied to all our patients without discrimination, whether they are in a clinical trial.[2] In addition, patients still require care even if they decline to participate with research or clinical care. They need to know they can stop the research or clinical care without any fear of reprisal.[1,4] The decision must be without undue influence. For example, a nurse or physician cannot withhold treatment if the patient refuses to participate.[2] "All subjects cannot receive less than the standard of care."[1] The patient or the patient's legal representative must be given access to this information as well. Informed consent may be given by another person in certain instances as described. Risks and benefits, if known, must be made known to potential subjects or participants in research. Information about alternate treatments must be shared as well. In addition, patients who are enrolled in clinical trials have the right to know the results of the trial or whether any new information is gained during the course of the trial.[3,5,6] This could affect their decision on whether to continue participation.

The principle of justice promotes a sense of trust between the patient, researcher, and/or health care provider.[1] According to the Belmont Report, inclusion and exclusion of people from clinical research must be ascertained before the study begins. Not all people will be eligible to participate in a clinical trial because the process of inclusion and exclusion must be followed without exception.[3] For example, if the trial is examining the possible benefits of an investigational stent after coronary angioplasty, there may be inclusion and exclusion criteria determined by the study sponsor. Some possible inclusion criteria may be (1) older than 18 years, (2) first-time angioplasty, and (3) the lesion must be of a specific length and width. Possible exclusion criteria could include (1) elevated laboratory levels, (2) end-stage renal disease, and (3) history of cerebrovascular disease. If any of the inclusion criteria and of the exclusion criteria are not met, the patient may not participate in the clinical trial.

When considering the principle of justice, results of any publicly funded research must be disseminated and shared with not only the participants or subjects in the trial but also all of society, even if the results are those not expected or hoped for.[1-3,5] In summary, the principle of justice is fairness and equality for all. Nurses are in an ideal position to make certain that this happens.

EXAMPLES OF THE BELMONT REPORT IN RESEARCH AND PRACTICE

A good example of how these principles work in practice can be found in an article by Quinlan-Colwell.[11] She presented a case study about pain management and the ethical issues involved when caring for a patient with a history of substance abuse. Although the patient in the case study was admitted with a painful condition and was receiving pain medication, she kept requesting more pain relief, particularly intravenously. Quinlan-Colwell[11] used the principles of beneficence, justice, and respect for persons while caring for this patient. There may have been issues in the patient's background of which the nurse was unaware that affected the need for additional pain medication. The patient may have a chronic pain condition that requires further treatment. Discussing the risks of increased use of opioids can be done while respecting the rights of the patient. In summary, the nurse in this case study integrated the principle of beneficence by not causing more harm and easing pain. The principle of justice was met by treating the patient fairly and in a nonjudgmental way. The patient was recognized as an autonomous being and was respected as such. The time to discuss the issue of substance abuse could come after the immediate problems are addressed. She allowed her patient the right to make an informed decision.[11]

A second example involved the author. As a research clinical coordinator, I worked closely with physicians in certain clinical trials. One of my roles was to the protect

the patient by making sure he or she had given informed consent, knew the possible risks and benefits and the alternate treatments, and knew that they could refuse without fear of reprisal. I was with a physician when he was discussing a study with a patient comparing 2 types of coronary percutaneous transluminal coronary angioplasty (PTCA) and atherectomy. We explained to the patient that both types of treatment was FDA approved, and this study was conducted to determine whether 1 procedure might be preferable over another. The type of procedure used would be decided with randomization. The patient refused to participate and only wanted physician A to choose. Physician A became very angry and walked out of the room. I spent the next 30 minutes calming the patient and assuring him he had the right to not participate in the study. The patient agreed to the initial PTCA but did not want physician A to perform the procedure. I then conducted the senior physician in the same group of cardiologists, and he came to meet the patient and explain the PTCA. The PTCA was successfully performed by physician B. I remained with the patient throughout the entire procedure. When the PTCA was completed, I went to the chairperson of the IRB and explained the matter to him. Physician A finished the rest of his scheduled procedures that day and continued to see patients. Approximately 2 weeks later, I asked physician B about the incident and was told the situation was handled by his group. The chairperson of the IRB related the same information. All 3 principles of the Belmont Report were used to protect the rights of this patient.

THE FUTURE

So what does the future hold concerning the Belmont Report? The report is now more than 30 years old.[5,6,12] The strengths of the report will continue to protect the rights of human subjects or participants. The core principles of respect for persons, justice, and beneficence will continue. One thing we must be aware of in the future, as we are now, is that not all potential participants will be able to provide informed consent.[12] Strenuous efforts must be undertaken to protect the rights of those who choose not to participate in a clinical study. Many consent forms may be more than 20 pages in length.[5,12] With regard to respect for persons, we must make certain potential participants know what they are consenting to before agreeing to participate in research.

Efforts must be taken to protect the confidential information of the patient involved in the clinical trial in this new era of electronic health records, gene therapy–biobanks, electronic signatures, and virtual consent formats.[11] Efforts must be made to protect the confidentiality of all patients involved with the technologies. The signed informed consent form must be placed in the electronic medical record to notify all health care providers of the patient's participation in a clinical trial. If questions arise from other health care providers, they should contact the principal or primary investigator of the trial or the clinical coordinator. All efforts must be taken to protect the confidentiality and anonymity of the research participant in the electronic medical record as well as electronic case report forms. Some information may need to be redacted from the case report form before others can review the record, such as study sponsor reviewers. The reviewers only need access to the information in the electronic health record and should not have access to any personal information.

Although The Belmont Report is an important document, it can always be improved.[13] New technology will continue to emerge, and the Belmont Report needs to change to reflect the times. One author suggests adding an ethical framework using the existing framework of the 3 core principles. The addition of an ethical framework may provide more clarity. For example, one person may have agreed to participate in a study, but later, a family member may want the patient to withdraw from the study. Friction may occur between the patient, the family member, the health care provider, and the research. An ethical framework may be extremely helpful in these situations.[13]

Briefly, the Belmont Report is a historical document that defines the guiding principles of ethical research. However, it is a flexible document to address future needs, such as incorporating the electronic medical health record, or to deal with any unforeseen issues at this time. The Belmont Report needs to be an evolving document to keep pace with the changing health care climate.

CONCLUSIONS

The Belmont Report was first released in 1979 and has recently been updated to meet the changing health care climate. The principles are still applicable today in both research and clinical practice. As nurses, we must remember the following:

1. Patients are autonomous agents and have the right to make informed decisions, that is, respect for persons.
2. First, do no harm and take measures to increase potential benefits and to decrease potential risks, that is, beneficence.
3. Treat each patient equally, that is, justice.

In addition, nurses must (1) serve as patient advocates, (2) assess the patient's ability to provide an informed consent, (3) ascertain the patient has information about the research study, (4) determine whether the patient knows the possible risks and benefits as well as the consequences, and (5) ascertain the patient's understanding that he or she may refuse to participate in the research without fear of reprisal. In other words, treat patients involved in research as you would all patients, fairly and in the best manner possible.

As there are 3 components of the Triple Crown of Thoroughbred Racing, there are 3 principles of the Belmont Report. Certainly, the 3 principles do overlap, and there is much repetitiveness as in most health care today. The most important thing to remember is that, as nurses, we must show respect for all people, first do no harm, explain risks/benefits to patients in clinical trials and in health care, and treat all patients fairly. As a side note, American Pharoah also won The Breeders Cup Classic in November 2015.

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