A Brief Review of the Belmont Report

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The Belmont Report is one of the leading works concerning ethics and health care research. Its primary purpose is to protect subjects and participants in clinical trials or research studies. This report consists of 3 principles: beneficence, justice, and respect for persons. This article reviews the Belmont Report and these 3 principles as well as its importance to nurse researchers.
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Critical-care nurses who conduct or participate in clinical trials may be familiar with the Belmont Report. However, those nurses who do not conduct research may not be aware of the Belmont Report (except for what they learned in nursing school during the course of their studies). The purpose of this brief article was to provide an overview of the Belmont Report and its 3 ethical principles: (1) beneficence, (2) justice, and (3) respect for persons.[1] The Belmont Report serves as one measure to protect human subjects in research.[1]

HISTORY OF THE BELMONT REPORT

The Belmont Report was first written by the National Commission for the Protection of Human Services of Biomedical and Behavioral Research. The report was written in 1978 and then sent to the President of the United States, President of the Senate, Speaker of the House, and the Secretary of Health, Education and Welfare. The report was 20 pages long, double-spaced, and its purpose was to "identify the basic ethical principles that should underlie the conduct of research involving human subjects."[2(p67)] Part of the reason for its existence was due to past deplorable acts in research and to protect human subjects in clinical research from this point forward.[3] The final form of the documents was release on April 18, 1979, after receiving approval from the US government.[3]

One of the main reasons for the Belmont Report came from the infamous Tuskegee syphilis study. These deplorable acts demanded more protection for subjects than was afforded by the Nuremburg Code or the Helsinki Report.[4] Institutional review boards (IRBs) were developed as a result of the Belmont Report. In addition, this report also "became the basis for federal regulation governing the protection of human subjects in research."[4(p41)]

The Belmont Report consists of 3 ethical principles that serve as a basis to protect the rights of human subjects in research. These are (1) beneficence, (2) justice, and (3) respect for persons.[1-5]

BENEFICENCE

Beneficence incorporates the principle of "first do no harm." In addition, all efforts must be made to maximize the benefits of research and to minimize any potential risks.[3-5] Of course, doing no harm requires participation from all involved in the research. The investigator needs to inform the IRB as well as any potential subject or participant about the plan to reduce risks as much as possible, how the study will be conducted, and any measures that will be taken to protect the rights of the subjects.[4] All researchers must take measures to identify potential risks and then take measures to reduce risks as well as inform all subjects about these potential risks.[5]

> ***"First do no harm."***

JUSTICE

The principle of justice includes efforts to describe the risks and benefits equally and to disseminate any research findings, both bad and good.[3] Researchers must be willing to share the findings of their research. Fairness is an important concept that leads to trust and justice.[4,5] Subjects and participants must be treated fairly and equally. Again, efforts must be taken to protect the subjects. Also, patients cannot be turned away from treatment because they decline to participate in research. All subjects cannot receive less than the standard of care.[5]

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RESPECT FOR PERSONS

People are autonomous agents and have the right to decide for themselves whether they want to participate in a research study.[3] In other words, the person has the ability to make decisions concerning whether to participate in a study, not to participate, or to withdraw from a study.[5] There are a few instances when someone other than the patient can make the decision to participate, such as with children, the mentally ill, or those in a comatose state.[3] Vulnerable populations such as these described require protection.[5] However, all efforts must be made to obtain informed consent from the patient or from a guardian before research can be conducted.

People are autonomous agents.

In almost all cases of research, the subject or participant must sign an informed consent document.[4] This document contains the purpose of the study, how it will be conducted, risks known at the time, possible benefits known at the time, the roles of all involved (subject, principal investigator, nurse coordinator, to name a few), any tests that will be completed for the research, what is expected of the subject, a statement concerning any unforeseeable or unknown risks, and the contact numbers of those involved in the study. Phone numbers are included so that subjects can contact investigators or coordinators if they have any questions about the study. This document, in some trials, can be quite lengthy.

WHAT THIS MEANS TO NURSES

As critical-care nurses, we already act as patient advocates whether the patient is enrolled in a study or not. Our role may increase when the patients is involved in a study. When your patient is in a clinical trial, you must do the following[1,4,5]:

1. Make certain the study has been approved by an IRB.
2. Ensure an informed consent has been signed.
3. Ensure the patient understands the clinical trial. If you are uncomfortable answering questions about the trial, contact someone involved with the study such as a research coordinator or the principal investigator.
4. Make sure the patient is not bullied or threatened to participate in the study.
5. When caring for a patient in a clinical trial, be alert for possible adverse events and report them to the appropriate person.
6. Show support and respect for the autonomy of the patients. Support their decision to participate in clinical research and, if they so choose, their decision to refuse to participate or to withdraw from the study.
7. Make certain all subjects receive at least the minimum standard of care.

CONCLUSION

The Belmont Report is an important document for research today. One purpose of this document is to protect the rights of human subjects in clinical trials. These rights are protected through the use of 3 ethical principles: (1) beneficence, (2) justice, and (3) respect for persons. Critical-care nurses must take measures to protect these rights and to protect all patients who are involved in clinical trials.

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