CHAPTER OBJECTIVES

At the end of this chapter, you will be able to:

- Define *research*.
- Discuss the contribution of research to evidence-based practice (EBP).
- Categorize types of research.
- Distinguish between quantitative and qualitative research approaches.
- Describe the sections found in research articles.
- Describe the cycle of scientific development.
- Identify historical occurrences that shaped the development of nursing as a science.
- Identify factors that will continue to move nursing forward as a science.
- Discuss which future trends may influence how nurses use evidence to improve the quality of patient care.
- Identify five unethical studies involving the violation of the rights of human participants or falsification of data.
- Discuss international and national initiatives designed to promote ethical conduct.
- Describe the rights of participants who volunteer for research studies.
- Describe the three ethical principles from the Belmont Report that must be upheld when conducting research.
- Explain the composition and functions of institutional review boards (IRBs) at the organizational level.

KEY TERMS

abstract
applied research
autonomous
basic research
Belmont Report
beneficence
cycle of scientific development
Declaration of Helsinki
deductive reasoning
descriptive research
discussion section
empirical evidence
explanatory research
exempt
expedited review
full review
human rights
inductive reasoning
informed consent
institutional review boards (IRBs)
introduction
Jewish Chronic Disease Hospital study
justice
list of references
methods section
minimal risk
mixed methods
Nazi experiments
Nuremberg Code
obligations
predictive research
qualitative research
quantitative research
red wine studies
replication studies
research
research imperative
respect for persons
results section
review of literature
science
theoretical framework
therapeutic imperative
Tuskegee study
Willowbrook studies

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CHAPTER 2

What Is Nursing Research?

Nola A. Schmidt and Janet M. Brown

2.1 Research: What Is It?

At the end of this section, you will be able to:

- Define *research*.
- Discuss the contribution of research to evidence-based practice (EBP).
- Categorize types of research.
- Distinguish between quantitative and qualitative research approaches.
- Describe the sections found in research articles.

Nursing is often described as "the art and science of nursing" (Vega & Hayes, 2019). The art of nursing encompasses important values such as caring, compassion, and communication. The science of nursing focuses on providing care that is based on rigorous scientific inquiry. ***Science*** is "(knowledge from) the careful study of the structure and behavior of the physical world, especially by watching, measuring, and doing experiments, and the development of theories to describe the results of these activities" (Cambridge University Press, 2020). Science is so foundational to nursing that the word *science* is even included in the degree conferred—Bachelor of Science in Nursing. Thus, nurses must generate new knowledge through research and apply that new knowledge to practice. ***Research*** is a planned and systematic activity that leads to new knowledge and/or the discovery of solutions to problems or questions

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KEY TERMS

science: Knowledge derived from rigorous observation and experimentation to systematically study the physical world for the purpose of testing or developing theories

research: Systematic study that leads to new knowledge and/or solutions to problems or questions

replication studies: Repeated studies to obtain similar results

descriptive research: A category of research that is concerned with providing accurate descriptions of phenomena

explanatory research: Research concerned with identifying relationships among phenomena

predictive research: Research that forecasts precise relationships between dimensions of phenomena or differences between groups

basic research: Research to gain knowledge for the sake of gaining knowledge; bench research

BOX 2-1 Steps of the Research Process

1. Identify the research question.
2. Conduct a review of the literature.
3. Identify a theoretical framework.
4. Select a research design.
5. Implement the study.
6. Analyze data.
7. Draw conclusions.
8. Disseminate findings.

(Polit & Beck, 2021). Simply stated, research means to search again. But the search must be deliberate and organized as relevant questions are examined. It is essential that established steps be followed.

Following a systematic approach (**Box 2-1**) is more likely to yield results that can be used with confidence. Through research, scientists aim to describe, explain, and predict phenomena. But isn't science supposed to prove that things are true? Sometimes you may hear or read the phrase "research proves"; however, the use of the word *prove* is inaccurate. Research findings *support* a particular approach or view because the possibility of error exists in every research study. This underscores why a planned, systematic approach is necessary and why ***replication studies*** are important.

Nurses use research to generate new knowledge or to validate and refine existing knowledge that directly or indirectly influences nursing practice. In nursing research, the phenomena of interest are persons, health, nursing, and environment. Nurses study patient outcomes, attitudes of nurses, effectiveness of administrative policy, and teaching strategies in nursing education. Nursing research contributes to the development and refinement of theory. But most important, as a baccalaureate-prepared nurse, you will use research as a foundation for evidence-based practice (EBP). Without research, nursing practice would be based on tradition, authority, trial and error, personal experiences, intuition, and borrowed evidence. This is why you must have the skills to read, evaluate, and apply nursing research so that as an early adopter you can be instrumental in moving an innovation to the point of care.

Types of Research

A variety of terms is used to describe the research conducted by scientists. Research can be categorized as ***descriptive***, ***explanatory***, or ***predictive***; ***basic*** or ***applied***; and ***quantitative*** or ***qualitative***. These categories are not necessarily

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mutually exclusive. For example, a study may be descriptive, applied, and qualitative. Although this sounds complicated, when you understand the definitions, it will become clear.

One way to classify research is by its aims. Descriptive research answers "What is it?" This category of research is concerned with providing accurate descriptions and can involve observation of a phenomenon in its natural setting. The goal of the explanatory research is to answer the question, "What is the relationship among the variables?" Explanatory research aims to identify the relationships a phenomenon has with individuals, groups, situations, or events. Predictive research is designed to answer the question, "Is there a difference between the groups?" The aim of predictive research is to forecast precise relationships between dimensions of phenomena or differences between groups. This type of research is often used to study new interventions and treatments. These three aims and the types of questions they answer drive decisions about how studies are conducted. **Table 2-1** provides an example of how these three aims helped nurses to better understand the phenomenon of pain during chest tube removal.

Another way to classify research is to consider whether findings can be used to solve real-world problems. Basic research, sometimes known as bench research, seeks to gain knowledge for the sake of gaining that knowledge. This knowledge may or may not become applicable to practical issues or situations.

FYI

Research can be categorized as descriptive, explanatory, or predictive; basic or applied; and quantitative or qualitative. Nursing research concerns persons, health, nursing practice, and environment, and can be used to generate new knowledge or to validate and refine existing knowledge that directly or indirectly influences nursing practice.

KEY TERMS

applied research: Research to discover knowledge that will solve a clinical problem

quantitative research: Research that uses numbers to obtain precise measurements

qualitative research: Research that uses words to describe human behaviors

TABLE 2-1 An Example of Building Knowledge in Nursing Science: Pain and Chest Tube Removal (CTR)

Study	Aim of Research	Findings
Gift et al. (1991)	Describe	Individuals reported burning pain and pulling with CTR. Women reported pain more frequently than men did.
Puntillo (1994)	Explain	Compared CTR pain with endotracheal suctioning. Patients reported less pain with suctioning than with CTR. "Sharp" was the most frequent adjective for CTR pain.
Carson et al. (1994)	Predict	Patients were assigned to one of four groups for treatment with pain medications: IV morphine, IV morphine and subfascial lidocaine, IV morphine and subfascial normal saline solution, and subfascial lidocaine. There were no significant differences in pain alleviation.

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Study	Aim of Research	Findings
Puntillo (1996)	Predict	Patients were assigned to either placebo normal saline interpleural injection or bupivacaine interpleural injection. There was no significant difference in pain reports.
Houston & Jesurum (1999)	Predict	Examined effect of quick release technique (QRT), a form of relaxation using a breathing technique, during CTR. Patients were randomly assigned to either an analgesic-only group or an analgesic with QRT. Combination of QRT with analgesic was not more effective than was analgesic alone in reducing pain.
Puntillo & Ley (2004)	Predict	Patients were randomly assigned to one of four combinations of pharmacological and nonpharmacological interventions to reduce pain: 4 mg IV morphine with procedural information, 30 mg IV ketorolac and procedural information, 4 mg IV morphine with procedural and sensory information, and 30 mg IV ketorolac with procedural and sensory information. There were no significant differences among the groups regarding pain intensity, pain distress, or sedation levels.
Friesner et al. (2006)	Predict	A group of adults who had undergone coronary artery bypass used a slow deep-breathing relaxation exercise with opioid analgesia. Their pain ratings were compared to a group using opioids only. There was a significant reduction in pain ratings for the patients who used the breathing exercise combined with opioids.
Demir & Khorsbid (2010)	Predict	Cardiac patients were randomly assigned to a group that received ice and analgesia, a group that received warmth and analgesia, or a group that received only analgesia. Patients who received the application of ice reported significantly less pain than did patients from the other two groups.
Ertuğ & Űlker (2011)	Predict	Patients were randomly assigned to either an experimental group that received cold prior to CTR or a control group that had no intervention for pain management. Patients receiving cold reported significantly less pain than did those in the control group.
Pinheiro et al. (2015)	Predict	Patients were randomly assigned to either an experimental group that received 1% subcutaneous lidocaine or a control group that received a combination of inflammatory agents and opioids. There was no significant difference in pain reported by patients.
Aktas & Karabulut (2019)		Patients were randomly assigned to either a control group that received standard of care or one of three experimental groups that received 1% subcutaneous lidocaine, cold therapy, or music therapy. There was no difference in pain levels between the interventions.

Note: CTR = chest tube removal.

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It may be years before a discovery becomes useful when it is combined with other discoveries. For example, vitamin K was studied for the sake of learning more about its properties. Years later, the knowledge gained about its mechanism of action during coagulation formed the foundation for vitamin K becoming an accepted treatment for bleeding disorders. In contrast, the aim of applied research is to discover knowledge that will solve a clinical problem. The findings typically have immediate application to bring about changes in practice, education, or administration.

Quantitative and *qualitative* are terms that are also used to distinguish among types of research. Philosophical approach, research questions, designs, and data all provide clues to assist you in differentiating between these two methods of classification. Sometimes, researchers even combine quantitative and qualitative methods in the same study. These studies are known as ***mixed methods*** designs.

Quantitative researchers view the world as objective. This implies that researchers can separate themselves from phenomena being studied. The focus is on collecting ***empirical evidence***—in other words, evidence gathered through the five senses. Researchers quantify observations by using numbers to obtain precise measurements that can later be statistically analyzed.

Many quantitative studies test hypotheses. Some study designs typically associated with quantitative methods include randomized controlled trial (RCT), quasi-experimental, correlational, and descriptive survey designs. For example, a nurse researcher may measure patient satisfaction with nursing care by having patients complete a survey to rate their satisfaction, using a scale of 0 to 5.

In contrast, the premise of qualitative research is that the world is not objective. There can be multiple realities because the context of the situation is different for each person and can change with time. The emphasis is on verbal descriptions that explain human behaviors.

In this type of research, the focus is on providing a detailed description of the meanings people give to their experiences. Some methods that are recognized as qualitative include phenomenology, grounded theory, ethnography, and historical. For example, a nurse researcher may measure patient

KEY TERMS

mixed methods: A design that combines both quantitative and qualitative data gathering and evaluation

empirical evidence: Evidence that is verifiable by experience through the five senses or experiment

CRITICAL THINKING EXERCISE 2-1

When you look for the root word in *quantitative*, what root word do you see? Do you see that it comes from the root word *quantity*? So, one knows the focus will be on numbers.

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KEY TERMS

deductive reasoning: Thinking that moves from the general to the particular

inductive reasoning: Thinking that moves from the particular to the general

satisfaction with nursing care by conducting individual interviews and summarizing common themes that patients expressed. Qualitative findings are helpful in EBP because they may provide the patient perspective. **Table 2-2** provides a comparison of these two approaches.

Another important point about quantitative and qualitative approaches is that there are two styles of reasoning associated with them. ***Deductive reasoning***, primarily linked with quantitative research, is reasoning that moves from the general to the particular. For example, researchers use a theory to help them reason out a hunch. If the researcher believes that the position of the body affects circulation, then the researcher could deduce that blood pressure readings taken while lying down will be different from those measured while standing. In contrast, ***inductive reasoning*** involves reasoning that moves from the particular to the general and is associated with qualitative approaches. By using inductive reasoning, researchers can take particular ideas and express an overall general summary about the phenomenon (**Figure 2-1**).

TABLE 2-2 Comparisons of Quantitative and Qualitative Approaches

Attribute	Quantitative	Qualitative
Philosophical perspective	One reality that can be objectively viewed by the researcher	Multiple realities that are subjective, occurring within the context of the situation
Type of reasoning	Primarily deductive	Primarily inductive
Role of researcher	Controlled and structured	Participative and ongoing
Strategies	Control and manipulation of situations Analysis of numbers with statistical tests Larger number of participants	Naturalistic; allows situations to unfold without interference Analysis of words to identify themes Smaller numbers of participants
Possible designs	Randomized controlled trial (experimental) Quasi-experimental Correlational Descriptive survey	Phenomenological Ethnographic Grounded theory Historical

CRITICAL THINKING EXERCISE 2-2

When you look for the root word in *qualitative*, do you see the word *quality*? This shows that the emphasis is on words, rather than on numbers.

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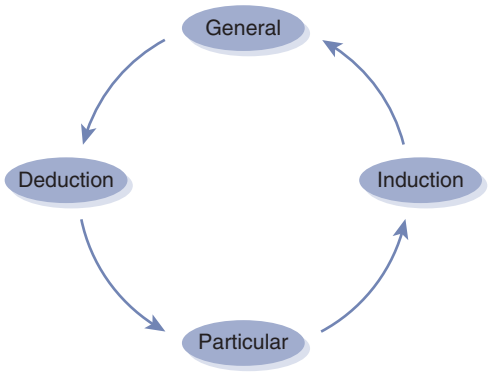
FIGURE 2-1 Ways of Reasoning



What Makes up a Research Article?

The development of EBP requires careful attention to research already published. Therefore, it is essential for nurses to identify research studies from among the many other types of articles included in the literature. The trick is knowing what sections are contained in a research article.

Typically, an ***abstract*** is the first section of a research article and is usually limited to 100 to 150 words. The purpose of the abstract is to provide an overview of the study, but the presence of an abstract does not necessarily mean that an article is a research study. Because abstracts can frequently be found online, it is usually helpful to read them before printing or requesting a copy of the article. Careful attention to abstracts can avoid wasted time and effort retrieving articles that are not applicable to the clinical question.

The ***introduction***, which follows the abstract, contains a statement of the problem and a purpose statement. The problem statement identifies the problem in a broad and general way. For example, a problem statement may read, "falls in hospitalized patients can increase length of stay." Authors usually provide background information and statistics about the problem to convince readers that the problem is significant. The background information provided should set the stage for the purpose statement, which describes what was examined in the study. For example, a purpose statement may read, "the purpose of this study was to examine the relationship between time of evening medication administration and time of falls." A good introduction convinces readers that the study was worthy of being conducted.

KEY TERMS

abstract: The first section of a research article that provides an overview of the study

introduction: Part of a research article that states the problem and purpose

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KEY TERMS

review of literature: An unbiased, comprehensive, synthesized description of relevant previously published studies

theoretical framework: The structure of a study that links the theory concepts to the study variables; a section of a research article that describes the theory used

methods section: Major portion of a research article that describes the study design, sample, and data collection

results section: Component of a research article that reports the methods used to analyze data and characteristics of the sample

discussion section: Portion of a research article where interpretation of the results and how the findings extend the body of knowledge are discussed

The third section is the ***review of literature***. An unbiased, comprehensive, synthesized description of relevant, previously published studies should be presented. For each study included in the review, the purpose, sample, design, and significant findings are discussed. The review should focus on the most recent work in the field but may include older citations if they are considered to be landmark studies. A complete citation is provided for each article so that readers can retrieve the articles if desired. A well-written literature review concludes with a summary of what is known about the problem and identifies gaps in the knowledge base to show readers how the study adds to existing knowledge.

Some research articles include a discussion of the ***theoretical framework***, which may be in a separate section or combined with the review of literature. A theoretical framework often describes the relationships among general concepts and provides linkages to what is being measured in the study. Authors frequently use a model or diagram to explain their theoretical framework.

A major portion of a research article is the ***methods section***, which includes a discussion about study design, sample, and data collection. In most cases, authors explicitly describe the type of design they selected to answer the research question. In this section, it is important for the authors to describe the target population and explain how the sample was obtained. Procedures for collecting data, including the types of measures used, should also be outlined. Throughout this section, authors provide a rationale for decisions made regarding how the study was implemented.

Readers frequently consider the ***results section*** to be the most difficult to understand. Here, authors describe the methods they used to analyze their data, and the characteristics of the sample are reported. In quantitative studies, data tables are frequently included for interpretation, and authors indicate which findings were significant and which were not. In qualitative studies, authors present themes that are supported by quotes from participants. After reading the results section, the reader should be confident that the researchers selected the appropriate analysis for the data collected.

The body of a research article concludes with a ***discussion section***. Authors provide an interpretation of the results and discuss how the findings extend the body of knowledge. Results should be linked to the review of the literature and theoretical framework. The authors discuss the limitations of the study design and sometimes suggest possible solutions to address them in future studies. Implications for practice, research, and education are proposed. Often it is helpful to read this section after reading the abstract and introduction because it provides clarity by giving readers an idea of what is to come.

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The article concludes with the ***list of references*** that are cited in the article. Although styles vary, many journals adhere to the guidelines provided in the *Publication Manual of the American Psychological Association* (2020). Because it is often helpful to refer to the original works listed in the reference section, it is wise for readers to obtain a copy of the entire article, including the reference list.

KEY TERM

list of references: Publication information for each article cited in a research report

How Research Is Different From EBP

Research and EBP complement one another, but it is important to understand how they differ. Research is about generating new knowledge, whereas EBP is about applying new knowledge to practice. Research questions are often posed when a gap in the literature is discovered. For example, perhaps all of the studies about the effect of relaxation on anxiety have been done about adults. Because only adults have been studied, a gap in the literature exists about the effect of relaxation on anxiety in adolescents. In contrast, most EBP questions are raised while nurses are providing care to patients. Research is a scientific process that involves collecting and analyzing data from research participants to evaluate the findings in light of the research question that is posed. Although EBP also involves analysis of data, the data are about patients, and the analysis focuses on whether patient outcomes have improved (see **Table 2-3**).

TABLE 2-3 Comparison of Research and EBP

Research	EBP
Generates new knowledge	Applies new knowledge to point of care
Fills gap in literature	Based on evidence in literature
Research question	Clinical question
Participants	Patients
Designed to describe a phenomenon, find a relationship, or test an intervention	Designed to change practice in clinical setting
Analysis of data	Analysis of data
Evaluates findings in light of research question	Evaluates practice change by measuring patient outcomes

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TEST YOUR KNOWLEDGE 2-1

True/False

1. When reading a quantitative research article, you would expect to see words being analyzed as data.
2. The purpose of research is to prove something is true.
3. It is possible for a descriptive, qualitative study to be applied to practice.

How did you do? 1. F; 2. F; 3. T

2.2 How Has Nursing Evolved as a Science?

At the end of this section, you will be able to:

- Describe the cycle of scientific development.
- Identify historical occurrences that shaped the development of nursing as a science.

Nursing has been described as both an art and a science. Historically, the emphasis was more on the art than the science. But as nursing has developed, the emphasis has shifted. We propose that nursing is the artful use of science to promote the health and well-being of individuals, families, and communities. Thus, nursing is based on scientific evidence that provides the framework for practice. The art of nursing is the blending of science with caring to create a therapeutic relationship in which holistic care is delivered. The profession of nursing is entering a new era in which the emphasis is on EBP, therefore reaffirming the importance of science in nursing.

Cycle of Scientific Development

To fully appreciate nursing as a science, an understanding of the history of research in nursing is necessary. Although a grasp of history is important, it can be confusing when one focuses on a list of events and dates to memorize. Instead, by focusing on the what and why of historical occurrences instead of the when, the evolution of nursing as a science will be more clear.

KEY TERM

cycle of scientific development: A model of the scientific process

Nursing has developed in a similar fashion to other sciences. **Figure 2-2** depicts the ***cycle of scientific development***. Scientists begin by developing grand theories to explain phenomena. A grand theory is a broad generalization that describes, explains, and predicts occurrences that take place around us. Research is then conducted to test these theories and to discover new

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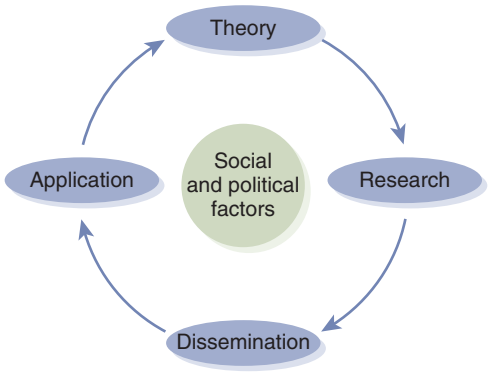
FIGURE 2-2 Cycle of Scientific Development



knowledge. Conferences and publications result from the need to disseminate research findings. Findings are applied to patient care, resulting in changes in practice, and are used to refine established theories and propose new ones. This cycle repeats, building the science as new discoveries are made. Political and social factors are central to the cycle in that they channel research priorities, funding, and opportunities for dissemination of findings.

A Glimpse of the Past

Before 1900

Florence Nightingale is considered by most to be the first nurse researcher. One could say that, as an innovator, she was the first nurse to create an EBP. Through the systematic collection and analysis of data, she identified factors that contributed to the high morbidity and mortality rates of British soldiers during the Crimean War (1853–1856). Health reforms based on her evidence significantly reduced these rates. Her observations during the war led her to theorize that environmental factors were critical influences on the health of individuals. In 1859, she disseminated her ideas in *Notes on Nursing: What It Is, and What It Is Not* (1859/1946), which continues to be in print today. Even though Nightingale was an innovator in nursing research, 40 years passed before nursing research reemerged as relevant to nursing practice.

1900–1929

During the first quarter of the 20th century, the focus of nursing research was closely aligned with the social and political climate. Women were empowered

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FYI

In the early 1900s, nursing research was primarily focused on education preparation.

by the suffragette movement; thus, their interest in higher education increased. Nursing education became the focus of nursing research. The work of nursing leaders such as Lavinia Dock, Mary Adelaide Nutting, Isabel Hampton Robb, and Lillian Wald was instrumental in reforming nursing education. Similarly, the Goldmark Report (1923) identified many inadequacies in nursing education and recommended that advanced educational preparation for nurses was essential. As a result, Yale University School of Nursing became the first university-based nursing program in the United States. Also during this time, the first nursing doctoral program in education was started at Teachers College at Columbia University (1924). These events are important because aligning programs of nursing with universities provided the environment for the generation and dissemination of nursing research.

During this era, nursing was prominent in community health, addressing clinical problems such as pneumonia, infant mortality, and blindness. Because nursing research was still in its infancy, descriptive studies focusing on morbidity and mortality rates of these problems were typically conducted. The first nursing journal, the *American Journal of Nursing*, was published (1900), and the American Nurses Association was established (1912). As a result, nursing was organized and promoted as a profession.

1930–1949

The period from 1930 to 1949 was influenced by the Great Depression, which was followed by World War II. During the Depression, families did not have money to provide a university education for their children. Consequently, university-based nursing education did not flourish, and nursing research did not advance. As a result of the war, the demand for nurses was so great that nursing education continued to take place primarily in hospital-based diploma programs because this was the quickest way to prepare individuals for the workforce. Nurses continued to focus their research on educational issues, and their studies began to be published in the *American Journal of Nursing*. At the close of this era, the Brown Report (1948) was published. Like the Goldmark Report published 25 years earlier, the Brown Report recommended that nurses be educated in university settings. These events illustrate how the social system can impede the diffusion of an innovation as accepted practice.

1950–1969

In the 1950s, significant events occurred that advanced the science of nursing. The innovation of moving nursing education into universities began to

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become accepted. Through the work of the Western Interstate Commission for Higher Education (1957), nursing research began to be incorporated into graduate curricula, which provided a structure for the advancement of nursing science. Several nursing research centers, including the Institute of Research and Service in Nursing Education at Teachers College (1953), the American Nurses Foundation (1955), the Walter Reed Institute of Research (1957), and the National League for Nursing Research for Studies Service (1959), were established. The availability of funds from government and private foundations increased awards for nursing research grants and predoctoral fellowships.

Also during the 1950s, the focus of nursing research shifted from nursing education to issues such as the role of the nurse in the healthcare setting and characteristics of the ideal nurse. Early nursing theories described the nurse–patient relationship (Peplau, 1952) and categorized nursing activity according to human needs (Henderson, 1966). To accommodate the growth of nursing science, journals were needed to disseminate findings. In response, *Nursing Research* (1952) and *Nursing Outlook* (1953) were published, and the *Cumulative Index to Nursing Literature* (CINL) became more prominent.

The scholarly work done by nurses during the 1960s propelled nursing science to a new level. Nursing's major organizations began to call for a shift to research that focused on clinical problems and clinical outcomes. Nurse researchers began to develop grand nursing theories in an attempt to explain the relationships among nursing, health, persons, and environment (King, 1964, 1968; Levine, 1967; Orem, 1971; Rogers, 1963; Roy, 1971). As in the evolution of any science, nursing began to conduct research to test these theories. Because of the volume of nursing scholarship, new avenues for dissemination of information became necessary. Conferences for the sole purpose of exposing nurses to theory and research were organized. For example, in 1965 the American Nurses Association began to sponsor nursing research conferences. Worldwide dissemination became possible with the addition of international journals, such as the *International Journal of Nursing Research* (1963), thus increasing the interest in nursing research.

1970–1989

The hallmark of the 1970s and 1980s was the increased focus on the application of nursing research. The Lysaught Report (1970) confirmed that research focusing on clinical problems was essential but that research on nursing education was still indicated. It was recommended that findings from studies on nursing education be used to improve nursing curricula. During this era, the number of nurses with earned doctorates significantly increased, as did the

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availability of funding for research fellowships. The scholarship generated by these doctoral-prepared nurses increased the demand for additional journals. Journals such as *Advances in Nursing Science* (1978), *Research in Nursing and Health* (1978), and the *Western Journal of Nursing Research* (1979) contained nursing research reports and articles about theoretical and practice issues of nursing. In 1977, CINL expanded its scope to include allied health journals, thus changing its name to the *Cumulative Index to Nursing and Allied Health Literature* (CINAHL), which allowed individuals in other disciplines to be exposed to nursing research.

On the national scene, the ethical implications of research involving human participants were given much attention. In 1973, the first regulations to protect human participants were proposed by the U.S. Department of Health, Education, and Welfare. The formation of institutional review boards (IRBs) to approve all studies was an important result of this regulation. Work regarding ethics in research continued throughout the decade with publication of the Belmont Report (1979). This report identified ethical principles that are foundational for the ethical treatment of individuals participating in studies funded by the federal government. Because the focus of nursing research on clinical problems involving patients was growing, nursing research was held to the same standards as other clinical research. Thus, the protection of human participants became an important issue for nurse researchers.

Despite the abundance of research produced during the 1960s and 1970s, little change occurred in practice. Because nurses recognized a gap between research and practice, the emphasis in the 1980s was on closing this gap. The term *research utilization* was coined to describe the application of nursing research to practice. Activities to move nursing science forward included the Conduct and Utilization of Research in Nursing Project. Through this project, current research findings were disseminated to practicing nurses, organizational changes were facilitated, and collaborative clinical research was supported.

The social and political climate of the 1980s included a major change in the financing of health care with the introduction of diagnosis-related groups (DRGs). As a result, significant changes in the way health care was reimbursed occurred. Nurse researchers began to respond to the social and political demand for cost containment by conducting studies on the cost-effectiveness of nursing care. Another important social and political influence on nursing research was the establishment of the National Center for Nursing Research (NCNR) at the National Institutes of Health (NIH) in 1986. This was significant because nursing was awarded a place among other sciences, such as medicine, for guaranteed federal funding.

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Activities that took place in the 1980s were consistent with the maturing of nursing as a science. As the body of knowledge grew, specialty organizations popped up, enabling individuals to share their expertise in various clinical areas. In addition, the demand for journals in which to publish research continued, and *Applied Nursing Research* (1988), *Scholarly Inquiry for Nursing Practice* (1987), *Nursing Science Quarterly* (1988), and the *Annual Review of Nursing Research* (1983) were started. In 1984, the CINAHL database became electronic. As nursing researchers became more sophisticated in the use of research methods, they embraced approaches new to nursing, such as qualitative methods. New theories (Benner, 1984; Leininger, 1985; Watson, 1979) that used caring as an important concept were especially amenable to emerging research methods.

1990–1999

In the 1990s, organizations began setting research agendas compatible with the social and political climate. For example, public concerns about the inequities of healthcare delivery were at the forefront. Priorities for nursing research included access to health care, issues of diversity, patient outcomes, and the goals of Healthy People 2000. Because nursing research was gaining respect for its contributions to patient care, opportunities for interdisciplinary research became available. In 1993, the NCNR was promoted to full institute status within NIH and was renamed the National Institute of Nursing Research. This was significant because the change in status afforded a larger budget that enabled more nurses to conduct federally funded research. Furthermore, with increased funding, nurse researchers designed more complex studies and began to build programs of research by engaging in a series of studies on a single topic.

The knowledge explosion created by technological advances vastly influenced nursing research. Electronic databases provided rapid access for retrieval of nursing literature, and in 1995 CINAHL became accessible to individuals over the Internet. Through email, nursing researchers were able to communicate quickly with colleagues. Software programs to organize and analyze data became readily available, allowing researchers to run more sophisticated analyses. Practice guidelines from organizations such as the Centers for Disease Control and Prevention (CDC) were easily obtained on the Internet. The *Online Journal of Knowledge Synthesis for Nursing* (1993) was the first journal to take advantage of this technology by offering its content in an electronic format.

In previous eras, the focus was on the application of findings from a single study to nursing practice. In the early to mid-1990s, the emphasis was on research utilization. The Iowa model of nursing utilization (Titler et al., 1994) and the Stetler model for research utilization (Stetler, 1994) were introduced to facilitate the movement of findings from one research study into nursing practice.

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In the late 1990s, it became apparent that multiple sources of evidence were desirable for making practice changes. Thus, EBP gained popularity over research utilization, and these models were adapted to fit with the EBP movement.

2000–2009

In the new millennium, nursing research continued to be influenced by social and political factors. Healthcare reform in the United States, although considered a political priority, remained elusive throughout the decade. Although Congress passed H.R. 3962, the Affordable Health Care for America Act, significant changes had yet to be implemented.

Globalization became an important influential factor during this decade. With the ease of retrieving information came the ability to share research findings internationally. Nurses were able to access articles about research conducted in a variety of other countries. Nurses in other countries became more equipped to conduct research as well. Sigma Theta Tau International significantly broadened its membership to include more chapters in other countries. Globalization also raised new concerns that provided nurses with opportunities for research.

During this decade, a renewed focus centered on patient safety and outcomes. The American Nurses Association was instrumental in creating the National Database of Nursing Quality Indicators (NDNQI). The purpose of this database is to collect and evaluate unit-specific nurse-sensitive data from hospitals in the United States. Participating facilities receive unit-level comparative data reports to use for quality improvement (QI) purposes. Some NDNQI outcomes focus on patient outcomes such as pressure ulcers and falls, whereas others focus on nursing workforce issues such as hours per patient day for nursing staff. Many of these measures are used by hospitals that have received Magnet Recognition for nursing excellence.

Another significant accomplishment during this time was the mapping of human genes. The Human Genome Project (HGP), an international research effort to sequence and map all of the genes of the human genome, was completed in 2003. As a result, knowledge about genetics was integrated into nursing education. Genetic-related research became a high priority for nursing and other health professions.

Another challenge faced in the new millennium was a nursing shortage. Topics such as nurse–patient ratios and interventions to decrease length of stay became priorities for research. Other changes occurred in nursing education. The use of technology for distance learning became more prominent as a way to educate nurses. Additionally, the Doctor of Nursing Practice (DNP) degree was recommended as the minimal educational requirement for those

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entering advanced practice nursing. Nursing programs across the country began to offer DNP degrees. Nurses who are prepared at the doctoral level and practice in clinical settings can serve as leaders in EBP.

2010–2019

Despite the growth in nursing research and the focus on EBP, improvement of patient outcomes was lagging. Evidence showed that hospitals were not meeting core benchmarks in these areas. In a study by Melnyk et al. (2016), a third of hospitals failed to meet NDNQI performance metrics. Additionally, oversight of the NDNQI shifted from the American Nurses Association to Press Ganey Associates. This change was congruent with the stronger emphasis that was being placed on benchmarking, the use of national data, and a trend toward withholding reimbursement to organizations that did not meet these critical indicators. For example, organizations that had patient satisfaction scores below a certain cutoff received reduced Medicaid reimbursement. This trend highlighted the need for nursing research about new interventions that improved patient outcomes and strategies for translating these findings into practice.

The electronic medical record (EMR) became a standard in health care. Concerns about the protection of personal information were paramount. Additionally, linking EBP to EMRs began to evolve. For example, when patient data were entered into the EMR, a message appeared suggesting practice guidelines based on the best evidence.

2020 to the Present

Many of the changes occurring since 2010 continue to drive innovations in health care. Ethical concerns about the EMR continue as security breaches in technology have become more sophisticated. Debate about the Affordable Care Act continues, as politicians weigh its value. For example, nurses can study the impact of even shorter hospital stays on readmission rates. As care moves away from hospitals to alternative settings, research will be needed to determine the effects of these changes on patient outcomes.

Globalization continues to be an important social factor in health care. With the introduction of the novel human coronavirus (SARS-CoV-2) and the ensuing COVID-19 pandemic, significant changes in delivery of health care occurred. Some healthcare providers faced shortages of medical and personal protective equipment. Adaptations were made to manage the flow of acutely ill patients. For example, operating rooms and other physical units were adapted to provide care typically obtained in ICU settings. Elective procedures were postponed so that hospitals could accommodate a potential

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surge of seriously ill patients. Convention centers were converted into places for patients to recover. Telemedicine emerged as an accepted mechanism for providing office visits to reduce exposure to the virus. Global forces were brought to bear on the development of diagnostic tests, immunizations, and cures. Furthermore, some changes, such as telemedicine, may become the norm even after the coronavirus pandemic is over.

Outbreaks of infectious diseases will continue to provide challenges that may be addressed through nursing research. Nurses are in an excellent position to study ways to effectively prevent the spread of diseases and to contribute to the implementation of strategies to care for infected populations. For example, the intervention of placing patients who were diagnosed with coronavirus in a prone position, rather than with the head of bed elevated, quickly became adopted by nurses.

The coronavirus has not only affected the health care of patients and how healthcare organizations operate, but it may also have major ramifications for the nursing profession. How will the nursing workforce be affected? What changes will occur in the education of nurses? Will individuals still want to enter the nursing profession? Will current nurses want to remain in the profession? These are some of the new research questions that need to be addressed.

CRITICAL THINKING EXERCISE 2-3

Ten years from now, nursing students will study how historical occurrences have shaped the evolution of nursing as a science. Discuss four current events that will be considered to have influenced the development of nursing science.

TEST YOUR KNOWLEDGE 2-2

True/False

1. Nursing research popular in the 1950s involved the study of nursing students.
2. Grand nursing theories were first introduced in the 1980s.
3. In the 1980s, DRGs were a driving force because they focused nursing research on cost-effectiveness.
4. Technological advances created a knowledge explosion that has vastly influenced nursing research.
5. Each historical era contributed to the development of nursing science.

How did you do? 1. T; 2. F; 3. T; 4. T; 5. T

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2.3 What Lies Ahead?

At the end of this section, you will be able to:

- Identify factors that will continue to move nursing forward as a science.
- Discuss which future trends may influence how nurses use evidence to improve the quality of patient care.

Factors similar to those that have propelled nursing research forward through history will continue to be influential into the future. As we continue to move through the 21st century, nursing research will grow in importance as EBP becomes more widely established and patient outcomes come under increased scrutiny. Nursing research agendas will remain driven by social and political influences.

The cycle of scientific development must continue in order to expand the body of nursing knowledge and to recognize nurses for their contributions to health care. Middle range and practice theories that are more useful in clinical settings need to be developed. Nursing research must include studies that replicate previous studies with different populations to confirm prior findings. Studies that demonstrate nursing's contribution to positive health outcomes will be especially important. A commitment to the continued preparation of nurses as scientists is vital to achieve excellence in nursing research. It will be increasingly important for nurses to advocate for monies and to draw on new funding sources. Interdisciplinary and international research will continue to be important as complex health problems are addressed. Technology will continue to offer new ways to communicate research findings to a broader audience, thereby improving diffusion of innovations. Research topics that are most likely to be priorities are listed in **Box 2-2**.

Nursing will continue to be challenged to bridge the gap between research and practice. EBP offers the greatest hope of moving research findings to the point of care. Nursing education must prepare nurses to appreciate the importance of basing patient care on evidence. Educators need to create innovative strategies that teach students to identify clinical problems, use technology to retrieve evidence, read and analyze research, weigh evidence, and implement change. Nurses must accept responsibility for creating their own EBP and collaborating with others to improve patient care.

FYI

The Doctor of Nursing Practice (DNP) degree is the recommended educational requirement for those entering advanced practice nursing. Nurses who are prepared at the doctoral level and who practice in clinical settings can serve as leaders in EBP.

Nurses who work in clinical settings and who are prepared at the doctoral level are especially well positioned to move EBP forward. Healthcare facilities are expected to embrace EBP to achieve Magnet Recognition. International collaborations, such as the Joanna Briggs Institute, are essential so that when best practices are identified they can easily be shared.

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BOX 2-2 Nursing Research Priorities

Bioterrorism
Chronic illness
Cultural and ethnic considerations
End-of-life/palliative care
Genetics
Gerontology
Global warming
Healthcare delivery systems
Health promotion
Immigration
LGBTQ health issues
Management of pandemics/natural disasters
Mental health
Nursing informatics
Opioid epidemic
Patient outcomes/quality of care
Racial health disparities
Safe administration of medications
Symptom management

CRITICAL THINKING EXERCISE 2-4

Recall a question you encountered during your last clinical experience. How might you have answered that question using an EBP approach?

TEST YOUR KNOWLEDGE 2-3

True/False

1. Topics for future research include the opioid epidemic, global warming, and patient outcomes/quality of care.
2. As the cycle of science continues, more middle range and practice theories will emerge that will be useful in clinical settings.

How did you do? 1. T; 2. T

2.4 Keeping It Ethical

At the end of this section, you will be able to:

- Identify five unethical studies involving the violation of the rights of human participants or falsification of data.
- Discuss international and national initiatives designed to promote ethical conduct.
- Describe the rights of participants who volunteer for research studies.
- Describe the three ethical principles from the Belmont Report that must be upheld when conducting research.
- Explain the composition and functions of institutional review boards (IRBs) at the organizational level.

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Five Studies Recognized as Unethical

Scientific research has made significant contributions to the good of society and the health of individuals, but these contributions have not come without cost. In the past, studies have been conducted without regard for the rights of human participants. In fact, even after national and international guidelines were established, unethical scientific research continued. Four major studies involved the violation of the rights of human participants: (1) the Nazi experiments, (2) the Tuskegee study, (3) the Jewish Chronic Disease Hospital study, and (4) the Willowbrook studies. In addition, falsification and fabrication of data by the "red wine researcher" provides another example of misconduct.

During World War II, physicians conducted medical studies on prisoners in Nazi concentration camps (U.S. Holocaust Memorial Museum, 2006). Most of the ***Nazi experiments*** were aimed at determining the limits of human endurance and learning ways to treat medical problems faced by the German armed forces. For example, physicians exposed prisoners of war to mustard gas, made them drink seawater, and exposed them to high-altitude experiments. People were frozen or nearly frozen to death so that physicians could study the body's response to hypothermia. The researchers infected prisoners with diseases so that they could follow the natural course of disease processes. Physicians also continued Hitler's genocide program by sterilizing Jewish, Polish, and Russian prisoners through x-ray and castration. The War Crimes Tribunal at Nuremberg indicted 23 physicians, many of whom were leading members of the German medical community. They were found guilty for their willing participation in conducting "crimes against humanity." Seven physicians were sentenced to death, and the remaining 16 were imprisoned. As a result, the ***Nuremberg Code***, a section in the written verdict, outlined what constitutes acceptable medical research and forms the basis of international codes of ethical conduct. The experiments conducted were so horrific that debate continues about whether the findings from these Nazi studies, or other unethical studies, should be published or even used (Swain, 2019), and publishers must decide whether they will abide by guidelines outlined in the Declaration of Helsinki (University of Missouri–Kansas City, 2020).

In the 1930s, the ***Tuskegee study*** was initiated to examine the natural course of untreated syphilis (Centers for Disease Control and Prevention, 2020). In this study conducted by the U.S. Public Health Service, Black men from Tuskegee, Alabama, were recruited to participate. Informed consent was not obtained, and many of the volunteers were led to believe that procedures, such as spinal taps, were free special medical care. The study compared 399 men with syphilis with 201 men who did not have syphilis. Within 6 years, it

KEY TERMS

Nazi experiments: An example of unethical research using human subjects during World War II

Nuremberg Code: Ethical code of conduct for research that uses human participants

Tuskegee study: An unethical study about syphilis in which participants were denied treatment so that the effects of the disease could be studied

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FYI

In the past, research was conducted with human participants who were not fully informed of the purpose and/or methods of the study. Today, studies must be reviewed to ensure that human participants are protected.

was apparent that many more of the infected men had complications compared with the uninfected men, and by 10 years the death rate was twice as high among the infected men as compared with the uninfected men. Even when penicillin was found to be effective for the treatment of syphilis in the 1940s, the study continued until 1972, and participants were neither informed about nor offered treatment with penicillin.

In 1963, the ***Jewish Chronic Disease Hospital study*** began and involved the injection of foreign, live cancer cells into hospitalized patients with chronic diseases (Hornblum, 2013). The purpose of the study was to examine whether the body's inability to reject cancer cells was due to cancer or the presence of a debilitating chronic illness. Because earlier studies indicated that injected cancer cells were rejected, researchers hypothesized that debilitated patients would reject the cancer cells at a substantially slower rate than healthy participants did. When discussing the study with potential participants, researchers failed to inform them about the injection of cancer cells because researchers did not want to frighten them. Although researchers obtained oral consent, they did not document the consent, claiming that the documentation was unnecessary because it was a standard of care to perform much more dangerous procedures without consent forms. Researchers also failed to inform physicians caring for the patients about the study. At a review conducted by the Board of Regents of the State University of New York, the researchers were found guilty of scientific misconduct, including fraud and deceit.

KEY TERMS

Jewish Chronic Disease Hospital study: Unethical study involving injection of cancer cells into participants without their consent

Willowbrook studies: A series of unethical studies involving coercion of parents to allow their children to participate in the study in exchange for admission to a long-term care facility

Also in the 1960s, a series of studies was conducted to observe the natural course of infectious hepatitis by deliberately infecting children admitted to the Willowbrook State School, an institution for children with mental disabilities (Reimann, 2017). During the ***Willowbrook studies***, administrators claimed overcrowded conditions and stopped admitting patients; however, children could be admitted to the facility if they participated in the hepatitis program. Because at that time facilities to care for children with mental disabilities were few, many parents found they were unable to obtain care for their children and fell victim to being coerced to allow their children to participate in the study.

Unfortunately, ethical violations are not a thing of the past. In 2008, a 3-year investigation was launched at the University of Connecticut into claims of scientific misconduct by Dr. Dipak Das (Callaway, 2012). Dr. Das conducted a

CRITICAL THINKING EXERCISE 2-5

Do you think that the findings from unethical studies should be published? Why or why not?

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series of ***red wine studies*** that focused on the beneficial health effects of red wine and other foods on cardiac health and longevity. He was found guilty of falsifying data in more than two dozen papers and grant applications. This type of behavior creates public distrust of research findings and can also inhibit researchers' ability to recruit participants.

International and National Factors: Guidelines for Conducting Ethical Research

Ethical research exists because international, national, organizational, and individual factors are in place to protect the rights of individuals. Without these factors, scientific studies that violate human rights, such as the Nazi experiments, could proceed unchecked. Many factors of ethical research, which evolved in response to unethical scientific conduct, are aimed at protecting human rights. ***Human rights*** are "rights (such as freedom from unlawful imprisonment, torture, and execution) regarded as belonging fundamentally to all persons" (Merriam-Webster, 2020). Rights cannot be claimed unless they are justified in the eyes of another individual or group of individuals. When individuals have rights, others have ***obligations***; that is, they are required to act in particular ways. This means that when nursing research is being conducted, individuals participating in studies have rights, and all nurses are obligated to protect those rights.

One of the earliest international responses to unethical scientific conduct was the Nuremberg Code. This code was contained in the written verdict at the trial of the German Nazi physicians accused of torturing prisoners during medical experiments. Writers of the Nuremberg Code (**Box 2-3**) identified that voluntary consent was absolutely necessary for participation in research. Research that avoided harm, produced results that benefited society, and allowed participants to withdraw at will was deemed ethical. The Nuremberg Code became the standard for other codes of conduct.

Another example of an international standard is the ***Declaration of Helsinki***, which was adopted by the World Medical Association (WMA) in 1964. Last amended in 2013, the declaration provides guidelines for physicians conducting biomedical research (WMA, 2020). ***Informed consent*** is considered to be the hallmark requirement for the conduct of ethical research (National Cancer Institute, 2020). The 32 articles and two clarifications included in the document address issues such as protecting the health of all patients, obtaining informed consent, and conducting research with the aim of benefiting science and society (WMA, 2020). The Declaration of Helsinki offers more specific detail about what constitutes ethical scientific research than does the Nuremberg Code.

KEY TERMS

red wine studies: Unethical studies involving the fabrication of data about the effects of red wine on heart health

human rights: Rights (such as freedom from unlawful imprisonment, torture, and execution) regarded as belonging fundamentally to all persons

obligations: Requirements to act in particular ways

Declaration of Helsinki: An international standard providing physician guidelines for conducting biomedical research

informed consent: An ethical practice requiring researchers to obtain voluntary participation by participants after they have been informed of possible risks and benefits

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BOX 2-3 Articles of the Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seemed to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably [sic] cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

From Trials of war criminals before the Nuremberg military tribunals under control council law no. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S. G.P.O., 1949–1953. https://www.loc.gov/rr/frd/Military_Law/pdf/NT_war-criminals_Vol-II.pdf

Like the WMA, the American Nurses Association (ANA) was ahead of the federal government in establishing codes of scientific conduct. In 1968, *The Nurse in Research: ANA Guidelines on Ethical Values* was approved by the ANA board of directors. The ANA established the Commission on Nursing Research, whose report emphasized the rights of human participants in three ways: (1) right to freedom from harm, (2) right to privacy and dignity, and (3) right to anonymity. Currently, the ANA (2016) has outlined recommendations for the role of the nurse in ethics and protection of human rights. Similar guidelines have also been created by professional nursing organizations.

Not until the 1970s were federal guidelines about the ethical treatment of human participants formulated (National Cancer Institute, 2020). In 1973, the U.S. Department of Health, Education, and Welfare published the first set of proposed regulations about the protection of human rights. One of the

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most important regulations to emerge was the mandated implementation of ***institutional review boards (IRBs)*** to review and approve all studies. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established in 1974 when the National Research Act was passed. One of the first charges to the commission was to identify basic ethical principles that are foundational to the conduct of ethical scientific research involving human participants. The commission was also charged with developing guidelines to ensure that medical research was conducted in a manner consistent with the principles the commission identified. The result was the ***Belmont Report***, issued in 1979. In the report, three major principles were identified: (1) respect for persons, (2) beneficence, and (3) justice. These same principles provide the foundation for present codes of conduct in many disciplines that conduct research with human participants.

KEY TERMS

institutional review boards (IRBs): Committees that review research proposals to determine whether research is ethical

Belmont Report: A report outlining three major principles—respect for persons, beneficence, and justice—foundational for the conduct of ethical research with human participants

respect for persons: Principle that individuals should be treated as autonomous and that those with diminished autonomy are entitled to protection

autonomous: Having the ability to make decisions

Principles of Ethical Research

To ensure ethical research involving human participants, researchers are obligated to adhere to three principles. These principles are respect for persons, beneficence, and justice (U.S. Department of Health, Education, and Welfare, 1979).

Respect for Persons

In the Belmont Report (U.S. Department of Health, Education, and Welfare, 1979), ***respect for persons*** is based on two ethical convictions. The first conviction is that individuals should be treated as ***autonomous***—that is, as having the ability to make decisions. An autonomous person can deliberate about personal goals and act in accordance with those goals. Nurses are obligated to show respect for the autonomy of others. When they elicit and act upon the opinions of others, nurses are fulfilling their obligations. The second conviction related to the ethical principle of respect for persons is the recognition that persons with diminished autonomy are entitled to protection. Individuals with diminished autonomy, often referred to as vulnerable, include children, individuals with mental disabilities, and prisoners. Some past research studies have violated this right. During the Nazi experiments, individuals were not allowed to refuse participation. In the Jewish Chronic Disease Hospital study, participants were not able to make deliberate decisions because the information about the injection of cancer cells was not shared. Researchers conducting the Willowbrook studies did not allow parents free choice; rather, researchers allowed admission to the facility in return for enrolling children in the study.

FYI

The primary mechanism in place for the protection of human participants at the organizational level (i.e., hospitals, nursing homes, and universities) is the IRB.

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KEY TERMS

beneficence: The principle of doing good

justice: The principle of equity or fairness in the distribution of burdens and benefits

Beneficence

Beneficence is the principle of doing good. In the Belmont Report, two rules were formulated: (1) to do no harm and (2) to maximize possible benefits and minimize possible harm (U.S. Department of Health, Education, and Welfare, 1979). Individuals may face risk of harm while participating in research because in order to learn what is harmful, participants risk being harmed. Therefore, researchers are obligated to identify and reduce possible risks as much as possible. Furthermore, the risks must be justified in light of the possible benefits that may result from the research. The principle of beneficence was not upheld in a number of earlier studies. In the Willowbrook studies, injection of live hepatitis virus created a monumental risk for harm that was not justified by the researchers' rationale that children were at risk for infection because they were institutionalized. Furthermore, learning about the natural course of the disease was not an outcome that could be justified by the high risk for harm. Individuals were also harmed in the Tuskegee studies. Men with syphilis were not offered penicillin even when it was known that penicillin was an effective treatment.

Justice

The principle of ***justice*** is concerned with equity or fairness in the distribution of burdens and benefits. In this third principle identified in the Belmont Report, the main consideration is that individuals ought to be treated equally (U.S. Department of Health, Education, and Welfare, 1979). Nurses and other healthcare providers are obligated to ensure that some groups of participants, such as ethnic minorities or institutionalized individuals, are not selected for studies because they are easily available or in compromised positions. Individuals cannot be denied treatment because they decline to participate in research. Participants cannot receive less than the standard of care. Furthermore, outcomes of publicly funded research need to be reported. Unfair treatment of individuals has been a problem in past studies. In the Tuskegee study, Black men were singled out and were not provided standard care. In the Jewish Chronic Disease Hospital study and the Willowbrook studies, vulnerable participants were targeted.

CRITICAL THINKING EXERCISE 2-6

Which vulnerable groups of individuals were targeted in the Jewish Chronic Disease Hospital study and the Willowbrook studies? Can you think of other groups of individuals who may be at risk for unjust selection?

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The IRB

A number of mechanisms also are in place for the protection of human participants at the organizational level (U.S. Department of Health and Human Services [U.S. DHHS], 2017). The primary mechanism is the IRB. Although the structure and functions of IRBs are federally mandated, organizations are held accountable. Hospitals, nursing homes, and universities commonly have established IRBs because these organizations typically have employees conducting research. Organizations without established IRBs or organizations with established IRBs that do not hold researchers accountable for upholding ethical standards are not eligible for federal funds to conduct research. Furthermore, conducting research without IRB approval is illegal. In 1991, a statutory framework was enacted, and these laws resulted in standards set forth in the Code of Federal Regulations 45 C.F.R. 46, which were last updated in 2017 (U.S. DHHS, 2017). IRBs do not review research involving animals, food and drug testing, and other kinds of research not involving human participants. Components and areas of concern that are reviewed by the IRB are listed in **Table 2-4**.

Federal guidelines stipulate the membership of the IRB (U.S. Department of Health, Education, and Welfare, 2017). The organization that establishes the IRB appoints or invites members to participate. Members are selected because they have knowledge of and experience working with people of vulnerable populations, because the major purpose of the IRB is to protect the rights of vulnerable populations. Members must also have knowledge of the research process and the ethical and legal regulations of research. IRBs must have a minimum of five members. Members' expertise must vary; all members cannot practice in the same discipline. At least one member of the IRB must be employed in a scientific area; at least one member, often a clergy member residing in the community, must be employed in a nonscientific area. At least one member must have no affiliation with the organization and no family member affiliated with the organization. Diversity in membership across gender, race, and culture is encouraged. When conflicts of interest arise, conflicted members must not participate in the review. For example, when a researcher who is a member of the IRB submits a proposal, that researcher is excused from the deliberations about that specific study. Each IRB has a chairperson who is accountable for leading the IRB and who can make decisions about how applications are reviewed.

There are two kinds of review: full and expedited. A ***full review*** is necessary when a proposed research study involves vulnerable populations or when risks are not minimal. A proposal might be eligible for an ***expedited review*** when the research study poses minimal risk to human participants (U.S. DHHS, 2017). ***Minimal risk*** means that the probability and magnitude

KEY TERMS

full review: A type of review by an institutional review board (IRB) that requires all members of the board to participate; an IRB conducts a full review if there is potential risk to human participants

expedited review: A type of review by an institutional review board (IRB) that can occur quickly; an IRB may conduct an expedited review if there is minimal risk to human participants

minimal risk: The probability and magnitude of harm from participating in a research study are not greater than those encountered in daily life

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TABLE 2-4 Components and Areas of Concern Appraised by IRBs

Component	Areas of Concern
Risk–benefit analysis	Are possible risks and benefits identified, evaluated, and described? Are risks greater than minimal risk? Have attempts been made to minimize risks? Will the risk–benefit ratio be reassessed as the study progresses? Are participants receiving less than the standard of care?
Informed consent	Does the study involve vulnerable participants? Is the language appropriate for the participants? Who will explain the study to potential participants? Do participants need to be reinformed about the purpose of the study periodically? Is a waiver of consent justified?
Selection of participants	Does the burden of participating in research fall (most likely) on those who will benefit from the findings? Does the research require using the proposed population? Are there groups of people who will be more susceptible to risk? Have vulnerable participants been overprotected?
Privacy and confidentiality	Does the research involve intrusion? How will information be kept private? Should permission be sought for records? Should documentation of consent be waived to protect confidentiality? Are procedures compliant with Health Insurance Portability and Accountability Act (HIPAA) rules?
Monitoring and observation	How will data be recorded and maintained? Who will have access to the data? Can information be provided to the IRB should unexpected results be discovered?
Additional safeguards	Are recruitment procedures designed to ensure that informed consent is given freely? Does the nature of the disease or behavioral issue permit free consent?
Incentives for participation	Are offered incentives reasonable? Should the IRB monitor participant recruitment to ensure that coercion is not a problem?
Continuing review	Are the actual risks and benefits as anticipated? Has any participant been seriously harmed? Have any unforeseen accidents or problems occurred?

Data from U.S. Department of Health and Human Services. (2017). *Electronic Code of Federal Regulations: Part 46—protection of human subjects.* https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107

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BOX 2-4 Key Points of the Code of Federal Regulations

1. Risks to participants are minimized.
2. The risks to participants are reasonable in relation to anticipated benefits.
3. The selection of participants is equitable.
4. Informed consent must be sought from potential participants or their legal guardians.
5. Informed consent must be properly documented.
6. When appropriate, research plans monitor data collection to ensure participant safety.
7. When appropriate, privacy of participants and confidentiality of data are maintained.
8. Safeguards must be in place when participants are vulnerable to coercion.

Data from U.S. Department of Health and Human Services. (2017). *Electronic Code of Federal Regulations: Part 46—protection of human subjects*. https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107

of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Prior to the review meeting, members of the IRB read the proposals in need of a full review, and then convene to discuss whether each study's protocols meet the requirements of the Code of Federal Regulations (**Box 2-4**). Members vote on whether to approve each study and might make recommendations for changes to researchers. Proposals of studies qualifying for expedited review are read by the chairperson of the IRB, who confirms that expedited review is appropriate and determines whether the standards of the Code of Federal Regulations are being met.

Examples of research qualifying for expedited review include the following:

- Collecting hair and nail clippings
- Collecting excreta and external secretions
- Recording data on participants 18 years or older using noninvasive routine clinical procedures
- Making voice recordings
- Studying existing documents, data, records, and specimens

Certain low-risk studies can be considered ***exempt*** from obtaining consent from individuals (**Box 2-5**). These studies still need IRB approval. These exemptions do not apply to prisoners, pregnant women, fetuses, newborns, and most children (U.S. DHHS, 2017). Researchers should never assume that their proposals qualify for exempt status, but rather must follow the policies specified by their organizations. Most policies require that another person, usually the IRB chairperson, review proposals to ensure that they qualify for exempt status.

KEY TERM

exempt: Certain studies may be low enough risk not to require consent from individuals

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KEY TERMS

therapeutic imperative: An ethical rule stating that nurses should perform actions that benefit the patient

research imperative: An ethical rule stating that nurses should advance the body of knowledge

In many organizations, other factors ensure that research is ethical. Many hospitals also have nursing research committees that review research proposals. These committees are usually composed of staff nurses, nurse managers, advanced practice nurses, and the director of nursing research if there is such a person in the organization.

It is important that nurses recognize that IRB approval does not guarantee that ethical dilemmas will not arise. Nurses have both a duty to care and a duty to advance nursing knowledge. This means that the research imperative must be weighed against the therapeutic imperative. When there is doubt, the ***therapeutic imperative*** must take precedence over the ***research imperative***. It is important that nurses recognize that IRB approval does not guarantee that

BOX 2-5 Examples of Exempt Research

- Research about normal educational practices that are conducted in established or commonly accepted educational settings.
- Most research that involves educational tests (i.e., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.
- Most research involving adults who consent to benign behavioral interventions coupled with the collection of data from verbal, written, or audiovisual recordings in such a manner that the identity of participants cannot be readily determined.
- Research involving analysis of data from existing datasets, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the researcher in such a manner that participants cannot be readily identified.
- Research and demonstration projects conducted by federal departments or agencies that are designed to study, evaluate, or otherwise examine public health benefit or service programs.
- Taste and food-quality evaluation and consumer acceptance studies.

U.S. Department of Health and Human Services. (2017). *Electronic Code of Federal Regulations: Part 46—protection of human subjects*. https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107

CRITICAL THINKING EXERCISE 2-7

A physician comes to the unit and states that she is working in the lab and needs some blood to run a lab test for her research study. The physician asks the nurse to assist with drawing some blood. The physician and nurse enter the room of one of the physician's patients. Without a parent present, the physician asks the 17-year-old patient if she can draw the patient's blood. The adolescent seems reluctant but agrees to the procedure. The physician and nurse draw the blood, and the physician leaves the unit without documenting the procedure. The nurse feels uncomfortable and talks with the charge nurse about the situation. Which ethical principles are violated in this situation? How did the nurse fail to act as a patient advocate? What should the nurse have done to protect the rights of the adolescent? What should the charge nurse recommend?

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ethical dilemmas will not arise. Unanticipated events can lead to unethical conduct, whether intentional or unintentional. Nurses must use their own ethical frameworks to judge whether their actions, or the actions of others, are in the best interest of patients and nursing science.

TEST YOUR KNOWLEDGE 2-4

Match the following.

1. Nazi medical experiments
2. Tuskegee study
3. Jewish Chronic Disease Hospital study
4. Willowbrook studies
5. Red wine studies

a. Infected participants with cancer cells
b. Coerced parents to allow children into study
c. Exposed participants to cold
d. Falsified and fabricated data
e. Failed to treat participants with penicillin

True/False

6. Informed consent is the hallmark of the Declaration of Helsinki.
7. The Belmont Report identified four ethical principles: respect for persons, nonmaleficence, beneficence, and justice.
8. IRB approval must be obtained for studies involving animals, foods, or drugs.
9. A qualitative study of adults that only involves tape recording interviews would likely receive an expedited review.
10. When there is a conflict, the therapeutic imperative takes precedence over the research imperative.

How did you do? 1. c; 2. e; 3. a; 4. b; 5. d; 6. T; 7. F; 8. F; 9. T; 10. T

RAPID REVIEW

- Research is a planned and systematic activity that leads to new knowledge and/or the discovery of solutions to problems or questions.
- Scientific research offers the best evidence for nursing practice.
- Research can be categorized as descriptive, explanatory, or predictive; basic or applied; and quantitative or qualitative.
- By analyzing words, qualitative research focuses on the meanings individuals give to their experiences. Quantitative research views the world as objective and focuses on obtaining precise measurements that are later analyzed.
- Most research articles include an abstract, introduction, review of literature, theoretical framework, and methods, results, and discussion sections, and they conclude with a list of references.
- The cycle of scientific development involves theory, research, dissemination, and application. Social and political factors are central to the cycle.

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- The cycle of scientific development can be seen operating in each historical era.
- Social and political factors will continue to influence nursing research.
- Four studies are recognized for their gross violation of human rights: Nazi medical experiments, the Tuskegee study, the Jewish Chronic Disease Hospital study, and the Willowbrook studies. A fifth study, involving research on the health benefits of red wine, involved falsification or fabrication of data.
- Many national and international entities have made considerable contributions to nursing research and EBP.
- The Nuremberg Code and the Declaration of Helsinki are international guidelines aimed at protecting the rights of human participants.
- Federal laws have been enacted to protect participants who participate in research. National organizations have created codes of conduct for researchers.
- The Belmont Report identified three ethical principles for guiding research: respect for persons, beneficence, and justice.
- IRBs are federally mandated organizational structures that review research proposals to ensure that the rights of human participants are protected. Nursing research committees can also be involved in the protection of human participants.

Apply What You Have Learned

Sign into a nursing database for nursing literature (e.g., CINAHL, Nursing and Allied Health Database, PubMed). For this chapter, you will need to obtain the following two articles:

- Karaoglu, M. K., & Akin, S. (2018). Effectiveness of hygienic hand washing training on hand washing practices and knowledge: A nonrandomized quasi-experimental design. *Journal of Continuing Education in Nursing*, *49*(8), 360–371. https://doi.org/10.3928/00220124-20180718-07

- Løyland, B., Wilmont, S., Hessels, A., & Larson, E. (2016). Staff knowledge, awareness, perceptions, and beliefs about infection prevention in pediatric long-term care facilities. *Nursing Research*, *65*(2), 132–141. https://doi.org/10.1097/NNR.0000000000000136

Identify the various sections of each of these articles. Look for similarities and differences between the quantitative and qualitative articles. After you've done that, you may want to share these articles with nurses during your next clinical experience and consider ways the recommendations can be incorporated into practice.

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