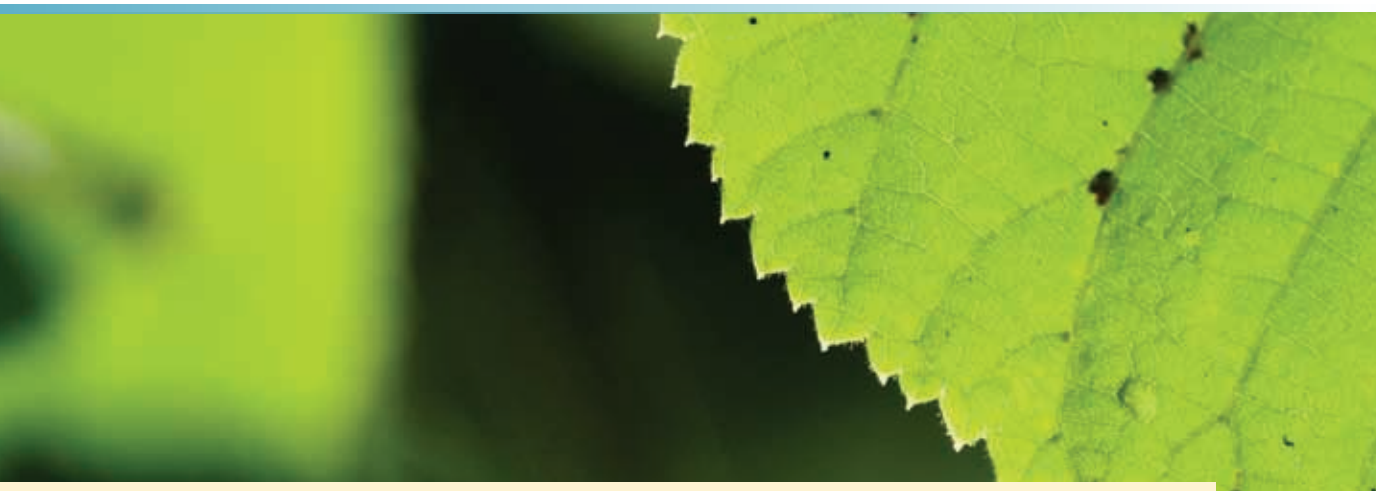


CHAPTER OBJECTIVES

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

- Discuss contributions to evidence-based practice (EBP) made by nurses practicing in various roles
- Examine organizational strategies that facilitate EBP
- Describe regional resources that foster collaborative EBP
- Identify national resources committed to EBP
- List international organizations that are committed to the promotion of EBP
- Discuss international and national initiatives designed to promote ethical conduct
- Describe the rights that must be protected and the three ethical principles that must be upheld when conducting research
- Explain the composition and functions of institutional review boards (IRBs) at the organizational level
- Discuss the nurse's role as patient advocate in research situations

KEY TERMS

autonomous
Belmont Report
beneficence
Declaration of Helsinki
exempt
expedited review
full review
human rights
individual nurse level
informed consent
institutional review boards
international level
justice
minimal risk
model of EBP levels of collaboration
national level
obligations
organizational level
regional level
research imperative
respect for persons
therapeutic imperative
translational research model

CHAPTER 2

Using Evidence Through Collaboration to Promote Excellence in Nursing Practice

Emily Griffin and Marita G. Titler

2.1 The Five Levels of Collaboration

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

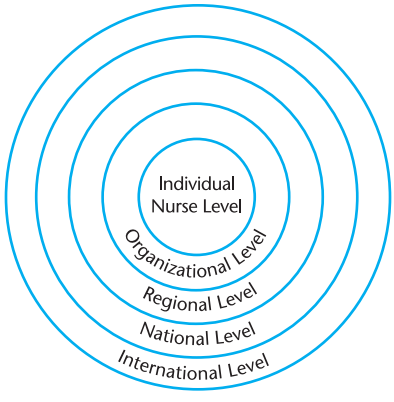
- Discuss contributions to EBP made by nurses practicing in various roles
- Examine organizational strategies that facilitate EBP
- Describe regional resources that foster collaborative EBP
- Identify national resources committed to EBP
- List international organizations that are committed to the promotion of EBP

In the late 1800s, Florence Nightingale followed many of the principles of EBP. Principles of EBP have been present for many years; however, until recently this process was not called EBP nor was EBP fully acknowledged as having an important impact on patient care. A culture of EBP is emerging within nursing through collaborative efforts by nurses and healthcare organizations, as well as by regional, national, and international entities. Nurses need to collaborate at these five levels. **Figure 2-1** illustrates the ***model of EBP levels of collaboration***.

FYI

A culture of EBP is emerging within nursing through collaborative efforts by nurses and healthcare organizations, as well as by regional, national, and international entities. Nurses need to collaborate at these five levels.

FIGURE 2-1 Model of EBP Levels of Collaboration



In the model, the five levels are intertwined with one another. An international entity can be a resource for staff nurses, and they can reciprocate and contribute to EBP nationally and internationally. Nurses or organizations may use regional-level resources to help move EBP projects forward. In return, nurses or organizations assist regional or national resources to advance EBP. For example, a staff nurse may use the Joanna Briggs Institute to find evidence to support an EBP project. When the project is complete, the staff nurse disseminates her work by publishing the project and presenting at an annual Sigma Theta Tau International (STTI) EBP conference. At the conference, the nurse educates other nurses so that best practices can be adopted at their organizations.

Individual Nurse Level

KEY TERMS

Model of EBP levels of collaboration: A model explaining how five levels are intertwined to contribute to EBP

Individual nurse level: Practice changes that can be implemented by an individual nurse

At the ***individual nurse level***, nurses play an integral role in advancing EBP. While it takes a team approach to be successful with EBP, each nurse has a unique set of skills to contribute that helps to advance EBP. Identifying clinical issues, education approaches, and implementation strategies are examples of some contributions that nurses can make to the team. Nurses can assume various roles for the team such as project leader, opinion leader, and mentor.

Staff nurses are an important link between research and the point of care. They are clinical experts and know how to access unit resources. They can contribute by problem solving, collaborating with the team, and acting as change champions. Because staff nurses are integral to EBP, many organizations provide performance criteria for promoting best practices. For example,

performance criteria for staff nurses may include critical thinking, continual questioning of practice, participating in making EBP practice changes, serving as leaders of change in their site of care delivery, and participating in evaluating evidence-based changes in practice (Titler, 2006; see **Table 2-1**).

TABLE 2-1 Sample EBP Performance Criteria for Nursing Roles

Staff Nurse (RN)
< Questions current practices
< Participates in implementing changes in practice based on evidence
< Participates as a member of an EBP project team
< Reads evidence related to one's practice
< Participates in quality improvement (QI) initiatives
< Suggests resolutions for clinical issues based on evidence
Nurse Manager (NM)
< Creates a microsystem that fosters critical thinking
< Challenges staff to seek out evidence to resolve clinical issues and improve care
< Role models EBP
< Uses evidence to guide operations and management decisions
< Uses performance criteria about EBP in evaluation of staff
Advanced Practice Nurse (APN)
< Serves as coach and mentor in EBP
< Facilitates locating evidence
< Synthesizes evidence for practice
< Uses evidence to write/modify practice standards
< Role models use of evidence in practice
< Facilitates system changes to support use of EBPs
Nurse Executive
< Ensures the governance reflects EBP if initiated in councils and committees
< Assigns accountability for EBP
< Ensures explicit articulation of organizational and department commitment to EBP
< Modifies mission and vision to include EBP language
< Provides resources to support EBPs by direct care providers
< Articulates value of EBP to chief executive officer and governing board
< Role models EBP in administrative decision making
< Hires and retains NMs and APNs with knowledge and skills in EBP
< Provides learning environment for EBP
< Uses evidence in leadership decisions
Source: Adapted from Titler, 2006, p. 472.

FYI

APNs are ideally positioned to be opinion leaders and change champions. To promote consistent practice changes, this core group of nurses should include nurses across different shifts to facilitate practice changes.

Nurse managers are also essential to EBP. Their aim is to "get their units on board" with practice changes. They help to set unit expectations by discussing projects with staff and other healthcare providers. Managers facilitate progress by rewarding nurses involved in EBP and assisting noncompliant nurses to improve their performances. "The nurse manager's commitment is critical to project success and can make a significant impact on project outcomes" (Cullen, 2006, p. 471).

Advanced practice nurses (APNs) are EBP experts who facilitate appraisal and synthesis of the literature for the purpose of improving nursing practice. They often are mentors and are thus important to the advancement of EBP in the clinical setting (Shirey, 2006). They help with problem solving, planning, leading, and coaching. As clinical experts, APNs are ideally positioned to be opinion leaders and change champions. Opinion leaders are experts in their fields who facilitate adoption of an innovation through modeling and peer influence. Their sphere of influence is broad, usually encompassing several units or departments (Doumit, Gattellari, Grimshaw, & O'Brien, 2007). Change champions are also experts in their fields and facilitate change by persistence. They often work with a core group of nurses who are also working toward making EBP changes. To promote consistent practice changes, this core group of nurses should include nurses across different shifts to facilitate practice changes.

Nurse executives are responsible for establishing the culture for EBP. They create a culture where making evidence-based decisions and changing practice are valued. It is important for nursing leaders to create a vision that includes EBP and identify methods to sustain this vision. Shirey (2006) states that there is an expectation that nurse leaders will work to maximize the capabilities of the staff and partner with key professional organizations with goals to advance EBP.

Table 2-1 provides examples of performance criteria that may be expected at the individual nurse level (Titler, 2006). It is important to remember that each nurse is part of a team that is moving EBP forward. Specific advantages to teamwork include division of workload, comprehensive problem solving, building "buy-in," and expanding expertise. Overall, teamwork builds a more comprehensive plan for EBP.

Organizational Level

National initiatives and accrediting bodies are supporting EBP and urging healthcare systems to base patient care on evidence. At the ***organizational level***, healthcare systems are finding increased interest from nurses wanting to practice from a research base, needing time to explore EBP, and desiring to

develop excellence in the profession. "The goal of achieving excellence requires development of an organizational capacity, culture, and vision for evidence-based practice" (Cullen, Greiner, Greiner, Bombei, & Comried, 2005, p. 127). Healthcare organizations with a vision to provide excellence in nursing need to have an infrastructure that accommodates what is needed to implement EBP. As organizations restructure to focus on EBP, a culture of EBP is embraced. This culture sets a tone so that nurses know what is valued within the organization. One method for developing this culture is adding value statements about EBP to organizational mission or vision statements. For example, at the University of Iowa Hospitals and Clinics (UIHC), the mission statement is, "to provide high quality patient care based on our strong commitments to practice, education, research, innovation, and collaboration" (UIHC Department of Nursing, 2007). This statement outlines expectations for nursing care at this organization. Other factors that build a culture for EBP include setting performance expectations for individual nurses, integrating EBP into governance structures, and providing recognition and rewards for involvement in EBP. To help build organizational capacity for EBP, it is recommended that responsibility be designated to at least one committee (Cullen et al., 2005). One recommendation is to create four committees: an EBP steering committee, an EBP committee, specialty focus teams, and nursing policy and procedure committees. The EBP steering committee would oversee the other three committees, allocate the resources, and provide support and direction for the work involved with adopting EBP (Hudson, 2005).

FYI

Librarians are important resources for EBP, making them critical partners. They are experts in searching databases such as the *Cumulative Index of Nursing and Allied Health* (CINAHL) and PubMed, and many healthcare librarians specialize in searching for evidence in nursing and medicine.

At the organizational level, the focus is not only about developing a capacity for EBP to take place but also facilitating the adoption of individual EBP protocols. As a social system, organizations can facilitate or impede change. The ***translational research model*** (**Figure 2-2**), which is based on Rogers's model on diffusion of innovation (Rogers, 2003), provides specific strategies that organizations can use to improve adoption of an evidence-based innovation (Titler, 2006; Titler & Everett, 2001). Specific components of this model describe how characteristics of the innovation, communication process, social system, and users lead to the adoption of innovations. Organizational characteristics that influence the use of EBP include providing expectations that policies are evidence based, access to clinical researchers, authority to change practice, and support from peers, administrators, and other disciplines (Titler & Everett, 2001).

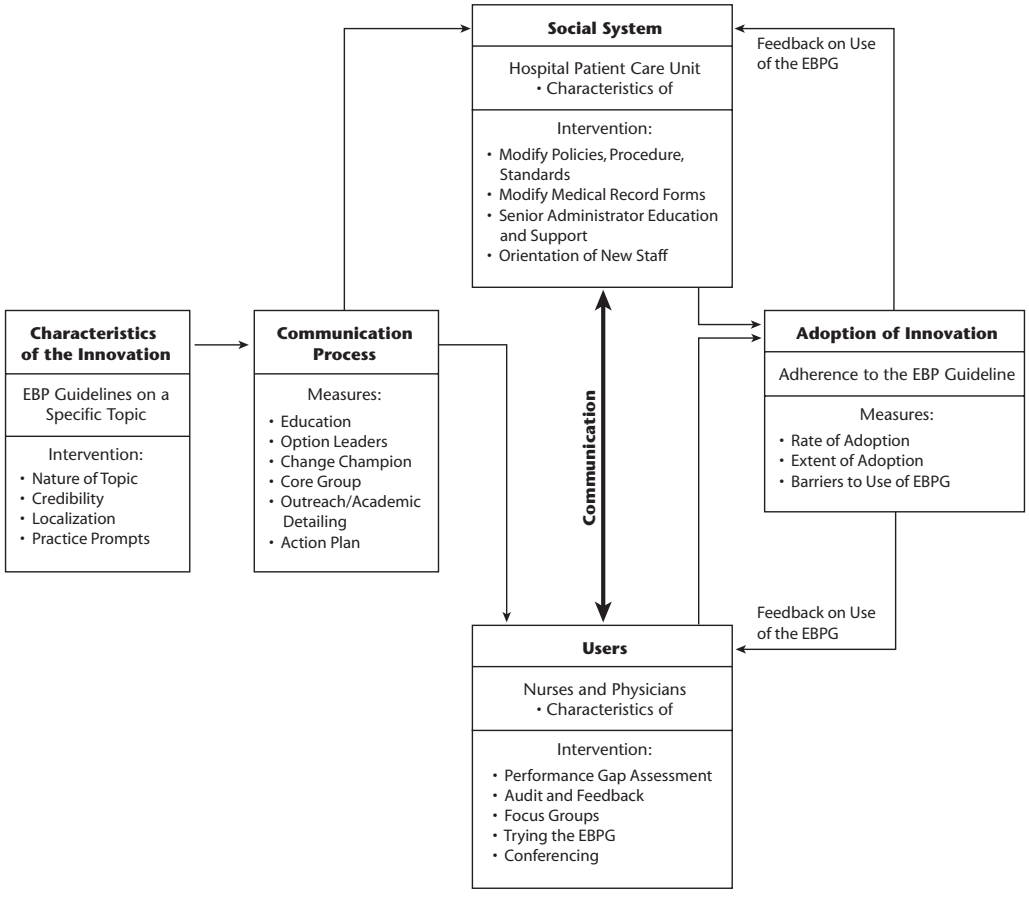
There are four specific interventions described in this model that social systems can use to promote excellence in nursing and move EBP forward. These interventions include modifying policies and standards, modifying medical record forms, senior administrator education and support, and orientation of new staff members.

KEY TERMS

Organizational level: When nurses in an organization affect practice changes

Translational research model: Provides specific strategies organizations can use to improve adoption of an evidence-based innovation

FIGURE 2-2 Translational Research Model



*Based on Rogers's model of Diffusion of Innovation.
Source: Titler, M.G., & Everett, L.Q. (2001). Translating Research into Practice: Considerations for Critical Care Investigators. *Critical Care Nursing Clinics of North America, 13*(4), 587–604. Reproduced with permission from Marita G. Titler, PhD, RN, FAAN; for permission to use and/or reproduce the model, please contact Dr. Titler.

The first intervention is for organizations to include EBP within policies and standards (Titler & Everett, 2001). Policies should be based on evidence, and there should be an attached bibliography with each policy identifying the evidence. For example, the UIHC developed a set of grading schema for each statement within a policy. There is a corresponding article from the bibliography included with each policy. To indicate the type of evidence available, each statement is assigned an R, N, E, or L that corresponds to research article,

national guideline, expert opinion, or literature review. Staff nurses, nurse managers, and APNs serve on committees to develop policies and procedures and collaborate to see them implemented.

Modifying medical record forms or electronic documentation, the second intervention, is an excellent way to help integrate evidence into care (Titler & Everett, 2001). Reassessment of pain after an intervention is an example of a recommended best practice that may not always be followed. A medical record form or electronic documentation field could be modified to include a place for nurses to document pain reassessment, thus increasing compliance with this standard of care. A clinical reminder can be set up within some computerized documentation systems to prompt nurses to reassess patient pain levels.

The third intervention recommended involves supporting education of senior administrators (Titler & Everett, 2001). It is important for leaders to receive frequent updates on EBP activities within the organization. Updates could be given through e-mail or a narrative summary or through rounds with a project team. While it is essential for senior administrators to develop the vision and the organizational culture, they also need to be kept up to date with changes that are being made. Keeping nurse leaders updated enhances the EBP culture while keeping the organization accountable.

The fourth intervention that a social system can implement involves orienting new staff and travel staff (Titler & Everett, 2001). The orientation should send a message that EBP is valued at the organization. New staff members should be made aware of how policies and standards are developed in the organization so they can participate in the process.

Regional Level

At the ***regional level***, collaboration is very important for the advancement of EBP. Using the skills of a local librarian, collaborating with a local program of nursing, and using resources from regional centers of excellence are examples of using regional collaboration.

KEY TERM

Regional level: When nurses from a large geographic area collaborate to change practice

CRITICAL THINKING EXERCISE 2-1

Consider the facilities that you have been to for clinical experiences. Which facilities appear to have embraced EBP? Why do you think that is the case? How are individual nurses involved?

KEY TERM

National level: Collaboration among nurses throughout the country to affect practice changes

It is critical to partner with a local librarian when trying to find the evidence. Many healthcare librarians specialize in searching for evidence in nursing and medicine. Librarians are an important resource for EBP because they are experts in searching databases such as CINAHL, PubMed, and Ovid (DiCenso, 2003). At the University of Iowa, the health sciences library has a program called "housecalls" whereby a librarian comes to your office to facilitate a literature search.

Programs of nursing are another regional resource available for collaboration. It is helpful to use the expertise of faculty to find, synthesize, and appraise the evidence. Some hospital systems match staff nurses with students or professors to appraise literature. Nursing professors can join organizational committees such as research committees, evidence-based planning committees, or quality outcomes committees.

Shirey (2006) identified four EBP regional resource centers of excellence (see **Table 2-2**). These regional centers resource provide resources for nurses and organizations incorporating best practices. Resources include toolkits, intensive training programs, conferences, and specific guidelines that are available for purchase. Most of these centers of excellence provide experts who are available by phone and e-mail to answer questions and guide nurses and organizations through the EBP process.

National Level

On the ***national level***, several entities have made considerable contributions to nursing research and EBP. The Agency for Healthcare Research and Quality (AHRQ) launched an initiative in 1997 to establish EBP centers around the United States. These centers review scientific literature about specific topics and publish technology assessments and evidence reports. The National Guideline Clearinghouse (NGC) is another initiative of AHRQ that maintains a comprehensive database of EBP guidelines. The NGC website provides abstracts of practice guidelines and access to full-text publications (AHRQ, 2007). The National Institute of Nursing Research (NINR) has also significantly contributed to the development of nursing research. NINR is a federal agency that allocates funds for clinical and basic research and research training (NINR, 2007). Funded areas of research are based on social and political factors involving health and illness across the lifespan. Nursing research generated as a result of NINR funding is disseminated for the purpose of improving patient outcomes. Specialty nursing societies, such as the Oncology Nursing Society (ONS) and Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), are other examples of national organizations that facilitate the generation, dissemination, and use of new knowledge. ONS

TABLE 2-2 Regional Resource Centers of Excellence

RRC	Region	Website
University of North Carolina at Chapel Hill	Eastern	http://www.ahrq.gov/clinic/epc/rti-unc.htm
Arizona State University at Tempe	Western	http://nursing.asu.edu/caep/index.htm
University of Iowa Hospitals and Clinics at Iowa City	Midwestern	http://www.uihealthcare.com/depts/nursing/rqom/evidencebasedpractice/index.html
University of Texas at San Antonio	Southern	http://www.acestar.uthscsa.edu/resources_www.htm

has an EBP area on its website. This resource area provides information for starting an EBP project. It provides topic reviews as well as a toolkit with more resources (ONS, 2007). AWHONN regularly publishes EBP guidelines in its journal and website (AWHONN, 2002). The National Nursing Practice Network (NNPN) is committed to the promotion and implementation of EBP through a collaborative model designed to encourage shared learning and participation. The mission of the NNPN is to foster exceptional healthcare outcomes, advance professional nursing practice through application of evidence, support nursing leadership development for EBP, and increase understanding of mechanisms and strategies that foster the use of evidence (NNPN, 2007). The vision of the NNPN is to be a national exemplar of nursing practice excellence, innovation, translation science, and promotion of EBP (NNPN, 2007). The American Nurses Credentialing Center (ANCC) has developed the Magnet Recognition Program to recognize healthcare organizations that provide nursing excellence. This program includes 14 forces of magnetism that are criteria required for organizations to become nationally recognized as Magnet Recognition Program healthcare facilities. Initiatives involving nursing research and EBP must be present to earn Magnet Recognition. For example, the organization must be able to demonstrate a culture that embraces EBP and nursing research. Structures and processes, such as committees, resources, and release time for research endeavors, must be evident. Nurses in direct care are expected to be involved in EBP, quality assurance, and nursing research. This national recognition has increased awareness about the importance of EBP at the individual nurse and organizational levels (ANCC, 2010).

KEY TERM

International level: Changes that result from collaboration among nurses from different countries

International Level

Efforts to enhance EBP are also conducted at the ***international level***. Dr. Archie Cochrane (1971) criticized the medical profession for not providing systematic reviews of evidence from existing studies. In response to this criticism, the Cochrane Center was established 20 years later in Oxford, England. One year after that, The Cochrane Collaboration was established. This international not-for-profit organization is dedicated to making up-to-date, accurate healthcare information available worldwide. The purpose of this establishment is to offer healthcare providers current systematic reviews of medical interventions and treatments. These summary reports are essential because mass media and the Internet provide an abundance of information, making it difficult for practitioners to stay current (The Cochrane Collaboration, 2007). STTI is a leader in the development and dissemination of knowledge to improve nursing practice. This organization has published a position statement on evidence-based nursing and strives to provide nurses with the most current comprehensive resources to assist them with translating evidence into nursing research, education, administration, policy, and practice. STTI presents awards to honor nurses that have demonstrated excellence in research and EBP. For example, the Founder's Award is given for excellence in research. Several specific research awards for research dissemination in nursing and research utilization are also given (STTI, 2007). The Joanna Briggs Institute is an international research and development unit of the Royal Adelaide Hospital, which is located in Adelaide, the capital city of

TEST YOUR KNOWLEDGE 2-1

Match the following:

1. APN	a. Individual nurse level
2. Joanna Briggs Institute	b. Organizational level
3. Policy committee	c. Regional level
4. AHRQ	d. National level
5. Librarian	e. International level
6. NINR	
7. Staff nurse	

How did you do? 1. a; 2. e; 3. b; 4. d; 5. c; 6. d; 7. a

South Australia (Joanna Briggs Institute, 2010). The Institute was established in 1995 and fully operationalized in 1996; it aims to improve the effectiveness of nursing practice and healthcare outcomes. Some initiatives include conducting systematic reviews, collaborating with expert researchers to facilitate development of practice information sheets, and designing, promoting, and delivering short courses about EBP.

2.2 Keeping It Ethical

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

- Discuss international and national initiatives designed to promote ethical conduct
- Describe the rights that must be protected and the three ethical principles that must be upheld when conducting research
- Explain the composition and functions of IRBs at the organizational level
- Discuss the nurse's role as patient advocate in research situations

Ethical research exists because international, national, organizational, and individual factors are in place to protect the rights of individuals. Without these factors, scientific studies, such as the Nazi experiments, could proceed unchecked. Many factors, which evolved in response to unethical scientific conduct, are aimed at protecting human rights. ***Human rights*** are "freedoms, to which all humans are entitled, often held to include the right to life and liberty, freedom of thought and expression, and equality before the law" (Houghton Mifflin Company, 2007). Rights cannot be claimed unless they are justified in the eyes of another individual or group of individuals (Haber, 2006). 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, subjects participating in studies have rights, and all nurses are obligated to protect those rights.

International and National Factors: Guidelines for Conducting Ethical Research

One of the earliest international responses to unethical scientific conduct was the Nuremberg Code. This code was contained in the written verdict given by those presiding at the trial of the German Nazi physicians accused of torturing prisoners during medical experiments. Writers of the Nuremberg Code

KEY TERMS

Human rights: Freedoms to which all humans are entitled

Obligations: Requirements to act in particular ways

KEY TERM

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

(Table 2-3) identified that voluntary consent was absolutely necessary for participation in research. Conduct avoiding harm, producing results that benefit society, and allowing 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 2006, the declaration provides guidelines for physi-

TABLE 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.

Source: U.S. Department of Health and Human Services. (n.d.). *IRB guidebook. Appendix 6* (pp. 7–8). Retrieved August 29, 2010, from http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

cians conducting biomedical research (WMA, 2004). ***Informed consent*** is considered to be the hallmark requirement for the conduct of ethical research (National Cancer Institute, n.d.). 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, 2004). The Declaration of Helsinki offers more specific detail about what constitutes ethical scientific research than does the Nuremberg Code.

KEY TERM

Informed consent: Voluntary participation by research subjects who have been informed of possible risks and benefits

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 (Haber, 2006). The ANA established the Commission on Nursing Research, whose report emphasized the rights of human subjects in three ways: 1) right to freedom from harm, 2) right to privacy and dignity, and 3) right to anonymity. The ANA (1985) published six ethical guidelines for nurses (**Table 2-4**). As a result of these guidelines, all nurses are charged

TABLE 2-4 ANA Guidelines for Protecting the Rights of Human Subjects

Rights/Guidelines	Obligations
Right to Self-Determination	< Employers must inform nurses in writing if participating as a subject in research is a condition of employment. < Potential subjects must be advised of risks and benefits of participation.
Right to Freedom From Risk or Harm	< Nurses must ensure freedom from harm. < Researchers must monitor vulnerable or captive subjects to reduce potential risk of injury.
Scope of Application	< All nurses must ensure that all human subjects enjoy protection of their rights.
Responsibilities to Support Knowledge Development	< All nurses must support the development of scientific knowledge.
Informed Consent	< Nurses must ensure that informed consent from potential subjects (or legal guardians) protects right to self-determination.
Participation on IRB	< Nurses should support inclusion of nurses on IRB. < Nurses have an obligation to serve on IRB.

Source: Adapted from ANA (1985).

KEY TERMS

Institutional review boards: A committee that reviews research proposals to determine that research is ethical

Belmont Report: A report outlining three major principles for the conduct of ethical research with human subjects

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

Autonomous: Having the ability to make decisions

with the responsibility of protecting the rights of all subjects in their care. Similar guidelines have also been created by professional nursing organizations (Ketefian, Bays, Draucker, Herrick, & Lee, 2002).

It was not until the 1970s that federal guidelines about the ethical treatment of human subjects were formulated (National Cancer Institute, n.d.). In 1973, the Department of Health, Education, and Welfare published the first set of proposed regulations about the protection of human rights. One of the most important regulations to emerge was the mandated implementation of ***institutional review boards*** 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 subjects. The commission was also charged with developing guidelines to ensure that medical research was conducted in a manner consistent with the principles it 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 subjects.

Respect for Persons

In the Belmont Report (U.S. Department of Health and Human Services [USDHHS], n.d.), ***respect for persons*** is based on two ethical convictions. The first conviction is that individuals should be treated as ***autonomous***, that is, 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 (USDHHS, n.d.). 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 studies, subjects 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, but rather they used admission to the facility in return for enrolling children in the study.

FYI

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

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 (USDHHS, n.d.). Individuals may face risk of harm while participating in research because in order to learn what is harmful, subjects 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 rationale provided by researchers 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 it was an effective treatment.

KEY TERMS

Beneficence: The principle of doing good

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

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 (USDHHS, n.d.). Nurses and other healthcare providers are obligated to ensure that some groups of subjects, such as ethnic minorities or institutionalized individuals, are not being selected for studies because they are easily available or in compromised positions. Individuals cannot be denied treatment because they decline to participate in research. Subjects 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, African American men were singled out and were not provided standard of care. Vulnerable subjects were also targeted in the Jewish Chronic Disease Hospital study and Willowbrook studies.

FYI

Individual nurses are accountable for ensuring that the rights of subjects are protected, which means they must be familiar with international, national, and organizational standards.

CRITICAL THINKING EXERCISE 2-2

What 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?

Organizational Factors: The IRB

There are also mechanisms in place for the protection of human subjects at the organizational level. 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 are organizations that 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 (National Cancer Institute, n.d.). Research involving animals, food and drug testing, or others kinds of research that do not involve human subjects is not reviewed by an IRB. Components and areas of concern that are reviewed by the IRB are listed in **Table 2-5**.

Federal guidelines stipulate membership of the IRB (USDHHS, n.d.; National Cancer Institute, n.d.). Members are appointed or invited to participate

TABLE 2-5 Components and Areas of Concern Appraised by IRB

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 subjects receiving less than the standard of care?
Informed Consent	
	< Does the study involve vulnerable subjects? < Is the language appropriate for the subjects? < Who will explain the study to potential subjects? < Do subjects need to be reinformed about the purpose of the study periodically? < Is a waiver of consent justified?

Component	Areas of Concern
Selection of Subjects	
	< 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 subjects 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 subject recruitment to ensure that coercion is not a problem?
Continuing Review	
	< Are the actual risks and benefits as anticipated? < Has any subject been seriously harmed? < Have any unforeseen accidents or problems occurred?

Source: Adapted from USDHHS (n.d.).

KEY TERMS

Full review: An IRB conducts a full review if there is potential risk to human subjects

Expedited review: An IRB may conduct an expedited review if there is minimal risk to human subjects

Minimal risk: The probability and magnitude of risk are not greater than those encountered in daily life

by the organization that is establishing the IRB. They are selected because they have knowledge of and experience in working with people of vulnerable populations because the major purpose of the IRB is to protect the rights of vulnerable populations. Knowledge of the research process and the ethical and legal regulations of research are also expected of members. There must be a minimum of five members. Their expertise must vary because all members cannot practice in the same discipline. At least one member of the IRB must be employed in a scientific area, and at least one member, often a clergy member residing in the community, must be employed in a nonscientific area. There must be at least one member of the IRB who is not affiliated with the organization and has no family member who is affiliated with the organization. Membership must include both men and women. When conflicts of interest arise, members must not participate in the review. For example, if a researcher who is a member of the IRB has submitted 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 vulnerable populations are involved or when risks are not minimal. Prior to the meeting, members of the IRB read proposals. Members then convene to discuss whether protocols meet the requirements of the Code of Federal Regulations (Table 2-6). A vote is taken whether or not to approve the studies, and recommendations for changes may be made to researchers. Proposals may be eligible for an ***expedited review*** when there is minimal risk to human subjects (USDHHS, n.d.). ***Minimal risk*** means that the probability and magnitude 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. Examples of research qualifying for expedited review include:

- Collection of hair and nail clippings
- Collection of excreta and external secretions
- Recording data on subjects 18 years or older using noninvasive routine clinical procedures
- Voice recordings
- Study of existing documents, data, records, and specimens

Proposals of studies qualifying for expedited reviews 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 Regulation are being met.

TABLE 2-6 Key Points of the *Code of Federal Regulations*

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

Source: Adapted from National Cancer Institute (n.d.).

Certain low-risk studies can be considered ***exempt*** from obtaining consent from individuals. These studies still need IRB approval. There are six exempt categories of research (**Table 2-7**). These exemptions do not apply to prisoners, pregnant women, fetuses, newborns, and most children (National Cancer Institute, n.d.). Researchers should never assume that their proposals qualify for exempt status, but rather they must follow the policies specified in 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

It is becoming more common for the IRB to require review of EBP projects. The reason is because personal data, for example demographic information or

CRITICAL THINKING EXERCISE 2-3

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 if she can draw some 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. What principles are being violated? 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?

TABLE 2-7 Six Categories Of Exempt Research

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research involving the use of educational tests (i.e., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: a) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to them. b) Any disclosure of the human participant's responses outside the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
3. Research involving the use of educational tests (i.e., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item (2) of this list, if: a) The participants are elected or appointed public officials or candidates for public office. b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that participants cannot be identified, directly or through identifiers linked to them.
5. Research and demonstration projects conducted by or subject to the approval of Federal department or agency heads and designed to study, evaluate, or otherwise examine public health benefit or service programs.
6. Taste and food-quality evaluation and consumer acceptance studies.
Source: National Cancer Institute (n.d.).

patient outcomes, may be collected to be shared publically. Because there is growing interest in EBP, data from such projects are being shared at conferences and in publications. Sometimes it is not until the end of a project that nurses consider the possibility of publically sharing their findings. At this point, it may be unethical to present findings, especially if personal data were collected without consent. Therefore, it is wise for nurses who are initiating EBP projects to obtain IRB approval prior to implementing data collection even when they do not anticipate publically sharing findings.

In many organizations, there are other factors that ensure ethical research. Many hospitals also have nursing research committees that review research proposals. These committees are usually composed of staff nurses, nurse man-

agers, advanced practice nurses, and the director of nursing research if there is such a person in the organization.

Individual Factors: Nurses as Patient Advocates

Individual nurses are accountable for ensuring that the rights of subjects are protected. The ANA has charged nurses to be patient advocates. Thus, nurses must be familiar with international, national, and organizational standards to be effective in their roles as patient advocates. Nurses must be able to distinguish between advocacy and science. Nurses have both a duty to care and 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. Nurses can act as patient advocates in a variety of ways. Nurses should be certain that subjects never receive treatment that is less than the standard of care and that participation in research is chosen freely by subjects. Ensuring that HIPAA guidelines are followed when data are collected advocates for the privacy of patients and confidentiality of information. When subjects express the desire to withdraw from a study, nurses can assist by contacting the researcher. If unethical behaviors are observed, nurses should report them to chairpersons of the IRBs at their institutions. Nurses can also contribute by participating on IRBs and nursing research committees.

KEY TERMS

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

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

TEST YOUR KNOWLEDGE 2-2

True/False

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

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

It is imperative that nurses recognize that IRB approval does not guarantee that ethical dilemmas will not arise. Unanticipated events can lead to unethical conduct, either intentionally or unintentionally. Nurses must use their own ethical frameworks for judging whether their actions, or the actions of others, are in the best interest of patients and nursing science.

RAPID REVIEW

- The model of EBP levels of collaboration has five levels: individual nurse level, organizational level, regional level, national level, and international level.
- Nurses, in a variety of roles, contribute to creating EBP. They can identify clinical problems, participate in EBP changes, serve as change agents or opinion leaders, or establish a vision for the organization.
- Organizational factors that build a culture for EBP include setting performance expectations for individual nurses, integrating EBP into governance structures, and providing recognition and rewards for involvement in EBP.
- Interventions that social systems can use to promote excellence in nursing and move EBP forward include modifying policies and standards, modifying medical record forms, senior administrator education and support, and orientation of new staff members.
- Regional interventions include using skills of a local librarian, collaborating with a local program of nursing, and using resources from regional centers.
- Many national and international entities have made considerable contributions to nursing research and EBP.
- The Nuremberg Code and the Declaration of Helsinki are international factors aimed at protecting the rights of human subjects.
- Federal laws have been enacted to protect subjects participating 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 subjects are protected. Nursing research committees can also be involved in the protection of human subjects.

APPLY WHAT YOU HAVE LEARNED

The National Cancer Institute offers a free web-based course about protecting the rights of human subjects. Many researchers complete this tutorial as a requirement for obtaining federal funds. Visit the National Cancer Institute website at http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp. Sign in, take the tutorial, and print your certificate. Successfully completing the tutorial means that you can qualify to be a research assistant over the next 2 years!

Nurses are expected to act as patient advocates by ensuring that their rights are upheld. Nurses are also expected to facilitate the development of scientific knowledge in nursing.

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