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

- Discuss contributions to evidence-based practice (EBP) nurses practicing in various roles have made
- 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
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 nurses practicing in various roles have made
- 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 evidence-based practice (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. Development of a culture of EBP is under way in nursing through collaborative efforts by nurses and healthcare organizations, as well as by regional, national, and international entities. Collaboration is critical for success with EBP, and Figure 2-1 illustrates the model of EBP levels of collaboration. Nurses need to understand how they can maximize their collaborative efforts at all five levels.
In the model, the five levels are intertwined with one another. An international entity can be a resource for staff nurses, and nurses 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.

### FIGURE 2-1 Model of EBP Levels of Collaboration

- **Individual Nurse Level**
- **Organizational Level**
- **Regional Level**
- **National Level**
- **International Level**

### Individual Nurse Level

At the *individual nurse level*, nurses play an integral role in advancing EBP. Although 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 is an example of 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. Essential for implementation, staff nurses are often the adopters of the EBP change. They can be designated as group leaders to help with planning and troubleshooting during the implementation phase (Cullen & Adams, 2012).

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, 2014; see Table 2-1).

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.
through 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.

Nurse executives are responsible for establishing the culture for EBP. They create a culture in which making evidence-based decisions and changing practice are valued. It is important for nursing leaders to create a vision that
includes EBP and to identify methods to sustain this vision. This can include celebrating successes or providing individual recognition during public forums (Cullen & Adams, 2012). Shirey (2006) states that nurse leaders are expected to work to maximize the capabilities of the staff and to 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, 2014). It is important to remember that each nurse is part of a team that is moving EBP forward. Specific advantages of 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 support EBP and urge healthcare systems to base patient care on evidence. At the organizational level, healthcare systems are finding increased interest from nurses who want to practice from a research base, need time to explore EBP, and desire 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 of providing excellence in nursing need an infrastructure that accommodates EBP. As organizations restructure to focus on EBP, they embrace a culture of EBP. 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, 2013). 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, a specialty focus team, and a nursing policy and procedure committee. The EBP steering committee oversees the other three committees, allocates the resources, and provides support and direction for the work involved with adopting EBP (Hudson, 2005).
At the organizational level, the focus is not only on developing a capacity for EBP to take place but also on facilitating the adoption of individual EBP protocols. As social systems, organizations can facilitate or impede change. The *translational research model* (Figure 2-2), which is based on Rogers's model of diffusion of innovations (Rogers, 2003), provides specific strategies that organizations can use to improve adoption of an evidence-based innovation (Titler, 2014; Titler & Everett, 2001). 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 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).

As social systems, organizations can use four specific interventions described in this model to promote excellence in nursing and move EBP forward. These interventions include modifying policies and standards, modifying medical record forms, ensuring senior administrators are educated and provide support, and orienting new staff members.

The first intervention is for organizations to include EBP within policies and standards (Titler & Everett, 2001). Policies should be based on evidence. For example, the UIHC developed a schema for rating the type of evidence for each statement within a policy. To indicate the type of evidence available, each statement is assigned an R, N, E, or L, which stands for research article, national guideline, expert opinion, or literature review, respectively. At the end of the policy, full citations are provided for each piece of evidence cited in the policy. 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 practitioners might not always follow. As a way to increase compliance with this standard of care, a medical record form or electronic documentation field could be modified to include a place for nurses to document pain reassessment. Similarly, 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 email or as a narrative summary or through rounds with a project team. It is essential for senior administrators to develop the
FIGURE 2-2 Translational Research Model

Characteristics of the Innovation
- EBP Guidelines on a Specific Topic
  - Intervention: Nature of Topic, Credibility, Localization, Practice Prompts

Communication Process
- Measures:
  - Education
  - Option Leaders
  - Change Champion
  - Core Group
  - Outreach/Academic Detailing
  - Action Plan

Social System
- Hospital Patient Care Unit
- Intervention:
  - Modify Policies, Procedure, Standards
  - Modify Medical Record Forms
  - Senior Administrator Education and Support
  - Orientation of New Staff

Adoption of Innovation
- Adherence to the EBP Guideline
  - Measures:
    - Rate of Adoption
    - Extent of Adoption
    - Barriers to Use of EBPG

Users
- Nurses and Physicians
  - Intervention:
    - Performance Gap Assessment
    - Audit and Feedback
    - Focus Groups
    - Trying the EBPG
    - Conferencing

Feedback on Use of the EBPG

*Based on Rogers’s model of Diffusion of Innovation.

Source: Titler, M.G., & Everett, L.Q. (2001). Translating Research Into Practice: Considerations for Clinical Care Investigators. Critical Care Nursing Clinics of North America, 13(4), 587–604. Reproduced with permission from Maria G. Titler, PhD, RN, FAAN; for permission to use and/or reproduce the model, please contact Dr. Titler.
vision and the organizational culture, and they 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.

It is imperative to find a model that is clear to those using the model and that matches the organization’s values. Many models continue to be developed and adapted to fit an organization. For example, Schaffer, Sandau, and Diedrick (2013) reviewed several models, such as the ACE Star Model of Knowledge Transformation and the Iowa model of EBP, that can be used within an organization to facilitate EBP.

**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.

It is critical for nurses to partner with a local librarian when trying to find 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” in which librarians call on individual researchers in their offices to facilitate a literature search.

Programs of nursing are another regional resource available for collaboration. The expertise of faculty can help nurses 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.

**CRITICAL THINKING EXERCISE 2-1**

Consider the facilities where you have been for clinical experiences. Which facilities appear to have embraced EBP? Why do you think that is the case? How are individual nurses involved?
Quality improvement committees or programs provide another opportunity for collaboration. These committees might be groups from within or outside the hospital setting. For instance, a unit-based committee might be formed to address infection rates. Examples of groups operating outside the hospital setting are a workgroup for fall prevention and a childhood obesity task force. Communities continue to develop and expand these types of workgroups, which often include nurses, public health employees, community members, parents, and other involved individuals. Okihiro, Pillen, Ancog, Inda, and Sehgal (2013) reported about a community collaborative project to improve childhood obesity. They used the chronic care model and its adaptation, the obesity care model, to guide the collaboration between primary healthcare, community-based, and public health approaches to support self-management. Evidence-based strategies included changing clinic personnel to include a dietician and pediatric clinical psychologist. The dietician met with children during their wellness visits. The authors also aligned the electronic medical record with obesity management best practice guidelines. The Department of Pediatrics and university provided research resources, infrastructure for training, and salary support. This EBP project shows how regional resources can be maximized to improve patient outcomes.

Shirey (2006) identified four EBP regional resource centers of excellence (see Table 2-2). These regional centers provide resources for nurses and

<table>
<thead>
<tr>
<th>Regional Resource Center</th>
<th>Region</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Iowa Hospitals and Clinics at Iowa City</td>
<td>Midwestern</td>
<td><a href="http://www.nursing.uiowa.edu/excellence/evidence-based-practice-guidelines">http://www.nursing.uiowa.edu/excellence/evidence-based-practice-guidelines</a></td>
</tr>
<tr>
<td>University of Texas at San Antonio</td>
<td>Southern</td>
<td><a href="http://www.acestar.uthscsa.edu/acestar-model.asp">http://www.acestar.uthscsa.edu/acestar-model.asp</a></td>
</tr>
</tbody>
</table>
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 email 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; http://www.ahrq.gov) 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 (http://www.guideline.gov/) provides abstracts of practice guidelines and access to full-text publications. 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, n.d.). Funded areas of research are based on social and political factors involving health and illness across the life span. 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 has an EBP area on its website (https://www.ons.org/practice-resources/pep) that provides information for starting an EBP project, topic reviews, and a toolkit with more resources. AWHONN regularly publishes EBP guidelines in its journal and on the website (http://www.awhonn.org/awhonn/index.do). The American Society of PeriAnesthesia Nurses provides position statements, standards of care, and forums in which to post questions and discussions to encourage collaboration (see http://www.aspan.org/).

The National Nursing Practice Network (NNPN; http://www.nnpnetwork.org) 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. The vision of the NNPN is to be a national exemplar of nursing practice excellence, innovation, translation science, and promotion of EBP.

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 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, 2013).

National associations, such as the American Heart Association (AHA) and the American Diabetes Association (ADA), continue to expand to provide patients and healthcare professionals with evidence-based guidelines and clinic practice recommendations. Many of these associations or foundations have a disease-specific focus. Other examples of national associations or foundations include the Crohn’s and Colitis Foundation of America, the American Lung Association, and the Asthma and Allergy Foundation.

Healthcare professionals can also find national evidence-based point-of-care resources such as DynaMed and Up to Date. A part of EBSCO, DynaMed provides the CINAHL database, which offers clinical references for nurses, physicians, pharmacists, physical therapists, and other healthcare professionals. Up to Date, a Wolters Kluwer Health product, also provides point-of-care solutions for the healthcare industry. The Institute of Medicine brief report discusses the importance of decision support and point-of-care tools (Smith, Saunders, Stuckhardt, & McGinnis, 2012). The authors of the report suggest that these tools be developed, accessible, and evidence-based through research organizations, advocacy organizations, and professional specialty societies, as well as emphasized within education programs. National collaboration continues to expand, and nurses can use these evidence-based recommendations at the point of care.
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 (see http://www.cochrane.org/). 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.

STTI is a leader in the development and dissemination of knowledge to improve nursing practice (see http://www.nursingsociety.org). 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 who 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.

The Joanna Briggs Institute is an international research and development unit of the Royal Adelaide Hospital, which is located in Adelaide, South Australia (see http://www.joannabriggs.org). The institute was established in 1995 and became

**KEY TERM**

**International Level**

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The Joanna Briggs Institute is an international research and development unit of the Royal Adelaide Hospital, which is located in Adelaide, South Australia (see http://www.joannabriggs.org). The institute was established in 1995 and became

**TEST YOUR KNOWLEDGE 2-1**

Match the following entities to the corresponding level of collaboration they provide:

1. APN  
2. Joanna Briggs Institute  
3. Policy committee  
4. AHRQ  
5. Librarian  
6. NINR  
7. Staff nurse  

a. Individual nurse level  
b. Organizational level  
c. Regional level  
d. National level  
e. International level

How did you do? 1. a; 2. e; 3. b; 4. d; 5. c; 6. d; 7. a
fully operational 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 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 “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, 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 at the trial of the German Nazi physicians accused of torturing prisoners during medical experiments. Writers of the Nuremberg Code (*Table 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, 2013). 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

### KEY TERM

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

### TABLE 2-3 Articles of the Nuremberg Code

<table>
<thead>
<tr>
<th>Article</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The voluntary consent of the human subject is absolutely essential.</td>
</tr>
<tr>
<td>2.</td>
<td>The experiment should be such as to yield fruitful results for the good of society, unprocu rable by other methods or means of study, and not random and unnecessary in nature.</td>
</tr>
<tr>
<td>3.</td>
<td>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.</td>
</tr>
<tr>
<td>4.</td>
<td>The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.</td>
</tr>
<tr>
<td>5.</td>
<td>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.</td>
</tr>
<tr>
<td>6.</td>
<td>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.</td>
</tr>
<tr>
<td>7.</td>
<td>Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.</td>
</tr>
<tr>
<td>8.</td>
<td>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.</td>
</tr>
<tr>
<td>9.</td>
<td>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.</td>
</tr>
<tr>
<td>10.</td>
<td>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.</td>
</tr>
</tbody>
</table>

of benefiting science and society (WMA, 2013). The Declaration of Helsinki offers more specific detail about what constitutes ethical scientific research than does the Nuremberg Code.

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). 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. ANA (1985) published six ethical guidelines for nurses (*Table 2-4*). As a result of these guidelines, all nurses are charged 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).

**KEY TERM**

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

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

<table>
<thead>
<tr>
<th>Rights/ Guidelines</th>
<th>Obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right to Self-Determination</td>
<td>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.</td>
</tr>
<tr>
<td>Right to Freedom from Risk or Harm</td>
<td>Nurses must ensure freedom from harm. Researchers must monitor vulnerable or captive subjects to reduce potential risk of injury.</td>
</tr>
<tr>
<td>Scope of Application</td>
<td>All nurses must ensure that all human subjects enjoy protection of their rights.</td>
</tr>
<tr>
<td>Responsibilities to Support Knowledge Development</td>
<td>All nurses must support the development of scientific knowledge.</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>Nurses must ensure that informed consent from potential subjects (or legal guardians) protects right to self-determination.</td>
</tr>
<tr>
<td>Participation on IRB</td>
<td>Nurses should support inclusion of nurses on IRB. Nurses have an obligation to serve on IRB.</td>
</tr>
</tbody>
</table>

Not until the 1970s were federal guidelines about the ethical treatment of human subjects 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 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 subjects.

**Belmont Report:**
A report outlining three major principles (respect for persons, beneficence, and justice) foundational for the conduct of ethical research with human subjects.

**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, 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, 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.

**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, 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 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 subjects, 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. 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, black men were singled out and were not provided standard care. In the Jewish Chronic Disease Hospital study and the Willowbrook studies, vulnerable subjects were targeted.

**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 organizations typically have employees con-
ducting 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.). IRBs do not review research involving animals, food and drug testing, and other kinds of research not involving human subjects. Components and areas of concern that are reviewed by the IRB are listed in Table 2-5.

Federal guidelines stipulate membership of the IRB (National Cancer Institute, n.d.; U.S. Department of Health, Education, and Welfare, 1979). 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Areas of Concern</th>
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<tr>
<td>Risk/benefit analysis</td>
<td>Are possible risks and benefits identified, evaluated, and described?</td>
</tr>
<tr>
<td></td>
<td>Are risks greater than minimal risk?</td>
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<td></td>
<td>Have attempts been made to minimize risks?</td>
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<td></td>
<td>Will the risk/benefit ratio be reassessed as the study progresses?</td>
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<td></td>
<td>Are subjects receiving less than the standard of care?</td>
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<tr>
<td>Informed consent</td>
<td>Does the study involve vulnerable subjects?</td>
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<td></td>
<td>Is the language appropriate for the subjects?</td>
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<td>Who will explain the study to potential subjects?</td>
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<td></td>
<td>Do subjects need to be reinformed about the purpose of the study periodically?</td>
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<td></td>
<td>Is a waiver of consent justified?</td>
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<tr>
<td>Selection of subjects</td>
<td>Does the burden of participating in research fall (most likely) on those who will</td>
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<td></td>
<td>benefit from the findings?</td>
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<td></td>
<td>Does the research require using the proposed population?</td>
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<td></td>
<td>Are there groups of people who will be more susceptible to risk?</td>
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<td></td>
<td>Have vulnerable subjects been overprotected?</td>
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<tr>
<td>Privacy and confidentiality</td>
<td>Does the research involve intrusion?</td>
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<td>How will information be kept private?</td>
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<td>Should permission be sought for records?</td>
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<td></td>
<td>Should documentation of consent be waived to protect confidentiality?</td>
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<tr>
<td></td>
<td>Are procedures compliant with Health Insurance Portability and Accountability</td>
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<td></td>
<td>Act (HIPAA) rules?</td>
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</tbody>
</table>

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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 because 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. Membership must include both men and women. 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 subjects (U.S. Department of Health, Education, and Welfare, 1979). 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.
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 (Table 2-6). Members vote on whether or not 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 subjects 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. 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 by their

**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: Data from National Cancer Institute (n.d.).
| 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 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: Data from National Cancer Institute (n.d.).

organizations. Most policies require that another person, usually the IRB chairperson, review proposals to ensure that they qualify for exempt status.

It is becoming more common for IRBs to require EBP projects to be reviewed, especially when personal data, for example, demographic information or patient outcomes, are to be collected. Because interest in EBP is growing, data from such projects are being shared at conferences and in publications. Sometimes nurses do not consider the possibility of publicly sharing their findings until the end of a project, but 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 sharing findings publicly.

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, APNs, 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. ANA has charged nurses to be patient advocates. Thus, nurses must be familiar with international, national, and organizational standards to be effective in their role as patient advocate. 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 receive treatment that meets the standard of care and that subjects choose freely to participate in research. 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 nurses observe unethical behaviors, they should report these violations to the chairperson of the IRB at their institution. 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

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 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?
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, 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.

**Rapid Review**

- The model of EBP 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, and 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, educating senior administrators and garnering their support, and orienting new staff members.

**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.

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 guidelines aimed at protecting the rights of human subjects.

Federal laws have been enacted to protect subjects 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 subjects are protected. Nursing research committees can also be involved in the protection of human subjects.

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

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://phrp.nihtraining.com/users/login.php. 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!

REFERENCES


References


