Evidence-Based Nursing Regulation: A Challenge for Regulators

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These are complex times for regulators on nursing boards, particularly in three areas. First, they must stay abreast of emerging practice issues emanating from technological advances, systems thinking, a more diverse patient population living longer with multiple chronic illnesses, and a national focus on patient safety and error prevention. Second, there has been a national call for the transformation of nursing education (Benner, Sutphen, Leonard, & Day, 2009; Greiner & Knebel, 2003), and nursing boards are seeing increasing numbers of substandard or fraudulent nursing education programs. This adds to the boards' workload. Third, disciplinary activity involving nurses has increased during the last 10 years (National Council of State Boards of Nursing, 2009), forcing regulators to stay on their toes regarding disciplinary action and investigation. In this challenging climate, the time is ripe to focus on evidence-based regulation as a strategy for making quality decisions related to regulation.

Learning Objectives

- Describe evidence-based nursing regulation
- Discuss the six steps of evidence-based nursing regulation
- Identify at least three strategies for implementing evidence-based nursing regulation

These are complex times for regulators on nursing boards. They must stay abreast of emerging practice issues emanating from technological advances, systems thinking, a more diverse patient population living longer with multiple chronic illnesses, and a national focus on patient safety and error prevention. Concomitantly, there has been a national call for the transformation of nursing education (Benner, Sutphen, Leonard, & Day, 2009; Greiner & Knebel, 2003). When considering whether to approve nursing education programs, nursing boards must be responsive to educators working to improve their teaching strategies.

Yet boards also must be aware of innovations that are ineffective. Furthermore, they are seeing increasing numbers of substandard or fraudulent nursing education programs (most likely because of the nursing shortage); this adds to their workload. At the same time, disciplinary activity involving nurses has increased during the last 10 years (National Council of State Boards of Nursing [NCSBN], 2009), forcing regulators to stay on their toes regarding disciplinary action and investigation. In this challenging era, the time is ripe to focus on evidence-based regulation.

Foundation of Evidence-Based Regulation

Nursing, medicine, and the allied health fields each possess a body of knowledge, which together inform evidence-based health care. Evidence-based health care is the umbrella under which evidence-based regulation falls, along with evidence-based practice and evidence-based education (see Figure 1). All three realms inform each other and provide evidence for establishing health-care policies.

Defining Evidence-Based Regulation

A well-accepted definition of evidence-based medicine is "the integration of best research evidence with clinical expertise and patient values" (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000, p. 1). Reaching beyond medicine, this definition is preferred because it addresses clinical expertise and patient values in addition to the best evidence.

For nurse regulators, incorporating patient values into the definition is particularly important because the mission of BONs is to protect the public. Integrating expertise into the definition also is crucial in light of the paucity of research available.

Ridenour (2009) states there is no consensus on a definition of evidence-based regulation. However, she adapts three global definitions (see Table 1). Pawson (2006, p. 20) does not present a formal definition when discussing evidence-based policy, but asks a crucial yet simple question: What works? In essence, he is asking:

- How do the regulations bring about their effects?
- How do the regulations intervene?
- What is the nature of the causality of regulations?

Ridenour (2009, p. 280) provides the following examples of specific questions nurse regulators might ask:

- Why are we conducting licensing and investigative programs this way?
- If we don't fix a particular issue, is the public or the board at risk?
- Why have we failed to solve problems and complaints from the public that we have known about for some time?

Differentiating Evidence-Based Health Care and Research Utilization

Although today's buzz term is *evidence-based health care,* in the 1980s and 1990s it was *research utilization* (Polit & Beck, 2004). According to Titler (2006), *research utilization* is the narrower term and addresses the use of findings from a study or set of studies in a practical application unrelated to the original investigation. The goal of research utilization is to translate research findings into actual situations. In contrast, the goal of evidence-based practice is to make decisions by using the best possible evidence.

Titler (2006, p. 441) points out that although *research utilization* and *evidence-based practice* sometimes are used interchangeably, their meanings differ. Evidence-based practice refers to "judicious use of the current 'best' evidence," whereas research utilization is a subset of evidence-based practice because it focuses on the application of research findings.

Six Steps of Evidence-Based Health-Care Regulation

The six steps of evidence-based health care discussed below resemble those used to develop a systematic review (Pawson, 2006; Sackett et al., 2000). However, the steps have been modified slightly so they are applicable to nursing regulation.

Step 1: Formulating the question. The researcher converts the need for information about a regulatory problem into an answerable question. For example, educators might wish to know why they cannot substitute 100% of students' clinical experiences with simulation. Thus, the researcher might develop the following answerable question: In prelicensure programs, are clinical experiences with actual patients essential for public protection?

Step 2: Identifying and collecting evidence. The researcher searches and retrieves published results of studies. This step requires a comprehensive review of databases and websites to ensure that all relevant primary studies have been collected.

Step 3: Appraising quality of the evidence. The researcher critically appraises the evidence for its validity and impact, or effect size, and for relevance to the question.

Step 4: Processing data. The researcher extracts and synthesizes the data, integrating them with regulatory expertise and the values of public protection.

Step 5: Disseminating findings. Results are reported to a wider policy community, and best practices are identified.

Step 6: Evaluating effectiveness and efficiency. Continuous quality improvement is conducted in an effort to seek ways to improve steps 1 through 5.

Hierarchy of Evidence

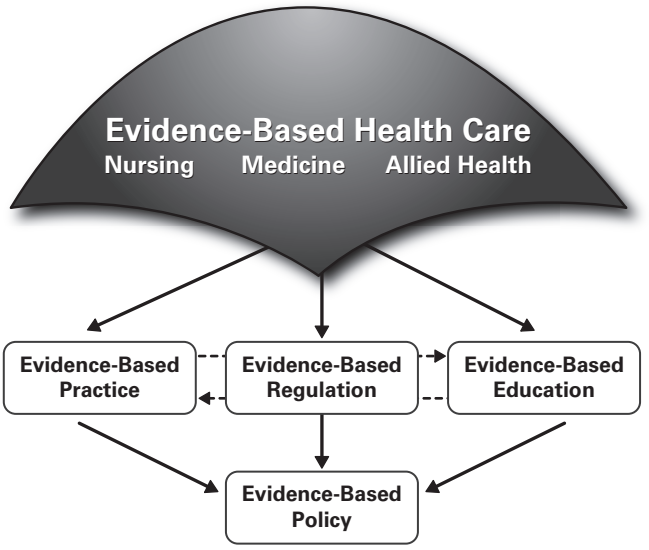
When appraising research, investigators grade relevant studies according to a hierarchy of evidence. Several hierarchies are used for medical interventions, all of them differing slightly (see Table 2).

Randomized controlled trials are not always appropriate for nursing interventions. Therefore, Evans (2003) devised a hierarchy-of-evidence rating system for nursing interventions that also can apply to nursing regulation (see Table 3).

FIGURE 1

Relationship of Evidence-Based Regulation to Evidence-Based Health Care

As this figure shows, evidence-based regulation, practice, and education fall under the umbrella of evidence-based health care.



Most hierarchies of evidence focus on studies that evaluate the effectiveness of interventions. Evans' hierarchy also grades studies that evaluate the appropriateness of health care. Studies addressing appropriateness might ask questions such as "Does the consumer view the outcomes as beneficial?" or "What health-care issues are important to the consumer?" Consequently, the range of research methods used in Evans' hierarchy is broader than in hierarchies that address only effectiveness. In addition, the Evans' hierarchy grades studies that address feasibility, which focuses on the context of the intervention. Evaluating feasibility is particularly valuable for regulation, as it acknowledges that intentional organizational change is highly complex. Such questions as "What are the required resources?", "How will it be accepted by consumers?", and "How should it be implemented?" are asked. Answering these questions requires a broader range of research methods.

Researchers adhere to a rigorous scientific methodology when developing systematic reviews, integrative reviews, and meta-analyses on particular topics for health-care professionals. These types of reports all use the steps listed above to provide the best available evidence. Because of the explicit criteria used to select and grade studies, they are reproducible so that other researchers can reach the same conclusions (Krainovich-Miller, 2006; Pawson, 2006).

- A *systematic review* can be qualitative or quantitative; a quantitative review also is termed a *meta-analysis*. A qualitative systematic review does not use statistical methods to combine findings, whereas a meta-analysis does. An example of a qualitative sys-

TABLE 1

Definitions of Evidence-Based Regulation

The definitions of evidence-based regulation given below are cited in Ridenour (2009) and adapted from global definitions.

1. The raw ingredient of evidence-based regulation is information. Good policy making depends on high-quality information derived from a variety of sources—expert knowledge, existing domestic and international research, statistics, stakeholder consultation, evaluation of previous policies, new research (if appropriate), and secondary sources (including the Internet). Evidence-based regulation also can include analysis of the outcomes of board functions and cost of policy options. (Adapted by Ridenour [2009, p. 277] from Strategic Policy Making Team Cabinet Office [1999]. *Professional policy making for the twenty-first century.*)
2. Evidence-based regulation is information that comes closest to the facts of the matter. The form it takes depends on context. Findings from high-quality, methodologically appropriate regulatory research are the most accurate evidence. Because research often is incomplete and sometimes contradictory or unavailable, other kinds of regulatory information are necessary supplements to or stand-ins for research. The evidence base for decision is multiple forms of evidence combined with rigor with expedience—while privileging the former over the latter. (Adapted by Ridenour [2009, p. 277-278] from Canadian Health Services Research Foundation. [2006]. 2005 Annual Report.)
3. Evidence-based regulation consists of findings from research and other knowledge that may serve as a useful basis for decision making in public health and health care. (World Health Organization Regional Office for Europe, 2004).

tematic review that regulators might use to support regulations is the one conducted by Issenberg, McGaghie, Petrusa, Gordon, & Scalese (2005) on simulation strategies.

- An *integrative review* resembles a qualitative systematic review but uses a broader and sometimes less rigorous method to combine results from a body of studies (Krainovich-Miller, 2006). An example of an integrative review that might interest regulators addresses the use of a journal club as a medium to disseminate evidence (Rogers, 2009).
- *Meta-analyses* are less common. An example of a meta-analysis useful to policy makers is the one conducted by Rice and Stead (2004), which investigates interventions for smoking cessation.

Challenges for Evidence-Based Nursing Regulation

Many challenges exist for evidence-based nursing regulation. Pawson (2006, p. 87) states, "I argue unambiguously that the hierarchy of evidence descending from biomedical interventions, with RCTs [randomized controlled trials] sitting imperiously atop, has to be abandoned."

Few RCTs exist in nursing regulation, or in nursing generally. Indeed, Sanares-Carreon, Waters, & Heliker (2009) argue that for patient issues, a substantial number of nursing interventions cannot be validated using RCTs, and this applies to nursing regulation as well. The Evans hierarchy (Table 3) may be somewhat helpful, although this issue must be addressed.

Similarly, Melnyk & Fineout-Overholt (2005) point out that qualitative and quantitative descriptive studies are especially important for answering questions that RCTs cannot address. Qualitative studies, for example, incorporate the patient's voice into evidence-based practice. Therefore, researchers are beginning to establish frameworks or systems for ranking qualitative studies in terms of feasibility, appropriateness, meaningfulness, and effectiveness.

Hammersley (2005) and Pawson (2006) make strong arguments that traditional evidence-based health care may fail to recognize the fallibility of scientific research. Hammersley further asserts that reliable evidence can derive from sources other than research and that using any evidence requires judgment—regarding not just its validity but also its implications for practice in particular contexts.

Publication Gap

Cooper, Betts, Trotter, Butler, & Gentry (2009) identify the so-called "publication gap," which also can pose a challenge for nursing regulation. Nurse regulators often are too busy to write and submit their findings for publication. Researchers commonly do not submit their findings if they obtain negative or inconclusive results, a practice reinforced by some journals' reluctance to publish them. (Interestingly, positive findings are more likely to be published in English-language journals, whereas negative findings are more likely to appear in other-language journals.)

Nurse-Related Barriers

Polit & Beck (2004) identify nurse-related barriers. One concern is nurses' educational preparation in the area of research skills. Negative attitudes toward research also can be barriers for evidence-based regulation; studies have found that the more positive a nurse's attitude, the more likely the nurse is to use research in practice.

Challenges Within the Profession

Challenges exist within the nursing profession itself. For example, few initiatives have taken place that encourage the collaboration and interaction of regulators and researchers. Likewise, mentors for evidence-based regulation are lacking.

According to Ridenour (2009), a significant regulatory challenge is the difficulty of attaching a dollar value to public protection. Executive directors in BONs serve diverse stakeholders from nursing applicants to legislators, always with the mission of public protection. Compare this with the situation in the business world, where a tangible return on investment or customer loyalty typically can be measured. For regulators, the market is public protection—something that is not easy to measure. In addition, re-

sources for conducting research or collecting data in nursing boards rarely are considered a priority.

In discussing knowledge management, Sin (2008) outlines several challenges related to the structures and culture of public institutions, which also could be barriers for fostering evidence-based regulation. They include:

- resistance to implementing evidence-based regulation
- rule-based culture that encourages compliance
- bureaucratic structure that slows communication and decision making
- high staff turnover and/or transfers
- political nature of government initiatives
- tendency for "change fatigue" to occur due to constant introduction of initiatives, often with confusing labels
- confidential nature of some information and knowledge, which inhibits sharing and access.

Implementing Evidence-Based Regulation in Nursing

How can regulators best implement evidence-based regulation in nursing? Many models can assist regulators to integrate the best available evidence into regulatory decisions and policy making. The examples below briefly describe three models regulators may find useful.

The *Disciplined Clinical Inquiry (DCI)* model (Sanares-Carreon, Waters, & Heliker, 2009) might be the most appropriate model for nursing regulation. It offers a pathway for integrating evidence-based health care into individual and organizational performance. Its primary goal is to embed evidence-based health care into the nursing culture.

DCI has five phases, which easily can be adapted for regulatory issues:

1. Phase I focuses on assessing the nurse's attitude and skills related to evidence-based health care and conducting an environment scan.
2. Phase II engages the nurse in learning about evidence-based health care.
3. Phase III verifies the nurse's ability to transfer learning into practice.
4. Phase IV evaluates the patient's receipt of effective and individualized nursing interventions.
5. Phase V ensures nurses are engaged in ongoing critiques and evaluation of the process and outcomes, establishing a continuous process.

The *Academic Center for Evidence-Based Practice model* (ACE model) depicts the relationships between the various stages of knowledge transformation.

1. During Discovery, the first stage, studies are identified.
2. During Summary, stage two, evidence is synthesized into a meaningful whole.
3. During Translation, stage three, scientific evidence is put in context with practice, and practice recommendations are made.
4. During Implementation, the fourth stage, changes take place and research is integrated into practice.
5. During Evaluation, the last stage, the impact of the change is evaluated. (For additional details on the ACE model, visit www.acestar.uthscsa.edu/Learn_model.htm.)

TABLE 2

Traditional Hierarchy of Evidence

Hierarchy systems for rating the quality of evidence vary slightly depending on the organizations or disciplines using them. This table shows a traditional hierarchy-of-evidence rating system used in evidence-based health care. The lower the level, the higher the quality of evidence. Level I evidence is of higher quality than Level II evidence, and so on.

Level I	Systematic reviews, meta-analyses, integrative reviews of well-designed RCTs
Level II	Well-designed RCTs
Level III	Well-designed quasi-experimental studies
Level IV	Well-designed nonexperimental studies
Level V	Consensus or expert opinions

Note: RCTs = randomized controlled trials.

A third model that can be used to implement evidence-based regulation is the *Iowa Model of Evidence-Based Practice* (Titler, 2006). The first step in this model is topic selection. Examples of potential topics are problems identified by staff or ideas generated from scientific papers or when encountering evidence-based guidelines published by federal agencies. If the topic is a priority for the organization, a team is formed to develop, implement, and evaluate the evidence-based practice. Next, the team retrieves the evidence, using the evidence-based health-care principles described above. After the studies have been critiqued and synthesized, the next step is to decide if the evidence supports changes in practice. If practice changes are warranted, these should be implemented and disseminated.

Benchmarking

While benchmarking per se is not a model for implementing evidence-based regulation, Ridenour (2009) and Howard & Kilmartin (2006) suggest it can be considered a strategy for measuring performance outcomes of governmental organizations. According to Howard & Kilmartin (2006, p. 8), 73% of governmental organizations currently use benchmarking activities; one third of the organizations achieved productivity gains and one fourth achieved cost improvements. One of the organizations saved the United States $28 million in 1 year.

Retrieval of Research Data

Nursing regulators need access to relevant studies to guide their evidence-based regulatory decisions. Primary sources of research data (such as peer-reviewed and refereed journals) rather than secondary sources should always be used.

TABLE 3

A New Hierarchy that Ranks Effectiveness, Appropriateness, and Feasibility

Evans (2003) proposes a new hierarchy of evidence that might be more appropriate for nursing regulation than the traditional hierarchy, because it considers the contributions of a wider range of research methodologies.

Ranking	Effectiveness	Appropriateness	Feasibility
Excellent	• Systematic review • Multicenter studies	• Systematic review • Multicenter studies	• Systematic review • Multicenter studies
Good	• RCTs • Observational studies	• RCTs • Observational studies • Interpretive studies	• RCTs • Observational studies • Interpretive studies
Fair	• Uncontrolled trials with dramatic results • Before and after studies • Nonrandomized controlled trials	• Descriptive studies • Focus groups	• Descriptive studies • Action research • Before and after studies • Focus groups
Poor	• Descriptive studies • Case studies • Expert opinions • Studies of poor methodological quality	• Case studies • Expert opinions • Studies of poor methodological quality	• Case studies • Expert opinions • Studies of poor methodological quality

Note: RCTs = randomized controlled trials.

From Evans, D. (2003). Hierarchy of evidence: A framework for ranking evidence evaluating healthcare interventions. *Journal of Clinical Nursing, 12,* 77-84. Reprinted with permission from Wiley-Blackwell.

Retrieval sources for such data may be fee-based or free. Common fee-based source providers include Aries Knowledge Finder, EBSCOhost, and Ovid Technologies.

Regulators who do not have access to fee-based providers can use free retrieval sources, such as PubMed, Google Scholar, Infotrieve, and ProQuest Research Library. ProQuest has more than 4,000 titles (with 2,800 in full text) from 1971 forward; this database may be available from a public library.

Other important databases for nursing regulation are:

- Cumulative Index to Nursing and Allied Health Literature (CINAHL), owned and operated by EBSCO Publishing, which has nearly 3,000 journals
- Medline (http://medlineplus.gov), which has more than 4,300 journal titles and 11 million records.

The Cochrane Collaboration (http://www.cochrane.org/) provides systematic reviews—the backbone of evidence-based health care. Other databases of interest to nurse regulators include the Education Resources Information Center (ERIC), with more than 650 journals on education; and PsychINFO, which has more than 2,450 journals addressing psychiatric, education, and related issues. (Regulators might want to use PsychINFO to obtain, for instance, literature on chemical dependency.)

Examples of How Regulators Might Use Evidence

How might nurse regulators use evidence when making decisions? States currently are implementing the Consensus Model for Advanced Practice, for which regulators need evidence on the outcomes of nurse practitioners (NPs) compared to those of physicians to present to legislators and other stakeholders.

A classic study of primary care outcomes in patients treated by NPs or physicians was published in 2000 (Mundinger, Kane, Lenz, Totten, Tsai, Cleary, Friedewald, Siu, & Shelanski). This randomized controlled trial concluded that NPs and primary care physicians had comparable outcomes when practicing in an ambulatory care situation. Similarly, a systematic review of randomized controlled studies and prospective observational studies conducted by Horrocks, Anderson, & Salisbury (2002) found no differences in outcomes between NPs and physicians.

A 2009 study (Mehrotra, Liu, Adams, Wang, Lave, Thygeson, Solberg, & McGlynn, 2009) showed that retail clinics provided less costly treatment than physician offices, with no adverse effect on the quality of care. Rudavsky, Pollack, & Mehrotra (2009) found retail clinics were positioned to provide adequate care for simple acute conditions in an urban U.S. population; such data support the practice of NPs. Because the latter two studies were conducted less rigorously than the previous two, the evidence is not as strong. Of the four studies, the systematic review holds the most weight for those making evidence-based regulatory decisions.

Research findings also support other aspects of regulatory functions. For example, BONs approve prelicensure nursing education programs; in light of the increased use of simulation in these programs, regulators are seeking to determine how simulation affects nursing education outcomes. The rigorously conducted systematic review by Issenberg and colleagues (2005) on the use of simulation in medical education provided crucial data for nurse regulators on how simulation might best be used in nursing education. Other nursing studies have provided similar answers (Jeffries, 2007). However, further studies on the effects of simulation on outcomes are needed.

The Future of Evidence-Based Nursing Regulation

Nursing regulatory bodies need to conduct more research—particularly systematic reviews. Ridenour (2009) suggests that a central clearinghouse be developed to catalog research results, including studies with negative results.

Because of the challenges posed by the hierarchy of studies and the need for RCTs, Pawson (2006) and McEvoy & Richards (2003) suggest the future will bring a paradigm shift from the positivist to a realist perspective in evidence-based health care. Realists believe in the fallibility of scientific observations; they study why and how interventions work rather than "delivering summative verdicts" (Pawson, 2006, p. 93), as is currently done with systematic reviews. Pawson boldly calls for a new protocol for systematic reviews using the realist synthesis.

The steps of the realist synthesis resemble those of the systematic review, but the focus differs. Realists spend much time developing questions, such as "How is the program supposed to work?" and "Is the program theory applied consistently and cumulatively?" Because the questions are more complex, the search procedures are more intricate; thus, these reviews are more likely to include "gray" literature.

An example of a realist review is Pawson's review of youth mentoring (2006). Pawson first developed from the research a theory describing mentoring. He then identified nine key studies, which included those with qualitative, quantitative, and multimethod designs as well as one highly technical meta-analysis. Mentoring involves a relationship; thus, diverse studies must be employed to analyze use of this strategy in developing policies. The conclusion of this review was offered as a model to describe why mentoring programs work and why they fail—not as a directive to develop or opt out of mentoring programs. This differs starkly from the conclusions of systematic reviews, which provide summative verdicts.

While the realist view and systematic review differ philosophically, both require the scientific rigor of methodological appraisals. Pawson (2006, p. 78) also emphasizes the need in realist reviews (as in traditional systematic reviews) for "auditability" or transparency.

Conclusions

With the body of knowledge in nursing regulation still emerging, regulators do not have a great deal of evidence on which to base regulatory decisions. As the knowledge base broadens and the science develops, it is critical that they study the issues rigorously. While regulators face many challenges in evidence-based regulation, opportunities exist for development in this field.

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