

**Clinical Education in Prelicensure
Associate Degree in Nursing Programs**

Prepared under contract for
Excelsior College

by

Diane L. Huber, PhD, RN, FAAN, NEA-BC

September, 2009

White Paper

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Executive Summary

The Institute of Medicine (Greiner & Knebel, 2003) has called for fundamental changes in health professions education to produce professionals who can function effectively in a reformed health system focused on quality and safety. Within the nursing community, awareness has been growing about the issues related to clinical education in nursing.

One major issue is how to ensure the clinical competence of graduates from nursing prelicensure programs. There is a perception that there is one right way to educate nurses (i.e., an apprenticeship model including a defined number of hours in a clinical setting), yet pressures such as cost and capacity are forcing educators to address how to most efficiently and effectively educate nurses. In their 2005 position paper on clinical instruction in prelicensure nursing education, the National Council of State Boards of Nursing (NCSBN) took the position that prelicensure nursing education programs shall include supervised clinical experiences with actual patients, such as those that occur in traditional programs. Subsequently, a few individual state boards of nursing took action to restrict or bar licensure to nurses who graduated from one named program, Excelsior College, which uses a non-traditional approach to nursing education for students with prior health care experience (University System of Georgia Board of Regents, 2009). Such actions have sparked controversy about the process of clinical instruction. Yet, despite disagreements about the process of education, there is broad general consensus that research needs to be done on prelicensure nursing education and the development of clinical competency for various types of learners to create the evidence base necessary for sound public policy decisions.

The NCSBN (2006) found no studies of programs that focus on alternative educational approaches, such as competency-based models, rather than traditional clinical learning experiences. The research base is thin, making it difficult to make firm policy decisions about approaches used in both traditional and non-traditional prelicensure programs. Open to question are assertions about the need for a defined number of clinical hours on actual patients, or whether competency-based education with assessment of prior learning is also valid for specified categories of learners. Because the current evidence base is weak to non-existent and the field lacks good data to support one method over another as the standard for clinical instruction and competency assessment in nursing prelicensure programs, it is time for a moratorium on restrictions targeted to specific programs and instead pursue a national nursing education research agenda.

Excelsior College's associate degree in nursing program uses a unique model for clinical education. The key differences are the role that experience plays, how students meet clinical learning outcomes, and how clinical competency is assessed. The student body is an exclusive cohort of advanced/experienced, self-directed adult learners in a competency-based program. The College has a more than 35-year track record of at-or-above benchmark national average NCLEX-RN® pass rates for first-time examination takers. Because Excelsior's educational model is unique, the learning processes employed by its students are different from

the processes employed by students in traditional programs. Yet Excelsior focuses on the same learning outcomes as traditional models of education and offers the field an innovative approach in the spirit of the IOM's call for radically different educational models.

The state of the art is a consensus that research is insufficient to support one method or set of criteria as appropriate for all types of learners. Given the climate of change and reform in health professions education, the profession of nursing would be well served by a high-profile national summit of stakeholders and thought leaders to discuss all models of nursing education. The summit will be a forum for debate and clarification of the issues, identification of a research agenda, and development of action plans for funding and launching targeted research projects.

Clinical Education in Prelicensure Associate Degree in Nursing Programs

White Paper, 2009

Introduction

There is a pressing need for transformation in nursing education to match the urgent imperatives of health care reform. According to the National League for Nursing “The overriding purpose of nursing education is to prepare individuals to meet the health care needs of the public...” (NLN, 2005, p. 2). With or without an evolutionary transformation in nursing education, health care reform in the United States is clearly in progress. This is occurring on a large scale at the national level and is situated within a complex practice environment. Societal needs call for quality, accountability, and strong demand for the use of evidence-based practice, which are all driving forces for reform. (Institute of Medicine [IOM], 2001; NLN, 2005: Page, 2004). According to the NLN (2005, p. 2), “The primary drivers of transformation in nursing education are societal need, societal demand, and accountability for efficient and effective use of educational resources, including best teaching practices based on research evidence.” In a 2005 position paper, the NLN, “encouraged nursing faculty to develop a science of nursing education...and challenged them to validate assumptions that underlie current teaching practices, abandon unsubstantiated practices, and realign nursing education to our contemporary health care system” (NLN, 2005, p. 2). Ferguson and Day (2005) defined evidence-based nursing education as consisting of four elements 1) evidence, 2) professional judgment of nurse educators, 3) the values of students as clients, and 4) resource issues, and echoed the concern that many teaching models for nursing education have no research base to support them.

The IOM has further highlighted the need for reform of health professions education and proposed across-all-disciplines strategies, including:

- definition of common language and core competencies across the professions
- development of evidence-based curricula and teaching approaches as they relate to the core set of competencies (Greiner & Knebel, 2003, p. 156)

Transformation is being urged, using the criteria of being innovative and evidence-based. Conditions are ripe for redesign of nursing education to include the IOM strategies.

Statement of the Problem

Today, the spotlight has been turned on prelicensure associate degree in nursing (ADN) education, as reflected in the National Council of State Boards of Nursing's (NCSBN) 2005 position paper (NCSBN, 2005, 2006a) and the National League for Nursing's position paper (NLN, 2003). In question is the process of clinical education in prelicensure ADN education. This question has arisen because of a perception in the field that there is only one way to educate nurses for clinical competence. The question is urgent because the national nurse shortage, coupled with anticipated demand for nursing services due to the "Baby Boomer" phenomenon and the shift to care coordination in the patient-centered medical home delivery model, will likely again increase the tension about how to graduate more nurses in a shorter period of time (Oermann, 2004). Driving the critical nature of questions about nursing education are the limited availability of clinical sites, a wide range in the number of clinical hours, the limited modes of educational delivery, and a lack of evidence about the kinds of experiences needed to assure safe and competent practice.

Controversy has arisen nationally about the number of clinical hours and the nature of clinical experiences in prelicensure nursing education programs. Specifically, the 2005 National Council of State Boards of Nursing's (NCSBN) position paper "Clinical Instruction in Prelicensure Nursing Programs" formed the basis for discussion and was developed out of a concern over "the issue of ensuring clinical competence in prelicensure programs" (NCSBN, 2005, p. 8). There appears to be no evidence available to guide prelicensure nursing education programs, state regulators, and the NCSBN with regard to best practices for clinical education.

One specific program, Excelsior College's associate degree in nursing program, has faced direct challenges and restrictions recently from individual state boards of nursing. As an example, a recent report from the Georgia Board of Regents (2009) specifically names Excelsior College in its policy analysis regarding non-traditional nursing programs and points out that the Georgia Board of Nursing should not reject Excelsior's nursing program just because it employs a different educational model. Excelsior College's associate degree in nursing program is a well-established, innovative, and a documented evidence-based, non-traditional program serving an exceptional student cohort of advanced beginner/experienced students. It clearly is not a traditional program for novice students, making comparisons about the process of education difficult. Its requirements are more stringent than are traditional programs; where, for example, admission criteria do not include mandatory prior experience in health care service delivery or performance assessment of clinical competency in a psychometrically sound manner. However, there have been specific challenges or restrictions to Excelsior College's associate degree program based on the single criterion of the number of clinical hours in the program, despite the general consensus that there is no research or evidence to support a requirement for a specific number of clinical hours or other restrictive approaches to models of education employed. It would seem reasonable to expect that restrictions or

prohibitions from a regulatory agency that are directed toward ensuring clinical competence in prelicensure programs would be put in place on the basis of research evidence or a safety issue—neither of which exist.

The IOM has called for reform of health professions education, including strategies to “develop evidence-based curricula and teaching approaches as they relate to the core set of competencies” (Greiner & Knebel, 2003, p. 156). The spirit of reform of health professions education would indicate that research needs to be undertaken to establish the evidence base for decisions about what works best for clinical education in prelicensure nursing programs. Then based on sound evidence, benchmarked evaluations need to be done to form the basis for policy and regulatory decisions. Restrictions imposed by state boards of nursing, where they occur, are not evidence-based.

Statement of the Purpose

The purpose of this white paper is to review the origins of ADN education as an innovative experiment in nursing education, describe the Excelsior College associate degree in nursing program, and discuss the NCSBN’s 2005 position paper.

Associate Degree in Nursing Education

Well-prepared registered nurses are needed worldwide, including the United States. Socioeconomic forces, such as a nurse shortage or high demand for nurses, create conditions that challenge the status quo in nursing education. These forces occurred in the 1950s and have re-surfaced today. One major response in the 1950s was the creation of the associate degree in nursing (ADN). This response has proven to be a safe, effective way for entry into the profession.

The history of the evolution of ADN education is foundational to studying issues currently facing nursing educators. In the early 1950s, ADN education arose from a nurse shortage, a growth in the number of community and junior colleges, and the interest taken by government and consumers in finding more efficient ways to educate nurses (Haase, 1990; Mahaffey, 2002). According to the National Organization for Associate Degree Nursing (2006, p. 1):

Associate Degree Nursing education had its inception in 1952 as the result of a research project conducted by Mildred Montag. The project sought to alleviate a critical shortage of nurses by decreasing the length of the education process to two years and to provide a sound educational base for nursing instruction by placing the program in community colleges. In 1958, the W. K. Kellogg Foundation funded the implementation of the project at seven pilot sites in four states (Haase, 1990).

The Cooperative Research Project in Junior and Community College Education for Nursing began in 1952, with Dr. Mildred Montag as project director. Her dissertation investigated a research-based plan to create and test a model for ADN education. Two major features of ADN programs were 1) the use of clinical sites in community settings, which was innovative at the time, and 2) the fact that these programs attracted a different student population than did traditional programs: students were older and there were more males (Haase, 1990; Mahaffey, 2002). See Table 1 for data on ADN demographics.

The beginning of ADN programs has been described as the first planned experiment in nursing education (Arlton, 1981). As far back as 1981, Arlton noted that challenges facing ADN programs included the lack of consensus about the appropriate scope of practice and the requisite competencies of ADN graduates and the increased difficulty involved in securing clinical experiences for students at area hospitals. Support from the W. K. Kellogg Foundation and from the federal government was instrumental in stimulating the growth and development of ADN programs. In the beginning there were seven pilot programs, and by 2002 there were more than 800 programs in the U.S. In 2002, about 60 percent of entry-level graduates came from ADN programs, and ADN programs graduated greater numbers of minorities and males (an under-represented minority in nursing) (Mahaffey, 2002).

RN Population Profile, 2004

Total U.S RN population: 2,909,467*		
Employed in nursing	2,421,461	
Employed full-time in nursing	1,696,916	58.3 %
Diploma as initial preparation	733,377	25.2 %
Associate degree as initial preparation	1,227,256	42.2 %
Baccalaureate as initial preparation	887,223	30.5 %
MSN or doctoral degree as initial preparation	15,511	0.5 %
Diploma as highest educational level	510,209	17.5 %
Associate degree as highest educational level	981,238	33.7%
Baccalaureate as highest educational level	994,240	34.2 %
MSN or doctoral degree as highest educational level	377,046	13.0 %

*In 2004, the average RN was 46.8 years of age; 94.3 percent were female; and 88.4 percent reported themselves White, non-Hispanic.

Source: National Organization for Associate Degree Nursing (N-OADN), 2009; Spratley et al., 2001).

Mahaffey (2002) noted that there are many features of ADN programs that continue to attract students, calling it a “compelling option.” Further, there are “exemplar programs across the nation that can serve as benchmarks for excellence in such areas as retention, creative teaching, alternative clinical sources, curriculum process, and student satisfaction” (¶ 32).

The Excelsior College Associate Degree in Nursing Program

Excelsior College in Albany, New York, was founded in 1971 as the Regents External Degree Program of the University of the State of New York and later called Regents College (Yarbrough et al., 2007). The name was changed in 2002, subsequent to its chartering as an independent higher education institution in 2000. Key distinguishing features of Excelsior College are that it began in 1971 as an external degree program and that its mission has always been to provide access to higher education for the traditionally underserved (Yarbrough et al., 2007). Associate degree education has been a focus of Excelsior College from its beginning. The profile of the Excelsior College associate degree in nursing program student body and graduates demonstrates that the program attracts and retains a unique segment of nursing students. Admission criteria specify prior experience in health care; students are mature adult learners, ethnically and gender diverse, and with years of health care experience. Thus Excelsior College’s associate degree in nursing students are at the advanced beginner level, rather than at the novice level on Benner’s novice-to-expert continuum (Benner, 1982, 1984). The Excelsior program can be characterized as a competency-based career articulation prelicensure program in nursing. It remains innovative and unique.

There are two degrees at the associate level offered at Excelsior: Associate in Science in nursing and Associate in Applied Science in nursing. The difference is in the general education requirements (Excelsior College, 2008). Arising from concerns about how to enhance nurses’ career mobility given the barrier of time requirements for repeating clinical practice and theory coursework already successfully completed elsewhere, Excelsior College developed nursing-specific College Proficiency Examinations (CPE) that are similar to advanced placement exams. An outgrowth from the success of the nursing CPE was a proposal for Excelsior’s associate degree in nursing program. Expert nurse scholars and educators, including Dr. Mildred Montag who is credited with originating associate degree programs in nursing, designed the original Excelsior College associate degree in nursing curriculum (Yarbrough, 2007). The prelicensure associate degree programs began in 1973 with crucial funding from the W.K. Kellogg Foundation and grants from the Ford Foundation and Carnegie Corporation. The curriculum included assessment of both theory and clinical knowledge and skills.

Today, the Excelsior’s AD in nursing program remains innovative despite its long successful history. The Georgia Center for Health Workforce Planning & Analysis (University System of Georgia Board of Regents, 2009) described the Excelsior College prelicensure nursing program as having distance education at its core. They identified three non-traditional approaches used by the Excelsior College associate degree in nursing program:

- 1) application of a competency-based model of education,
- 2) assessment of prior learning, and
- 3) use of distance education.

The Excelsior College associate degree in nursing program can be characterized as a well-established, evidence- and competency-based, distance education prelicensure curriculum offered exclusively to students meeting specific admission criteria. The defined admission criteria assure that students enter the program with clinical health care experience. Each student's type of healthcare experience is evaluated prior to entry into the program and each student's clinical competency is assessed prior to exit from the program, with graduation dependent upon passing the psychometrically sound, Clinical Performance in Nursing Examination (CPNE®). The CPNE® is a criterion-referenced assessment of clinical competency that takes place in the authentic patient care environment. That is, candidates taking the CPNE® provide nursing care to actual adult and pediatric patients in hospital settings while being assessed by trained nursing faculty raters. There is no known examination in the field that is comparable to the evidence-based CPNE® as a psychometrically sound measure of clinical competence expected of a first-day ADN graduate.

Excelsior's Clinical Competence Testing: The CPNE®

It is important to note that Excelsior College's associate degree in nursing program requires successful completion of both Excelsior College-developed theory and clinical performance examinations in addition to general education requirements. Each candidate for graduation has to pass the final, capstone clinical requirement, the *Clinical Performance in Nursing Examination* (CPNE®). The CPNE® is designed to assess essential clinical content and performance skills not measured by theory examinations. The essential clinical content domains of the CPNE® are

- 1) application of the nursing process to demonstrate critical thinking,
- 2) implementation of critical elements within areas of care representing the entire universe of nursing care, and
- 3) use of the specified psychomotor skills deemed essential to beginning nursing practice (Yarbrough et al., 2007, p. 11).

This examination requires candidates to perform psychomotor skills and deliver actual nursing care. It is scored by a fully oriented and trained expert clinical examiner who is a master's or doctorally prepared nurse faculty member. These faculty assess application of critical thinking through application of the nursing process and theoretical knowledge, psychomotor skills and actual nursing care delivery using predetermined scoring criteria in conjunction with an on-site CPNE® nurse examination coordinator, also a master's or doctorally prepared nurse faculty member.

The CPNE® was developed by Excelsior College under a W.K. Kellogg grant and implemented in 1974, designed to be the capstone clinical competency assessment used by Excelsior College's nursing program. The content of the CPNE has been continuously updated to reflect the progression/evolution of nursing practice over time. The CPNE® is a rigorously developed and psychometrically tested exam, as delineated in the Excelsior CPNE® *Technical Manual* (Yarbrough, 2007). Original test development followed a three-part model (Lenberg, 1976), and concept mapping and field testing were done. McCallan's (2006) Unitary Concept of Validity Model is the performance test construction and administration framework currently in use.

CPNE® test construction and scoring are congruent with standards for performance test development of the American Educational Research Association, American Psychological Association, and the National Council of Measurement in Education (Yarbrough, 2007). It is a criterion-referenced performance exam, administered in an actual patient care environment over a two-and-a-half day period and scored by an expert nursing faculty member called clinical examiners and associates. Faculty members use predetermined administration and scoring criteria to assure validity and reliability of CPNE scores. The CPNE has demonstrated acceptable levels of reliability and validity (see Clinical Performance in Nursing Examination Technical Manual: Sources of Validity Evidence and Threats) over 35 years (1974-2009). CPNE psychometric testing reveals that the examination generates scores that are stable and accurate estimates of clinical competence. In addition, Excelsior College's associate degree graduate pass rate for first-time takers of the NCLEX-RN® is consistently equal to or above the national associate degree pass rates, which is the national standard of performance for nurse licensure (Yarbrough et al., 2007).

Accreditations

Excelsior College is accredited by the Commission on Higher Education of the Middle States Association of Colleges and Schools, a regional accreditation recognized by the U. S. Secretary of Education and the Council for Higher Education Accreditation. The Excelsior College's associate degree nursing program started in 1973 and has been continuously accredited by the National League for Nursing Accrediting Commission (NLNAC) since 1975. It is registered (approved) by the New York State Education Department. Excelsior College's School of Nursing has been peer reviewed and twice designated as one of 15 Centers of Excellence in Nursing Education by the National League for Nursing (NLN). The current designation as an NLN Center of Excellence in Nursing Education™ Student Learning and Professional Development is for the time frame 2008-2011.

Admission Criteria

Excelsior College's School of Nursing strives to increase access to quality nursing education for a diverse and underserved population of adult learners. The program is unique and innovative. It is the original evidence-based external degree program in nursing at the prelicensure level. The explicit purpose of Excelsior College's associate degree in nursing program

is to provide an alternative educational approach to achieving an associate degree. As noted in the *School of Nursing Catalog*, “Our nursing degree programs are specifically designed to serve individuals with significant experience in clinically oriented health care disciplines” (Excelsior College, 2008, p. 13). Students with a limited background in nursing or a related health care discipline are advised to attend a traditional nursing education program.

Admission to the Excelsior College’s associate degree in nursing program is specifically limited by admission criteria to licensed practical/vocational nurses, military service corpsmen, paramedics, and individuals who hold degrees in clinically-oriented health care fields in which they have provided direct patient care (e.g., MDs, respiratory therapists, and physician’s assistants). A candidate who has successfully completed at least 50 percent of the clinical nursing credits in an associate, baccalaureate, or RN diploma nursing program may be eligible if they apply within five years of obtaining the credits (Excelsior College, 2008). These highly prescribed pre-requisites mean that the student body is an exceptional student cohort (distribution is skewed at the highest end of clinical experience on admission and not normally distributed). They are advanced/experienced nursing students, having substantial and documented clinical health care experience at admission, and their competency in nursing is verified at exit via the evidence-based CPNE®. The student body’s demographic profile is students who are 40 years old on average and mature workers who have an average of 10 years of documented clinical health care experience.

The NCSBN 2005 Position Paper

In 2005 the National Council of State Boards of Nursing (NCSBN) adopted a position paper titled “Clinical Instruction in Prelicensure Nursing Programs.” This was authored by the NCSBN’s Practice, Regulation, and Education Committee (PR&E Committee) with the goal “to provide guidance to the boards of nursing for evaluating the clinical experience component of prelicensure programs” (p. 1). The position paper was developed subsequent to a 2004 NCSBN Delegate Assembly resolution (NCSBN, 2005, p. 1):

Resolved that NCSBN and its Member Boards support the necessity for inclusion of planned, structured, supervised clinical instruction across the life-span as essential to nursing education; and be it further resolved that the issue of ensuring clinical competence in prelicensure programs be referred to NCSBN’s Practice Regulation and Education Committee to research and develop a position statement that provides guidance to nursing boards in evaluating whether entry-level nursing applicants have received sufficient hands-on, effective, supervised clinical nursing education to ensure safe nursing practice, in both traditional and alternative educational nursing programs utilizing distance learning, simulation laboratories and other technical innovations; and that the PR&E Committee shall report back at the 2005 Delegate Assembly.

According to the NCSBN (2005), the genesis of concern arose from: “whether nursing educational programs leading to initial licensure can successfully educate nurses with alternative methodologies that take the place of traditional clinical experiences” (p. 3).

The NCSBN position paper contains definitions, premises, and recommendations, along with background and literature review. The PR&E Committee recommended 5 position statements (2005, p. 1):

1. Prelicensure nursing educational experiences should be across the lifespan.
2. Prelicensure nursing education programs shall include clinical experiences with actual patients; they might also include innovative teaching strategies that complement clinical experiences for entry into practice competency.
3. Prelicensure clinical education should be supervised by qualified faculty who provide feedback and facilitate reflection.
4. Faculty members retain the responsibility to demonstrate that programs have clinical experiences with actual patients that are sufficient to meet program outcomes.
5. Additional research needs to be conducted on prelicensure nursing education and the development of clinical competency.

It was noted in the executive summary that they “realize that there is the need for more research of clinical education in nursing” (2005, p. 1), yet recommendations #2 and #4 dictate “clinical experiences with actual patients.”

The NCSBN Approach to the Literature

The Literature Search

The NCSBN’s PR&E Committee’s approach to their literature search was described as:

online databases of CINAHL, Medline and ERIC ...used with the keywords of: education, nursing, teaching, education research, learning methods, learning strategies, research-based education and outcomes of education. These studies were evaluated for relevance for this position statement (2005, p. 3).

The 2005 position paper did not describe further the literature search strategy and decision rules, so it is not known which years were searched, whether there were limits or parameters such as research-only articles, nor the amount (volume or number of retrievals) of literature returned from each search. Thus, it is not possible to determine whether related relevant articles may have been missed; or, for example, whether a focused search of keywords such as “nursing clinical education,” “clinical competence,” or “competency-based education” might yield a richer stream of literature. Inclusion/exclusion criteria need to be specified because they are filters that affect the yield of literature that is actually critiqued for the evidence base.

Thus it is not known whether there was an exhaustive or selective search of the literature or to what extent the search yielded evidence-based articles. This is important because the literature that is retrieved will be used as substantiation for taking a policy position.

The Evaluation of the Scientific Rigor of the Literature

The 2005 position paper described the evaluation of the literature's evidence base as:

In order to be evidence-based this review includes either studies or systematic reviews (Mayer, 2004), though PR&E also included some relevant state-of-the-art reviews from nursing or health care literature (p. 3).

There are multiple grading and scoring schemas for rating the evidence base for health care and educational practices. The NCSBN's (2005) position paper is lean on description of their selection and grading of the evidence-based literature they chose and reviewed. It did not identify which scheme they chose for evaluating individual studies and the overall weight of the evidence available. For example, White (2003) was discussed under learning clinical decision making without evaluating whether using a qualitative design with 17 students (ages 21-37 with no previous degree in nursing who were interviewed one time) was strong enough to draw conclusions. Grading criteria are critical evaluative components in determining whether to accept a study or collection of studies as rigorous enough to support a recommendation for a change in practice. One of the major purposes of a review of literature with evaluation of the evidence base is to substantiate the basis for recommendations for the position paper. Appendix A contains a brief overview of systems to grade the strength of the evidence for practice changes. Use of a more rigorous and established system to evaluate the evidence base is needed, and the NCSBN has moved in this direction since 2005.

The NCSBN's Current Focus

Subsequent to the NCSBN's 2005 position paper, the NCSBN has continued its activities related to the search for the evidence base for nursing education with an initiative called Evidence-Based Nursing Education for Regulation (EBNER). They first conducted a systematic review of nursing education outcomes studies and then held an invitational forum for about 30 diverse nursing and health care experts in January, 2006, followed by a Webcast on the EBNER findings for the boards of nursing. They issued two papers in 2006: one describing the EBNER project (NCSBN, 2006b) and one with supporting documentation (Spector, 2006).

In the 2006(b) document, the NCSBN discussed the factors stimulating their EBNER initiative "to study evidence-based nursing education that will provide for safe and effective entry to practice," noting that in 2000–2001 their constituent boards began to ask NCSBN for evidence to support their educational rules and regulations (p. 1). Spector (2006) discussed the EBNER evidence-based elements of nursing education which were identified from the published literature, past NCSBN research, and NCSBN's elements of nursing edu-

cation study. Each element is documented by a source(s) and its level of research, with Level I research being properly conducted randomized controlled trials and systematic reviews or meta-analyses (the strongest support). This research is intended to be updated yearly.

The evidence-based elements for nursing education were categorized into five areas (NCSBN, 2006b, p. 3):

- 1) Adjunctive teaching methods
- 2) Assimilation to the role of nursing
- 3) Deliberate practice with actual patients
- 4) Faculty-student relationships
- 5) Teaching methodologies

The NCSBN (2006b) noted that of the three elements “in the adjunctive teaching methods section, using simulation and combining online strategies with traditional strategies, were supported by the highest level of research. The research strongly supports using simulation. Currently, NCSBN is studying the role of simulation in nursing education. Given the evidence for faculty-student relationships in traditional learning, it is not surprising that faculty interaction is an important aspect of online learning as well. Programs using online teaching strategies should evaluate whether or not they provide enough faculty interaction for their students” (pp. 3-4).

In addition, as part of their strategic initiatives, NCSBN will continue to conduct studies to provide evidence for nursing education. The NCSBN’s 2009 Research Agenda (NCSBN, 2009a) has the following as research priorities for 2009-2010:

- 1) patient safety;
- 2) practice role clarity, challenges (LPN/VN, RN and APRN);
- 3) innovations in nursing education and clinical (simulation);
- 4) continued competence of RNs practicing beyond five years;
- 5) effective discipline and alternatives to discipline; and
- 6) models for state-based nursing regulation to support national and international portability and data consistency.

The intersection points of the NCSBN’s EBNER and research agenda initiatives with Excelsior College’s competency-based alternative prelicensure program evaluation include a consensus that the available research is very lean and not rigorous; thus, the need to deliberately stimulate a research action plan. A similar conclusion was recently reached by the Georgia Board of Regents (2009). There was no evidence at all cited in the NCSBN work regarding the number of clinical hours needed for prelicensure programs: “Five studies provided evidence that clinical experiences improve students’ abilities to think critically when

caring for patients, though there were no studies found that investigated specific numbers of clinical hours. Likewise, there were no studies that evaluated those programs that do not have, or have very limited, clinical experiences” (Spector, 2006, p. 14). The issue of competence is a concern shared by all. Spector (2006, p. 14) noted “Three Level I systematic reviews were identified. Epstein & Hundert (2002) defined ‘professional competence’ and provided some guidance for boards for assessing the competence of health care workers.” The NCSBN’s 2009 research agenda element #4 is focused on continued competence of RNs practicing beyond five years. Thus, clinical competence appears to be a fruitful common conceptual framework.

NCSBN’s Relevant Studies in Clinical Education in Nursing

The 2005 position paper reviewed as theories Benner’s stages of skill acquisition, Ericcson’s deliberate practice, and Situated Cognition Theory. The studies with students and faculty that were annotated are:

1. White (2003) on how nursing students learned clinical decision making
2. for the confidence in role component, NCSBN discussed Benner, 2004; Bjørk & Kirkvold, 1999; and Yates et al., 1997
3. the Greiner and Knebel 2003 IOM report and Smith and Crawford (2003) were discussed in relationship to interdisciplinary teams and for building relationships
4. White, 2003, and Angel et al., 2000 were reviewed for critical thinking performance
5. Bjørk and Kirkvold, 1999, Joubert et al., 2002; and Platzer et al., 2000 were noted for the importance of feedback and reflection.

The NCSBN’s conclusions from their literature review, presented according to the five areas above, are (NCSBN, 2005):

1. These five components require deliberate practice within the authentic environment, which is essential to teaching nursing students.
2. The evidence showed benefits in increasing confidence levels and is worthy of future investigation.
3. NCSBN has found that when newly licensed nurses did not work effectively within a health care team or did not know when and how to call a patient’s physician, they were more likely to report being involved in patient errors, thus working within an interdisciplinary team is important for patient safety.
4. Their results showed that the characteristics of their learners (e.g., age or previous degree) affected which teaching strategy was more effective. Younger learners tended to have better outcomes with the more structured approach, while the older learners improved more with the unstructured approach. Students without previous degrees

tended, as well, to benefit more from the unstructured approach to the health assessment assignment. Most importantly, though, this study clearly provides evidence that a learner's knowledge and critical thinking improve after a semester of faculty-supervised clinical experiences. This evidence suggests that clinical experience with actual patients improves nursing practice.

5. It is clear from studies that the themes of immediate feedback and the opportunity to reflect in the context of practice are essential for the development of entry into clinical practice competencies.

The NCSBN's review of literature did include studies of knowledge acquisition in nursing (e.g., Angel et al., 2000). The differentiation between best practices for knowledge acquisition and critical thinking, including the optimum teaching/learning strategies, was not explained and may or may not be appropriate for psychomotor skills acquisition or the demonstration of clinical competence, however that is defined. Schmalenberg et al. (2008) said that competency is evident through actions. There is a distinction between learning and doing, didactic and clinical. It is important to note that no evidence was presented for or against a required number of clinical hours.

The NCSBN's (2005) literature review covered five topics of learning which are clinical decision making, role confidence, interdisciplinary teamwork, critical thinking performance, and feedback and reflection. For each topic, one to three articles were discussed, and recommendations for policy were generated. However, it is not clear that the studies reviewed in the 2005 position paper were those most specific to the "issue of ensuring clinical competence in prelicensure programs" or "guidance to nursing boards in evaluating whether entry-level nursing applicants have received sufficient hands-on, effective, supervised clinical nursing education" (NCSBN, 2005, p. 1). "Clinical competence" was not defined, although "competence" was defined as the application of knowledge and skills. "Clinical judgment" and "critical thinking" were defined separately, but they were not differentiated in the discussion nor related to a theoretical framework that links to "clinical competence."

This absence of clarity and synthesis in the position paper reduces confidence that the literature review supports the NCSBN's conclusions and policy recommendations. For example, the NCSBN (2005) noted that the confidence component has been mentioned in other studies "as being important when learning from the clinical context" (p. 5), yet "there is a paucity of studies on relating these clinical decision-making components with improved outcomes of learning in the clinical setting" (p. 5). They noted that a lack of confidence can interfere with student learning. The NCSBN's conclusion was that the evidence showed benefits in increasing confidence levels and is worthy of future investigation. Although this conclusion may be accurate, there is no synthesis or linkage to later recommendations such as "prelicensure nursing education programs shall include clinical experience with actual patients" (p. 1) or "faculty members retain the responsibility to demonstrate that programs have clinical experiences with actual patients" (p. 1).

For literature conclusion #4, it would seem important but common sense that “this study clearly provides evidence that a learner’s knowledge and critical-thinking improve after a semester of faculty-supervised clinical experiences” (NCSBN, 2005, p. 5). Although it may be true and is an expected finding, the immediate leap to the assertion “This evidence suggests that clinical experience with actual patients improves nursing practice” (p. 5), is not directly tied to the study cited or to an evidence-based synthesis of the literature. *No research was presented that would be strong enough to substantiate assertions and recommendations #2 and #4 regarding “shall include clinical experiences with actual patients.”* There is some evidence that “clinical experiences with actual patients” creates positive outcomes, but there is no demonstration of the body of evidence to prove that “clinical experiences with actual patients” is absolute as compared to using alternative methods. There is some evidence that simulation may be effective, but the desirable balance of strategies has not been examined.

One aspect of the NCSBN 2005 position paper’s review of the literature was presented in its journal article (NCSBN, 2006a). In discussing the evidence, it noted (p. 13):

Although there are few studies addressing clinical experiences with actual patients, it is important to note that there are no studies of programs that have little or no clinical experiences. The existing clinical literature finds that gaining comfort in the role of a nurse and being confident in that role are best learned from practice with actual patients, where there is time for reflection and feedback from a qualified nursing instructor.^{2,5,6}

Under “Other Evidence,” the 2005 NCSBN position paper discussed their survey of all 60 boards of nursing (n=36 responding, 60 percent response rate) and the RN and LPN nursing educational organizations. Key points were (pp. 7-8):

1. A majority of the boards of nursing replying to the survey defined clinical experiences as “hands-on” nursing experiences.
2. While many boards say that “supervised” clinical experience is defined as a clinical instructor being physically present, a majority of the boards that responded do not define that term.
3. It is clear that a large majority of the respondents think that direct care of patients across the lifespan is essential in a nursing program.
4. There is variability on how structured the boards of nursing should be in requiring clinical experiences with actual patients. Of the 28 answering the question on whether predetermined hours should be required, the results were more variable—17 said yes, 11 said no.
5. The nursing boards, by a large majority (19 of the 30 comments), replied that the measure they use to demonstrate clinical competency of new graduates is graduation from an approved nursing program.

6. The boards of nursing predicted that in the future there would be more clinical education using simulation, clinical laboratories, and online learning.
7. One nursing education organization commented that the clinical nursing literature focuses on competent performance and student-centered learning in nursing programs, moving away from rigid parameters.
8. The American Organization of Nurse Executives (AONE)'s 2004 position statement on prelicensure, supervised clinical instruction noted: "Although innovative approaches may be developed, it is the position of AONE that all prelicensure nursing education programs must contain structured and supervised clinical instruction..."

NCSBN's Conclusions and Recommendations

The 2005 NCSBN position paper ends with conclusions and recommendations. This position paper was noted to have been generated from a 2004 NCSBN Delegate Assembly resolution to the PR&E Committee with the goal "to provide guidance to the boards of nursing for evaluating the clinical experience component of prelicensure programs" (p. 3) and which reads in part that the:

issue of ensuring clinical competence in prelicensure programs be referred to NCSBN's Practice Regulation and Education Committee to research and develop a position statement that provides guidance to nursing boards in evaluating whether entry-level nursing applicants have received sufficient hands-on, effective, supervised clinical nursing education to ensure safe nursing practice, in both traditional and alternative educational nursing programs utilizing distance learning, simulation laboratories and other technical innovations (p. 3).

The conclusions section of the 2005 position paper starts off with (p. 9): "Because the mission of the boards of nursing is to protect the public, the boards asked for guidance with evaluating prelicensure nursing programs that do not provide experiences with actual patients." This statement changes the tone from one of providing guidance about evaluating the clinical experience component of all prelicensure programs, both traditional and alternative ones that have distance learning, simulation laboratories and other technical innovations, to one of narrowly targeting only "nursing programs that do not provide experiences with actual patients." There is dissonance between the stated charge to the PR&E Committee (p. 3) and the first sentence of the conclusion (p. 9). *The literature review presented in this NCSBN's position paper does not appear to contain any evidence to support a conclusion that prelicensure nursing programs that do not provide experiences with actual patients are a threat to the public safety, nor is there evidence presented that prelicensure nursing programs which do provide experiences with actual patients are not a threat to the public safety.* In addition, the NCSBN's own survey of boards of nursing revealed that there is variability from state to state with regard to

their opinions about how structured boards of nursing should be in requiring clinical experiences with actual patients. Sixty boards of nursing were surveyed, and their opinions were summarized as follows (NCSBN, 2005, p. 7):

While many boards say that “supervised” clinical experience is defined as a clinical instructor being physically present, a majority of the boards that responded do not define that term. Of the 31 boards that answered the question asking whether students should practice on actual patients, 28 said yes, while three said no. The boards responded that nursing is a practice discipline in which safety is involved, and that students cannot learn critical thinking without practicing with actual patients. Similarly, when asked whether students can achieve their objectives in a nursing program without supervised clinical experiences, 27 said no and four said yes.

Lacking evidence, most boards of nursing have neither mandated a specific number of hours nor specified the method(s) or circumstances for how students acquire clinical experience. No evidence was presented in the position paper to support the assertion “students cannot learn critical thinking without practicing with actual patients” (NCSBN, 2005, p. 7). It is unknown whether or not this statement is accurate. This is likely the reason why “The nursing boards, by a large majority (19 of the 30 comments), replied that the actual measure they use to demonstrate clinical competency of new graduates is graduation from an approved nursing program” (p. 7). The state of the art is that if a nursing program meets board of nursing criteria to be approved within a school’s home state, the outcomes used to assess clinical competency are meeting program criteria and objectives. The ultimate outcome for all programs is NCLEX-RN® pass rate.

Common Ground from the NCSBN Position Paper

The common ground that all can agree on is 1) recommendation #3: prelicensure clinical education should be supervised by qualified faculty who provide feedback and facilitate reflection, and 2) that the evidence for decision making about best practices is not available, and therefore rigorous research is urgently needed. The quality of the regulation that state boards of nursing can provide is directly tied to the availability of the evidence to guide decision making. There is some indication that the concept of competency could be a more appropriate framework for investigating clinical instruction in prelicensure nursing education programs.

Analysis of the NCSBN Position Paper

The 2005 NCSBN position paper’s literature review search strategy appears to use key words that were too broad, especially if clinical competency is the issue. Non-U.S. international studies were cited without a discussion of applicability to U.S. associate degree programs. The position paper did not discuss or critique non-traditional programs (what are they, how do they vary, how are they defined for comparison?); but the NCSBN (2006a) article did suggest that its focus was on those programs that have alternative clinical education using distance

learning, simulation, and other technical teaching modalities, but little or no clinical experiences...There is too little detail to know if the search strategies were on target or if the rating of the rigor of the evidence was done in a way to support major practice change conclusions. This position paper is four-years-old, and it may be time for a fresh look and integration with the ongoing NCSBN work on Evidence-Based Nursing Education for Regulation (EBNER) (NCSBN, 2006b). The NLN, IOM, and nurse experts (Donley & Flaherty, 2008) have emphasized the need for innovative change in clinical nursing education, which further highlights the need to conduct research about alternative programs.

The state of the art is that the national registered nurse licensure exam (NCLEX-RN®) is not, and has not been, a psychomotor skills or performance competency exam. It tests knowledge and critical thinking. The same is true for medicine—MDs do not have, for example, a surgery performance exam for their licensure. Thus, across all RN prelicensure programs, there is no standardized capstone required clinical performance exam for nursing education programs that is required by boards of nursing for sitting for the NCLEX-RN®. It is an open question whether any nursing education program can assure clinical competency at graduation unless they use the CPNE® or similar valid clinical performance exam. Meeting program objectives is the proxy measure for most boards of nursing. Program quality and outcomes are ultimately gauged by the NCLEX-RN® pass rate.

The nursing profession uses the NCLEX-RN® examination to ensure that students who have graduated from an approved nursing program have successfully internalized the necessary knowledge and critical thinking for practicing nursing. In 2008 nearly 14 percent of the ADN students taking the NCLEX-RN® for the first time failed the examination. In 2007, the figure was more than 15 percent (NCSBN, 2009b). Those taking the examination were deemed qualified to take the examination because of the formal nursing education they had received.

Excelsior College uses the CPNE® examination to assure its students have successfully mastered the necessary clinical skills for practicing nursing. Although Excelsior graduates pass the NCLEX-RN® examination the first time at about the same or higher rate as all ADN students in the nation, 35 percent of the Excelsior students do not pass the CPNE® the first time and therefore do not become eligible to take the NCLEX-RN® until they do pass the CPNE. The stringency of the CPNE exam is additional evidence of the rigor of the Excelsior program.

Other nursing education programs generally do not test for clinical skills the way that Excelsior students are tested (i.e., via systematized, psychometrically sound, competency-based performance examination). In fact, state boards of nursing around the country require very little evidence that clinical skills were taught, let alone internalized, as part of the nursing education program. A recent NCSBN study showed that only seven states required a certain number of clinical hours be included in a nursing education program, with no requirement of what content or types of assessment should be included in those hours. Many states only require that the clinical hours included be sufficient to meet the outcomes of the program.

Given the concern about fly-by-night “new programs,” the need to set standards to uphold quality in clinical education in nursing programs is likely to be real and significant. It would be possible to do some form of national consensus conference to develop beginning standards and metrics (like length of time the program is in existence, number of graduates, NCLEX-RN® pass rate, state approvals, accreditations, “sentinel events” generated by new graduates, employer satisfaction surveys, etc.). However, it is clear (generally and in feedback discussed in the 2005 NCSBN position paper) that there will be more and more aspects of clinical nursing education delivered using simulation, clinical laboratories, and distance learning methodologies.

Effectiveness research focusing on various educational models is sorely needed. Also, a dialogue about “traditional programs” is needed. Both traditional and alternative programs, such as the Excelsior College program for advanced/experienced students, have worked to produce graduates who pass NCLEX-RN®. Yet, comparative and effectiveness research on traditional programs needs to be done. Particular types of educational models could be very costly and/or inefficient at acquiring needed clinical experiences. These programs could be doing the wrong things or not doing the right things in some areas. Before deciding that as NCSBN states, students must have traditional type learning experiences with actual patients rather than avatars of 3-D simulations, it would be helpful to have a widely inclusive debate. One approach is to derive consensus on core clinical competencies and then design and test educational strategies to most effectively and efficiently teach them as suggested by the NLN (2005). Research questions should explore the following: the right components, the right mix/timing/sequencing of educating for those components, the best strategies, the best mix/timing among alternative strategies, and the strategies best suited to traditional and to alternative programs (are these different)? What is common and unique between traditional and alternative programs, the learning outcomes achieved, and the types of students best served by each approach?

Competency

Excelsior College and the NCSBN are not alone in identifying the issue of ensuring clinical competence in RN prelicensure programs as important and urgent. In 2003, the National League for Nursing (NLN) called for dramatic reform and innovation in nursing education. They noted that significant paradigm shift changes were needed. Their recommendation #4 for faculty was to re-think clinical education in order to design new methods, and recommendations #5 & #6 were for faculty to address conducting pedagogical research and creating an evidence base (NLN, 2003).

Arising from the NLN’s discussion of priorities for research in nursing education, an invitational think tank, functioning as an expert panel, was held in 2008. The final report (NLN, 2008) noted that NLN saw clinical nursing education as the most critical component of transforming nursing education. A pressing general issue is “thinking of new ways to conceptualize the clinical component of nursing education and create an evidence base for current and new educational practices” (p. 3). A pressing student learning issue is “re-

thinking what students actually do during their clinical experiences and how the time spent in clinical settings can be most effective in helping them learn the practice” (p. 2). The attributes of an ideal clinical education model were identified as:

- 1) integrative experience,
- 2) new relationships,
- 3) learning experiences, and
- 4) environmental considerations.

Under #2, new relationships, faculty were encouraged to focus on patient outcomes rather than tasks and to design experiences matched to the learner’s needs, interests, and concerns. Under #3, learning experiences, there is a call to address core concepts that are transferable from one setting to another. Called out in bold was the statement “in essence, we need to focus on what students need to learn instead of how we deliver education, the number of hours required, the ‘rotations’ students complete, etc.” (NLN, 2008, p. 8).

The prestigious IOM (Greiner & Knebel, 2003) also recommended the implementation of a core set of competencies for clinical education (see Appendix B). The IOM recommendation flowed from a summit on health professions education and the need for educational reform. The IOM presented a set of 5 core competencies that all health care professionals should have, regardless of discipline. These are:

- 1) provide patient-centered care,
- 2) work in interdisciplinary teams,
- 3) employ evidence-based practice,
- 4) apply quality improvement, and
- 5) utilize informatics.

These competencies are interrelated. The IOM noted that educational institutions are moving toward outcome-based education as an approach to ensure that students can demonstrate core competencies at graduation. Identification of competencies is a first step. Then “the knowledge, skills, and attitudes underpinning each competency need to be clearly articulated in writing and related measures developed. Assessment tools must then be matched to each competency to evaluate outcomes...” (Greiner & Knebel, 2003, p. 89).

In a recent analysis of the articulation of nursing education and practice, Donley and Flaherty (2008) analyzed the issue of the value nursing places on achievement of clinical experience in educational programs. They noted (p. 5):

Nursing leaders have failed to reach agreement or consensus about the amount, type, and measurement of the clinical experience necessary for academic or clinical advancement. Additionally, divergent opinions exist among nursing’s leaders, faculty, and nurses at the

point-of-service regarding the clinical experience needed before seeking additional academic preparation. There are also differences of opinion about the amount, type, and measurement of clinical experience necessary to meet licensing, accreditation, and certification standards. They also noted that although provision for adequate and supervised clinical experience is embedded in nursing's academic tradition, beliefs about the amount, type, and measurement of clinical experience are barriers to overcome in innovative curricula. They stated (pp. 5-6):

Commonly held opinions suggest that a specified number of clock hours/clinical practice credits are essential for students in pre-professional and specialty programs. A new initiative by nurse practitioner groups, the American Nurses Credentialing Center (ANCC) and the National Council of State Boards links the title advanced practice nurse to a new set of definitions, one of which prescribes the number of clinical hours spent in direct care of individuals during educational programs and prior to applying for re-certification (ANA, 2008; ANCC, 2008; ANCC, 2007). Specifically, the American Nurses Association (2008) recently published a white paper which uses licensing, accreditation, certification, and education (LACE) themes to promote a regulatory model which identifies characteristics of advanced practice and the use of the title APRN. This model states that applications for certification and licensure must provide evidence that a specified number of clinical hours has been achieved. These opinions, arising from nursing's roots in apprenticeship education and concerns with process elements in the curriculum, have been accepted, codified by practice acts and accrediting bodies, but never tested. Second-wave, career ladder programs, especially accelerated programs, and first professional degree programs challenge this unexamined belief.

It appears that Excelsior College's program is enmeshed in a current context of national scrutiny regarding clinical instruction in nurse prelicensure education. National organizations such as NCSBN, NLN, the IOM, and thinkers in the field of nurse education see urgent issues and are calling for educational reform. Particularly, the theme of a call for determining core competencies appears across national organizations such as the NLN and IOM.

Core Competencies

Determining core competencies are vital to standardized preparation of nursing students. The NLN does publish core competencies for ADN education (NLN, 2000). Core competencies were defined by Axley (2008, p. 216) as referring specifically to "a group or compilation of skills or procedures requiring the ability of an individual to successfully or competently perform the requisite action." Logic would indicate that demonstration of benchmarked performance on core competencies would be accepted as evidence of sufficient clinical competence.

Axley (2008) noted that a review of the literature suggests that there is no clear definition of competency, despite research in nursing and health care on competency in cognitive ability and clinical proficiency. There appears to be confusion and lack of consensus with regard to the overall core competencies in nursing practice. There are at least three broad areas of competency: knowledge, critical thinking, and clinical/psychomotor skills. Zhang et al. (2001) reviewed nursing studies from 1990 to 2000, finding multiple different, overlapping classifications of core competencies, and noting that some agreement exists for three categories of nurse core competencies:

- 1) interpersonal competence,
- 2) critical thinking, and
- 3) technical skills.

There is a notable lack of a consensus definition of nursing competency (Axley, 2008; Chen & Naquin, 2005), although Axley's (2008) concept analysis using the Walker and Avant (1995) eight-step method provides beginning clarity. Schmalenberg et al. (2008, p. 54) said "competency is multifaceted and evident through actions." They equated competency with adequacy with regard to the accepted standard of practice, having sufficient knowledge, judgment, or skill. Their qualitative study of competency performance domains, obtaining descriptions of effective nurse performance from 446 professionals (including 244 staff nurses, 105 managers, and 97 MDs), led to six categories of competency performance domains:

- 1) autonomous clinical decision making,
- 2) prioritizing and multitasking,
- 3) interpersonal competence,
- 4) technical skill competence,
- 5) knowledge competence, and
- 6) quality of patient outcomes competence.

Confusion abounds about the definition, core aspects, measures, and educational strategies needed for nurse competency.

Conclusions

Despite the lack of evidence, the issue first presented in the NCSBN's (2005) Delegate Assembly resolution regarding ensuring clinical competence in prelicensure programs remains an important and urgent one for the profession of nursing and its regulation to safeguard the public. The 2005 NCSBN position paper contains many hints about the pressures which are or may come to bear on this issue. For example, "whether nursing educational programs leading to initial licensure can successfully educate nurses with alternative methodologies that take the place of traditional clinical experiences" (p. 3) has many implications for the rapidity

with which the nursing workforce might be able to be prepared, the availability of clinical sites especially in hospitals, the costs of nursing education, the looming faculty shortage, and many other professional issues of access to, quality of, and costs related to nursing education. Indeed, “One nursing education organization commented that the clinical nursing literature focuses on competent performance and student-centered learning in nursing programs, moving away from rigid parameters” (NCSBN, 2005, p. 8).

The 2005 NCSBN position paper features the prediction that in the future there will be more clinical education using simulation, clinical laboratories, and online learning. Some would argue that in 2009, these non-traditional methods that leverage technology to provide nursing clinical educational experiences are already fairly sophisticated and rapidly growing, even further challenging ways to address the need to demonstrate clinical competence in prelicensure nursing programs.

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Table 1.
Comparison of Associate Degree Nursing Population Demographics to Total RN Population

	Associate Degree Nursing	Total RN Population
White	76.4 %	86.6 %
Black	10.0 %	04.9 %
Hispanic	06.3 %	02.0 %
Asian	03.9 %	03.5 %
American Indian	01.1 %	00.5 %
Women	89.3 %	94.6 %
Men	10.7 %	05.4 %

Note: Data from *The Registered Nurse Population, March 2000, Findings from the National Sample Survey of Registered Nurses* by Spratley, E., Johnson, A., Sochalski, J., Fritz, M., and Spencer, W. (2001), published by U.S. Department of Health and Human Services.

Appendices

Appendix A: Systems to Grade the Strength of Evidence: An Overview

Appendix B: Overview of the Institute of Medicine

References

APPENDIX A

Systems to Grade the Strength of Evidence: An Overview

The Mayer reference in the NCSBN's 2005 position paper is from an evidence-based medicine book from Cambridge, England. In the U.S., the authoritative source for grading the evidence base, especially for creating evidence-based practice guidelines, comes originally from the Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research) (AHRQ, 2002a). Their hierarchy of study types is:

- Systematic reviews and metaanalyses of randomized controlled trials
- Randomized controlled trials
- Nonrandomized intervention studies
- Observational studies
- Nonexperimental studies
- Expert opinion

This conceptualization is often cited but relies on the evaluation of the study design alone. It has been criticized for its weaknesses (Harbour et al., 2001). Harbour (2001) and colleagues noted that guideline developers “often fail to take adequate account of the methodological quality of individual studies and the overall picture presented by a body of evidence rather than individual studies or they fail to apply sufficient judgment to the overall strength of the evidence base and its applicability to the target population of the guideline” (p. 334). AHRQ, in technical bulletin #47, reviewed seven different systems to grade the strength of evidence and compared them in a table, found at (<http://www.ncbi.nlm.nih.gov/books/bv.fcgi?indexed=google&rid=hstat1.table.71628>) (AHRQ, 2002b). This table is reproduced below.

The U.S. Preventive Services Task Force of AHRQ has as its purpose to provide users with information about the extent to which recommendations are supported by evidence, allowing them to make more informed decisions about implementation. The general principles the task force follows in making recommendations can be found at (<http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm#source>). Harris et al. (2001) described the task force's evidence-based scoring system.

Another perspective on grading the evidence for practice suggests that there is a better way to refine the system for evaluating guideline evidence and grading recommendations to increase the robustness by having the grading system incorporate formal assessment of the methodological quality, quantity, consistency, and applicability of the evidence base (Harbour et al., 2001). Individual studies need to be evaluated in more depth than rating the study's design alone, and Harbour and colleagues explain how they suggest this be done. A full and detailed description of how to interpret levels of evidence and grades of health care recommendations can be found in DiCenso and Guyatt (2005).

Table 23.

Characteristics of Seven Systems to Grade Strength of Evidence

Source	Domain				
	Quality	Quantity	Consistency	Strength of Evidence Grading System	Comments
Gyorkos et al., 1994 ⁸¹	Validity of studies	Strength of association and precision of estimate	Variability in findings from independent studies	<p>Overall assessment of level of evidence based on four elements:</p> <ul style="list-style-type: none"> ■ Validity of individual studies ■ Strength of association between intervention and outcomes of interest ■ Precision of the estimate of strength of association ■ Variability in findings from independent studies of the same or similar interventions <p>For each element a qualitative assessment of whether there is strong, moderate, or weak support for a causal association</p>	
Clarke and Oxman, 1999 ¹¹	Based on hierarchy of research design, validity, and risk of bias	Magnitude of effect	Consistency of effect across studies	<p>Questions to consider regarding the strength of inference about the effectiveness of an intervention in the context of a systematic review of clinical trials:</p> <ul style="list-style-type: none"> ■ How good is the quality of the included trials? ■ How large and significant are the observed effects? ■ How consistent are the effects across trials? ■ Is there a clear dose-response relationship? ■ Is there indirect evidence that supports the inference? ■ Have other plausible competing explanations of the observed effects (e.g., bias or cointervention) been ruled out? 	<p>Other domains:</p> <ol style="list-style-type: none"> 1. Dose-response relationship 2. Supporting indirect evidence 3. No other plausible explanation

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Source	Domain				
	Quality	Quantity	Consistency	Strength of Evidence Grading System	Comments
Briss et al., 2000 ⁸²	<p>Threats to Validity:</p> <ul style="list-style-type: none"> ■ Study description ■ Sampling ■ Measurement ■ Data analysis ■ Interpretation of results ■ Other <p>Quality of Execution:</p> <ul style="list-style-type: none"> ■ Good (0-1 threats) ■ Fair (2-4 threats) ■ Limited (5+ threats) <p>Design suitability:</p> <p>Greatest concurrent comparison groups and prospective measurement Moderate all retrospective designs or multiple pre or post measurements; no concurrent comparison group. Least single pre and post measurements; no concurrent comparison group or exposure and outcome measured in a single group at the same point in time.</p>	<p>Effect size</p> <ul style="list-style-type: none"> ■ Sufficient ■ Large ■ Small <p>Larger effect sizes (absolute or relative risk) are considered to represent stronger evidence of effectiveness than smaller effect sizes with judgments made on an individual basis</p>	<p>Consistency as yes or no.</p>	<p>Evidence of effectiveness is based on execution, design suitability, number of studies, consistency, and effect size</p> <p>Strong:</p> <ul style="list-style-type: none"> ■ Good and greatest, at least 2 studies consistent, sufficient ■ Good/fair and great/moderate, at least 5 studies, consistent, sufficient ■ Good/fair and any design, at least 5 studies, consistent, sufficient ■ Sufficient ■ Good and greatest, one study, consistency unknown, sufficient ■ Good/fair and great/moderate, at least 3 studies, consistent, sufficient ■ Good/fair and any design, at least 5 studies consistent, sufficient <p>Expert opinion: sufficient effect size</p> <p>Insufficient: insufficient design, too few studies, inconsistent, small effect size</p>	

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Source	Domain				
	Quality	Quantity	Consistency	Strength of Evidence Grading System	Comments
Greer et al., 2000 ⁸³	Strong design not defined but includes issues of bias and research flaws	System incorporates number of studies and adequacy of sample size	Incorporates consistency	<p>Grade</p> <p>I: Evidence from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.</p> <p>II: Evidence from studies of strong design but there is some uncertainty due to inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Or, evidence consistent from studies of weaker designs.</p> <p>III: The evidence is from a limited number of studies of weaker design. Studies with strong design either haven't been done or are inconclusive.</p> <p>IV: Support solely from informed medical commentators based on clinical experience without substantiation from the published literature.</p>	Does not require a systematic review of the literature—only six “important” research papers.
Guyatt et al., 2000 ⁸⁴	Based on hierarchy of research design, with some attention to size and consistency of effect	Multiplicity of studies, with some attention to magnitude of treatment effects	Consistency of effect considered	<p>Hierarchy of evidence for application to patient care:</p> <ul style="list-style-type: none"> N of 1 randomized trial Systematic reviews of randomized trials Single randomized trials Systematic review of observational studies addressing patient-important outcomes Single observational studies addressing patient-important outcomes Physiologic studies Unsystematic clinical observations <p>Authors also discuss a hierarchy of preprocessed evidence that can be used to guide the care of patients:</p> <ul style="list-style-type: none"> Primary studies—by selecting studies that are both highly relevant and with study designs that minimize bias, permitting a high strength of inference Summaries—systematic reviews Synopses—of individual studies or systematic reviews Systems—practice guidelines, clinical pathways, or evidence-based textbook summaries 	<p>Evidence defined broadly as any empirical observation about the apparent relationship between events.</p> <p>“The hierarchy is not absolute. If treatment effects are sufficiently large and consistent, for instance, observational studies may provide more compelling evidence than most RCTs.”</p>

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Source	Domain				
	Quality	Quantity	Consistency	Strength of Evidence Grading System	Comments
NHS Centre for Evidence Based Medicine, (http://cebmr2.ox.ac.uk) (Accessed 12-2001) ⁸⁵	Based on hierarchy of research design with some attention to risk of bias	Multiplicity of studies, and precision of estimate	Homogeneity of studies considered	<p>Criteria to rate levels of evidence vary by one of four areas under consideration (Therapy/Prevention or Etiology/Harm; Prognosis Diagnosis and Economic Analysis). For example, for the first area (Therapy/Prevention or Etiology/Harm) the levels of evidence are as follows:</p> <p>1a: SR with homogeneity of RCTs 1b: Individual RCT with narrow 1c: All or none (this criteria met when all patients died the treatment became available and now some survive or some died previously and now none die) 2a: with homogeneity of cohort studies 2b: Individual cohort study (including low quality RCT; e.g., <80% follow-up) 2c: "Outcomes" research 3a: SR with homogeneity of case-control studies 3b: Individual case-control study 4: Case-series and poor quality cohort and case-control studies 5: Expert opinion without explicit critical appraisal or based on physiology, bench research or "first principles."</p>	
Harris et al., 2001 ⁸⁶ (for the U.S. Preventive Services Task Force)	Based on hierarchy of research design and methodological quality (good, fair, poor) within research design	Number of studies, see Consistency	Consistency Consistency is not required by the Task Force but if present, contributes to both coherence and quality of the body of evidence	<p>Levels of evidence:</p> <p>I Evidence from at least one properly randomized controlled trial</p> <p>II-1 Well-designed controlled trial without randomization</p> <p>II-2 Well-designed cohort or case-control analytic studies, preferably from more than one center or group</p> <p>II-3 Multiple time series with or without the intervention (also includes dramatic results in uncontrolled experiments)</p> <p>III Opinions of respected authorities, based on clinical experience, descriptive studies, and case reports, or reports of expert committees</p> <ul style="list-style-type: none"> ■ Aggregate internal validity is the degree to which the study(ies) provides valid evidence for the population and setting in which it was conducted. ■ Aggregate external validity is the extent to which the evidence is relevant and generalizable to the population and conditions of typical primary care practice. ■ Coherence/consistency 	<p>Other domains:</p> <p>Coherence</p> <p>Coherence implies that the evidence fits the underlying biologic model</p>

Source: Agency for Healthcare Research and Quality (AHRQ). (2002). Table 23. Characteristics of seven systems to grade strength of evidence. AHRQ Evidence Report Number 47 (AHRQ Pub. No. 02-E015). Rockville, MD: AHRQ. Retrieved June 4, 2009, from (<http://www.ncbi.nlm.nih.gov/books/bv.fcgi?indexed=google&rid=hstat1.table.71628>)

APPENDIX B

Overview of the Institute of Medicine

Background

The Institute of Medicine (IOM) is a nonprofit organization chartered in 1970 as a part of the National Academy of Sciences (IOM, 2009a). The National Academy of Sciences is described as:

...created by the federal government to be an adviser on scientific and technological matters. However, the Academy and its associated organizations (e.g., the Institute of Medicine) are private, non-governmental, organizations and do not receive direct federal appropriations for their work. Studies undertaken for the government by the Academy complex usually are funded out of appropriations made available to federal agencies. Most of the studies carried out by the Academy complex are at the request of government agencies (IOM, 2009a, p. 1).

The Institute of Medicine (IOM) has become the nation's authoritative voice for science-based advice on matters of biomedical science, medicine, and health. It is a nonprofit organization specifically created for this purpose:

The Institute provides a vital service by working outside the framework of government to ensure scientifically informed analysis and independent guidance. The IOM's mission is to serve as adviser to the nation to improve health. The Institute provides unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large (IOM, 2009b, p. 1).

The IOM is uniquely positioned to be an expert resource on health care issues due to its congressional charter yet independent nonprofit status. Unpaid volunteer experts author most reports. "Each report must go through the IOM/NRC institutional process, assuring a rigorous and formal peer review process, a requirement that findings and recommendations be evidence-based whenever possible and noted as expert opinion where that is not possible" (IOM, 2009a, p. 1).

Current Projects of Interest

Two current projects of potential interest are:

1. The Robert Wood Johnson Foundation Initiative on the Future of Nursing, at the Institute of Medicine (IOM, 2009c), and

2. The Committee on Planning a Continuing Health Care Professional Education Institute (IOM, 2009d)

The Robert Wood Johnson Foundation and IOM project is described as:

The Institute of Medicine (IOM), in collaboration with the Robert Wood Johnson Foundation (RWJF), has established a major initiative on the future of nursing. Nursing faces a number of challenges that must be overcome to fulfill the promise of health care reform and meet the nation's health needs. The future of health care is closely tied to the future of nursing, and it is critical to ensure that the nursing workforce has the capacity in numbers and skill competencies to meet present and future needs. The IOM committee will define a clear agenda and blueprint for action including changes in public and institutional policies at the national, state, and local levels. The committee's recommendations will address a range of system changes, including innovative ways to improve health care quality and address the nursing shortage in the United States (IOM, 2009c, p. 1).

The Committee on Planning a Continuing Health Care Professional Education Institute project is described as:

undertaking a review of issues in continuing education of health care professionals (in particular physicians and nurses) that are identified from the literature and from data-gathering meetings with involved parties. Based on this review, the committee is making recommendations for the establishment of a national inter-professional Continuing Education (CE) Institute to advance the science of CE by promoting the discovery and dissemination of more effective methods of educating health professionals over their professional lifetimes, by developing a research enterprise that encourages increased scientific study of CE, by developing mechanisms to assess research applications, by stimulating new approaches to both intra- and inter-professional CE, and by being independent and composed of individuals from the various health professions (IOM, 2009c, p. 1).

Crossing the Quality Chasm Series

In 1996, the Institute of Medicine (IOM) launched a targeted, ongoing effort focused on assessing and improving the nation's quality of care, called the Crossing the Quality Chasm series. The Crossing the Quality Chasm series is now in its third phase (IOM, 2009e).

The first phase documented the serious and pervasive nature of the nation's overall quality problem, finding that the burden of harm from health care quality problems was staggering. A framework was established that defined the nature of the problem as one of overuse, misuse, and under use of health care services (Chassin et al., 1998; IOM, 2009e).

The second phase was from 1999-2001. The Committee on Quality of Health Care in America presented a vision for how the health care system and related policy environment must be radically transformed in order to close the chasm between what we know to be good quality care and what actually exists in practice. The landmark reports released during this phase were *To Err is Human: Building a Safer Health System* (Kohn, 2000) and *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM, 2001), both highlighting the essential need to address health care delivery systems. The *Quality Chasm* report defined six aims: care should be safe, effective, patient-centered, timely, efficient and equitable.

The IOM currently is the third phase of its quality initiative. The focus now is on operationalizing the vision of a future health system described in the *Quality Chasm* report. Phase three features the engagement of clinicians/ health care organizations, employers/ consumers, foundations/ research, government agencies, and quality organizations also working to create a more patient-responsive health care system. The focus is on reform at three different overlapping levels of the system: the environmental level, the level of the health care organization, and the interface between clinicians and patients (IOM, 2009e).

Relevant Documents from the IOM

Keeping Patients Safe: Transforming the Work Environment of Nurses (Page, 2004). This report:

identifies solutions to problems in hospital, nursing home, and other health care organization work environments that threaten patient safety through their effect on nursing care. The report puts forth a blueprint of actions that all health care organizations which rely on nurses should take. The report's findings and recommendations address the related issues of management practices, workforce capability, work design, and organizational safety culture. Actions needed from the federal and state governments, as well as from coalitions of parties involved in shaping the work environments of nurses also are specified. The report presents evidence from health services, behavioral, and organizational research, and human factors and engineering to address pressing public policy questions including nurse staffing levels, nurse work hours, and mandatory overtime (IOM, 2009e, p. 1).

Health Professions Education: A Bridge to Quality (Greiner & Knebel, 2003). This report focuses on reforming health professions education and:

sets out a vision for all programs and institutions engaged in clinical education, recommending the implementation of a core set of competencies and targeting a mix of approaches including leveraging oversight organizations, fostering enhanced training environments, and initiating public reporting. This report benefited greatly from the ideas of 150 interdisciplinary experts who attended an IOM summit on health professions education and contributed ideas about educational reform (IOM, 2009e, p. 1).

The IOM proposed a set of core competencies for all health care practitioners, summed up as: “All health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidence-based practice, quality improvement approaches, and informatics” (Greiner & Knebel, 2003, p. 45).

IOM Charge to the National Council of State Boards of Nursing (NCSBN)

In the IOM report on patient safety that addressed transforming the work environment and the changes that are needed at the organizational level in health care (p. 15, 2004), the IOM included a specific recommendation for the NCSBN (Recommendation 7.2 on page 15):

Recommendation 7-2. The National Council of State Boards of Nursing, in consultation with patient safety experts and health care leaders, should undertake an initiative to design uniform processes across states for better distinguishing human errors from willful negligence and intentional misconduct, along with guidelines for their application by state boards of nursing and other state regulatory bodies having authority over nursing.

The inclusion of a specific charge to the NCSBN about the need for uniform processes, in this case to better distinguish human errors from negligence and misconduct, brings to the forefront the critical public protection aspect of nursing regulation. It suggests that the variance in the regulations and practices among the 50 states may be detrimental to patient safety. With the Nurse Licensure Compact (NLC) currently implemented in 23 states (NCSBN, 2008) but not in 27 states, there still exists a gap in the nurse licensure and professional practice regulations from state to state.

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