The Comprehensive Osteopathic Medical Licensing Examination, COMLEX–USA: a new paradigm in testing and evaluation

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Medical licensure in the United States demands a dynamic and current means to evaluate the competency of physicians seeking to practice medicine. A systematic measuring tool is required—one that is based on actual patient encounters and how physicians should apply their knowledge and skills to the clinical setting according to their level of training and professional development. Osteopathic physicians have a distinctive approach to healthcare, applying the biopsychosocial model with emphasis on the neuromusculoskeletal system. A component of this distinctive approach is a high level of knowledge and skill in the application of osteopathic manipulative treatment.

Developed by the National Board of Osteopathic Medical Examiners, COMLEX–USA is the new sequential three-level examination process for osteopathic medical licensure in the United States. The examination process is interdisciplinary and highly clinical, with even basic science components tested within a clinical context. Examination content is based on wide expert consensus and data consistent with osteopathic medical education, training, and practice. Its design is a novel multidimensional structure that emphasizes clinical problem-solving skills and osteopathic principles and practice within the context of life cycle, gender, ethnicity, and points of service. Design schemata and blueprints are included along with descriptions of strategic research and development. COMLEX–USA represents the most appropriate pathway for initial licensure for a distinctive and unique professional: the osteopathic physician in the United States.

(Key words: COMLEX–USA, licensure, osteopathic medical education, training, practice)

All physicians begin their medical careers the same way: they attend medical school, complete their graduate medical training, and successfully pass a medical licensing examination that is deemed acceptable by the state in which they choose to practice. For more than a century, state licensing boards have had ultimate authority for determining whether physicians have met those criteria.

Historically, state medical boards have consistently relied on two discrete pathways to licensure: allopathic and osteopathic. The osteopathic pathway integrates medical knowledge with osteopathic theory, technique, and practice. Recognizing that osteopathic physicians are trained to practice a comprehensive style of medicine that emphasizes how the structural harmony of the body affects efforts to prevent and treat illness, many state boards use separate examinations to test those qualifying as osteopathic practitioners and candidates seeking qualification as allopathic practitioners.

The role of the examination is critical in the licensing process because it is the instrument that objectively places the knowledge and skills learned in medical school and graduate medical education in the context of the environment of physicians' practices. To the best extent possible, the licensing examinations must mirror the setting in which diagnostic and management decisions on patient care are made and place the questions about patient care in the context of the demanding cost-conscious framework of today's medical practice.

In 1990, the National Board of Osteopathic Medical Examiners (NBOME) responded to the dramatic changes occurring within the healthcare community and in the broader demographic landscape. They began developing a new paradigm of osteopathic medical licensing examination that would better integrate the education, training, and practice of osteopathic physicians and the real-world marketplace of medical care. After years of planning, NBOME launched the initial administration of Level 3 of the Comprehensive Osteo-

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pathic Medical Licensing Examination (COMLEX–USA) in 1995. Level 2 was implemented in March 1997, and the entire examination sequence was completed with the first administration of Level 1 in June 1998.

COMLEX–USA differs from previous osteopathic licensing examinations not only in its enhanced clinical relevance to current practices, but also in its renewed and heightened attention to the distinctiveness of osteopathic principles and practices, its commitment to what is essential in primary care, and, most distinctly, its use of an integrated single outline throughout all three components of the examination process for initial licensure.

The COMLEX–USA sequence—lifelong learning

The COMLEX–USA sequence is consistent with the lifelong learning approach to osteopathic medical education, training, and practice. Students begin this pattern of obtaining knowledge and skills at their entry to medical school and continue throughout their careers. Traditionally, the first 2 years of osteopathic medical school curriculum have been concerned with teaching preclinical knowledge and skills that focus on the fundamentals of basic science and introductory patient assessment. Recently, however, many osteopathic medical schools are advancing more "problem-oriented" curricula so that even the basic sciences are taught in a clinically oriented manner. The COMLEX–USA Level 1 is ordinarily taken near the end of the second year of osteopathic medical school and reflects this newer problem-oriented approach by using a uniform outline focused on the practical applicability of the "cone" of core knowledge, illustrated by the vertical band extending throughout the entire practice life of an osteopathic physician (*Figure 1*).

As students advance through school, the cone of knowledge widens to include the expanding base of core knowledge plus the increasing range of clinical experience gained throughout the last 2 years of school and rotating or track internships. The core subject areas remain constant over the entire practice life of the physician, but the advancing student doctor has a progressively wider breadth of assessment. Level 2 is ordinarily taken during the senior year of osteopathic medical school and examines clinical knowledge and problem solving consistent with this phase of the 4-year curriculum.

The final examination, Level 3, is the last step in initial osteopathic medical licensure. Taken toward the end of the candidate's first postgraduate year, this level assesses the wide scope of practical clinical information a candidate is expected to bring to the core areas of osteopathic medical knowledge with strong emphasis on patient management knowledge and skill.

The lifelong learning cone also takes into consideration the degree of specialization that begins during the internship process as physicians might begin to specialize in specific areas of practice and research. The inverted cones in *Figure 1* indicate the increasing degree of sophistication over a narrow area of knowledge, with the accompanying assessment points being those examinations given by the specialty and subspecialty certifying boards.

For some physicians, a further assessment of their continued competency may be necessary if for any reason their practice is interrupted. In contrast to the preceding narrow focus of the specialty boards, the process of continued competency assessment covers medical practice in the broadest sense. At this point in a physician's practice, it is expected that the candidate has a wide variety of clinical experiences combined with a solid grasp of the underlying foundation of core knowledge. The COMLEX–USA sequence continues its emphasis on a lifelong learning approach by extending a uniform line of measurement to the relicensure process. NBOME's newest product, the Comprehensive Osteopathic Medical Variable-Purpose Examination (COMVEX–USA), initiated in April 1997, allows state boards to use a uniform path of osteopathic assessment examinations. It was first administered in February 1998 and has been adopted by a number of state boards.

By utilizing a single integrated outline, the COMLEX–USA licensure and continued competency sequence allows an examinee's knowledge base to be assessed in a uniform pattern throughout his or her entire practice life. Both the increasing breadth of examinee knowledge as applied to core subject areas, and the increasing sophistication of physician decision-making can be measured against the same criteria from the process of initial licensure to relicensure.

COMLEX–USA development

The design and development of the COMLEX–USA series began in the summer of 1993. Enlisting a large group of academicians and practicing physicians in a variety of specialty areas and wide geographic representation, the committee first articulated the foundation of a new examination blueprint. The committee reviewed a wide selection of primary source materials, including studies by Koch and McLemore (National Center for Health Statistics 1987 and 1991) on surveys of osteopathic office practice. The committee also undertook a profession-wide survey to determine the high-frequency/high-impact patient problems presenting in the osteopathic primary care setting. The group then began to designate areas of examination content to address those subject areas most characteristic of the practice of osteopathic medicine with an emphasis on ambulatory settings. Thus, from the beginning, the intention of the COMLEX–USA sequence was to use the actual practice patterns of osteopathic primary care physicians as an overlay to the curricula of osteopathic medical schools.

Working in reverse manner, the team determined the preceding knowledge and clinical decision-making elements that an osteopathic physician must have to make clinical decisions independently. Beginning with Level 3, the test committee determined by consensus the degree of sophistication and knowledge discrimination the candidate should pos-

sess. Then, using an overlay of high-impact/high-frequency patient encounters, committee members decided which skills and information a practicing osteopathic primary care physician would use to make decisions about patient care. From this clinical starting point, the test construction team determined the preceding knowledge blocks of scientific understanding and biomechanical mechanisms that are the underpinning of clinical decision making. By beginning with Level 3, the team steered the preceding two levels to become more clinically relevant and permitted the fundamentals of biomedical science to be applied to clinical situations and settings.

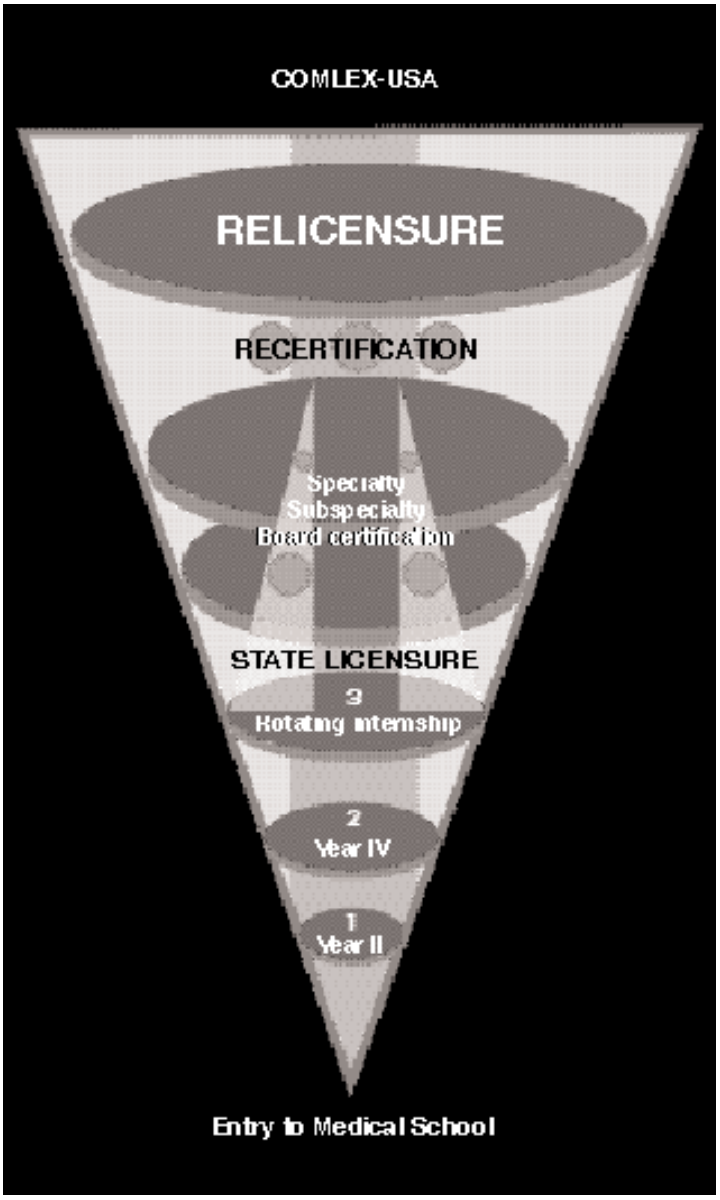
COMLEX–USA osteopathic practice model

The examination outline is organized along the integration of two major axes or dimensions of patient encounters and physician knowledge and skills. Both of these dimensions are uniform and consistent through all levels of the COMLEX–USA sequence, as the same grid was used to compose the examination. The first axis (Dimension I) is modeled after a problem-oriented approach to patient care. On the axis, patient encounters are broadly collapsed into the homeostatic categories of body systems, capabilities, and clinical signs and symptoms.

Figure 2 details the patient encounters and healthcare delivery issues of Dimension I. The two primary divisions are those of patient physician encounters—the immediate reasons why patients visit their clinicians—and the medical setting that a physician must balance to effectively deliver medical care. These issues form the working environment of today's healthcare professionals and include cost management, regulatory agencies, medical ethics and jurisprudence, and other related matters. With an emphasis on the listed subject areas, Dimension I is consistent over each examination level. In the lifelong learning cone, the core knowledge areas of Dimension I are indicated by the vertical plane running throughout the length of an osteopathic physician's practice life (*Figure 1*).

The second axis, Dimension II, contains six components (*Figure 3*) and considers the expanding knowledge that an examinee would bring to the situations of Dimension I. The changing emphases of Dimension II across the three levels of COMLEX–USA are shown in the *Table*. At Level 1, the examination outline reinforces the clinical relevance of the first 2 years of osteopathic medical school by placing the knowledge and understanding of biological, behavioral, biomechanical mechanisms, and osteopathic manipulative techniques in a clinically oriented setting. Approximately 80% of the items from Dimension II address basic science concepts underlying disease mechanisms. Integrated throughout is an emphasis on ambulatory care and stages of the life cycle that represent the scope of patients seen in typical primary care settings. Additionally, the examination grid was constructed to be flexible to accommodate the constant changes in medical knowledge and practice.

Using the identical outline, Level 2 emphasizes the evolving areas of clinical knowledge examinees possess as their medical education is completed, with the majority of examination items focusing on clinical application to the patient encounters of Dimension I. Level 3



◀ **Figure 1.** *Lifelong learning: osteopathic physician education, training, and practice.*

COMLEX–USA Dimension I content outline

■ **Patient encounters**
- ☐ Alimentation
- ☐ Circulation
- ☐ Cognition
- ☐ Consciousness
- ☐ Daily activities
- ☐ Emotions
- ☐ Growth
- ☐ Integument
- ☐ Movement
- ☐ Personal habits
- ☐ Relationships
- ☐ Reproduction and sexual function
- ☐ Respiration
- ☐ Sensations
- ☐ Sleep
- ☐ Thermoregulation
- ☐ Urination

■ **Patient encounters, continued**
- ☐ Alteration in activity
  - fatigue
  - weakness
- ☐ Alteration in comfort
  - disequilibrium
  - pain, acute/chronic
  - paresthesia/dysthesia
  - pruritus
  - vertigo
- ☐ Asymptomatic
- ☐ Bleeding
- ☐ Discharge
- ☐ Masses
- ☐ Swelling

■ **Healthcare delivery**
- ☐ Administrative and regulatory agencies
- ☐ Community medicine
- ☐ Community resources
- ☐ Cost management
- ☐ Laws and regulations
- ☐ Medical ethics
- ☐ Medical jurisprudence
- ☐ Patients' rights
- ☐ Practice management
- ☐ Quality assurance

Figure 2

stresses the management knowledge osteopathic physicians should utilize to practice independent, unsupervised care.

The use of the same outline for all three levels allows test construction teams to modify examination questions to appropriately assess examinee knowledge across all three examination levels. This allows NBOME to not only provide a clear level of assessment, but to allow for efficiency of item use. The following test items provide examples of how test items are practically revised.

At Level 1, the test item focuses on the basic biological defects caused by a vitamin B_{12} deficiency:

A 70-year-old man presents with anemia. The red cell indices indicate hyperchromia, macrocytosis, and hypersegmented neutrophils. The underlying abnormality best explaining the anemia is:

(A) abnormal β-globulin synthesis resulting in ineffective erythropoiesis
(B) failure of erythropoietin secreting function of the kidney
(C) G-6-PD deficiency causing damage to cells via oxidative stress
(D) impairment of DNA syntheses secondary to vitamin B_{12} deficiency
(E) impairment of RNA syntheses secondary to iron deficiency

Answer *D* is correct. The distractors are a variety of physiologic findings associated with anemias. The answer suggests a specific abnormality for B_{12}.

The same item presented in Level 2 focuses on the diagnostic skills a fourth-year osteopathic medical student would bring to the same problem:

A 70-year-old man presents with anemia. The red cell indices indicate hyperchromia and macrocytosis. The abnormality suggesting B_{12} deficiency is:

(A) generalized lymphadenopathy
(B) hepatosplenomegaly
(C) scleral icterus
(D) increased reticulocyte count
(E) hypersegmented neutrophils on peripheral smear

Answer *E* is correct. The distractors are a variety of laboratory and physical findings associated with anemia. The answer suggests a specific abnormality seen with B_{12} deficiency.

The item as used in Level 3 assesses the treatment and management skills expected of a resident osteopathic physician:

A 70-year-old man presents with anemia. The red cell indices indicate hyperchromia, hypersegmented neutrophils, and macrocytosis. The most likely clinical benefit from the correction of the cause of the anemia is:

(A) improvement in dementia
(B) improved renal function
(C) improved respiratory function
(D) reversal of jaundice
(E) reversal of splenomegaly

Answer *A* is correct. The sequelae of anemia can result in a variety of abnormalities that can be reversed with appropriate treatment. The answer highlights a common abnormality that can be improved with treatment when caused by a B_{12} deficiency.

Each of the three examples are categorized in the same way under Dimen-

sion I, yet the physician knowledge that each example demonstrates is classified uniquely under Dimension II—Level 1 illustrates the scientific understanding of basic mechanisms, Level 2 stresses clinical assessment, and Level 3 presents the item with a case-management orientation.

Application of osteopathic principles is interwoven throughout the entire examination at all three COMLEX–USA sequence levels, with a significant number of test items having clear osteopathic orientation. An example of this integration is seen in the application of structural and palpatory diagnosis and osteopathic manipulative techniques in the diagnosis and management of patients.

In Level 1, knowledge of basic osteopathic concepts and biomechanical principles are examined as illustrated in the following test item:

A 24-year-old man with thoracic back pain has acute tissue texture changes in the right midthoracic paraspinal tissues. Palpatory examination reveals a posterior transverse process of T7 on the right side that becomes more prominent when the thoracic spine is extended. Which of the following is true regarding this somatic dysfunction?

(A) flexion motion is restricted
(B) left sidebending is restricted
(C) motion between T6 and T7 is abnormal

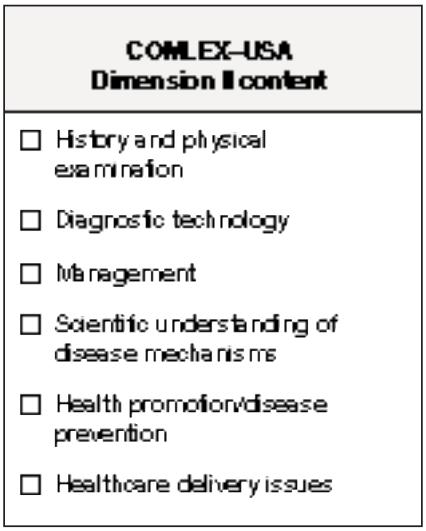


Figure 3

(D) motion restriction is maintained by long restrictor muscles
(E) rotation toward the right is restricted

Answer *B* is correct. The student must understand the physiologic motion characteristics of the thoracic vertebral column and the proper terminology for describing abnormalities of motion in this region.

In Level 2, the integration of structural findings in the differential diagnosis is one aspect of the osteopathic examination:

A 44-year-old woman with a complaint of vague abdominal pain has tissue texture changes in the right paraspinal tissues at the T8-T9 level. The most likely viscerosomatic relationship is with which of the following organs?

(A) colon
(B) gallbladder
(C) ovary
(D) spleen
(E) stomach

The correct response is *B*. The visceral afferent nerves from the gallbladder enter the spinal cord in the T8-T9 region on the right side. The distractors are organs whose visceral afferents enter the cord at other sites.

In Level 3, where unsupervised patient care is emphasized, osteopathic manipulative treatment (OMT) in patient management is highlighted:

A 35-year-old man presents with right lower back pain that began after moving furniture at home. Neurologic examination is normal. A diagnosis of lower back strain of mechanical origin is made. Structural findings include hypertonicity of the left psoas muscle. Correct position of this patient for direct muscle energy treatment of this dysfunction includes:

(A) patient supine, trunk sidebent left
(B) patient prone, left hip extended
(C) patient seated, trunk rotated right
(D) patient supine, right hip and knee flexed
(E) patient prone, lumbar spine hyperextended

The correct response is *B*. To choose

Table
COMLEX–USA Dimension II Level Differentiation

Content	Level 1 (%)	Level 2 (%)	Level 3 (%)
History and physical examination	5 to 12	35 to 40	10 to 15
Diagnostic technology	to 5	5 to 20	20 to 25
Management	3 to 7	10 to 17	30 to 35
Scientific understanding of disease mechanisms	75 to 85	5 to 8	5 to 0
Health promotion/ disease prevention	1 to 5	15 to 20	5 to 10
Healthcare delivery issues	0	5 to 8	5 to 0

the correct answer the student must have knowledge of the anatomy and the function of the psoas muscle and an understanding of basic muscle energy treatment principles.

While the above examples focus on the diagnosis and management of patient care using osteopathic manipulative techniques, the osteopathic medical focus is evident throughout the COMLEX–USA sequence in the tendency of the test items to emphasize the body's capacity for self-regulation and repair and the corresponding interrelationship of bodily structure and function. Osteopathic integration is further achieved by other interdisciplinary items that reflect the significance of musculoskeletal findings, as shown in the following test item:

A 26-year-old woman is observed pacing in the waiting room prior to a new-employee physical examination. She startles as the physician enters the exam room and appears much more concerned than seems appropriate to the situation. The physician tactfully comments about her demeanor, and she replies, "Oh, I've always been like this and even get teased because I worry about everything constantly." She admits to problems concentrating and also to having difficulty falling asleep even when fatigued. Physical examination is within normal limits except for mild tachycardia and high levels of tension bilaterally in her masseter, temporalis, and trapezius muscle groups. Her presentation is most consistent with:

(A) agitated depression
(B) hypochondriasis
(C) somatization disorder
(D) generalized anxiety disorder
(E) obsessive-compulsive disorder

The correct answer is *D*. Increased muscle tension is a DSM-IV diagnostic criterium for generalized anxiety disorder (Diagnostic and Statistical Manual of Mental Disorders, American Psychiatric Association, 1994). Her musculoskeletal findings are corroborative to the other generalized anxiety disorder features with which she presents.

Osteopathic integration is even further achieved by test items that challenge examinees to consider OMT along with conventional management issues. The following item illustrates this feature:

A 53-year-old woman with rheumatoid arthritis of 13 years' duration, stable on a maintenance dose of a nonsteroidal anti-inflammatory drug (NSAID), returns for a follow-up visit. She now complains of a 4- to 5-week history of increasing dorsal neck pain, and dyesthesias involving both hands and occasionally her arms. Her exam reveals chronic rheumatoid arthritis deformities. Evaluation of her neck reveals restricted range of motion with tenderness in the upper cervical area more pronounced on the right. Routine lab is normal. Which of the following should be done next?

(A) change to a different NSAID
(B) begin methotrexate
(C) begin oral steroids
(D) direct action OMT to the upper cervical spine
(E) cervical spine x-ray in flexion

The correct answer is *E*. The first concern is to rule out cervical spine subluxation and myelopathy. Direct action manipulation is contraindicated, and more extensive treatment of the rheumatoid arthritis would probably be of no benefit or could possibly transiently mask the symptoms placing the patient at higher risk. This question illustrates further that examinees must consider the indications and contraindications of adjunctive OMT as they should with any other therapeutic modality.

COMLEX–USA administration

COMLEX–USA is a sequential process: each level must be successfully completed before moving on to the next level. Levels 1, 2, and 3 are each 2-day, multiple-choice tests administered twice annually. Each day of testing is divided into two 4-hour sessions consisting of approximately 200 examination items with the range of topics randomly ordered. Virtually all osteopathic medical schools require their students to sit for Levels 1 and 2 of COMLEX–USA, and the vast majority of osteopathic medical graduates in both AOA-approved and ACGME PGY-1 programs sit for Level 3 of COMLEX–USA.

The COMLEX–USA examination is appropriate for U.S. osteopathic medical students and graduates and closely follows the general progression of osteopathic medical education and training of the 19 osteopathic medical schools in the United States, and it is consistent with a model of osteopathic practice. Because of the integrated sequential nature of the examination, there is no mechanism that allows medical students to take the examinations out of order.

COMLEX–USA research and development, current and future

Primary areas of ongoing research are the refinement of examination reliability and validity. The extent to which the examination is reliable is the degree to which the examination yields the same results on multiple administrations. Reliability asks, "Is the examination a tool that will provide a stable, dependable measurement for different groups of candidates over different periods of time?" The COMLEX–USA sequence performs at a range of 0.85 and higher on a value range of 0 to 1, which is considered a high coefficient value for multiple choice examinations.

The validity question asks, "Does the examination measure what we say it is measuring?" The COMLEX–USA construction and review committees regularly ask faculty members and administrators to give feedback on examination items. Items are routinely submitted to those in the fields of osteopathic medical education for feedback about the items' perceived appropriateness. Candidates likewise are surveyed after taking the examination to learn their opinions on whether the examination reflected their expectations and whether it represented an appropriate relationship to their medical education and training experiences.

The development of COMLEX–USA included the adoption of new pass/fail standards to reflect the profession's vision and expectations of minimum competency to practice osteopathic medicine within the current and emerging healthcare system. Standard setting

is achieved by a method generally accepted for high-stakes examinations. The new standards are content-based and are, therefore, independent of performances of specific examinee groups.

These new standards were set by carefully selecting committees of experts within osteopathic medical education. For Levels 1 and 2, the selection of committee members began with a review of nominations from the osteopathic medical schools and leaders within osteopathic graduate medical education. Final selection was designed so each discipline would be represented. The committees also represented the widest possible cross-section of those faculty having good professional reputations and seasoned understanding of osteopathic medical practice. The process of standard setting involves all committee members reviewing each item used in the examination. Each member then makes an independent judgment about the percentage of borderline candidates who would answer each of the aggregated percentage correct for the total exam. NBOME policy requires reexamination of pass/fail standards for each level of COMLEX–USA every 3 years.

In the past, NBOME's policy has been to accommodate an osteopathic school's request to have their faculty review the actual COMLEX–USA examination materials and booklets. The new NBOME policy is to affirmatively offer to each osteopathic medical college the opportunity for faculty to review the examination under secure conditions. Since the 1998 cycle of COMLEX–USA, osteopathic faculty are asked to fill out a standard survey instrument after reviewing the examination. Over 80% of those faculty members rated the quality of the items, connection to osteopathic education, and the balance of the examination content as "good" or "excellent." NBOME will continue to survey formally and systematically a wide sample of osteopathic educators. There are also plans to expand the survey to collect the opinions and impressions of osteopathic practitioners in the field who are not actively involved in education. This "field test" of the examination style and content will provide an added dimension to our ongoing assessment of validity.

The Board of Directors of the NBOME has approved a long-range plan that calls for a clinical skills performance examination to be implemented in late 2002. The introduction of a computerized delivery system for each level of COMLEX is planned after 2003.

COMLEX–USA Construct Validity Project

As a component of a continuous quality improvement strategy, NBOME is engaged in a study to examine the construct validity of the novel design features of COMLEX–USA. A uniform content specification across all three levels is a unique feature not shared by any other licensing examination process. This new design provides a method to raise the standard of the quality of licensing examinations. It does this by addressing the critical issues of both continuity and differentiation that are characteristic of progressive professional education and training, which are comprised within each level of the examination. These complex issues of continuity and differentiation have never before been empirically formulated. The purpose of the COMLEX–USA Construct Validity Project is to examine whether the outcomes of the novel features realize the goals of the uniform test specification design.

An inherent assumption of the COMLEX–USA design is that the three examinations together define the minimum competencies to practice osteopathic medicine in an independent, unsupervised setting. Each exam level has its own emphasis in both areas of breadth and depth. Each level is intended to measure the degree of competency expected according to the respective point in the educational/training process. The Construct Validity Project will specifically examine if each higher sequential level demonstrates a difficulty increment over its lower-level counterparts. It will measure the extent to which these increments are reasonably spaced. It will also address if the pass/fail standards of the three levels are meaningfully spaced.

Other parts of the NBOME research agenda include a systematic practice analysis of osteopathic medicine so that the clinical performance assessment will be integrated meaningfully with the written components. Additionally, a future project will examine whether a content bias exists within the examination, especially for the osteopathic manipulative medicine (OMM) components. OMM curricula vary across the osteopathic medical schools, and this study will examine differentiating features of curriculum as it relates to student performance on OMM items. NBOME is also collaborating with the AACOM and a number of osteopathic medical schools to promote cooperative research. The NBOME research staff and educational researchers from osteopathic medical schools have completed a variety of studies confirming the validity of each level of COMLEX–USA. NBOME, likewise, will be working with specialty colleges and certifying boards to develop research into predictive validity of our examinations. Continuous refinement and quality improvement is an ongoing process for this new examination paradigm. In addition to licensure and continuing competence, NBOME is in the process of developing a wide new array of evaluation tools for the osteopathic profession and will continue to refine all of the examination products.