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"I have always found that mercy bears richer fruits than strict justice."

— *Abraham Lincoln*

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MESSAGE FROM THE CHAIR

CONTINUING EFFORTS TO ENSURE COMPETENCY

J. William McCord Jr., D.O., *Chair, Federation of State Medical Boards*

For the better part of a century, medical boards have concerned themselves with the quality of treatment provided by physicians. Through the decades, boards have established rigorous criteria for entering the practice of medicine and developed complex systems for licensing, regulation and discipline. Despite these efforts, the quality of care provided by physicians and the health care system in general has become an issue of increasing concern to the American public. The 1998 report *To Err is Human: Building a Safer Health System*, published by the Institute of Medicine, served as a dramatic wake-up call not just to medicine, but to the entire health care industry.

The significance of this report was not lost on the FSMB, which during the past several years has devoted significant resources to developing resources for use by medical boards to ensure physicians are competent to provide patient care throughout their professional careers. I want to provide a brief review of a few of those initiatives.

A NATIONAL DIALOGUE REGARDING ENSURING CONTINUED COMPETENCE

At the direction of its membership, the FSMB hosted an invitational summit in March 2005 to engage the national medical community in a dialogue about how the health care community will measure, evaluate and assure the public regarding a physician's competence throughout his or her professional career. Three additional meetings have taken place since then, and I must tell you the level of commitment and engagement on the part of both the individuals who are participating in the initiative and the organizations they represent has been very rewarding. This initiative, titled *Physician Accountability for Physician Competence*, has provided a much needed venue wherein the many independent organizations that comprise the system of physician self-regulation are discussing concerns related to ensuring the continued competence of physicians, and more importantly, collaborating to develop solutions to identified issues. You'll hear more about this effort in the months to come, but it is increasingly clear that maintenance of licensure is being viewed as critical to the success of any system that seeks to ensure the continued competence of physicians, and state medical boards need to embrace that reality.

SPECIAL COMMITTEE ON MAINTENANCE OF LICENSURE

Constituted in 2003, the Special Committee on Maintenance of Licensure has been hard at work developing resources medical boards may use to assure the continued competence of their licensees. The committee has produced two work products: a policy statement recommendation to the FSMB House of Delegates and an interim report to the FSMB board of directors on issues that should be considered by state medical boards seeking to implement maintenance of licensure requirements. The committee, which has been monitoring the progress being made through the PAPC summits, is poised to issue its final report in May 2008. In addition to recommendations regarding how medical boards should approach maintenance of licensure initiatives, the report will include recommendations on how to deal with physicians who are seeking to resume patient care duties following an extended period of clinical inactivity.

POST-LICENSURE ASSESSMENT SYSTEM

Established in 1996, PLAS is a joint program of the FSMB and the National Board of Medical Examiners (NBME) that provides resources for evaluating physician competence. The system has two components: the Special Purpose Examination (SPEX), a one-day examination used to evaluate a physician's general medical knowledge and ability to provide safe care; and the Assessment Center Program (ACP), a battery of assessment tools for use in assessing a physician's competence in areas such as medical knowledge, clinical judgment, patient management skills and communication skills. These tools are available

to regional assessment programs around the country for use as part of their personalized assessment programs. Seven assessment programs use PLAS assessment tools to complement their programs; a listing of those programs is available on the FSMB website.

Efforts to develop a modular MCQ-examination system as the next generation of the Special Purpose Examination (SPEX) are progressing, with program committees and staff working to develop a modular, menu-based array of multiple-choice examinations that could be mixed and matched to reflect an individual's practice.

PLAS is also active on the research front, working in collaboration with the Robert Wood Johnson Medical School to complete a national needs assessment that will provide data for use in understanding physician assessment and intervention needs. This information will be very useful in developing additional assessment resources for the future.

CONTINUING MEDICAL EDUCATION

The FSMB has participated with the Conjoint Committee on Reforming CME, a multi-stakeholder initiative to reform the CME enterprise so that it is practice relevant and supports physicians' ongoing need for periodic re-licensing, re-credentialing, re-privileging and MOC. The Conjoint Committee created a series of white papers outlining issues facing CME, and in 2005 released a report, *Reforming and Repositioning Continuing Medical Education*, containing recommendations for change in seven strategic areas. In addition to our work with the Conjoint Committee, FSMB has been very active in shaping the policies that form the basis for how CME providers are accredited. Due in part to the FSMB's emphasis to make CME more relevant, in 2005 the Accreditation Council for Continuing Medical Education (ACCME) announced a CME model based on practice-based, self-directed physician learning and change. In July 2006, the ACCME took another major step forward with the adoption of new compliance criteria for accreditation that places the value of CME accredited within the ACCME system on improving physician learning and practice, and ultimately, the health of patients. These enhancements will contribute significantly to national initiatives to assure the continued competence of physicians.

CONTINUING EFFORTS TO ENSURE COMPETENCE

The licensure system in place today has reasonably served the public, but it has become clear facets of the system are no longer in sync with societal expectations, particularly in regards to ensuring competence. We must transition to a new paradigm in which we move beyond today's system of "licensure for life" to a system wherein licensure is truly viewed as a privilege and is maintained only if one is able to provide evidence of competence. The FSMB, in cooperation with state medical boards and our many collaborative partners, will continue to be at the forefront of efforts to develop policies and systems to better ensure physicians maintain the competency they need to treat the public we all serve.

EDITORIAL

"WHATEVER WE DO ... MUST BE TRANSPARENT AS LIGHT"

Kathleen Haley, J.D.

The poet was Thoreau: "Our most indifferent acts may be a matter for secrecy, but whatever we do with the utmost truthfulness and integrity, by virtue of its pureness, must be transparent as light." In the world of medicine and medical regulation there is little allowance for "indifferent acts." Rather licensing, education, investigation and discipline must be performed with the utmost truthfulness and integrity. Thus, they must be performed transparently.

Webster defines transparency as being capable of being seen through. While the privilege of self-regulation means medical professionals overseeing one another, increasingly, medical regulation is viewed as a partnership between the professions and the public.

In Oregon and most other states, the quest for truthfulness and integrity in government has manifested itself in public meetings and public records laws. For most of us they provide a baseline in terms of making our wealth of data available to the public. The past several years have seen an increase in the numbers of physician profiles maintained by medical boards. These profiles act as resources for the public in making critical decisions about health care, and may include geographic, licensure, malpractice and disciplinary data about physicians in those states.

Medical boards are continually seeking ways to enhance transparency beyond our statutory mandates, without sacrificing the confidentiality of investigations or patient health information. In Oregon, we have responded to the Internet boom and to innovations in digital information in an ongoing effort to fully serve our citizens. The latest such innovation involves scanning public orders and placing them on the Oregon Board of Medical Examiners (BME) website (www.oregon.gov/BME). By making the full texts of orders available to the people of Oregon in this fashion, we have provided them with more, and more readily accessible, information vital to their health and safety. That is government transparency at its best. And citizens continue to respond to this initiative by accessing the BME website an average of 232,000 times per month.

In an effort to make our licensure process easier to "be seen through," we instituted an online status report for applicants. With an easy-to-use password, applicants and persons they have authorized to access the reports may see which documents the BME has received, and which are still needed to complete application files. Online status reports also have benefited board staff, by reducing telephone inquiries regarding license application status. Thus far, staff have noted a 28 percent decrease in such inquiries, and a 19 percent reduction in the duration of these phone calls.

THE 'FLIP SIDE' OF TRANSPARENCY

There is a flip side to transparency of information in our domain. If we do not keep investigatory material out of the public domain prior to adjudication, our access to information that could generate further essential action may be compromised. Our richest source of material comes from members of the health care community and, most often, those persons want assurance of confidentiality before stepping forward with complaints.

For example, I recently received a call from a physician who worried that his father – also a physician – had early symptoms of dementia that might be compromising his ability to safely practice. The caller clearly did not want his father to know he had called the medical board. Thanks to his report, and the confidentiality with which we treated it, we were able to persuade the elderly physician to retire and close his solo practice before a patient problem occurred.

Likewise, the public and, by extension, medical boards, expect the practice of medicine to be conducted with the

utmost truthfulness and integrity. Increasingly, physicians are being held publicly accountable for their private conduct as it affects their medical practice. In particular, life with the Internet is such that the privacy of one's home or hospital computer is not sacrosanct when one logs on. Some health care professionals have engaged in online conduct of an egregious nature, by visiting with patients in sexually-oriented chat rooms, by accessing and downloading child pornography or videotaping patients. This behavior is traceable, and has lead to criminal prosecutions as well as medical board investigations and discipline.

As medical regulators, we regularly face the demand to provide more information in an understandable format, more expeditiously, to the public – including the news media. This demand can seem overwhelming and, at times, invasive. The feeling, no doubt, is the same for the physicians and other medical professionals we regulate. Yet it is incumbent upon us to open the drapes wider as we conduct the public's business with truthfulness and integrity.

AFFILIATIONS

Kathleen Haley, J.D., has served as executive director of the Oregon Board of Medical Examiners since 1994. She has served as a member of the Federation of State Medical Board's board of directors and as Western Region representative for the Administrators in Medicine board of directors. Haley has been active in helping Oregon's health care-related agencies and institutions prepare for implementation of state legislation dealing with physician reporting, pain management and patient safety.

CASE FILES: WHAT WOULD YOU DO?

Jane Cracraft

THE NORTH CAROLINA CASE

A complaint was filed with the North Carolina Medical Board against Joseph Jemsek, M.D., an infectious disease specialist who has been licensed since 1979, for unorthodox diagnosis and treatment of Lyme disease in 10 patients. He also was accused of failing to inform the patients that his methods were a departure from recognized standards.

Each patient presented with non-specific symptoms such as fatigue, non-localized aches and pains, and decreased concentration, with little or no historical, physical, or serological evidence supporting a diagnosis of Lyme disease. However, in Dr. Jemsek's view, chronic forms of the disease are often misdiagnosed by reliance on standard tests. He had the reputation of being a leading Lyme care provider, seeing hundreds of patients at his clinic near Charlotte.

Dr. Jemsek treated these 10 patients with oral or intravenous antibiotics for months — and in some cases, years — even though there is a risk of infection with long-term use of intravenous antibiotics. In fact, some of them did suffer infections. One young woman had five infections in an 18-month period from her indwelling catheter.

Responding to the disciplinary complaint, Dr. Jemsek acknowledged that he was the only North Carolina physician using these methods to diagnose and treat Lyme disease. He testified that his diagnosis and treatment of the 10 patients was correct. Two expert witnesses agreed that standard tests for diagnosing Lyme disease are not reliable. They said a diagnosis should also be based on the presence of symptoms, such as headache, joint pain, memory loss and confusion. However, the experts questioned the long-term use of oral and intravenous antibiotics to treat Lyme disease.

Many patients of Dr. Jemsek and various Lyme disease support groups rallied to his cause, raising funds for his defense and testifying on his behalf.

HOW OTHER BOARDS WOULD HANDLE THE CASE

The Connecticut Medical Examining Board Responds

"We have a very similar, high profile case right now in our state," said Dennis O'Neill, M.D., chairman of the Connecticut Board. "It has pitted the Health Department and the Medical Board against zealous patients and patient-advocates who are strong supporters of the doctor and his methods. He is a medical crusader who says he has treated hundreds of patients successfully."

Dr. O'Neill said he couldn't predict the outcome of the Connecticut case. The case is being heard by the Connecticut Hearings Panel, and then the full board will be asked to approve, modify or reject its findings.

Connecticut is one of the states where Lyme disease is common. The bacterial infection, usually transmitted by a tick bite, was named after a cluster of cases in Lyme and Old Lyme, Conn.

The Kentucky Board of Medical Licensure Responds

If such a case came before the Kentucky Board, Chairman Danny M. Clark, M.D., said the board would start by reviewing all of the information presented along with the views of the board's own infectious disease consultants.

Then, "The Board's Inquiry/Hearing Panel would probably be faced with two options. The first would be to file a complaint and allow the process to go through an administrative hearing, which most likely would result in some form of Order restricting the physician."

Dr. Clark added that the second option would be to find that the physician's misconduct warrants only a "Letter of

Admonishment," directing the physician to inform his patients in writing prior to treatment that his method of diagnosing and treating Lyme disease is a departure from recognized standards.

The Wisconsin Medical Examining Board Responds

Steven M. Gloe, general counsel for the Wisconsin Department of Regulation and Licensing, said: "My response assumes the evidence was sufficient to establish Respondent's conduct fell below the minimum standard of care in the following ways:

1. Respondent failed to adequately inform patients of treatment options and the unorthodox nature of the treatment he administered.
2. Respondent failed to consider differential diagnoses for the patients' symptoms.
3. After commencing a course of treatment, Respondent failed to adequately monitor and evaluate the treatment's efficacy.
4. In the absence of evidence that the treatment was effective, Respondent failed to discontinue the use of intravenous antibiotics when the patient developed repeated infections.

"The investigative team would consult with a case advisor from the board, as well as an independent medical expert. Assuming Respondent had no prior discipline, cooperated fully with the investigation, and ultimately agreed to alter his practice methodology, the disposition would probably include these features:

1. A reprimand
2. Limitations on Respondent's license to practice medicine, including:
   - Passing scores on an assessment of Respondent's diagnostic skills
   - Completion of board approved continuing education in the diagnosis and treatment of Lyme disease; patient communication and counseling; and, if indicated by the board's assessment, other courses designated by the board
   - Peer monitoring by a board approved mentor for a period of not less than two years
3. Respondent must pay costs of the investigation, costs associated with continuing education, and costs associated with monitoring

THE NORTH CAROLINA OUTCOME

After hearing Dr. Jemsek's case, the North Carolina Medical Board decided to suspend his license for one year, and then stayed the suspension, with the following terms and conditions:

1. Dr. Jemsek must develop an informed consent form approved by the board president.
2. If a patient's diagnosis is not supported by the current Center for Disease Control criteria, then the patient must have a consultation or second opinion from another North Carolina physician specializing in infectious diseases and approved by the board president.
3. Any antibiotic treatment longer than two months must be included in a formal research protocol with Institutional Review Board supervision.
4. Any complications of treatment must be addressed immediately.

R. David Henderson, executive director of the North Carolina Board, explained, "The Order of Discipline reflects the Board's belief that Dr. Jemsek can practice safely with these conditions and, thus, not deprive patients of their physician. In sum, the Order in the case of Dr. Jemsek imposed discipline, brought the physician's practices within acceptable and prevailing standards of medical practice, and most importantly, protected the public."

THE MEDICAL SOCIETY'S ROLE IN ASSESSING PHYSICIAN'S PERFORMANCE: AN ANALYSIS OF SIX YEARS OF GRIEVANCES CONSIDERED BY AN URBAN MEDICAL SOCIETY

Arthur Frank, M.D., Howard A. Hoffman, M.D., Edward H. Stolar, M.D.

ABSTRACT

Context:

Although they have no legal authority, medical organizations are frequently asked to assess physician conduct. These organizations have established a variety of procedures to review grievances brought for their consideration.

Objective:

This analysis was conducted to assess the nature and the disposition of the complaints considered by the Professional Standards Committee (Committee) of an urban medical society.

Design:

All cases considered by the Committee (193 complaints) during a six-year period were arbitrarily sorted into categories and the nature of how the case was resolved was tabulated.

Results:

Of all the cases considered 108 (56 percent) were categorized as related to quality of care and physician/staff behavior issues. Of these, 39 (20 percent) dealt with the characteristics of the care provided, 28 (15 percent) with physician and staff behavior, 23 (12 percent) with physician and staff communications and 18 (nine percent) with ethical issues. An additional 85 cases (44 percent) were related to administrative issues and office procedures. Of these, 50 (26 percent) were related to billing, fees and charges, 23 (12 percent) concerned medical records, 10 (five percent) dealt with office practices and procedures and two (one percent) were related to worker's compensation. Of 141 cases in which a judgment could be made, 48.2 percent were decided in the complainant's favor and corrective recommendations were made. The grievance appeared to be inappropriate in 51.8 percent of the cases and the reason for this decision was explained to the complainant. In the remaining 22 percent of the cases irreconcilable descriptions of the circumstances made it impossible for the Committee to make a decision or recommendation about the grievance.

Conclusion:

The mechanism of review by the Professional Standards Committee of a medical society does appear to offer a procedure by which there can be some resolution of these complaints. In cases in which a judgment could be made the complaint was decided in favor of the complainant as frequently as in favor of the physician.

INTRODUCTION:

Associations of physicians and professional organizations have no legal authority. They do not confer, nor can they withdraw a license to practice medicine. They cannot limit or obligate the form of an individual's medical practice. Hospital staff organizations are similarly constrained. Although they can control the character of an individual practice within their own facilities, they cannot affect an individual's practice elsewhere.

Nevertheless, these professional organizations often are called upon to assess the performance, professional activities and behavior of physicians. Assessment of quality of care, competence, administrative matters and ethics are often brought to these organizations for review. These organizations, with very little power, are asked to consider these matters, but it is not clear what kinds of issues are considered and what disposition is made of these reviews. Does this review provide any benefit to the patient, the community, the individual physician or the medical profession?

To explore some of these questions we analyzed the records of the Professional Standards Committee of the Medical Society of the District of Columbia. The study was not designed to evaluate the effectiveness, implications or consequences of this committee's review, but rather to assess the nature of the issues that were raised and the characteristics of how the committee considered and disposed of these issues.

METHODS:

The records of the Professional Standards Committee of the Medical Society of the District of Columbia during a six-year period (1995-2001) were reviewed. The committee consists of 23 volunteer physicians, all members of the Medical Society, who were selected to represent a diversity of medical specialties. The committee met as a group monthly to consider all of the issues brought to its attention. All of the members served without compensation.

Prior to each meeting, detailed records and other related documents were assembled regarding the case under consideration. The complete file was sent to three members of the committee who analyzed the material and presented their findings to the entire committee. The full committee discussed and assessed the case and recommended a course of action.

The committee made a particular effort to maintain the privacy and confidentiality of all parties to the complaint. None was identified by name in the initial review. The participants were identified only in the final deliberations of the committee. All members of the committee understood, however, that a condition of the their participation is their absolute obligation to maintain confidentiality relating to all aspects of the committee's deliberations.

The committee has a policy of accepting cases from any source. Most cases were derived from patient complaints but some were presented by hospitals, physicians or health insurance or managed care companies. Occasionally, the local government licensing board, because of its own limited resources, requested that the committee review a case on its behalf.

The committee relied substantially on documents submitted to it. It did not generally interview participants and did not take testimony in any legal sense. It did occasionally appoint a subcommittee to discuss issues in greater detail with participants.

The committee considered that its primary purpose was to assist the public and the medical community. It was considered appropriate to make recommendations to the physician about modifications of behavior or practice patterns if this was thought to be useful. In cases in which a complaint appeared unjustified, the committee tried to explain the situation and its reasoning to the complainant. In some cases it referred cases to the appropriate agency within the medical society for disciplinary action (typically, reprimand or the suspension or termination of membership) or referred the case to the government licensure or disciplinary agencies with a recommendation for further action.

RESULTS:

During the six-year period, 193 cases were received and, after review, assigned by the committee chairmen to one of eight categories of complaint. There often was an overlap of issues in an individual complaint; the dominant issue determined which category the complaint represented. The complaints were sorted in the two general sections. One related to quality of care and physician-staff behavior. The other concerned issues of administrative office procedures. These were subdivided as shown in Table 1.

The number of cases per year reported to the committee appeared to have decreased during the six years of the study. In 1995 and 1996 there were 47 and 41 cases respectively reported to the committee. In 1999 and 2000 the number of cases were 25 and 23 respectively.

I.A. Quality of Care:

Most of the cases that dealt with quality of care issues focused on the patient's concern that the physician did not meet expectations in the delivery of care. Patients characterized the doctor with phrases such as: "incompetent," "unresponsive," "uncaring," or "too busy." Patients

Table 1. Categories of complaints submitted

	Cases	Percentage
I. Quality of care/physician staff behavior		
A. Quality of care	39	20%
B. Physician/staff behavior	28	15%
C. Communications (physician/staff)	23	12%
D. Ethics	18	9%
II. Administrative/office procedures		
A. Billing, fees, charges	50	26%
B. Medical records	23	12%
C. Office practices and procedures	10	5%
D. Disability and worker's compensation	2	1%

considered by the physician to be demanding or a "difficult patient" often complained that the "doctor should have spent more time" or that they felt "rushed" or in other ways felt that their needs were not being met. Many cases were associated with billing complaints and it appeared that the unsuccessful medical encounter could have been tolerated except for the eventual presentation of an unpaid bill.

Specific issues included complaints such as delay in reporting test results, the timely return of telephone calls, proper awareness of the patient's allergies, unnecessary testing or services and lack of appropriate supervision of a resident or medical student in the performance of an examination or procedure.

Of the 39 cases in this category the committee judged that care was appropriate in 18 (46 percent) and inappropriate or unacceptable in nine cases (23 percent). Because of the inability to corroborate conflicting descriptions of events, or because of the possibility of associated litigation, the committee was not able to make a judgment, chose not to make a judgment or provided a limited response in 12 cases (31 percent).

I.B. Physician and Staff Behavior:
Cases in this category involved the subjective description of how the physician (or how the physician's staff) interacted directly with the patient. The physician was described with terms such as: "rude," "offensive," or "insulting." Sexually based complaints included lewd comments, examinations without a chaperone, inappropriate discussions of issues of a sexual nature or "sexist" language. Some patients complained that the physician did not return calls in a timely manner, thus demonstrating "rude" behavior. Clearly, there was an overlap of categories and some of these complaints could be considered a quality of care or communication issue. Some of the complaints in this category involved confusion in the physician's termination of the doctor-patient relationship.

Because of the inherently subjective nature of interpreting behavior and comments made by individuals, it was often difficult to make a definitive determination or recommendation. Where issues were clearly identifiable, as improper termination of a relationship or unambiguous instances of missed telephone calls, the committee recommended changes that could improve practice procedures. When seemingly irreconcilable issues, such as a mismatch in personalities occurred, the committee first established that the characteristics of the medical services were appropriate, and then suggested that an alternate physician be selected for continuing care.

Of the 28 cases in this category, the committee judged that the physician or staff behavior was appropriate in 10 (36 percent), and inappropriate or unacceptable in 11 (39 percent). The records were insufficient to make a determination in the remaining seven cases (25 percent).

I.C. Patient-physician communication:
Twenty-three of the cases considered were grouped in the category of communication; the complex problem of the difficulty that the physician and patient have of conveying information to one another. Since so large a part of the quality of medical care relates to this issue, there is considerable overlap in these cases and in those related to quality of care. Patients often said that they were not given necessary information to enable them to understand what was happening. Patients who were perceived as "difficult" or "demanding" challenged the physician's resources and professionalism, creating problems with physician frustration, strained relationships and the allocation of time and tact. The complexity of this ineffective communication was interpreted as uncaring, uncompassionate or exhibiting a lack of interest in the patient's problem.

Of the cases considered 12 (52 percent) were clearly related to inadequate physician communication. In five (22 percent) it appeared that the communication was related to patient issues and the physician acted reasonably with adequate physician effort to elicit patient understanding. Because the description of events was contradictory no judgment could be made in six of the cases (26 percent).

I.D. Ethics:
Many of the cases brought in the various categories could be considered violation of physician ethics. We have, nevertheless, separated a special group of complaints here which relate to the particular issues of breaches of confidentiality, conflicts of interest, misrepresentation in advertising, improper sexual conduct and abandonment.

Of 193 cases, only 18 (9 percent) specifically involved ethical issues. It was judged that there was no significant breach of ethical conduct in seven of these cases (39 percent) and that significant improper behavior occurred in five cases (28 percent). No judgment could be made in six cases (33 percent). The inability to render a specific

decision was typically related to conflicting and inconsistent characterization of events occurring between two individuals, with no possibility of independent verification of assertions.

II.A. Billing:

The most frequent category of complaint was related to billing, charges, insurance reimbursement and associated administrative matters. The range of billing complaints included issues that were clearly illegal (e.g., fraudulent billing), or administratively inappropriate (e.g., withholding of records or necessary care due to an unpaid bill), to matters of judgment (e.g., the magnitude of charges), administrative concerns (e.g., timeliness of patient refunds) or issues related to the nature of reimbursement from health insurance companies.

The most common complaint was excessive billing; the contention that the bill was too high for the service rendered. This matter was particularly accentuated when the patient felt that the quality of the care was substandard. In some cases, the concern became a complaint when it became apparent that an unpaid balance existed because an insurance company had not paid an entire fee. Other billing complaints included improper collection practices, delayed refunds, staff billing errors and business office policies. This last group includes items such as prepayment for services in an allergy practice or cosmetic surgery, fees for copying medical records and missed appointment charges.

Of the 50 complaints in this category, the committee judged that the physician (and/or the physician's office staff) was in error in 22 cases (44 percent) and that patient's complaint appeared not justified in 20 cases (40 percent). No clear judgment could be made in eight cases (16 percent).

II.B. Medical records:

Twenty-three cases involved problems with medical records. These included delays in the transmittal of records, fees charged or the withholding of records pending payment of an outstanding bill or a copying charge. In a number of cases it was necessary to inform the patient that charging a fee for this service was not inappropriate. On the other hand, physicians often needed to be reminded of the unacceptability of the withholding of records because of the patient's unpaid bill and had to be cautioned to avoid what appeared to be excessive charges. In 13 cases (57 percent) it was judged that the records were sent in a timely manner with a reasonable fee. In nine cases (39 percent) these procedures were not followed. No judgment could be made in one case.

II.C. Office practice procedures and II.D. Disability and worker's compensation:

A small group of miscellaneous cases were grouped in the category of office practice procedures (10 cases) and disability and worker's compensation (two cases). These included a diverse group of issues including scheduling, telephone procedures, insurance eligibility or misunderstandings about the nature of disability evaluation procedures. No generalizations could be made from this small number of diverse cases.

DISCUSSION:

A number of studies have considered the activities of state licensing and professional regulatory authorities and have tabulated and analyzed their experiences.[1-5] Studies of these agencies have been directed at assessing their ability to identify health care professionals who "may be incompetent, impaired, uncaring or may have criminal intent." The government licensing agencies and state medical boards appropriately resolve these issues.

There are relatively few studies of the process of the review of professional conduct by voluntary professional organizations that have no legal authority. To what extent, and in what format, with what authority, should any group of professionals be asked to review the work of its colleagues? The nature of the review by medical societies, specialty medical organizations or hospital staffs is variously structured, vaguely characterized and little studied. The concept of peer review may mean one thing in the assessment of material for publication, but may mean something very different for evaluating professional competence, or for the work of a governmental licensing agency and different still for review of ethical misconduct or administrative misunderstandings by a medical society. In all cases, the process appears to have been inconsistently organized and implemented.

Hickson, et al[6] analyzed patient complaints presented to the patient affairs office of a large medical group. They focused on the relationship of these complaints to the risk of malpractice litigation. Wofford et al[7] analyzed the unsolicited complaints collected at a large academic medical center. They established seven categories of complaints related to physician behavior and explored their epidemiology: disre-

spect (36 percent), disagreements about expectations of care (23 percent), inadequate information (20 percent), distrust (18 percent), perceived unavailability (15 percent), interdisciplinary miscommunication (four percent) and misinformation (four percent), with overlapping categories in 19 percent of the cases. A descriptive summary report of the activities of one medical society was published in 1952.[8]

The AMA Council on Judicial and Ethical Affairs has no data on the patterns of patient complaints.[9] In a report analyzing the experience of the Saskatchewan Medical Society[10], "rudeness" accounted for the greatest number of complaints against a physician. The lack of proper role modeling in physicians' training was cited as a cause for creating arrogant physicians. The report speculated that contributing factors included physicians' intolerance of a more knowledgeable patient-consumer and an unwillingness to spend necessary time discussing care with the perceived obligation to cope with burdensome time constraints and increased administrative responsibilities.

An 11-year study of the complaints submitted to the Grievance Committee of the medical society of a two county area of North Carolina[11] analyzed 29 complaints that were sorted into five categories: failure to fulfill expectations for examination and treatment (38 percent), failure to properly diagnose (20 percent), rudeness (17 percent), producing excessive pain or practicing beyond the area of expertise (13 percent) and inappropriate behavior related to billing (10 percent). This Grievance Committee judged that there was no breach of professional standards in 45 percent of their cases. In an accompanying editorial[12] Localio estimated the number of medical encounters in this community and calculated a grievance rate of 0.6 per million patient encounters. He reflected on the "... remarkable decade of amicable human interaction."

Such reassurance can be misleading. The spectrum of patients' reaction to medical care extends from enthusiastic praise to mere satisfaction, and then to dissatisfaction or the perception of it being inappropriate or, in the extreme, to unacceptable. Even then, it is likely that relatively few cases are thought to be so unacceptable as to justify the time and effort involved in the submission of a complaint. While not all complaints appear justified and many do not involve a breach of standards or conduct, it should be assumed that only a small fraction of perceived grievances actually result in the submission of a complaint to any grievance committee through any mechanism.

Several issues emerge from reviewing these cases. It is apparent that many of these grievances could have been avoided by the use of some simple preventive and educational procedures.

1. **Fees.** The most common complaints were related to billing and financial matters. In large part, this appears to relate to patient and physician confusion and uncertainty about what services are reimbursed by various health insurance and managed care programs. The issue is confounded by the administrative complexity of adjusting bills and collecting fees. The reasonableness of a fee is a matter of judgment and, similarly, what an insurance company will pay for that service is uniquely determined by that insurance company. Because many grievances derive from these issues, it seems obvious many of these complaints could be avoided if fees were published or discussed in advance of the provision of services.

2. **Medical records.** Physicians should be cautioned of their obligation to make medical records promptly available regardless of outstanding patient balances. Patients should be informed that a fee can be charged for the preparation of these records.

3. **Termination of physician-patient relationship.** Physicians should be informed of their options in the termination of the care of a patient and should understand the proper legal and ethical standards with which this can be implemented, including the timing of this termination, the arrangements for alternate care and the availability of medical records.

4. **Chaperones.** Physicians should avoid any situation that might create an appearance of impropriety. They should use chaperones for patient comfort, in patient-sensitive and unstable-patient situations, or in any case in which their judgment suggests the use of a chaperone would be helpful.

5. **Communications.** Physicians should make a particular effort to review administrative policies and procedures and staff behavior to ensure that inappropriate administrative practices are not adversely affecting the provision of professional care. Physicians should make a particular effort to try to understand the variability of patient behavior and expectations, and should be prepared to adapt their behavior to accommodate this variability and to avoid untoward results.

They should make a particular effort to provide information, including the prompt return of telephone calls and the reports of studies in a format that is comfortable for their patients.

The experience of this Professional Standards Committee suggests that this function can assist the community in the resolution of some physician-patient conflict. Although the committee has no legal authority, very few physicians ignored the requests by the committee for information, comments and records and very few were unresponsive. Physicians were respectful of this obligation to their colleagues. Although about half of the cases involved physicians who were not members of this medical society, the non-members were as responsive to the committee's inquiry as were the members.

Professional committees are always at the risk of appearing to dismiss complaints and to favor their colleagues. There is, of course, an element of sympathy for the often-difficult position of a colleague, but the committee made a particular effort to avoid this professional bias — perhaps with some success. Of the 141 cases in which it was thought possible to make a judgment 51.8 percent were decided in the physician's favor and 48.2 percent were decided in the patient's favor; not clearly a whitewash or a universal condemnation of behavior This fraction is comparable to the North Carolina experience[11].

It seemed striking that relatively few cases clearly involved misconduct or ethical behavior. Although one could argue that any case judged in the patient's favor involved some element of inappropriate behavior, the ethical issues thought by the committee to involve breaches of confidentiality, conflicts of interest, misrepresentation in advertising, improper sexual conduct and abandonment were relatively few; only 9.3 percent of the total cases.

It is not possible to accurately estimate the prevalence of complaints in this community. The population base is undefined since many suburban patients obtained care in the urban center (and vice versa). Similarly, the number of physicians in the community is difficult to measure since many had both urban and suburban offices. There is no simple way of estimating the number of patient encounters. Nevertheless, a crude calculation can be made. There are about 3000 practicing physicians in the community. If one assumes that they each have 10 patient encounters on each working day, and about 225 working days in each year, there would have been about 40.5 million patient encounters in the six years of the study. The 193 complaints represent a frequency of about 4.8 complaints per million professional encounters. This is slightly higher than the results in the North Carolina study[11]; a difference that may be related to the rural/urban differences in the two studies. It is of concern that there are so many complaints, but similarly, it is remarkable that there are so few. It is, of course, not possible from this study to assess how many grievances are unreported.

It also is reassuring that patients can feel comfortable that this mechanism can offer an outlet for their grievance. There are no data in this study about patient satisfaction with the process or its outcome, but in at least 48.2 percent of the cases in which a judgment could be made (and 37.6 percent of the total cases) a decision favorable to the patient was made and some satisfaction was provided. No judgment was made in this study whether deliberations and considerations of the committee actually affected physician practice patterns or subsequent behavior.

Finally, it does appear that one can make a reasonable case that volunteer physicians, working under the aegis of a medical society, can review these cases, can reach a decision, can do it with confidentiality and can, in doing so, provide a service to the complainant and to the community, the medical profession and to the affected physician.

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A MODEL-BASED APPROACH TO PRIORITIZING MEDICAL SAFETY PRACTICES

Richard S. Marken

ABSTRACT

This report shows how a model of skilled human performance can be used to evaluate safety practices aimed at reducing medical errors when randomized trials evidence regarding the effectiveness of such practices is not available. In the modeling approach, safety practices are described by a collection of variables, and the impact of these practices is estimated in terms of the effect of changes in these variables on the behavior of the model. The usefulness of this approach depends on having a model that is validated in terms of the available data. The report describes evidence for the validity of the human performance model and illustrates the use of the model to prioritize safety practices.

BACKGROUND

In response to the Institute of Medicine (IOM) report, *To Err Is Human*,[1] the Agency for Healthcare Research and Quality (AHRQ) commissioned the Stanford University–University of California, San Francisco Evidence-based Practice Center to develop a compendium of evidence-supported medical safety practices as a resource for health care safety professionals. The result was an AHRQ report containing recommendations for a number of patient safety practices for which there is clear evidence of effectiveness.[2] Notably absent from these recommendations were many well-accepted safety practices that are aimed at reducing the incidence of medical errors.[3] These error-reduction practices were not mentioned in the report because they did not meet rigorous evidence-based standards for proof of demonstrated effectiveness.[4]

Evidence and error reduction

Leape, et al[5] argue that the implementation of error-reduction practices is too urgent to await rigorous proof of efficacy in randomized trials tests that may never be done. But Shojania, et al[4] note that the implementation of unproven error-reduction practices could be a costly mistake. They point to several examples of practices that common sense says should be effective, but that research shows are not. For example, requiring handwritten (as opposed to verbal) medication orders is thought to reduce medication error. The only study comparing error rates for handwritten versus verbal orders, however, found a four-fold decrease in error rate with verbal orders.[6] So a practice that should "obviously" reduce errors (e.g., requiring handwritten medication orders) may actually increase them. Shojania, et al[4] further notes that the costs of implementing unproven error-reduction practices could exceed the benefits. For example, the expense involved in obtaining evidence through randomized trials of the true effectiveness of a proposed error reduction practice such as the use of Computerized Physician Order Entry (CPOE), an automated approach for entering medication orders, would be costly. Still, such research would be far less costly in terms of dollars (tens of billions) and person hours (tens of millions) than the price of implementing the practice in every U.S. hospital, were it found to be actually ineffective.

The best evidence of the effectiveness of error-reduction practices comes from properly conducted randomized trials testing, but such tests have been rare.[7] One reason for the lack of testing is the actual rate at which medical errors occur, which is rather low. Prescribing errors, for example, occur in 0.4 percent to 1.9 percent of all medication orders, and only a fraction of these errors cause harm to patients in the form of adverse drug events (ADEs).[8-10] Leape, et al[5] point out that it would be "incredibly difficult to mount a controlled study of sufficient power…to prove that the ADE rate was decreased" by a proposed error reduction intervention. Such a study would require the observation of many thousands of orders — half written with the proposed intervention in effect and half without

it — in order to be able to conclude with confidence that the intervention was or was not effective.

Despite their emphasis on the urgency of the medical errors problem, Leape, et al[3] recognize that it is not practical to implement error-reduction practices without some evidence of their effectiveness. For this reason, they recommend development of evidence-based methods for prioritizing error-reduction practices, in lieu of randomized trials testing for the effectiveness of such practices. Indeed, Leape, et al[5] suggest that evidence-based "methods for prioritizing medical safety practices be a key area for health policy research." Such methods would provide a basis for determining the most effective means by which to tackle patient safety issues, as called for by the IOM and more recent findings recognizing threats to patient safety from medical errors.[11-13]

Modeling and policy analysis

One approach to the problem of prioritizing safety practices in the absence of randomized trial evidence is through the use of modeling. Modeling is a standard means of evaluating policies in areas such as bioterrorism, where there has been little randomized trails research regarding the effect of the proposed policies.[14] In the health safety area, the policies being evaluated are medical safety practices aimed at reducing harm to patients that can result from medical error. The models used in policy analysis are simulations of the system to which the policies are applied. Since medical safety practices are applied to the problem of eliminating the errors that occur when people implement health care practices, the relevant system consists of people working in various health care environments. A model that can be used to evaluate the effectiveness of medical safety practices will, therefore, simulate the behavior of people carrying out health care activities in appropriate clinical environments. Such a model must be informed by an understanding of how health care practices are carried out, as well as by psychological theories regarding human errors and why they occur.[15-17]

Psychology of error

Psychology has a long history of interest in the causes of human error. The analysis of everyday errors — slips of the tongue and memory lapses — was a central feature of Freud's approach to understanding the "psychopathology of everyday life."[18] More recently, human error has been of particular interest to psychologists known as "human factors engineers," who are interested in understanding the causes of workplace errors.[19-21] Their work is motivated by the need to improve the "usability" of systems, such as personal computers, by designing them to prevent errors such as those that immediately destroy hours of work.[22] It is further motivated by the fact that human error is a main contributor to many industrial incidents, such as the near-meltdown occurrence at the Three Mile Island nuclear power plant.[23]

Human factors engineering has contributed several theories of human error.[24-26] These theories describe possible causes of human error, but they do not say why these causes operate at certain times and not others. Theories of human error attribute errors to factors such as poor system design, but these theories do not offer explanations for why these factors come into play only occasionally.[27] In order to use modeling to analyze error reduction policies, the model must be based on a theory that identifies not only the causes of human error, but also the reasons behind the rate of error occurrence. Such a model was developed as part of a project aimed at evaluating the appropriate role of electronic prescribing (e-prescribing) technology in health care.[28,29] The model describes the psychological processes involved in writing prescriptions and was used to estimate the potential error reduction benefits of e-prescribing technology.[30]

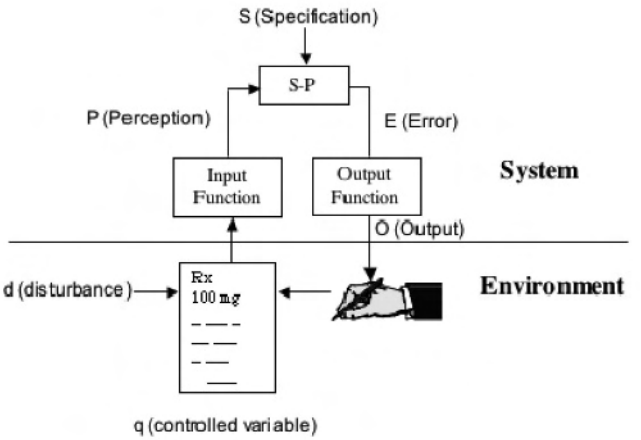
METHODS

A model of medical error

The prescribing error model is a computer simulation of a skilled human activity — writing prescriptions. The model is based on control theory, a psychological theory of human performance that has been used successfully to explain several different kinds of skilled human behavior.[31,32] Control theory assumes that behavior is a purposeful process aimed at producing consistent results in an unpredictably changing environment.[33] Writing prescriptions is a control process because it involves the production of consistent results (e.g., a prescription that is always appropriate for the patient) in an unpredictably changing environment and one in which the patients' symptoms and indications, drug allergies, and medication histories vary unpredictably.

A functional flow diagram of the prescribing control model is shown in Figure 1. The model acts to bring a perceptual representation of a prescription (P), to a specified or intended state of a prescription (S). The prescription that is being produced (q) is a *controlled variable*. The model compares the current state of the prescription (P), to the specified (intended) state (S). Any difference

Figure 1. Control model of prescribing



between S and P is an *error* (E), causing the output (O), that brings the prescription to the intended state. The output is complex cognitive and motor activity. Cognitive activities include consideration of the patient's condition and history, as well as possible drug side effects and interactions. Motor activities include the writing or typing movements that produce the prescription.

The prescription that is being produced (q) is dependent upon system output, as well as the effects of unpredictable *disturbances* (d). These disturbances correspond to variable characteristics of the environment, such as patient symptoms and indications, drug allergies, similar sounding drug names, and even leaky pens. The model acts to produce the intended prescription, while compensating for disturbances that can sometimes interfere with the successful production of the prescription. The production of the intended prescription is a dynamic process that occurs over time. The model introduces errors (which represent a failure of control), when the process of producing the intended prescription stops before the prescription is sufficiently close to the intended state.

The prescribing control model provides a general framework for understanding human error. The model can be generalized to many health care behaviors that are performed by individuals, such as filling prescription orders or administering medications. It is called a "working model" to distinguish it from the more common "descriptive models" of behavior seen in the behavioral sciences. A descriptive model is an equation such as the "general linear model" of statistics that represents a guess about the mathematical relationship between environmental and behavioral variables.[34] A working model, on the other hand, is organized to produce an analog of the behavior under study. Such models are most common in the study of human motor skills, and less common in the study of human error.[35]

"Wind tunnel" tests

The advantage of working models over descriptive models is that they allow researchers to predict the effects of variables that have not yet been determined through experimental testing. In the analysis of safety policies, we make these predictions by seeing how variables that correspond to dimensions of error reduction interventions affect the error rate produced by the model. The process is similar to testing a new aircraft design by placing a model in a wind tunnel.[36] The wind tunnel sets up a flow of air that simulates flight through the atmosphere under the desired conditions. Engineers use instruments attached to the model to measure the lift forces and air resistance of the aircraft. Changing the model's angle of attack and orientation in the tunnel allows the engineers to better assess the proposed aircraft's stability and controllability.

The control model of error is used to test the effectiveness of safety practices in the same way that the aircraft model is used in a wind tunnel to test the flying characteristics of the real plane. We use the error model by placing it in a "wind tunnel" that corresponds to the relevant health care environment. We can then measure the error rate produced by the model as we vary its "angle of attack" by varying parameters of the model and the environment that correspond to generalized aspects of the health care process under study. The parameters that can be varied include skill level, system design characteristics, the time available to carry out the health care process, and the range of different results that can be produced.

The usefulness of the model-based approach to evaluating error-reduction practices depends on having a model that has been validated. We can validate the control model of error by testing its ability to account for existing medical error data. The validated model's reaction to changes in variables representing different error-reduction practices then should provide a good idea of the kind of error reduction that could be expected, if these practices were to be implemented.

Validating the model

We validated the prescribing model shown in Figure 1 by testing its ability to account for existing data on the rate of occurrence for different types of prescribing errors. Studies by Leape, et al[37] and Lesar, et al[8] determined the rate of occurrence for several different types of prescription

Table 1. Distribution of different types of prescription error

	Drug	Dose	Route	Other
Leape/Lesar data	39%	57%	3%	1%
Model data	39%	57%	4%	0%

errors, including wrong drug name, dosage, route, and other prescription aspects. The results of these two studies were combined and the overall rates for the different types of prescribing errors are shown in the top row of Table 1. The error rates produced by the prescribing model are shown in the lower row of the table. Clearly, the distribution of the different types of errors produced by the model corresponds almost exactly to the empirical distribution of error rates.

The results in Table 1 provide some evidence that the control model is a valid representation of the prescription-writing process and of the causes of error inherent to this process. Further quantitative validation of the model comes from the fact that the distribution of model error rates shown in Table 1 was produced when the model's overall error rate was one percent, which is close to the overall error rate found in the prescription error studies. Of the one percent of prescriptions that are written in error, the model (like those individuals writing prescriptions) attributes the majority of the errors to incorrectly written drug doses. The next largest cause of errors was incorrectly written drug names.

Prescription fulfillment errors

Other tests of the model were done using prescription-fulfillment error data collected by Flynn and Barker.[38] This data showed error rate as a function of workload, where the number of prescriptions filled per half hour was the measure of workload. The data provided a nice opportunity to test the model's ability to account for a different kind of medical error — prescription fulfillment rather than prescription-writing error. It further enabled testing of the model's ability to predict the effect of an environmental variable (workload) on error rate.

Prescription-fulfillment error rates are shown as a function of workload in Figure 2. The observed error rate (filled squares) actually declined as the workload increased, at least up to the levels of workload observed in the study. The fulfillment-error rates produced by the model (open triangles) also are shown as a function of workload in Figure 2. Workload was measured in terms of the number of prescriptions filled per hour. As the workload increased, the average time available to produce the intended result (a properly filled prescription) decreased. Increased workload allows less average time available to fill each prescription. Having the model simulate the actions required to fill thousands of prescriptions at each workload level and counting the proportion of erroneous fulfillments resulted in the model predictions.

Figure 2 shows that the behavior of the error model can be made to match the behavior of pharmacists filling prescription orders fairly closely. Like the pharmacists, the model's error rate goes from about three errors per 100 opportunities (three percent) when only two prescriptions are filled per hour to about one error per 200 opportunities (0.5 percent) when 40 prescriptions are filled per hour.

The control model had to be extended in order to account for the error data shown in Figure 2. The extended model's error rate goes down as workload increases, because it is designed to act more carefully in order to successfully fill the prescriptions at a higher rate. The model's error rate does not continue to decrease with increasing workload, however, because there is a limit to how careful the model can become. The "predicted" results in Figure 2 (filled diamonds) show the model error rate starting to increase again as workload goes above the maximum level observed (42 prescriptions per hour). The model, therefore, makes the rather sensible prediction that error rate will not continue to decrease as workload increases, and suggests that there is an optimal workload. Below that optimal level, errors decrease with the increasing workload; above it, however, errors increase precipitously as a result of the reduced time allowed for the completion of the task.

More tests against existing data are needed before the model can be considered properly validated. The testing

Figure 2. Error rate versus workload

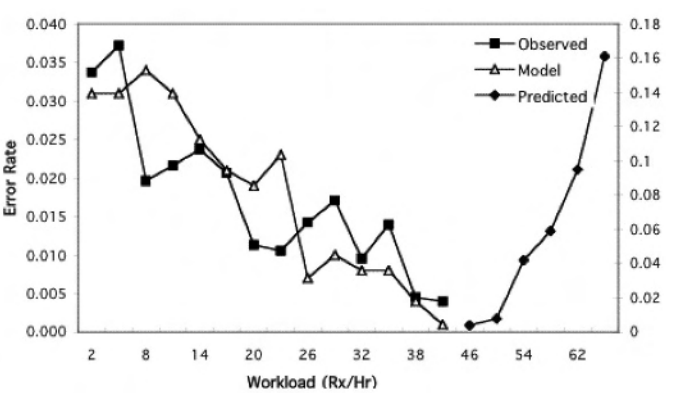
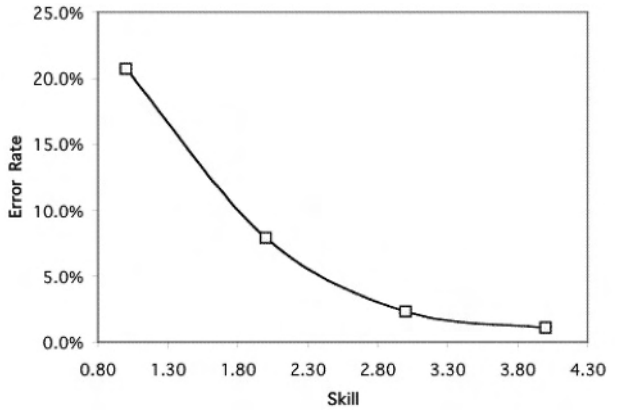


Figure 3. Error rate as a function of skill level



that has been done to date, however, suggests that the model provides a reasonably accurate framework for understanding the factors that influence the rate at which errors occur in highly skilled activities such as writing and fulfilling prescription orders.

RESULTS

Model excursions

The validated error control model can be used to determine how proposed error-reduction practices might affect error rate. The first step in this process is to look at how variations in safety-related parameters of the model affect error rate. These "model excursions" are the initial wind tunnel tests, designed to determine how the behavior of a health care provider might be affected by these same factors. The parameters that were tested in the model excursions were skill level, system design, workload, range of results and external checks.

Skill level — The skill level of the control model has a large effect on the produced error rate while carrying out health care tasks. With all other factors held constant, increases in skill are associated with decreases in error rate. This result, which is consistent with the common sense notion that highly skilled health care providers make fewer errors, is shown in Figure 3.

While the results in Figure 3 show that error rate decreases as skill level increases, the size of the decrease is negligible when error rate is already low (around two percent). Because health care error rates are already quite low — about one percent for prescription writing errors — the model suggests that very large increases in skill would be necessary to significantly reduce error rate from its current level. It takes several years of training for health care providers to reach the skill level associated with a one percent error rate. The model suggests that several more years of training would be needed to get the provider's skill level up to a point where error rate is cut in half, to 0.5 percent. Health safety practices aimed at reducing error by increasing skill level are, therefore, likely to be an inefficient way to reduce error when the error rate already is quite low.

System design — System design characteristics, such as system interfaces and drug name similarities, are associated with environmental disturbances that can interfere with the health care provider's ability to produce correct results. The magnitude of these disturbances corresponds to the impact of system design on the correctness of the prescription components that are being produced. The model excursions suggest that these system design factors have surprisingly little effect on error rate, when the error rate is already quite low. Doubling the magnitude of environmental disturbances did result in a five-fold increase in the error rate (from one percent to about five percent.) However, halving the magnitude of these disturbances (which translates to an improvement in the system design) brought about no decrease in the error rate. The model shows that improvements in external system design characteristics bring about only small error-rate reductions when those rates are already relatively low. This finding is most surprising, since human factors experts have suggested that external system design characteristics such as human-computer interface designs and confusing drug names, are one of the main causes of human error.[39]

Workload — The effect of workload on error rate can be seen in the "model" curve shown in Figure 2. The curve identifies an optimal workload in terms of error reduction. When the workload is very low, the error rate is actually higher than when the workload is at an optimal level (about 45 filled prescriptions per hour, in this case). Increasing the workload above the optimal level results in a steep error-rate increase. What constitutes the optimal workload depends on the task being performed. The faster a task can be performed (on average), the higher the optimal workload for that task.

Range of results — The range of results parameter is associated with the range of different results that might have to be produced to successfully complete a health care task. In prescription writing, for example, the range of results parameter is associated with the number of different kinds of prescriptions a physician might produce in a practice. This model parameter has a large effect on the error rate, even when the error rate is already low. Halving the value of this parameter cuts the error rate in half. This result sug-

Table 2. A mapping of model parameters to safety practices

	Model Parameters						
Safety Practice		Result Range	Skill	System Design	Workload	External Checks	Weighted value
	Weight	0.7	0.1	0.1	0.8	0.9	
	Culture of safety	1	1	1	1	1	2.60
	HF principles	1		1	1		1.60
	Alarm devices			1		1	1.00
	Redundancy					1	0.90
	Interception					1	0.90
	Consequence mitigation					1	0.90
	Working conditions				1		0.80
	Standardization	1		1			0.80
	Training		1				0.10
	Sanctions		1				0.10
	Distinct drug names			1			0.10
	Leading zeros			1			0.10
	Interface design			1			0.10
	Improved communications			1			0.10
	Error reporting		1				0.10

gests error-reduction practices making use of standardization (such as "unit dosing," where a standard prepackaged medication dosage is delivered to the patient), which effectively reduce the range of results that must be produced, could make a significant contribution to error reduction.

External checks — External checks for errors are carried out by such technologies as electronic decision-support systems. Such a system was added to the model by having a simulated decision-support system detect error with some probability. The results of running the model with this decision support error-reduction scheme were not surprising: error rate was reduced in proportion to the probability the decision support system detected errors. The model, therefore, shows prescribing error can be reduced to the extent a system can detect errors. Indeed, there is evidence decision-support systems, such as CPOE, will reduce errors to the extent that incorrect results can be recognized and flagged by the system.[40,41]

Parameters of error-reduction practice

Many different strategies aimed at reducing medical errors have been proposed, including: (1) using distinct drug names; (2) standardization; (3) encouraging the development of a culture of safety; (4) implementing an error-reporting system; (5) using e-prescribing systems for ordering medications; (6) using human factors principles in the design of medical information systems; (7) improving working conditions; and (8) increasing the amount of training given to medical practitioners.[42-44] Each of these strategies can be related to parameters of the prescribing error model. For example, the use of distinct drug names relates to the magnitude of environmental disturbances that affect the behavior of the model; distinctly different drug names are less of a disturbance to prescription writing than are drug names that could be easily confused.

In order to evaluate error-reduction practices, it is necessary to map these practices to the parameters of the model examined in the model excursions. One possible mapping of model parameters to safety practices is shown in Table 2. The columns of the table describe the model parameters affecting the rate at which errors are generated. The value of the weight under each model parameter is proportional

to the effect size of variations in that parameter on the error rate, when the error rate is already in the one percent range. The result range and workload parameters, for example, have relatively large weights. This is because changes in these parameters have a large effect on the error rate, even when the error rate is already low.

The rows of Table 2 represent various error-reduction practices that have been proposed as a means of reducing the occurrence of human error. "Working conditions," for example, refers to practices aimed at optimizing workload and reducing interruptions, thereby improving the working environment. The entries in the matrix indicate whether or not a particular safety practice (row) affects a condition in the real world that is associated with a model parameter (column). A "1" in a cell means that the practice does affect a condition corresponding to a model parameter; a blank cell means that the practice does not affect a condition that corresponds to a model parameter.

Prioritization

The "weighted value" numbers in the rightmost column of Table 2 are error reduction scores. They are assigned to each safety practice, according to their ability to reduce error from the perspective of the prescribing error model. These "weighted value" scores are just the sum of the error reduction weights of parameters that are associated with the safety practice. Safety practices that are associated with model parameters having a large effect on error rate are the practices that score high in likely effectiveness. Human factors (HF) principles, for example, are associated with the result range, system design, and workload parameters of the model, and have a weighted value score of 1.60, the second highest score.

The error-reduction practices in Table 2 are ordered from highest to lowest in terms of their composite scores. This ordering is a preliminary prioritization of error reduction practice classes, based on "wind tunnel" simulation tests of the human error control model. The two most prioritized error-reduction practices, culture of safety and HF principles, are associated with the largest number of model parameters. The next four error-reduction practices (alarm devices, redundancy, interception and consequence mitigation) have been given a high priority because they are associated with external checks (such as second looks in the case of redundancy), that are assumed to be very effective (resulting in a parameter weight of 0.9). The next two error-reduction practices (working conditions and standardization) are effective because each is associated with a single parameter of the model (workload and result range, respectively) that has a very pronounced effect on the error rate.

Several error-reduction practices had surprisingly low error-reduction scores. Distinct drug names and leading zeros, for example, had very low error-reduction scores despite having been touted as important error-reduction practices.[45] These practices score low because they are associated with skill and system design — model parameters that have only a small effect on error reduction, when error rate is already low. Error reporting also receives a low score when it is treated as an error reduction practice. Error reporting can be used as the basis for training, so it is associated with the skill parameter of the error model, which has very little effect on error reduction when error rates are already low. Although error reporting gets a low priority as an error-reduction practice, it is still very important to the process of monitoring and maintaining the quality of health care services.

CONCLUSION

A control model of human error can be used as the basis for evaluating the likely effectiveness of error-reduction practices in the absence of randomized trail evidence of their effectiveness. The model also shows that to err is, indeed, human in the sense that human performance never can be completely error-free. No matter how skillfully created, the error model will never produce an error rate of zero (Figure 3). The model shows that the most effective error-reduction practices are those involving standardization, workload optimization, and automated information systems that prevent error. However, while error-reduction practices can sometimes reduce errors significantly, they cannot eliminate them completely. Therefore, the most effective way to deal with the problem of human error in health care may ultimately be to combine effective error-reduction practices with systems designed to protect patients from error by placing barriers, such as double checks, between providers and patients.

ACKNOWLEDGMENTS

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ADMINISTRATIVE WARNINGS

Ansel R. Marks, M.D., J.D., Maria L. Izquierdo, R.N., Elyse Williams

ABSTRACT

The Administrative Warning is a process utilized extensively in New York State, pursuant to PHL §230, for the resolution of cases where there is substandard medical practice of a minor or technical nature that does not rise to the level of misconduct under the law. These warnings have been effective in alerting and educating practitioners without being public or disciplinary in nature. The New York State Board for Professional Medical Conduct has recognized the value of administrative warnings and increasingly recommends them as a vehicle for informing physicians and physician assistants of practice problems. The recidivism rate appears to be low for those who have been given warnings.

INTRODUCTION

The administrative warning (AW) is an effective prevention and educational tool utilized for the resolution of cases where there is substantial evidence of professional misconduct of a minor or technical nature or of substandard medical practice that does not constitute professional misconduct. Since 2000, the Office of Professional Medical Conduct (OPMC) has delivered approximately 824 AWs. Of those, 524 were delivered in person and the other 260 were given in writing. Although no empirical based study was conducted, a recent statistical in-house study which looked at a five-year period, found a recidivism rate of only 2.14 percent, confirming the effectiveness of the AW as a means to address minor, technical or single instance cases of poor practice. The Board for Professional Medical Conduct has recognized the value of AWs and increasingly recommends them as a vehicle for informing physicians and physician assistants of practice problems.

PUBLIC HEALTH LAW SECTION 230 (10)(M)(II)

> Administrative warning and consultation [consultation has been construed to be synonymous with Administrative Warning]. If the director of the office of professional medical conduct, after obtaining the concurrence of a majority of a committee on professional conduct, and after consultation with the executive secretary, determines there is substantial evidence of professional misconduct of a minor or technical nature or of substandard medical practice which does not constitute professional misconduct, the director may issue an administrative warning and/or provide for consultation with a panel of one or more experts, chosen by the director… Administrative warnings and consultations shall be confidential and shall not constitute an adjudication of guilt or be used as evidence that the licensee is guilty of the alleged misconduct. However, in the event of a further allegation of similar misconduct by the same licensee, the matter may be reopened and further proceedings instituted as provided in this section.

CASE SELECTION

The following may not rise to the level of provable misconduct under the law and are often the subject of administrative warnings:

- Single act of negligence, which is not gross
- Inappropriate/incomplete record keeping
- Minor violation of boundaries
- Inappropriate physical examinations (perceptions)
- Verbal abuse
- First instance of wrong site surgery where there is limited patient harm, physician has appropriately corrected and made an admission of error
- Inappropriate prescribing practices
- Lack of supervision

WRITTEN ADMINISTRATIVE WARNINGS

For lesser offenses, or when the physician is living out of state, the board will often recommend that the AW be

delivered in writing. The incident, the scope of the investigation, and the deficiencies are described, followed by a statement outlining the concerns of the board and any recommendations they may have made (Enclosure 1).

IN PERSON ADMINISTRATIVE WARNINGS

The Players

Board, staff and expert consultants play an integral part and are players in every step of the disciplinary process in New York State. Consistent with that philosophy and practice, the director of OPMC has designated the issuance of AWs to be in the hands of the executive secretary to the board, a physician who can comfortably and effectively discuss medical practice issues as well as any other nonpractice issues. When needed, medical coordinators or board members participate in the AW to provide a specialty-specific level of expertise in the discussion. Investigative and senior staff may occasionally play a role during the meeting, serving to answer any administrative questions that may arise. When in person, the subject physician is invited to attend the meeting with or without the presence of legal counsel. In practice, it is estimated that 75 percent of the time, counsel is present. (Enclosure 2).

The Setting and Location

In support of the meaning and importance of the AW, the atmosphere and environment emphasize austerity, ritual and judicial process. Small conference rooms properly furnished with state and national flags, seals and emblems, have been set aside for the purpose of AW meetings at several regional office sites throughout the state. This environment helps to set the tone of the meeting, dispelling any notion that it may be a casual or insignificant matter.

Most in-person AWs are held either in OPMC's New York City regional office or in its central office in Troy, N.Y. As indicated, the executive secretary also will travel to Syracuse, Rochester or Buffalo to conduct such meetings. Decorum, demeanor and dress are also in keeping with the formality and importance of the occasion. Parties are addressed by their formal titles such as Dr., Mr., Ms., etc. Small talk and joviality are discouraged. Coffee, cell phones and coats are not permitted inside the conference room. Punctuality of all parties is expected.

The Process

After introductions are made, the executive secretary reviews the evolution of the process that led to the recommendation of a warning. It is stressed that although the warning is neither disciplinary nor public, a permanent record of the case file will be kept in the event that future similar instances arise. The subject is advised not to take a defensive posture as the time for interview took place during the investigative phase. Instead he/she is advised to listen and to factor into future practice patterns the concerns raised by the board in order to avoid a repetition of those mistakes and to avoid similar interaction with the board. The case is then summarized and the substantive issues of concern to the board are enumerated. When appropriate, a redacted copy of the expert's report is provided to the subject physician. If CME is recommended, a list of such courses is offered. Useful handouts, appropriate to the issues of concern are offered on the variety of subjects.

In closing, the subject is asked to identify any changes made to date in his/her practice to avoid a reoccurrence. An opportunity is given to the subject to ask any questions before the meeting is concluded. A follow up letter is mailed to the subject and his attorney, memorializing the meeting (Enclosure 3). A permanent record of the meeting is made for the record (Enclosure 4). When appropriate, the following handouts are given to the subject physician:

- The appropriate method of disengaging a patient from the professional relationship
- The physical examination environment
- Prescribing of controlled drugs
- Pain management
- Record keeping
- Wrong site surgery
- Medical ethics
- Telemedicine

CONCLUSION

OPMC tracks AWs carefully, ensuring that they are delivered within 30-60 days of the board and director's decision. Administrative warnings would appear to be an effective prevention, intervention and educational tool for physicians and physician assistants to assist them in correcting practice problems and avoiding more serious violations. Many of the recipients of AWs express appreciation for the opportunity to correct problems before they reach the level of misconduct. Several states issue Letters of Concern for relatively minor deviations from acceptable standards of professional medical conduct. In a similar fashion our office issues letters entitled Physician Informed of Minor Violation(s) (PIMV). These letters do not rise to the level of the issuance of an Administrative Warning.

The ascending ladder of disciplinary concern would be:

1. An administrative closure containing a closure letter to the physician indicating a concern of this office
2. A PIMV letter
3. A written administrative warning
4. An in-person administrative warning
5. A disciplinary hearing

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Enclosure 1.

New York State Board for Professional Medical Conduct
433 River Street, Suite 303 • Troy, New York 12180-2299 • (518) 402-0863

Antonia C. Novello, M.D.,M.P.H., Dr. P.H.
Commissioner
NYS Department of Health

Dennis P. Whalen
Executive Deputy Commissioner
NYS Department of Health

Dennis J. Graziano, Director
Office of Professional Medical Conduct

Kendrick Sears, M.D.
Chair

Michael A. Gonzalez, R.P.A.
Vice Chair

Ansel R. Marks, M.D., J.D.
Executive Secretary

December 21, 2005

PERSONAL AND CONFIDENTIAL
CERTIFIED MAIL-RETURN RECEIPT REQUESTED

RE: Administrative Warning
OPMC #

Dear Dr. XXXX:

The Office of Professional Medical Conduct has completed its investigation into the above referenced matter.

The investigation revealed that 78-year-old XXXX was admitted to XXXX Hospital through the ER on 03/10/XX. Ms. XXXX had been taking prednisone daily at home and her record indicated that she had been admitted to the hospital twice in 2004 with a diagnosis of adrenal insufficiency. As part of an on-call arrangement, you conferred by telephone with the physician assistant who cared for the patient the night of her admission and then countersigned his notes the following morning. While reviewing the record, you noted that a diagnosis of adrenal insufficiency had been missed in the ER and upon admission. You immediately initiated appropriate orders.

Medical staff from this office as well as an outside expert who is board certified in Emergency and Internal Medicine reviewed XXXX's medical records and other relevant documents. It was determined that the 11-hour delay in identifying the patient's adrenal insufficiency did not meet an acceptable standard of practice.

The findings were then reviewed by an Investigation Committee of the New York State Board for Professional Medical Conduct. Upon this Committee's recommendation, the Director of the Office for Professional Medical Conduct has determined that an Administrative Warning be issued. **This is your Administrative Warning in accordance with Public Health Law § 230 (10) (m) (ii).**

This Administrative Warning does not constitute formal disciplinary action against your license. However, should similar or other professional conduct issues be raised again in the future, the matters in this case may be reexamined in light of the new information. This Administrative Warning is considered confidential and is not releasable pursuant to the provisions of § 230 of the Public Health Law.

The Board understands that on the night of this patient's admission you may have been given insufficient information to make a proper diagnosis, however the Board holds you accountable for systemic failures within your group practice and with any other group you may contract with. The Board looks with favor upon your having brought the issues of concern in this matter to the attention of your group partners.

If you have any questions concerning this matter, please contact Maria Izquierdo, Hospital Nursing Services Consultant at (518) 402-0863 or by e-mail at mli02@health.state.ny.us.

Sincerely,

Ansel R. Marks, M.D., J.D.
Executive Secretary
Board for Professional Medical Conduct

Enclosure 2.

New York State Board for Professional Medical Conduct
433 River Street, Suite 303 • Troy, New York 12180-2299 • (518) 402-0863

Antonia C. Novello, M.D.,M.P.H., Dr. P.H.
Commissioner
NYS Department of Health

Dennis P. Whalen
Executive Deputy Commissioner
NYS Department of Health

Dennis J. Graziano, Director
Office of Professional Medical Conduct

Kendrick A. Sears, M.D.
Chairman

Michael A. Gonzalez, R.P.A.
Vice Chair

Ansel R. Marks, M.D., J.D.
Executive Secretary

Date

PERSONAL AND CONFIDENTIAL
CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Re: Administrative Warning
OPMC #

Dear Dr. :

The Office of Professional Medical Conduct has completed its investigation into the above referenced matter.

At the conclusion of the investigation, this matter was presented to an Investigation Committee of the New York State Board for Professional Medical Conduct. Pursuant to the provisions of Public Health Law 230 (10) (m) (ii), the Director of the Office of Professional Medical Conduct, having obtained the concurrence of that committee, has directed that an Administrative Warning be issued.

This warning will be issued, in person, at the Office of Professional Medical Conduct, 433 River Street - Annex building (aka Leonard Duffy Building), Troy, New York (driving instructions enclosed). You may bring legal counsel if you deem it appropriate. You will be expected to appear promptly on **Date/Time a.m.**

Upon receipt of this letter, contact this office to confirm your appointment. If you have any further question, contact Elyse Williams, Administrative Associate, at (212) 417-4445.

Sincerely,

Ansel R. Marks, M.D., J.D.
Executive Secretary
Board for Professional Medical Conduct

cc: Attorney

Enclosure 3.

Date

PERSONAL AND CONFIDENTIAL
CERTIFIED MAIL-RETURN RECEIPT

RE: Administrative Warning
OPMC #

Dear Dr.:

The Office of Professional Medical Conduct has completed its investigation into the above referenced matter.

The findings in this matter were reviewed by an Investigation Committee of the New York State Board for Professional Medical Conduct (Board). Upon this Committee's recommendation, the Director of the Office of Professional Medical Conduct determined that an Administrative Warning be issued. **Our meeting on (DATE) to discuss the concerns raised by the Board, constitutes your Administrative Warning, in accordance with Public Health Law 230(10)(m)(ii).**

This Administrative Warning does not constitute formal disciplinary action against your license and this case should be considered administratively closed. However, should similar or other professional conduct issues be raised again in the future, the matters in this case may be reexamined in light of the new information. This Administrative Warning is considered confidential pursuant to the provisions of Section 230 of the Public Health Law.

Sincerely,

Ansel R. Marks, M.D., J.D.
Executive Secretary
Board for Professional Medical Conduct

cc: Dennis J. Graziano, Director, Office of Professional Medical Conduct
Attorney

Enclosure 4.

OFFICE OF PROFESSIONAL MEDICAL CONDUCT
ADMINISTRATIVE WARNING

Subject Physician:	
DOB:	
ABMS:	
OPMC #:	
Date/Time:	
Location:	
Attorney:	
OPMC:	Ansel R. Marks, M.D., J.D., Executive Secretary Maria Izquierdo, RN, HNSC
IC Date:	

Explanation of Administrative Warning Process

* Directed by OPMC Director
* Privileged nature: non-disciplinary, *not* public, not reported to NPDB, FSMB, Hospitals, HMOs etc.
* Response if asked about AW
* Effect of future similar cases, re-examine this case

Issues of concern raised by the Board:

Adjustments made to amend issues of concern:

Physician reaction/Conclusion:

Handouts:

Completed by: _____
Ansel R. Marks, M.D., J.D., Executive Secretary
Board for Professional Medical Conduct

Date: _____

Patient 1:
Age/DOB/Gender:
Event Location:
Event Date:
Summary:_____

Patient 2:
Age/DOB/Gender:
Event Location:
Event Date:

IMPLEMENTING ASSESSMENT OF PRACTICING PHYSICIANS: THE DEVELOPMENT AND BENEFITS OF A COLLABORATIVE MODEL

Thomas R. Henzel, Ed.D., Andrea Ciccone, M.S., Frances Cain, Carol A. Clothier, Richard Hawkins, M.D.

ABSTRACT

The Post-Licensure Assessment System of the Federation of State Medical Boards and the National Board of Medical Examiners has been evolving for nearly 10 years in its effort to develop a system of evaluation for practicing physicians. The development of such a system requires collaboration among a variety of assessment and educational institutions. To be credible, the system must be grounded in reliable and valid assessment tools, provide unbiased information about particular physician competencies, and be accepted by both licensing authorities and physicians. It also should provide feedback for planning remedial educational opportunities and be useful to physicians who wish to participate in continuing professional development.

Assessments using the same standardized protocol addressing competence in medical knowledge, clinical reasoning, and patient management have been completed at three different sites for 79 physicians. Results show that when compared with non-certified physicians, certified physicians were twice as likely to achieve adequate levels of performance. In relation to licensure outcomes obtained for 53 physicians, of the 29 who performed in the less than adequate performance levels, eight remained in practice with restrictions and three returned to fully independent practice. All of the 24 whose performance was adequate were in practice.

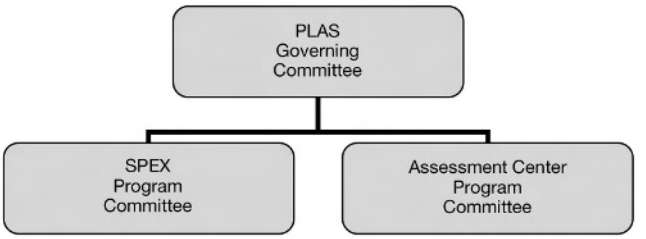
For nearly a decade, the Post-Licensure Assessment System (PLAS) has provided state licensing medical authorities information, in the form of objective assessment data, for use in making licensure decisions about physicians whose competence is in question. With membership of state licensing authorities changing, there are many representatives who may be unaware of the PLAS and the resources it offers now and for the future. This article first will briefly describe the origins and components of the PLAS and then focus on the initial years of work in the newer component, the Assessment Center Program. It will provide the rationale for a collaborative model of regional assessment programs and review the barriers to physician assessment. Then assessment data will be presented and discussed for its potential impact on licensure decisions. The article will conclude with plans for the future and the need to focus on how the educational recommendations resulting from assessments will contribute to the continuing professional development of physicians.

BACKGROUND

The Post-Licensure Assessment System (PLAS) was introduced in 1998 as a collaborative program between the National Board of Medical Examiners (NBME) and the Federation of State Medical Boards (FSMB). The PLAS was established with the purpose of providing state-of-the-art assessment services to state licensing authorities and other health care agencies for their use in evaluating the competence of licensed or previously licensed physicians. In creating the program, the sponsoring organizations formalized their commitment to meeting state medical boards' (SMBs) needs for access to high-quality assessment resources for licensed physicians, and recognized the role of assessment as an important and pertinent initiative to assure the public of the competence of practicing physicians.

The PLAS comprises two programs: the Special Purpose Examination (SPEX) Program and the Assessment Center Program (ACP) (see Figure 1). The SPEX is a one-day multiple choice examination of current knowledge requisite for the general, undifferentiated practice of medicine. It was originally introduced in 1988 to help SMBs in making decisions regarding licensure endorsement or reciprocity for applicants whose medical knowledge had not been tested for some time. The SPEX was first administered as a paper and pencil examination and subsequently transitioned to

Figure 1. Post-Licensure Assessment System (PLAS) structure.



computer-based administration in 1995. At the time that SPEX was established, the relationship between the FSMB and NBME was one of client-vendor: the FSMB owned the program and NBME provided test development and analysis services. With the formation of PLAS in 1998, both organizations assumed equal responsibility for enhancing the examination's capabilities.

The second PLAS program, the ACP, encompasses the Institute for Physician Evaluation (IPE), which provides comprehensive, objective and personalized assessment tools for use in evaluating physicians about whom there is a question regarding clinical competence. The ACP Program Committee evolved from a joint task force that began investigating the potential needs for assessment of practicing physicians in 1993.

The PLAS programs are governed by committees that are responsible for adopting policies and procedures, approving testing methods and examination blueprints, and overseeing a research agenda for their respective programs. These program committees are under the jurisdiction of the Governing Committee, which provides oversight of the PLAS. Together, the PLAS programs have assessed hundreds of physicians over the past several years for reasons that range from endorsement of licensure to license reactivation after disciplinary action.

In the current environment where such issues as tort reform, malpractice insurance rates and changes in continuing medical education predominate, the value of competence assessment is beginning to be recognized as a key step in evaluating physician performance and designing educational programs. Accordingly, as the perception of the need for more attention to physician assessment has broadened, so has the number of initiatives wherein competence and/or performance assessments will play a role. Some of these are: a) maintenance of licensure initiatives, b) specialty board certification or maintenance of certification, c) credentialing and privileging actions and d) continuing medical education/continuing professional development needs or outcomes assessment. The evolution of these activities is expected to increase demand for assessment resources.

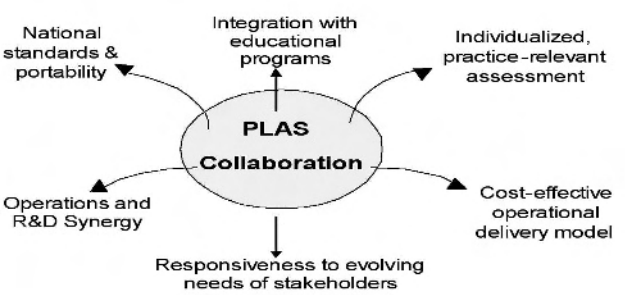
A COLLABORATIVE MODEL OF PHYSICIAN ASSESSMENT

In 2004, the governing boards of the FSMB and NBME endorsed a proposal that would optimize the capability of the PLAS program to meet the assessment needs of practicing physicians in the next decade. IPE activities shifted from an operational model of providing competence assessments at NBME and FSMB headquarters, to a model wherein the program provides assessment tools to third-party collaborators who conduct performance assessments and targeted remedial education for practicing physicians. This collaborative model represents an innovative approach to tailoring physician assessment and remedial education. It supports enhancement of locally developed and administered assessments and provides additional data for use in the formulation and monitoring of specific educational plans. A primary goal of the regional delivery model (displayed in Figure 2) is to facilitate the movement toward attainment of national standards for physician assessment and remediation, while providing flexibility to the independent assessment centers and geographic convenience and individualized approaches to assessment and remedial education for the participating physicians. The delivery system, like the available assessment tools, is not static and will evolve as other assessment centers develop in regions of need.

BARRIERS TO PHYSICIAN ASSESSMENT

The design of a system to improve assessment of competence must overcome current barriers to change and identify techniques that will succeed in achieving system-wide change. A variety of barriers to an effective assessment and remedial educational system for practicing physicians have been identified. First among these barriers is the perception of the assessment process as a punitive exercise. Physicians are probably among the most tested professionals by the

Figure 2. The benefits of collaboration.



time they begin their practice careers. However, the notion that knowledge testing and performance assessment is a stage that is "over and done with" after one obtains initial licensure is receding quickly into the past as the concept of continuing professional development evolves. In 2004, the FSMB's House of Delegates adopted a policy that for the first time in its history, puts the FSMB on record as affirming state medical boards' responsibility to ensure the continued competence of physicians as a condition of re-licensure. In its report introducing this recommendation to the House for consideration, the FSMB's board of directors noted such requirements should be non-punitive and facilitate practice improvement.[1] Several SMBs and hospitals have been working in collaboration to reflect this approach to assessment through the PreP (Practitioner Remediation and Enhancement Partnership) 4 Patient Safety program.[2] A program of the Citizen Advocacy Center (CAC) that was supported contractually by the Health Resources Service Administration (HRSA), PreP 4 Patient Safety is intended to identify and remediate practitioners whose practice is not up to standards, but does not require formal disciplinary action by a state licensing board. The value of this program is its focus on changing the culture of blame. It promotes a proactive quality improvement culture instead of one that is perceived as reactive and punitive.

Second, and related to the first, is the reluctance of physicians to be continuously assessed. After many years of training and testing, the first opportunity to practice comes as welcome relief from the role of a tuition-bound student who is constantly being evaluated. The transition is made all the more enjoyable by the opportunity to earn income and pay down educational loans. By the time seven to 10 years have passed, the sharply honed skills for test-taking have dulled and the idea of returning to the encyclopedic knowledge of the training years lacks appeal.

Third, the focus on a narrower area of practice adds to the reluctance to be tested in areas beyond the scope of the practice. While the license granted to practice medicine is not restricted, the credentialing of hospitals and health systems, and the contact with peers, encourages the development of a comfortable, if limited, area of expertise. In reality, a physician's practice has a tendency to narrow over time such that tailoring of assessments to match practice patterns is required for the assessments to carry credibility. Melnick et al.[3] described the conceptual challenges that are required of "practice friendly" assessments. Primary considerations include the purpose of the assessment, the description of the practice, and the availability of assessment tools to evaluate the desired aspects of the physician's competence. To assess an established, practicing physician, it is necessary to have tools available that are relevant to the practice. Such assessment organizations as the NBME are in the process of developing more practice-friendly measures to meet this need, which in part is being driven by the concept of maintenance of certification, adopted by the American Board of Medical Specialties (ABMS)[4], based on the six competencies approved by the Accreditation Council on Graduate Medical Education (ACGME).[5]

Fourth, the measurement community is working to meet the needs for more practice-friendly assessments, including workplace assessments. These *in situ* activities will require more intensive and costly development to attempt to attain the high standards of competence testing (multiple-choice knowledge tests); progress is being made in many countries on many types of assessments.[6,7] With the development of new assessments comes the need for research to validate the methods and approaches to measuring aspects of clinical competence. Meanwhile, competence tests and performance tests are making progress in adapting to individual practice needs. Modular testing and flexibility in test blueprinting technology are making it easier to adapt a knowledge examination to a particular array of concepts or practice profiles. The current SPEX examination will be replaced in the near future with a system that allows an individual physician to select a series of one-hour modular examinations in desired topic areas.

Fifth, and finally, there are few opportunities to educate physicians seeking to redefine their career, adjust the scope of their practice or participate in remedial education in an area of identified weakness. Further, the costs of participation in an educational program are expensive. A small cadre of institutions is developing the capacity to provide educational services for physicians seeking training program opportunities. The need for and use of community-based or academic preceptors is growing rapidly. As part of their search for a systems-level solution for individual physicians, Leape and Fromson[8] have called for the development and testing of models for the construction of successful remedial education programs.

REGIONAL SITES AS A NATIONAL NETWORK

The PLAS is in the process of aiding the development and coordination of assessments among a network of regional sites that are or will function as assessment and educational centers. This collaboration makes state-of-the-art tools available to organizations assessing the clinical competence of

practicing physicians. An initial collaborative model has been developed with the Physician Assessment and Clinical Education (PACE) program of the University of California at San Diego (UCSD) where more than 100 physicians were assessed in 2004 and 2005. Collaborations with similar programs are underway at medical schools including the Albany Medical College, the University of Florida College of Medicine and the University of Wisconsin School of Medicine and Public Health.

The PLAS is also fostering collaborative relationships to facilitate research in assessment and standard setting at other institutions such as the Texas A&M University Health Sciences Center and the Medical Review and Accrediting Council (MRAC) of New Jersey, which are developing new programs for physician assessment and remedial education. The Texas A&M model is developing a program of life-long learning to complement its current efforts in peer review for rural and community health facilities within Texas. The MRAC program employs local preceptors to work with physicians to determine their assessment needs and identify appropriate educational intervention following the assessment. Through these regional collaborators, the PLAS program expects to define the best practices of a model program for delivery of physician assessment and educational services. Collaborating sites are depicted in Figure 3.

An umbrella organization known as the Coalition for Physician Enhancement (CPE) is an association of assessment centers in North America that is dedicated to the support and development of expertise in personalized assessment and education to enhance physician performance to promote optimal patient management.[9] Some members of the CPE are already collaborating with the PLAS to encourage consistency within assessment protocols by using common assessment instruments and standards. The CPE is beginning to develop an accreditation system for educational programs in collaboration with the Accreditation Council for Continuing Medical Education (ACCME).

Figure 3. Map of USA identifying collaborating sites.

MULTIMODAL, TAILORED ASSESSMENT PROTOCOLS

A standard assessment battery offered to PLAS collaborators currently includes multiple methods of evaluating four main areas of competence: medical knowledge, clinical reasoning and judgment, patient management, and communication skills. The PLAS provides nationally standardized competency-based examinations (MCQs) in the major clinical clerkship subject areas, mechanisms of disease, pharmacotherapeutics, ethics and communication and interpreting the medical literature. There are performance-based, simulation-type assessments such as the computerized Primum®/CCS and its associated Transaction Stimulated Recall (TSR) structured interview. A hands-on clinical skills examination for practicing physicians currently is in transition to being routinely available to assess patient communication and data gathering skills. Table 1 shows the various evaluative methods used to assess each aspect of competence.

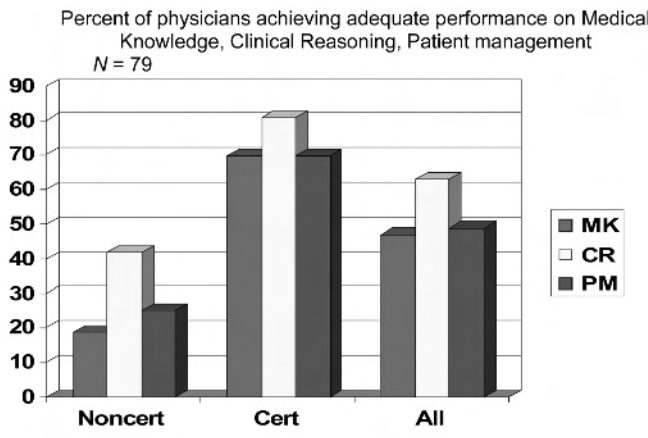
The collaborative delivery model promotes linkages with educational programs, enhances local capacity to individualize assessments, and facilitates local practice-based performance assessments as supplements to the PLAS tools.

Table 1. Assessment Process: Multiple Aspects by Multiple Methods.

Aspect of Competence	Assessment Modalities
Medical Knowledge	MCQs CCS/Primum® Simulations
Clinical Reasoning	TSR (Structured Clinical Interview)
Patient management	MCQs CCS/Primum® Simulations TSR (Structured Clinical Interview)
Communication	MCQs *Clinical Skills Examination *Professionalism tool
Data Gathering/ Documentation	*Clinical Skills Examination *Chart Auditing

* represents assessments under development or recently becoming operational; MCQ=multiple choice questions; CCS=computer case simulations; TSR=transaction-stimulated recall.

Figure 4. Adequate Performance Levels Achieved by Noncertified & Certified Physicians.



Some of these local assessments include chart audits, chart stimulated recall interviews and professionalism instruments, usually in the form of a 360° review (a rating scale assessment of interpersonal skills conducted by peers, allied health professional staff and in some instances, patients). The measurement expertise of the PLAS staff professionals is available to help to develop best practices at the local level.

SUMMARY OF RESULTS TO DATE

The IPE is in the process of gathering data on the performance and outcomes of physicians assessed. To date, most of the results were obtained through the IPE assessments at FSMB and NBME offices; however, one collaborating program has begun to share data. Figure 4 shows the performance of 79 physicians about whom there are complete data (53 IPE and 26 from the PACE Program at the University of California at San Diego).

As shown in Figure 4, certified physicians performed better on all three aspects than noncertified physicians. These data were reported in the assessment reports submitted to the SMBs following full assessments of physicians referred for a variety of reasons. Fewer than half of the noncertified physicians demonstrated adequate performance (medium or high levels) on any of the three aspects investigated. Less than 20 percent of the non-certified physicians performed adequately on the tests of medical knowledge, whereas more than 70 percent of the certified physicians performed at least adequately on medical knowledge tests.

During the three-year interval in which the 53 IPE assessments were conducted, the physician usually underwent a full two-day assessment that included the computer simulations (CCSs), the follow-up TSR interview, and several MCQ tests. Those assessment reports summarized the same three aspects of competence: medical knowledge, clinical reasoning, and patient management. In the new collaborative model and as more evaluative tools are developed, other aspects of competence, such as communication skills or professionalism, will also be assessed and summarized depending upon the focus of the prescribed or desired, tailored assessment.

Table 2 shows the overall performance of the 53 IPE physicians who were assessed during 2002 through 2005 in medical knowledge, clinical reasoning and patient management. Each assessment report was 12 to 15 pages of descriptive information and included recommendations for education or retraining. These recommendations could be undertaken at the discretion of the participant physician, but most often were negotiated to comply with the requirements of the SMB. Low performances usually warranted a full-scale educational plan and a recommendation for a mini-residency training program. For a substantial number of low-performing physicians, a full residency training program was recommended. A current IPE research study seeks to identify how and whether physicians undertake any of the report recommendations. Borderline performance usually warranted an extensive remedial educational plan and some form of personalized guidance, such as an individual preceptor. Medium performance involved tailoring an educational plan designed to address discrete areas of need. High performance may have included a suggestion for an educational course, but maintaining good standing in CME/CPPD was the typical recommendation. (For summary purposes, low and borderline performance constituted less than adequate performance. Medium and high performance represented adequate performance.) Recommendations for further study and structured clinical education varied based on time out of practice, regardless of performance. For instance, a practitioner who performed adequately on all three aspects might still have received a recommendation to seek an alliance with a preceptor if the practitioner had been out of practice for more than a few years.

In some cases, the physician's training and certification are not related to his or her current practice. Building the assessment for these physicians in transition is particularly precarious. Usually the transition is from a more specialized practice to a general practice. For instance, one physician certified in anesthesiology was practicing emergency medicine at the time of the investigatory process. Two others were certified in surgery but are now in general practice; another from obstetrics and gynecology is seeking to be a

Table 2. Overall Performance Ratings on IPE Assessment Protocols (2002-2005).

Specialty training in	Performance level								Total
	Low		Borderline		Medium		High		
	Not	Cert	Not	Cert	Not	Cert	Not	Cert	
General Practice	8**		7*		1		1		17
Family Medicine		2	2	2			1	1	8
Internal Medicine	2	1		1	2			8	14
Obstetrics & Gynecology				2	1	2		2	7
Pediatrics						1		2	3
Other: Surgery, Anesth., Emerg.		1	1				1	1	4
Total	10	4	10	5	4	3	3	14	53
% of total	26%		28%		13%		32%		100%

Cert = number certified; Not = number not certified; each * = one physician in transition.

general practitioner. The assessments currently are better suited to broader areas of practice such as family medicine, internal medicine and emergency medicine. Thus, physicians in transition are more difficult to accommodate with personalized assessments and add complexity to attempts to summarize results. When the data set is larger, these physicians in transition may constitute a separate data set with its own research questions. For now, in this small data set, these physicians are more likely to perform in the low or borderline range. It remains unclear as to whether this is because they have difficulty with assessments outside their area of training or are not prepared for assessment in general. Regardless of cause, they are likely to require more structured clinical educational experiences to demonstrate adequate performance levels in their new area of practice. These limited data suggest that previous certification in one specialty should not be viewed as a pass to practice in another area without some guided educational experience. The development of more personalized and in-office evaluations should facilitate a more physician-friendly and realistic assessment process, which may help to identify more specific learning needs.

Table 3 shows the distribution of licensure outcomes as best as could be ascertained. Some participants are so recent no outcome has yet been determined by the licensing body. Thus, the outcomes in Table 3 are based on a review of information reported to the FSMB's Physician Data Center and available on SMB websites. It also is critical to note the assessment results were only a part of the decision-making process and not the sole criterion for a licensing authority's decision. Making direct comparisons of performance to outcome may present problems for interpretation that are not resolvable. Some case examples will be discussed.

Of course, one cannot presume an assessment was the basis for the licensure decision. There is no way to know how much these reports were weighted in the decisions made by either SMBs, or in some cases, hospitals. For example, there are four physicians in the cell comprising the intersection of high performers on the assessment but who have conditions on their license. These four physicians illustrate the diversity of the impact of the assessment process. One physician whose license was suspended and was on probation had the suspension lifted the day after the assessment, but remains on probation for another four years. Within three months of the assessment, the second physician was required to take courses both related and unrelated to the findings of the assessment report. The third had the license restored one year later, but it was limited for two years with the requirement of additional CME. The fourth physician had different outcomes from two different states. In the state for

Table 3. Assessment Performance Levels by Licensure Outcomes of IPE Participant Physicians (2002-2005) N= 53

Performance level	Licensure level				Total
	Not in practice		In practice		
	Denied/ revoked/ surrendered	Suspended/ Pending	Conditionally reinstated/ probation	Full	
High			4	13	17
Medium			3	4	7
Borderline	3	3	6	3	15
Low	7	3	4		14
Total	10	6	17	20	53
Percent	19%	11%	32%	38%	100%

which the assessment was performed, the license was reinstated with probation three months post-assessment. In a neighboring state the license was surrendered six months after the assessment in lieu of investigation or other action, such as that taken by the board of the state requiring the assessment. These examples point out the variability in how individual states approach assessment outcomes in considering the totality of information available on individual practitioners.

Another group of interest would be those four physicians who performed in the low level on the assessment but still have full or partial licensure. These four physicians all have restricted licenses: two must participate in a one-year residency; one is limited to physical exams and has no prescription writing privileges; one may not do office procedures and must undergo a medical record review. The latter two physicians also lost their license in a neighboring jurisdiction because of the restrictions.

The review of the three physicians with borderline performance and full licensure identified some striking similarities: All three were English-speaking international medical school graduates (IMGs) and reticent participants in the TSR interview. All were slow in responding in the interview and had great difficulty recalling case details. None were able to describe a reasoning process or even to express an interest in trying to think about such a process. They each used an algorithmic approach to test ordering and had difficulty in an unstructured environment in deciding what tests to order. All three are currently in practice, with no action being reported on two of them by their respective SMBs more than two years after the assessment was completed. The third was granted full licensure two weeks after the assessment when the consent order was satisfied.

In reviewing the outcomes relating to licensure, it appears that the IPE-reported performance levels were usually concordant with the decisions of the SMBs, though it is difficult to tell how much impact an individual report might have had due to the timing and reporting policies of various SMBs. In some cases the physician was required to complete the assessment, with the results not necessarily used in the decision-making process. In all 14 cases of reported low performance, no physician was in independent practice. This represents good agreement between the outcomes from the SMB deliberations and the report findings. Nevertheless, it remains unknown as to the degree to which an assessment report assisted an SMB to make the decision to monitor the physician, or suspend or revoke a license.

Of the 15 borderline performance reports, nine physicians are practicing; six are practicing conditionally and the other three physicians, who illustrate the similarities described above, are practicing unrestricted. The remaining six are not currently in practice. All of the 24 medium- or high-performing physicians currently have licenses to practice; seven are under conditions of some kind, with variability of the four high performers described above.

The IPE assessment process was used by 18 different SMBs in the three years that it performed assessments in Euless, Texas and Philadelphia, Pa. One state had more than 10 reports, eight states had two reports, and five states received only one report. Two physicians of the 53 physicians assessed were self-referrals. Four osteopathic physicians were evaluated. One physician was assessed twice. The expansion of the collaborative network with regional sites should improve the accessibility such that more SMBs might use the services provided by the closest site, but also the one that best fits the assessment and educational needs of the individual physician.

THE FUTURE OF PLAS ASSESSMENT

The PLAS system is facilitating the growth of emerging and established assessment centers as regional sites for a national network of high-quality and reliable evaluative services. New research and development initiatives are intended to continue to customize the assessments toward more practice-friendly content and to introduce more practice-based (in-office) tools, such as chart audits and structured interviews.

One example of a recent innovation is the newest tool in the continually growing assessment tool box, which is a clinical skills assessment to accommodate the efficiencies of practicing physicians. To be effective, this tool had to take into account that the hands-on examination of a patient and associated data gathering becomes more efficient with experience. This use of standardized patients is a major step forward in being able to assess more than knowledge in practicing physicians.

At this time it is not possible to evaluate the educational recommendations of the assessment reporting process. A wide variety of recommendations were included in the assessment reports ranging from obtaining training in a mini-residency training program or with a preceptor, to taking courses to solidify knowledge bases or joining a journal club. Efforts to gather data on how physicians use the reported recommendations have begun, however, the nature of the process and availability of education resources suggest that it will be years before significant data are collected.

As the collaborative network develops and expands, the experience gained in the past three years, when the IPE conducted assessments, will facilitate the processes implemented in cooperation with the collaborative sites. The cyclical nature of the feedback process will enhance the evolution of the network itself. The IPE is now referring SMBs to the collaborating sites, usually in the regional arrangement shown in Figure 3. The list of contact persons at each site is included as an appendix to this article.

The PLAS intends to continue to address the evolving needs of regulatory agencies, the public, and the profession in prioritizing ongoing and future development. The PLAS is interested in collaborating in studies such as the research sponsored by a grant from the Robert Wood Johnson Foundation. This project is a needs assessment focusing on what medical boards and other components of the medical community perceive to be the features associated with physicians who are at risk for practice difficulties.

SUMMARY

This article was intended to provide a snapshot of the progress being made in the continually evolving arena of post-licensure assessment. The history of the PLAS demonstrates the close relationship of the two sponsoring organizations (the FSMB and the NBME) and the dedication of both to adjusting to the difficulties encountered in the operating environment. A variety of evaluation tools are now available or are coming into more widespread use to assist in competence assessment.

One of the specific goals of this article was to describe the transition in the role of the IPE from conducting assessments for referring SMBs to providing reliable and standardized assessment tools to independent assessment centers, where the assessments can be localized and personalized to regional or specialized areas of expertise. Another specific goal was to show the performance data of the participating physicians and relate that performance to the outcomes of the deliberations of the individual SMBs. The review of specific intersections of performance and outcome suggests that the data from the assessment reports is generally supportive of the resulting licensure decisions of the SMBs. Finally, and of highest significance, the PLAS is evolving slowly but positively as an effective facilitator of competence assessments for practicing physicians. The personalized assessment process and concomitant education recommendations have implications across several developing initiatives in the arena of maintenance of licensure or certification and the continuing professional development of physicians.

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ALBERTA, CANADA
CPSA MEETS WITH HEALTH MINISTER TO CLARIFY IMPACT OF "THIRD WAY" PROPOSAL

In a meeting with Health Minister Iris Evans, the College of Physicians and Surgeons of Alberta (CPSA) said they are cautiously optimistic about the proposed Health Policy Framework, but noted that some elements of the plan need further clarification.

"We understand this document is a work in progress," notes CPSA Registrar Dr. Trevor Theman. "While we applaud the Health Ministry's efforts to be innovative in proposing ideas for change, we need more information on how this framework will affect physicians and the public before we can provide constructive feedback."

Some Health Policy Directions received conditional support from the College. For example, Policy Direction #2 outlines plans to promote flexibility in scope of practice amongst health professionals. "This approach could help address the physician shortage," Dr. Theman says, "and we have supported expansion of the scope of practice of other professions when they have demonstrated the necessary knowledge, skills, clinical training and assessment." Theman went on to explain that the CPSA does not support primary prescribing for pharmacists because "we have not been provided evidence that pharmacists are properly trained to diagnose conditions safely, a necessary precursor to safe prescribing."

According to Theman, other elements of the Health Policy Framework will require significant consultation and collaboration to be successful. "We look forward to working with the Ministry to ensure these recommendations improve quality, safety, and access — regardless of ability to pay." In particular, the College will focus their efforts on the following:

- Helping to develop a knowledge infrastructure that includes quality indicators, measurement tools and improved monitoring of health care facilities
- Assisting in addressing the shortage of physicians without compromising quality patient care
- Helping to create the necessary guidelines for physicians should they be allowed to work in both the public and private system

Reprinted from the College of Physicians and Surgeons of Alberta website.

WELLINGTON, NEW ZEALAND
RECENT IMG DEVELOPMENTS

New Zealand is critically dependent on international medical graduates (IMGs) with 41.5 percent of doctors currently registered in New Zealand having graduated overseas. The 2003 workforce survey reveals that 36 percent of specialists in New Zealand are IMGs.

Under the Medical Council of New Zealand's (Council) current policy there are two pathways to registration within a vocational scope for IMGs:

- The IMG is required to satisfactorily complete 12 months of supervised practice, ensuring the doctor has adjusted to New Zealand conditions; or
- The IMG needs to complete further assessments which may include a requirement to sit and pass a vocational branch advisory body (BAB) or College examination or other forms of assessment, in addition to a minimum of 12 months of satisfactory supervised practice.

Difficulties facing the Council and BABs

There are a number of difficulties in assessing IMGs applying to the Council for registration within a vocational scope of practice. These difficulties include:

- Some overseas training programs use very different assessment processes and training programs. This makes it difficult to determine whether the IMG is practicing at the standard which would be expected of a New Zealand trained doctor registered in a vocational scope of practice.
- Applicants may not have completed a clinical or external assessment similar to those used in New Zealand.
- Several overseas postgraduate training providers are not

accredited by external agencies. College or BAB examinations, although suitable for those involved in or completing training programs, may not be suitable for IMGs who have been in specialist practice for a number of years.

In December 2005, the Council circulated a consultation paper, Pathway to registration within a vocational scope for international medical graduates, suggesting changes to the current pathway to registration within a vocational scope for IMGs. We sought comment from various external stakeholders, including BABs, the chief medical advisors of district health boards and the NZMA. There was a very encouraging response to the document with 40 submissions received.

The consultation process was useful in identifying:

- Support from BABs for the Council to develop a wider range of assessment tools for those IMGs that the Council considers need more assessment than simply the year of supervision, but for whom further College examinations are not suitable.
- A consensus that the length of time a doctor has practiced as a specialist in a comparable health system would not necessarily exempt him or her from completing further assessment.
- Inconsistencies in the interview process and in the advice provided to Council by BABs. The objective of the interview with an IMG is for the BAB to give advice to Council on whether the doctor is of a comparable standard to a New Zealand doctor registered within the same vocational scope of practice.
- A range of views about whether it would be appropriate for Council to assess and restrict IMGs to small specialty areas. There were concerns about increasing the number of doctors registered in sub-specialties. This may create problems in providing on-call services particularly in smaller hospitals.

Third pathway to registration within a vocational scope

As a result of the consultation process Council is exploring three pathways that may lead to registration within a vocational scope for IMGs:

- 01 A year of supervision only, where the IMGs' training and assessment programs are well known and similar to those in New Zealand and Australia.
- 02 An external clinical examination and 12–18 months of supervised practice where there are differences between the IMGs' training program and assessment compared with a New Zealand trained specialist.
- 03 Twelve to 18 months of supervised practice with an external performance assessment. The performance assessment would use a variety of assessment tools.

Assessment tools

The Council's professional standards team currently uses performance assessment to ensure a New Zealand doctor is practicing at the required standard of competence in accordance with his or her scope of practice. These tools, based on international research, are valid and reliable. They would require modification for each vocational scope.

Most BABs supported the Council's move to adapt its current tools so that they can be used to assess selected IMGs applying for registration within a vocational scope of practice. It is proposed that Council staff will work with BABs to modify the tools to ensure they are appropriate for assessment of IMGs within the different vocational scopes.

Council continues to work closely with the BABs in moving forwards on the pathways to registration within a vocational scope. Council considers that it will offer a more appropriate and valid form of assessment for a number of well established specialists coming to New Zealand.

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ARIZONA

TWO NEW AREAS OF UNPROFESSIONAL CONDUCT

Two new laws approved by the Arizona Legislature during the 2006 legislative session and signed by Gov. Janet Napolitano took effect on Sept. 21. They define two new areas of unprofessional conduct for physicians and physician assistants.

The first, House Bill 2786, deals with the problem of abandoned medical records. Every year, the state agencies that regulate health care professionals receive numerous complaints regarding abandoned or unavailable medical records that can create privacy and continuation of care concerns. In response to this problem, the legislature enacted a law requiring all health care professionals to develop a written protocol for the secure storage, transfer and access of patient medical records.

The Arizona Medical Board and the Arizona Regulatory Board of Physician Assistants have modified their initial and renewal application forms to require licensees to certify that they had developed the required protocol. The law makes it an act of unprofessional conduct for a health care professional who fails to implement the required protocol.

The second new law, House Bill 2426, makes it an act of unprofessional conduct for a health care professional to request that a laboratory send its bill through the health care professional, rather than bill the patient or the payor directly. This law requires what is called "direct billing." It does not apply to tests conducted by the health care professional or by a laboratory operated by the health care professional.

Reprinted from the Arizona Medical Board website.

CONNECTICUT

LAW REQUIRES HEALTH CARE INSTITUTIONS TO REPORT INFECTIONS BEGINNING IN 2008

In a ceremony at Greenwich Hospital in June, Gov. M. Jodi Rell signed into law an Act Concerning Hospital Acquired Infections (Public Act 06-142) which establishes a mandatory statewide reporting system for health care-associated infections by health care institutions to the Connecticut Department of Public Health (DPH) beginning in 2008.

"Simply put, people go to the hospital to get better, not to become ill by contracting new infections — infections that are proving to be fatal too often throughout the nation," said Governor Rell. "By collecting and analyzing more information on infections and their causes, we will be able to better protect patients. While Connecticut has one of the best health care systems in the world, we must continuously strive to improve patient care through oversight, education and public reporting. Only through full and transparent reporting can we aggressively reduce these preventable infections."

Infections contracted in hospitals are the fourth largest killer in the United States, causing as many deaths as AIDS, breast cancer and automobile accidents combined. The Centers for Disease Control and Prevention estimates that annual health care-associated infections number more than two million, resulting in approximately 90,000 deaths and $4.5 billion in excess health care costs.

The new law creates an 11-member Committee on Healthcare Associated Infections that will be responsible for developing, operating and monitoring a mandatory reporting system for health care-associated infections in conjunction with DPH. The committee is also responsible for recommending to DPH methods and programs aimed at reducing the spread of infections, particularly in health care settings.

The committee will provide an initial report to DPH by Oct. 1, 2007, detailing the appropriate standardized reporting measures and recommending processes designed to prevent infections. Public reporting of health care-associated infections in Connecticut will begin in October 2008 and continue annually thereafter. Members of the committee, as appointed by DPH Commissioner J. Robert Galvin, M.D., M.P.H., will

come from the hospital and public health communities, as well as the public at large.

"Working with this new committee and with the health care institutions of Connecticut, we can surpass the high quality of health care that the residents of our state have come to expect," said Commissioner Galvin.

A health care-associated infection is defined as any localized or systemic condition resulting in an adverse reaction to the presence of an infectious agent (or its toxin) in a patient, occurring in a health care setting, and which was not present or incubating prior to the patient's admission.

Reprinted from the Connecticut Medical Examining Board website.

WEST VIRGINIA
LEGISLATIVE UPDATE

Engrossed Senate Bill 463 became effective in March 2006. This law amends the requirements for physician and podiatric licensure in West Virginia by declaring the Virginia Board of Medicine may not issue a license to a person whose license has been revoked or suspended in another state until the reinstatement of the license in that state. Also, the requirements for medical licensure are modified. Now the board may not only extend the period of seven consecutive years for passage of all components of the USMLE for up to three additional years for any medical student enrolled in a dual M.D.-Ph.D. program, but also for a medical student participating in an accredited fellowship training.

Finally, a special provision in the law, which previously expired, has been revived until July 1, 2007. A license applicant who does not meet the requirements for medical or podiatric licensure, under extraordinary circumstances may be granted a license under several conditions. First, the board must find that the applicant's exceptional education, training, and practice credentials are substantially equivalent to West Virginia medical licensure requirements. Secondly, the license granted under such extraordinary circumstances must be approved by three-fourths of the board members. Third, orders denying such license applications are not appealable, and the board must report to the Senate President and Speaker of the House of Delegates all decisions made pursuant to this section and the reasons therefore.

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EXPERT TESTIMONY

Garcia v. Marichalar,
No. 04-05-00344 (Tex. App. Apr. 5, 2006) – DEx

Finding that a medical malpractice plaintiff failed to adequately plead a claim against a doctor under Texas statutory law because her expert report did not make any specific mention of the doctor or his actions, the Texas Court of Appeals reversed the trial court's denial of the doctor's motion to dismiss.

On Jan. 30, 2003, Lizalde Marichalar underwent exploratory surgery at Christus Santa Rosa Healthcare and Hospital as a result of an ectopic pregnancy. For a month after the surgery, she experienced abdominal pain. On Feb. 28, 2003, Marichalar was admitted to an emergency room where she underwent surgery to remove a 10-inch gauze sponge that had been left in her body after the January surgery.

Marichalar sued the hospital and a number of doctors, including Luis Garcia, M.D., for medical malpractice. Within 120 days of filing her claim, Marichalar sent her expert report to Garcia. Because the report did not mention him at all, Dr. Garcia filed a motion to dismiss Marichalar's claim, arguing that she did not "serve him" with an expert report within the statutorily prescribed 120-day period. The trial court denied his motion.

Dr. Garcia appealed, again arguing that Marichalar did not serve him with an expert report relating to his actions. Marichalar countered by arguing that the submitted expert report constituted a good faith effort to comply with Texas law, and that she was not even required to serve Garcia with such a report because his actions were covered by the doctrine of res ipsa loquitur.

The appellate court noted that an adequate expert report must include the expert's opinion on standard of care, breach and causal relationship, and may not merely state the expert's conclusions about those elements. The appellate court then found that Marichalar's report failed to discus how the care rendered by Dr. Garcia failed to meet the applicable standard of care or how his failure caused her to suffer harm or injury. Where the expert report failed to mention him at all, it did not constitute a good faith effort to comply with state statutory requirements.

The appellate court went on to find that even if the doctrine of res ipsa loquitur did apply to Marchalar's claims, she would still be required to supply a sufficient expert report regarding the defendant.

Because she failed to do so, the appellate court reversed the trial court's order denying Dr. Garcia's motion to dismiss and remanded the case for further consistent proceedings.

Robins v. Garg,
No. 256169 (Mich. Ct. App. Apr. 4, 2006) – DEx

The Michigan Court of Appeals reversed a trial court's grant of summary judgment in favor of a doctor in a medical malpractice action, finding that the plaintiff's expert witness was qualified to testify on the standard of care at issue.

Tilak Garg, M.D., a general practitioner, began treating Ilene Robins in January 1986. In 1998, he began prescribing medication to control Robins' cholesterol, but she refused to take the medication. On June 1, 2001, Robins came to Dr. Garg's clinic with chest pains. He called an ambulance, but she went into cardiac arrest and died before the ambulance arrived. Robins' estate filed a medical malpractice action against Dr. Garg on behalf of the deceased and attached to his complaint the affidavit of Marvin Werlinsky, M.D., a licensed family medicine practitioner. Dr. Garg moved to strike that doctor as plaintiff's standard of care expert and for summary judgment.

The trial court granted Dr. Garg's motions, and the estate appealed. The appellate court reversed, finding that the trial court abused its discretion in striking Dr. Werlinsky's testimony because he was a family, rather than general, practitioner. The estate presented evidence that Werlinsky was familiar with the standard of care for an area similar to the area in which Dr. Garg practiced, and interacted with

general practitioners throughout his own practice.

Therefore, he was qualified as a standard of care expert. The appellate court concluded by finding that the trial court erred in granting Dr. Garg summary judgment where Dr. Werlinsky's testimony created a question of fact regarding whether Robins' heart condition caused her death.

Wallenquest v. Brookhaven Mem'l Hosp. Med. Ctr.,
No. 02742 (N.Y. App. Div. Apr. 11, 2006) – DEx

The New York Supreme Court, Appellate Division, Second Department, affirmed a trial court's denial of a doctor's motion for summary judgment in a medical malpractice action, finding that a causal link could be reasonably inferred from the alleged misconduct and the injury at issue.

Richard Rubenstein, M.D., treated Lauranne Wallenquest for a pulmonary embolism at Brookhaven Memorial Hospital Center from Dec. 21 through Dec. 24, 1999. Dr. Rubenstein saw Wallenquest again on Dec. 27. On Jan. 3, 2000, he was notified that Wallenquest would not be keeping a follow-up appointment, but would instead be seeing her internist, David Goldstein, M.D. Wallenquest saw Dr. Goldstein several times, but died on Jan. 14, 2000.

Wallenquest's husband sued both doctors and the hospital for medical malpractice. Dr. Rubenstein moved for summary judgment, and the trial court denied his motion. Dr. Rubenstein appealed.

The appellate division found that Dr. Rubenstein satisfied his prima facie burden of demonstrating his right to summary judgment by submitting an expert report indicating that he followed proper procedure in his treatment of Wallenquest. The report further indicated that no causal link existed between any act or omission by Dr. Rubenstein and the patient's death.

INFORMED CONSENT

Curran v. Buser,
No. S-04-1303 (Neb. Mar. 31, 2006) – DEx

The Nebraska Supreme Court ruled a trial court did not err in disallowing a patient in his medical malpractice action against a doctor to introduce evidence of the doctor's previous disciplinary action and his failure to inform the patient of that action. The patient failed to establish the proper standard of care.

Matthew and Emily Curran sued Matthew's surgeon, Kerrey Buser, M.D., for medical malpractice because of complications arising after Dr. Buser removed Matthew's gallbladder. Before Matthew's surgery, the Department of Health and Human Services Regulation and Licensure disciplined Dr. Buser for "unprofessional conduct" and restricted his surgical privileges for one year. Nine days after the year had passed, Dr. Buser operated on Matthew.

The Currans alleged both negligence and lack of informed consent. The Currans wanted to introduce evidence of Dr. Buser's disciplinary history. Dr. Buser filed a motion in limine, prohibiting mention of his disciplinary issues, which the trial court granted. The jury found for Dr. Buser on the negligence issue, and the Currans appealed only the court's ruling on the motion in limine.

The Supreme Court affirmed the trial court's judgment. The thrust of the Currans' argument was that Dr. Buser operated on Matthew without informed consent because Dr. Buser failed to inform him of his disciplinary history.

However, the Supreme Court noted the legislature had adopted the professional theory as governing the standard of care in all informed consent cases. The professional theory holds that a doctor's duty to inform his patient of the risks involved in treatment is measured by the standard of the reasonable medical practitioner under the same or similar circumstances. The Currans failed to demonstrate the standard of care in similar communities required Dr. Buser to disclose his disciplinary history.

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