

***“...even health, is not much good unless you can
take a healthy view of it...”***

Gilbert Keith Chesterton
On St. George Revivified



Commonwealth of Massachusetts

**Board of Registration
In Medicine**

**Annual Report
~ 2001 ~**

*Her Excellency Jane Swift
Governor of the Commonwealth
And the Honorable Members of the
General Court of Massachusetts*

*Dear Governor Swift
and Members of the General Court:*

On behalf of the Board members, I submit this report summarizing the Agency's activities for the calendar year 2001. The Board of Registration in Medicine continues to make tremendous improvement in all areas of public protection and health care quality assurance. The backlog of open consumer complaints has been reduced, the work is being handled in an expeditious manner, and public confidence in the Board continues to grow. I believe that we strike the appropriate balance between imposing necessary disciplinary action and supporting the practice of those physicians who continue to provide the people of Massachusetts with the world's highest quality health care.

This improvement can only continue through the collaborative efforts of the Board, the legislature, the administration, and other interested parties. The Massachusetts Board of Registration in Medicine continues to operate with approximately half the funding of comparable state medical boards across the country. Additional sources for investment in licensing processes, investigators, public information systems, and patient safety must be identified. The Board looks forward to working with its many partners to secure adequate funding to meet its mission in these challenging economic times.



***Dr. Peter N. Madras**
Board Chair*

I express the Board's gratitude to our staff for their tireless effort and dedication. In addition, I am indebted to your staff for re-invigorating our agency and creating an environment in which the above work remains not only possible, but highly rewarding. Finally, the Board members must be lauded for the long hours they devote to this important work.

Sincerely,

Peter N. Madras

*Peter N. Madras, MD
Chairman, Massachusetts Board of Registration in Medicine*



Seated

Dorothy Keville, M.Ed
Vice-Chair

Martin Crane, MD
Physician Member

Mary Anna Sullivan, MD
Physician Member

Standing

Rafik Attia, MD
Secretary

Roscoe Trimmier Jr, Esq.
Public Member

Peter N. Madras, MD
Chair

Regis De Silva, MD
Physician Member

The Board's mission is to ensure that only qualified physicians are licensed to practice in the Commonwealth and that those physicians and health care institutions in which they practice provide to their patients a high standard of care, and support an environment that maximizes the high quality of health care in Massachusetts.

2001 Annual Report

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STRUCTURE OF THE BOARD OF REGISTRATION IN MEDICINE

Board & Committee Work

The Board of Registration in Medicine consists of seven members who are appointed by the Governor to three-year terms. A member may serve only two consecutive terms. Members sometimes serve beyond the end of their terms before a replacement is appointed. There are two public members and five physician members of the Board. Each member also serves on one or more Committees of the Board. Committees of the Board include:

Complaint Committee

Members review allegations against physicians and recommend cases for disciplinary action to the full Board. The Complaint Committee members oversee the “triage” process by which complaints are prioritized, direct the Litigation staff in setting guidelines for possible consent orders, recommend matters for prosecution to the full Board, and hold intensive remedial and investigatory conferences with physicians who are the subject of complaints.

Data Repository Committee

Members review reports filed about physicians from statutorily mandated reporting sources. Reports include malpractice payments, hospital discipline reports, and reports filed by other health care providers. Although sometimes similar in content to allegations filed by patients, Data Repository reports are subject to different legal standards regarding confidentiality and disclosure than are patient complaints. The Data Repository Committee refers cases to the Enforcement Unit for further investigation, as needed.

Licensing Committee

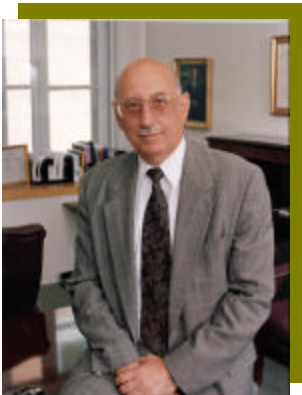
Members review applications for licensure and requests for waivers from certain Board provisions. The members present candidates for licensure to the whole Board. The two primary categories of licensure are full licensure and limited licensure. Limited licensees include all physicians in training, such as those enrolled in residency programs.

Patient Care Assessment Committee

Members work with hospitals and other institutions to improve quality assurance programs through the review of Major Incident Reports. These reports describe adverse outcomes, full medical reviews of the incidents, and the corrective action plans of the facilities. The plans are part of the Committee's commitment to preventing patient harm through the strengthening of medical quality assurance programs in all institutions. The work of the Committee has become a national model for health care excellence in response to the recent Institute of Medicine Report on the prevention of medical errors.

Committee on Acupuncture

The Board of Registration in Medicine also oversees the licensing and discipline of licensed acupuncturists through the Committee on Acupuncture. The current members of the Committee on Acupuncture include four licensed acupuncturists, one public member, and a designee of the Board Chair.



Dr. Rafik Attia
Board Secretary

Ad Hoc Committee on Regulation Revision

In order to better serve the people of the Commonwealth of Massachusetts, the Board of Medicine is undertaking an intensive review of its regulatory and statutory authority. The review process will result in recommendations for change and an opportunity for public comment on these recommendations. The Committee is chaired by former Board member Carl Sapers, Esq.

Ad Hoc Committee on Licensing Fees

The Board also convened a special committee to review licensing fees in Massachusetts. The committee was comprised of representatives of the Board, area hospitals, and physician groups. The Committee will make recommendations to the Board on the appropriate structure, revenue stream, and amount of physician licensing fees.

Functions and Divisions of the Agency

The Executive Director of the agency reports to the Board and is responsible for hiring and supervising a staff of legal and medical professionals who perform research and make recommendations to the members of the Board on issues of licensure, discipline, and policy. In addition, the Executive Director is responsible for all management functions, budget and contract issues, and public information activities of the agency.

Although the policies and practices of the Board of Registration in Medicine are established by its Board, the agency resides administratively within the Office of Consumer Affairs and Business Regulation (OCABR). Through its close contact with the OCABR, the Board is able to keep the issues of importance to health care consumers at the forefront of consumer rights initiatives.

The Executive Director oversees senior staff members who, in turn, manage the various areas of the agency. The Divisions of the agency include the following:

Enforcement Division

The Enforcement Division is responsible for the investigation of all consumer complaints and statutory reports referred from the Data Repository Committee. The Consumer Protection Unit coordinates the initial review of all complaints as part of its "triage" process. Complaints with allegations of substandard care are reviewed by experienced clinical nurses from the Clinical Care Unit, then sent to outside expert reviewers. Experienced investigators research complaints by interviewing witnesses, gathering evidence, and working with local, state, and federal law enforcement agencies. The Disciplinary Unit is staffed by prosecutors who represent the public interest before the Complaint Committee, the Board, and the Division of Administrative Law Appeals (DALA).

Licensing Division

The Licensing staff performs the initial review of all applications for medical licensure to ensure that only competent and fully trained physicians are licensed in Massachusetts. The staff also works with applicants to clarify requirements for examinations and training that must be met before a license will be issued.

Education & Outreach Division

Massachusetts continues to lead the nation in the quality and accessibility of information for patients and the general public. Since the launch of the Physician Profiles project in 1996, thousands of Massachusetts residents have found the information they needed to make informed health care decisions for their families using this innovative program.

In addition to on-line access to Profiles, the Board of Registration in Medicine assists consumers who do not have Internet access through a fully-staffed Call Center. Call Center employees answer questions about Board policies, assist callers with obtaining complaint forms or other documents, and provide copies of requested Profiles documents to callers.

Division of Law & Policy

The Division operates under the supervision of the General Counsel. The Office acts as legal counsel to the Board during adjudicatory matters and advises the Board and staff on relevant statutes and regulations.

Among the areas within the Division of Law and Policy are the Office of the General Counsel, the Patient Care Assessment Unit, the Data Repository Unit, the Physician Health & Compliance Unit, and the Committee on Acupuncture.

EXECUTIVE DIRECTOR'S REPORT

Nancy Achin Sullivan

Two years ago, a new management team began its work at the Massachusetts Board of Registration in Medicine. There was a clear mandate from the Administration, the Legislature, and the public for meaningful change in how the agency operated. The volunteer Board of five physicians and two public members led a massive effort to restore public confidence in the agency, re-engineer key work processes, and reinvigorate the agency. In 2000, the agency focused on accomplishing a reduction in the huge backlog of consumer complaints. In 2001, the agency built upon the successes of 2000 to further streamline the complaint resolution process.

The Board of Registration in Medicine also developed plans for meaningful technological enhancements to better reach its goals. In addition to the early development of plans for on-line license applications, the agency is in the process of adding on-line edit capabilities for physicians who wish to update demographic information, business address, insurance plan affiliations, hospital affiliations, and other information. By accepting this information electronically, the Board of Registration will increase the accuracy and timeliness of its data files and provide better service to physicians. Electronic capture of the updates will also allow the agency to incorporate the changes immediately into its Physician Profiles system, resulting in improved services for patients and other consumers.

The most important factor in the long-term success of the Board of Registration in Medicine is adequate funding. In 2001, the Board proposed an increase in licensing fees. Fees have not been increased in over a decade. Although most physicians recognize the importance of a well-funded Board as a means of protecting both the profession and their patients, there is discontent among many physicians about the funding mechanism for the Board. Currently, forty percent of licensing fees are retained by the Board and sixty percent revert to the General Fund. The Board receives a General Fund appropriation.

The Board strongly recommends a change to allow for 100% fee retention by the Board. There is precedent for self-funding agencies in Massachusetts, such as the Department of Public Utilities. Such a structure would bring Massachusetts into alignment with the majority of medical boards throughout the country.

Currently, investigators, complaint counsels and nurse investigators carry large caseloads. A single case can involve numerous individual complaints. For example, the Board may decide to conduct an intensive investigation of a physician with a number of adverse reports in his record. A single case may require a full medical care review of a half dozen patient records, audits of all prescriptions written by the physician, and interviews with many complainants or witnesses.

AVERAGE CASELOAD in 2001

Enforcement Staff	Average Caseload
Complaint Counsel	23 physicians
Investigators	28 physicians
Nurse Investigators	33 physicians

During the past two years, the agency has made tremendous improvement in the management of its caseload of consumer complaints. When the new management team assumed responsibility for the agency, the case management statistics were daunting: there were nearly seven hundred open cases and the average case was over two years old. Many cases were so old that they no longer met the requirements of the Board’s “staleness policy” for consideration. Certainly, the situation did not represent the high level of customer service that citizens expect and deserve from their government.

Today, the complaint process is managed in a far more responsive manner. Both the open caseload and the average age of cases have been cut in half.

Caseload Statistics

YEAR	Average Age of Complaint	Open Complaints at End of Year
2001	356.78 days	361
2000	456.29 days	537
1999	790.51 days	698

Looking Forward

The accomplishments of the past year have been impressive, but the Board of Registration in Medicine will not rest on its laurels. Instead, the Board has identified barriers to continued improvement and has developed strategies to respond to these challenges. In 2002, the Board will build upon its successes of the past year.

Among the specific goals for 2002 are the following projects and initiatives:

Finalize Revisions to Regulations

The Board will issue draft regulations for public comment and implement revisions to existing regulations during 2002. Among the important issues to be addressed by this process are minimum requirements for licensure and clarification of many aspects of the disciplinary process.

The regulations review process has also identified gaps and inconsistencies in some areas of the Board's underlying statutory authority. For example, the Board does not have clearly-defined authority to take disciplinary action in most cases of alleged substandard care unless there are three or more incidents of substandard care. The Board also lacks clear subpoena authority to obtain medical records as part of an investigation. To rectify these and other issues, the Board will submit all requests for amendments to current statutes to the appropriate legislative bodies for action.

The process of addressing the need to amend the statutes and regulations related to the Board of Registration in Medicine presents a unique opportunity to foster meaningful conversation among the Board, the Legislature, and other interested parties.

Implement Needed Changes to the Board's Licensing Fee & Funding Structure

There are two major problems with the structure of the Board's licensing process. First, the fees should be set and appropriated in a manner that allows the Board of Registration in Medicine to meet its public protection mission. Massachusetts should fund the operation of the Board through the complete retention of the fees collected from its licensees. There is precedent in state government for such "self-funding" by agencies. Such a change in structure would bring the Massachusetts Board into alignment with most medical boards in the United States.

There are important policy reasons to allow the Board to self-fund, as well. Historically, the Massachusetts medical board has operated with approximately half the funding of similar-sized boards across the country. Clearly, the Board cannot be successful without a secure level of appropriate funding. In light of the serious fiscal constraints facing the Commonwealth, it is not reasonable to assume that additional support can be identified through the General Fund. Under the proposed fee-retention structure, the Board could achieve appropriate funding without negatively impacting the state's General Fund.

The second problem relates to the biennial renewal of physicians. Currently, nearly all licensees renew their licenses during the same, odd-numbered calendar year. Few renewals are processed during the even-numbered calendar year. By reassigning some licensees to the even-numbered calendar year, the Board could equalize the caseload of work in its licensing division. The change would result in better service for physicians renewing their licenses and less reliance on costly temporary workers to address the "peak year" processing. Similar changes in the term of licensure for physicians in training could result in administrative cost savings for the Commonwealth's teaching hospitals. The Board looks forward to working with all interested parties to implement this beneficial change.

Through a creative response to a problem, the Board believes it can offer better customer service while reducing costs for both teaching hospitals and the agency. Realistically, such a change cannot be accomplished unless the Board's initiative to retain 100% of its licensing fees is approved. There will be some disruption in cash flow during the implementation period of the scheduling change; full retention of licensing fees would allow the Board to plan for this temporary short-fall.

Continued Focus on Technology

The Board of Registration in Medicine is a nationally-recognized leader in the use of technology to assist consumers and physicians. The Board will complete an aggressive document imaging and electronic document management project in 2002. The completion of the project will allow the Board to share more information with consumers and physicians through its website and other points of access. The Board is also fully committed to the implementation of on-line licensure for physicians. An on-line licensure system will help Massachusetts to continue to attract the best physicians from around the world. By reducing its internal administrative tasks through such a system, the Board can refocus more resources on reviewing, investigating, and verifying the credentials of applicants.

The Board also recognizes its responsibility to use technology to reduce the cost of health care whenever possible. In 2002, the Board will expand a 2001 model program designed to help hospitals and health plans maintain important information about their affiliated physicians. The Board will supply regular updates of license status, disciplinary actions, and other information to hospitals and insurers. These entities will help the Board to keep accurate and timely information on hospital affiliations, insurance affiliations, and other information of interest to the consumers who access the Board's "Physician Profiles" system each day. Through collaboration, creativity, and leadership the Board hopes to improve the quality of physician information available to both the profession and consumers.

ENFORCEMENT DIVISION REPORT

The **Enforcement Division** of the Board is mandated by statute to investigate all potential disciplinary matters involving physicians and acupuncturists licensed to practice medicine within the Commonwealth of Massachusetts. The Division strives to pursue complaints against licensees efficiently, fairly and effectively in order to ensure that the public is protected and that Board statutes, regulations and policies are followed.

Throughout 2001, the Division continued to meet its mandate of public protection through ongoing changes and goals that focused on decreasing the backlog of open cases, improving communication with consumers filing complaints against physicians, expediting the review and resolution of cases and increasing disciplinary actions. The Enforcement Staff's commitment in these areas had a major and positive impact on the successful functioning of the Enforcement Division during 2001. The case backlog has been drastically reduced, cases are reviewed and resolved more effectively and disciplinary actions are on the rise.

The Enforcement Division is supervised by the Director of Enforcement and is comprised of three units: the **Consumer Protection Unit**, the **Clinical Care Unit** and the **Disciplinary Unit**. Each Unit plays an essential and important role in the Enforcement Division's mission to ensure quality health care for consumers.



Roscoe Trimmier, Jr., Esq.
Complaint Committee
Public Member

CONSUMER PROTECTION UNIT

The **Consumer Protection Unit** (CPU) is the first line of review for consumers filing complaints with the Board. It is staffed by the Unit Manager and one administrative assistant. Staff screens the complaints, flags serious and priority cases, bringing them to the attention of the Director of Enforcement for immediate action, obtains responses from physicians and coordinates the initial review of all complaints as part of its "triage" process.

The consumer protection staff coordinates the Triage Team, the Voluntary Mediation Program, and other patient advocacy initiatives. The Unit also keeps consumers updated on the status of their complaints during the initial intake and screening phase. During 2001, the Unit docketed six hundred and seventy (670) cases.

CLINICAL CARE UNIT

The **Clinical Care Unit** (CCU) reviews complaints alleging substandard care. The Unit is staffed by the Unit Manager and two nurse reviewers, all experienced clinicians, as well as a paralegal. Staff members analyze patient records and physician responses, act as liaisons with Board experts, assist the Division's attorneys with the preparation and litigation of complex substandard care cases and prepares various analyses for the Data Repository Committee and the Licensing Committee.

DISCIPLINARY UNIT

The **Disciplinary Unit** is responsible for the investigation and litigation of all cases that may result in disciplinary action against licensed physicians and acupuncturists. The Unit is staffed by a Managing Attorney, six complaint counsels (or Board prosecutors), four investigators, a paralegal and an administrative assistant. Complaints are referred to the Unit by the Data Repository Committee, the Consumer Protection Unit, and various other sources. Staff members interview witnesses, gather evidence, work with local, state, and federal law enforcement agencies on coordinated investigations, and present cases to the Complaint Committee and the Board. The Complaint Counsels also draft pleadings, negotiate Consent Orders, identify and present cases for Summary Suspension and prepare and litigate Board cases at administrative hearings at the Division of Administrative Law Appeals (DALA).

Significant Accomplishments During 2001

INCREASED DISCIPLINARY ACTIONS AND PRIORITIZATION OF CASES

During 2001, the Board disciplined 55 physicians. This number represents a **20%** increase over 2000 and a **44%** increase over 1999.

Category	2001	2000	1999
Doctors Disciplined	55	44	38
Statements of Allegations Issued	39	40	29
Summary Suspensions	7	7	5
Voluntary Agreements Not to Practice	4	5	5

If the Board determines that disciplinary action is appropriate, the matter may be resolved through a negotiated settlement such as a Consent Order or Assurance of Discontinuance. During 2001, twenty-five (25) physicians entered into Consent Orders and five (5) signed Assurances of Discontinuance. Both actions are public and disciplinary in nature.

If a negotiated settlement is not a realistic alternative, the Board issues a Statement of Allegations and refers the matter to DALA for a full evidentiary hearing on the merits. There were nineteen (19) cases pending at DALA as of December 31, 2001. These nineteen cases are comprised of twenty-eight (28) separate complaints. Although no longer within the administrative purview of the Board, the cases remain in the Board's open case backlog until a recommended decision is received from the DALA magistrate and the Board issues a Final Decision & Order. Seventeen (17) new cases were referred to DALA during 2001.

When a doctor appears to be a serious threat to the public health, safety, or welfare, it is the responsibility of the Complaint Counsel to bring this matter to the attention of the Board to recommend that the doctor no longer practice medicine until safeguards are in place. In the most serious cases, the Complaint Counsel may recommend that the Board summarily suspend the license of a physician or attempt to seek a voluntary agreement not to practice medicine from the physician. These actions are immediate, public and disciplinary. Of

greatest importance, these actions ensure that the licensee cannot continue to practice medicine while the Board order remains in effect.

The team approach is being utilized on a more widespread basis, especially on complicated or emergency cases. Paralegals, investigators, nurse investigators and supervisors play a more integral role in the investigation and prosecution of each case. Another Complaint Counsel is assigned to “second-seat” the primary attorney on complex adjudicatory matters.

The most serious cases are given the highest priority in terms of resource allocation, investigation and prosecution. The investigative team makes these cases their top priority, acting immediately to fully and fairly investigate the allegations before making a recommendation to the Board. Cases with disciplinary potential are identified and prioritized sooner due to changes in the Triage process.

Enforcement Division Cases Presented to Complaint Committee

Source of Case	# of Cases Presented
Disciplinary Unit	203
Appearances	88
Non-Appearances	115
Clinical Care Unit	171
Remedial Conferences	41
Non-Appearances	130
Consumer Protection Unit	492
TOTAL	869

The Executive Director and the Director of Enforcement have conducted statewide proactive outreach with law enforcement agencies to familiarize these organizations with the mission of the Board and encourage prompt reporting of criminal misconduct by physicians. These efforts are resulting in cooperative and collaborative investigative efforts by law enforcement agencies and the Board.

REDUCTION OF CASE BACKLOG AND EXPEDITED CASE REVIEW, INVESTIGATION AND RESOLUTION

The Enforcement Division made tremendous efforts to eliminate its backlog of cases in all units within the Division during 2000 and continued to make substantial progress during 2001. These efforts have resulted in the significant reduction of all backlog matters as well as the expedited review, investigation and resolution of incoming matters.

The intake, review and tracking of complaints have all improved. Licensees are immediately requested to respond to complaints so that all relevant information concerning a complaint can be reviewed by the Triage Team in a timely manner. This has resulted in the more expedient review and resolution of cases that do not merit formal disciplinary actions by the Board. During 2001, 90% of these cases were resolved within 60 days of receipt, compared to 180 days during 2000 and 365 days or longer prior to 2000.

COMPLAINTS	2001	2000	1999
Docketed	670	626	584
Closed	846*	773*	365
Pending as of 12/31	361	537	698

*14 complaints resolved in 2001 were closed in Board administrative records in 2002. The actions are reported in 2001.

Investigators, Nurse Investigators and Complaint Counsels have regular case review meetings with their supervisors. This process assists in the identification of priority cases, problem areas and the need for additional resources as well as the implementation of appropriate timelines on a case-by-case basis.

The Clinical Care Unit received 80 new complaints alleging substandard care this year. Approximately 35% of these cases are on the disciplinary track and are joint investigations with Complaint Counsels. The Board continued to utilize the services of the Center for Health Care Dispute Resolution (CHDR) and outsourced the expert review of many of these cases. CHDR is a national company based in New York that employs a wide range of

medical and legal professionals who conduct case reviews for a variety of public and private health care organizations. Outsourcing of these cases has significantly reduced the backlog of open substandard care cases, resulting in the prompt review and evaluation of substandard care matters and allowing the CCU staff to work on potential disciplinary matters with the Disciplinary Unit.

Status	NUMBER OF SUBSTANDARD CARE CASES	
	2001	2000
Opened	111	177
Closed	168	322
Pending	99	156

The Complaint Committee and the Enforcement Division have worked expediently and efficiently to review all cases in a timely manner. Once an investigation is completed, it is the responsibility of staff members to present the case to the Complaint Committee, a subcommittee of the Board consisting of at least two members. The Complaint Committee makes a determination as to whether disciplinary action should be taken against physicians and makes recommendations accordingly to the full Board. The Complaint Committee also reviews and resolves all matters without disciplinary potential, often with informal Board action such as letters and remedial conferences.

NON-DISCIPLINARY ACTIONS	2001	2000
Closed with a Letter of Acknowledgement	0	1
Closed with a Letter of Education	0	1
Closed with a / Letter of Information	14	12
Closed with a Letter of Advice	103	140
Closed with a Letter of Concern	71	58
Closed with a Letter of Warning	27	19
Dismissed	500	476
TOTAL	715	707

SEXUAL MISCONDUCT INVESTIGATIONS DURING 2001

Special safeguards implemented during 2000 remain in place for sexual misconduct cases. All complaints that allege sexual misconduct, including inappropriate touching or remarks, are immediately docketed and given to the Director of Enforcement for assignment to an Investigator and Complaint Counsel. All such allegations are prioritized and fully investigated. The alleged victim is interviewed in person whenever possible, as is the physician. Serious cases of sexual misconduct are always evaluated immediately in order to determine if a summary suspension of the physician's license would be appropriate.

SEXUAL MISCONDUCT CASES

	2001	2000
Docketed	19 doctors, 22 complaints	17 doctors, 17 complaints
Resolved	27 doctors, 58 complaints	10 doctors, 10 complaints
Pending 12/31	22 doctors, 29 complaints	28 doctors, 43 complaints

At the end of 2000, twenty-two of the forty-three pending complaints alleging sexual misconduct were before the Division of Administrative Law Appeals (DALA). At the end of 2001, ten of the twenty-nine open complaints alleging sexual misconduct were before DALA.

IMPROVED COMMUNICATIONS WITH COMPLAINANTS

The Consumer Protection Unit now sends the physician's response to complainants in every case. In the past, this was only done at the specific request of the complainant. Complainants are also sent letters informing them of the resolution of their complaints with specific details on the Board action taken.

PROFESSIONAL DEVELOPMENT

Staff members are encouraged to take practice-related courses to enhance their skills and keep abreast of recent legal, medical and investigative techniques and developments. During the past year, staff members attended a number of such programs including the Walter Reid course on Interviewing and Interrogation, the Annual New England Drug Diversion Conference, the Federation of State Medical Boards Annual Meeting, information sessions



*Dr. Regis De Silva
Complaint Committee
Physician Member*

on the Colorado Physicians Evaluation Program, Ethics training, courses on clinical care issues, continuing legal education seminars, and other such programs.

WORKING GROUPS

In an effort to meet the Agency goals set by the Executive Director, the Division has convened working groups in the areas of Regulations Revision, Standardization of Forms, Pleadings and Correspondence, Investigative Reports, Timelines, Scanning and MIS Issues.

Enforcement Division staff members have also contributed to the revision and development of new Board Policies such as the *Prescribing Practices Policy and Guidelines* and the *Office-Based Surgery Guidelines* and participated in the “*Managing for Results Initiative*” sponsored by the Governor.

PUBLIC INFORMATION DIVISION REPORT

From January through December 2001, the Board of Registration in Medicine provided important health care information to thousands of consumers, physicians, and health care organizations.

The Board's website enhancements provided better service to 3,705,668 visitors during this period. There were 2,573,439 visits during the comparable period in 2000. This represents a 44% increase since CY 2000. Some of this increased interest is attributable to the comprehensive education and outreach efforts that have made more citizens aware of the Board's work. The following is a sample of e-mails received at BORIM from consumers:

- *“Just a note to let you know how much I appreciated the written and verbal information about your system. You have done a lot with little and I am sure are very proud of your accomplishments.”*
- *“I found this web site to be very useful. It help(ed) me feel more comfortable about the doctor I chose to perform my operation.”*
- *“Thank you so much for your quick response...That is a wonderful profile...I am just a nervous Mom, that's all... You have made me feel much better... Thanks again.”*



*Dorothy Keville, M.Ed
Vice-Chair*

The Board also operates a Call Center for consumers who do not have Internet access or who may need additional services. In 2000, the Call Center handled almost 15,000 calls from consumers; in 2001 that number more than doubled. In 2001, the Call Center staff received nearly 36,000 calls.

The Call Center staff also performs all data entry relating to the updates in the Physician Profiles system. In 2000, there were 8,286 updates – in 2001, there were more than 16,600 updates. Physicians are required to review and update their Physician Profiles at the time of their renewals.

In gauging the higher number of calls and page views to date, it appears that the increased attention is a direct result of physicians and consumers taking advantage of a much broader scope of information afforded them. Physicians can now download license application kits for full and/or limited licenses and check the website for approval of their licenses. The Board has included educational bulletins and linkage to other sites as a supplement to the website. Consumers and physicians may also access information on board policies, prescribing guidelines, and log on to banner headlines for information on various topics. Information targeting consumers assists individuals in learning how to file a complaint, downloading the complaint form, and locating answers to frequently asked questions before filing a complaint. The Board also provides a list of disciplinary actions taken against a physician.

As part of its ongoing commitment to increase communications with health care professionals and patients, the Board of Registration in Medicine has also established a Speakers Bureau.

Physician Profiles Output Summary

Year	Calls Received By Call Center	Profiles Mailed/Faxed By Call Center	Physician Profiles Web Site Hits	Total # Profiles (Web Hits+ Call Center Requests Processed)
1996	17,127	25,771	0	25,771
1997	43,698	57,619	529,250	586,869
1998	30,085	32,316	1,642,500	1,674,816
1999	22,642	22,779	2,555,000	2,577,779
2000	20,400	15,647	2,573,439	2,589,086
2001	35,876	32,490	3,705,668	3,738,158

LICENSING DIVISION REPORT

The Licensing Division is the point of entry for physicians applying for a license to practice medicine in the Commonwealth and has an important role in protecting the public as the "gatekeepers" of medical licensure. This is accomplished by conducting an in-depth investigation of a physician's credentials before forwarding a license application to the Board for issuance of a license to practice medicine.

There are three types of licenses: full, limited, and temporary. A full license allows a physician to practice medicine independently. A limited license is issued to a physician who is participating in an approved residency or fellowship program in a teaching hospital. The Board issues temporary licenses to eminent physicians who previously held a faculty appointment in another country or territory and who are granted a faculty appointment at a medical school in the Commonwealth. Temporary licenses are also granted to physicians for providing *locum tenens* services or for participating in a continuing medical education program in the Commonwealth. Full licenses are renewed every two years on the physician's birth date and limited licenses are renewed at the end of each academic year. Temporary licenses are issued for eight months, and may be re-issued at the discretion of the Board.



Dr. Martin Crane
Licensing Committee Chair

Before an application for a full or limited license is forwarded to the Board for approval, the Licensing Division conducts an extensive investigation of the applicant's credentials and collects documentation from primary sources; these documents include verification of medical school training, licensing examination scores, postgraduate training information, evidence of professional experience and profiles from the Federation of State Medical Boards, National Practitioner Databank and the American Medical Association. In addition to processing license applications, the Licensing Division also provides information and

verification of the status of a physician’s license for state licensing boards, credentialing for privileges at healthcare facilities and consumers.

Licensing Division Statistics

Licenses Approved by the Board	2001 *	2000	1999 *
Initial Full Licenses	1,705	1,642	1,670
*Full Renewals	20,960	6,331	21,141
Lapsed Licenses	136	137	175
Initial Fulls In process 12/31/2001	437	401	321
Initial Limited Licenses	1,419	1,384	1,509
Limited Renewals	2,663	2,591	3,246
Limited Applications in Process	18	31	36
Temporary (initial) Licenses	9	6	10
Temporary Renewals	5	7	7
Voluntary Non-renewals	494	320	527
Revoked by Operation of Law	784	474	803
Deceased	93	7	123

* The majority of full licenses are renewed in odd-numbered years, 1999, 2001, etc.

Licensing Committee Activity Report

The Licensing Committee is a sub-committee of the Board comprised of two Board members. The primary role of the Licensing Committee is to ensure that every physician applying for licensure in the Commonwealth is qualified and in compliance with the Board’s licensing regulations.

As a subcommittee of the Board, the Licensing Committee is responsible for reviewing all license applications with legal, medical, malpractice or competency issues. Physicians applying for an initial limited license or renewing a limited license who had competency issues in a training program or substandard clinical performance in a training program are reviewed by the Licensing Committee. The Licensing Committee customarily interviews the physician and the program chairperson in such cases before making a recommendation on

issuance of a limited license to the full Board. The Committee may recommend approval or denial of a limited license, depending on whether the Committee is satisfied that the physician will be closely supervised in the training program. A recommendation for issuance of the limited license in such cases is usually contingent on a performance monitoring agreement with the physician and the program chairperson to provide regular monthly, bi-monthly or quarterly performance monitoring reports to the Board. Renewal of the limited license is contingent on satisfactory performance monitoring reports over the course of the entire academic year. Performance monitoring agreements are customarily required for the duration of the training program. However, the performance monitoring may be discontinued if the physician has a track record of satisfactory clinical performance. If the Licensing Committee determines that there is a pattern of substandard clinical performance anytime during the academic year, the Committee may recommend additional action.

Licensing Committee Activity Report

Cases Reviewed by Licensing Committee	2001	2000	1999
Malpractice	23	29	19
Competency Issues	78	93	51
Legal Issues	39	24	28
Medical Issues	28	28	26
CME Waivers	12	5	3
Miscellaneous Issues	134	88	141
Total Cases Reviewed	314	267	268

Issuance of a limited license based on a performance monitoring agreement was established in 1997. Since that time, there has been a noticeable decrease in the number of physicians with competency issues applying for limited licenses. The number of limited licenses issued based on performance monitoring agreements dropped from twenty in 1999 to six in 2001. This may be attributed to the vigilance of training programs that are more selective in screening physicians to fill the open training positions in the Commonwealth.

2001 Licensing Division Accomplishments

Revisions Of Board’s Regulations 243 CMR 2.00

The Licensing Division drafted revisions of the Board’s Licensing regulations, 243 CMR 2.00, to streamline the licensing process. One highlight of the revisions is the extending of the expiration period for an initial limited license from one to three years. Extending the expiration date of limited licenses will significantly reduce the workload of the Licensing Division and training programs. Only limited licensees with any legal, medical, malpractice or competency issues will be required to renew their limited license at the end of the academic year.

License Survey Results

The Licensing Division conducted a random survey of physicians who were issued an initial full license. The objective of the survey was to identify problems in the licensing process and opportunities for improved services for physicians. Responses were tabulated using the Likert Scale from 1–5, with 1 rated as “poor”, 2–3 rated as “average” and 4-5 in the “excellent” range. The overall average score was 4.03, which is in the high average to excellent range.

Survey Questions (based on 80 responses)	Responses
Was the Licensing staff courteous?	4.15
Was the staff knowledgeable?	3.93
Did the staff provide you with the correct information?	4.00
Did the staff direct you to the appropriate person to answer your questions?	4.06
Overall average score	4.03

Scanning License Applications

In 2001, the Legislature approved funding for the purchase of scanning equipment that enabled the Board to scan over 17,000 full license renewal applications for 2001. In addition to providing security for licensing files, Board staff will have immediate electronic access to retrieve information in a physician's licensing file that is vital to the Board's Enforcement and Legal investigation process.

Initial Full License Application Process Revised

The full license application instructions were redesigned to permit an applicant for an initial full license to collect specific documents and submit them in sealed envelopes, in one packet, with the full license application. This will significantly reduce the number of documents that are currently sent to the Board piecemeal, resulting in a reduction in staff time required to sort, identify and file documents. In addition, initial full license applicants will have more control over the application process and significantly reduce the processing time.

Verification of medical school training, license examination scores, ECFMG (Education Commission for Foreign Medical Graduates) status reports, legal reports, malpractice information and medical issues will be sent directly to the Board from the primary source.

Limited License Workshops

Four Limited License Workshops were presented for training program personnel who are responsible for staffing the Commonwealth's training programs. Annual Limited License Workshops are crucial in providing information on changes in the limited license process, new forms and new procedures. The workshops also provide an opportunity for the exchange of information between Board staff and the training program coordinators to identify opportunities for improving the limited license process.

DIVISION OF LAW AND POLICY REPORT

OFFICE OF THE GENERAL COUNSEL

During 2001, the Division of Law and Policy worked on a large-scale review of the regulations and underlying statutes that provide the framework for the operation of the Board of Registration in Medicine. The agency plans to have proposed revisions available for public comment during Spring 2002. Along with this important project, the staff members continue to offer legal guidance to the Board on issues of licensure, disciplinary actions, and other key functions. The Office of the General Counsel also performs legal and policy research for the Board and the Executive Director, and responds to legal inquiries from physicians, attorneys, and the public.

In addition to the **Office of the General Counsel**, the Division of Law and Policy includes the **Data Repository Unit**, the **Physician Health and Compliance Unit**, the **Patient Care Assessment Unit** and the **Committee on Acupuncture**. Each unit plays an important role in meeting the agency's mission of public protection through the regulation of physicians and acupuncturists.

The Data Repository Unit collects, analyzes and recommends action on mandated reports of malpractice payments, hospital disciplinary actions, and other adverse information about physicians. The Physician Health and Compliance (PHC) Unit assists physicians who are successfully battling substance abuse problems or physical or mental impairments. In conjunction with outside resources, the PHC staff recommend monitoring agreements and report on a physician's readiness to resume practice. The PHC staff also monitor physician compliance with Board-ordered probation agreements. The Patient Care Assessment (PCA) Unit is a nationally recognized program that assists hospitals and other facilities in their efforts to promote patient safety and enhance health care quality. The Committee on Acupuncture regulates all aspects of the practice of acupuncture in Massachusetts, including setting standards for practice and licensure.

DATA REPOSITORY UNIT

The Data Repository counsel receives and processes statutory reports concerning physicians licensed in the Commonwealth. Data Repository staff work with the Board's Data Repository Committee to review mandated reports to determine which should be referred to the Board's Enforcement Division, and to develop policies relating to statutory reporting.

The Data Repository Unit also disseminates information regarding Board disciplinary actions to national data collection systems and via the Board's website, and ensures that appropriate statutory report information is accurately posted on Physician Profiles.

In 2001, the Data Repository received and processed 5,838 statutory reports. One hundred and sixty-six (166) reports were forwarded directly to the Enforcement Division for further investigation. Statutory reports related to potential impairment issues were forwarded directly to the Physician Health and Compliance Unit.

Statutorily Mandated Reports Received in 2001

Report	# Received in 2001	# Received in 2000
Total Medical Malpractice Reports	2,442	1,525
<i>Cases reported by physicians on license renewals*</i>	<i>740</i>	
<i>New cases reported by Courts</i>	<i>605</i>	
<i>Payments reported by malpractice insurers</i>	<i>350</i>	
<i>Cases closed without payments</i>	<i>747</i>	
Health Care Facility Discipline Reports	114	124
5D & 5F Reports <i>(5D & 5F are mandatory Peer Reports)</i>	35	46

* *Physicians renew bi-annually. 2001 was a renewal year.*

PHYSICIAN HEALTH AND COMPLIANCE UNIT

The Physician Health and Compliance Unit (PHC) was established in 1993 to address the issue of physicians with chemical dependency problems. Since that time, the PHC Unit's role has expanded to include a review of physicians with mental illness, physical illness and behavioral problems. Since an estimated one third of the Board's disciplinary cases involve physicians dealing with impairment issues, procedures have been established that reduce the risk of patient harm. Toward this end, the PHC Unit reviews physician self-reports and statutory reports of mental or physical conditions that may impact the physician's ability to practice medicine.

Overview of Physician Health & Compliance Activities

CATEGORY	# OF PHYSICIANS 2001	# OF PHYSICIANS 2000
Monitoring/Probation Agreements	106	108
Self-Report Evaluations License Renewal Applications	217	41
New License Applications	29	23
Noncompliance Reports from PHS/UMMC	53	30

The Board has established both disciplinary and non-disciplinary procedures, which in appropriate cases may permit a physician who is participating in on-going recovery to return to the practice of medicine under a structured monitoring agreement. Such an agreement will contain sufficient safeguards, such as clinical and sobriety monitoring to protect the public. The PHC Unit assists with the negotiation of agreements, and addresses probationary issues such as modification, termination or violation of probation.

Types of Physician Monitoring Programs in 2001

Type of Agreement	TOTAL	<i>Mental Health</i>	<i>Chemical Dependency</i>	<i>Dual Diagnosis</i>	<i>Clinical Competency</i>
Probation Agreement	53	7	30	10	6
Letter of Agreement	23	12	6	5	0
Consent Order (With/ CME Requirement)	8	0	0	0	8
Suspension	16	4	6	3	3
Miscellaneous Monitoring	6	3	1	0	2
TOTAL	106	26	43	18	19

In addition, the PHC Unit monitors compliance with the terms of non-disciplinary and disciplinary agreements that can include provisions for treatment programs, as well as requirements for continuing education programs or community outreach programs. The PHC Unit also advises the Board on policy issues and works with agency staff on questions involving impairment and probationary matters.

Reports of Non-Compliance with Physician Health Monitoring Agreements

Category	2001	2000
Total Number of Physicians	53	30
Non-Compliance Reports	7	11
Positive Substance Screens	29	14
Termination of Monitoring	4	5
Missed Test	8	0
Relapse	5	0
TOTAL REPORTS	53	30

In the past year, the PHC staff has worked with the Board to address the issue of disruptive physician behavior. Toward that end, the PHC Unit assisted in the development of the

Disruptive Physician Behavior Policy. The Unit has also worked closely with the Licensing Unit to review those license applications or renewal applications that indicate potential problems with disruptive physician behavior.

At the recommendation of the PHC Unit, four physicians identified with disruptive behavior were required to enter into PHS Behavioral Health Monitoring Contracts within this past year. The results of this monitoring have been mixed. Three of these four physicians were non-compliant with their PHS contracts and are no longer employed by their hospitals. The remaining physician is in compliance with his contract. There is one other physician being monitored by PHS for disruptive behavior, and he also remains in compliance with his agreement. This high rate of non-compliance indicates how difficult it can be to treat physicians with disruptive behavior. A significant barrier to compliance seems to be the lack of insight by these physicians into their behavioral problems, and a resultant lack of motivation to effect a behavioral change. Although these physicians are often not “successful” in their contracts, they are now more readily identified and held accountable for behavior that could negatively affect patient care.

During 2001, PHC staff members were also able to assist the Board with its education and outreach programs. Early last year, staff joined a panel discussion on the topic of physician impairment led by Chairman Peter Madras and Dr. Luis Sanchez at the Harvard Medical School. Staff members have also provided basic information about impairment issues and mandatory reporting to the ProMutual Group for its physician newsletter. In December 2001, PHC staff and Board Member Dr. Mary Anna Sullivan were given an opportunity to participate in the Massachusetts Medical Society’s *“Caring for the Caregiver”* Conference.

COMMITTEE ON ACUPUNCTURE

The Committee on Acupuncture works in cooperation with the Board of Registration in Medicine to regulate the practice of acupuncture. The Committee on Acupuncture functions include setting standards for acupuncture licensure and practice through 243 CMR 4.00 and 243 CMR 5.00 (the acupuncture regulations), approving acupuncture schools and training programs, reviewing applications for licensure, setting standards for safe practice, disciplining acupuncturists who engage in misconduct and interpretation of the regulations and/or discussion on any relevant issues. The Committee on Acupuncture meetings, which are open to the public, are held every three months at the Board of Registration in Medicine. The Acupuncture Unit aids the Committee in its work; in addition to providing assistance to the Committee members, the Unit handles issues relating to acupuncture raised by the public and licensees, and works with the Legal and Disciplinary Units within the Board on matters involving acupuncture.

2001 Committee on Acupuncture Statistics

Category	Number
Total Number of Licensees	687
Initial full license applications processed	75
Renewal of full license applications processed	300
Complaints opened against licensees	8

PATIENT CARE ASSESSMENT UNIT

The Board's Patient Care Assessment (PCA) Committee is responsible for implementing regulations that require most health care facilities in the state to establish and maintain institutional systems of quality assurance, risk management, peer review and credentialing, known collectively as PCA programs. Over 800 health care facilities in the state are affected by the PCA requirements, including hospitals, clinics, HMOs, and nursing homes. Currently, the PCA Committee consists of five physicians, two of whom are members of the full Board and three of whom serve as consultants. Medical specialties represented by the Committee include internal medicine, surgery, nephrology, vascular surgery, and psychiatry.

The Legislature placed responsibility for institutional systems of quality assurance at the Board in 1986. It is a function unique among the nation's medical licensing boards; its presence at the Board of Medicine recognizes the principle that without physician leadership and participation, institutional quality assurance programs cannot and will not be successful. An approved PCA program is a condition of hospital licensure; moreover, no licensed physician in Massachusetts may work at a health care facility that does not have an approved PCA program. The Legislature also mandated, by statute, that information submitted to the Board as required by the PCA regulations is confidential and not subject to subpoena, discovery or introduction into evidence.

The Board ensures that health care facilities have PCA programs in place by reviewing and approving their PCA plans. The PCA plan must describe how the facility carries out the requirements found in the PCA regulations. To monitor the ongoing operations of a facility's PCA program, the Board requires three types of reports, two of which are, in essence, quality assurance "progress" reports and must be submitted to the Board on a routine basis.

The third type of report, called the "major incident" report, is the principal method by which the Board ensures that institutional quality assurance systems are functioning effectively and appropriately. Major incidents are serious, unexpected patient outcomes. They are defined as maternal deaths related to delivery; deaths in the course of, or resulting from, elective ambulatory procedures; invasive diagnostic procedures or surgical interventions performed

on the wrong organ, extremity or body part; and deaths or major or permanent impairments of bodily functions that are not ordinarily expected as a result of the patient's condition on presentation. Certain major incidents involve medical errors that could have been prevented, while others represent unexpected, unpreventable patient outcomes.

When reporting major incidents to the Board, the facility must provide a thorough medical description of the event, the results of its internal investigation, and, if applicable, all corrective measures taken to prevent a recurrence. Major incident reports are reviewed and analyzed by the members of the PCA



Dr. Mary Anna Sullivan
PCA Committee Chair

Committee and by staff. Following their reviews and analyses, the Committee and staff must be reassured that each reporting facility responded thoroughly and appropriately to all serious, unexpected outcomes. Moreover, if the event was the result of an error or errors (involving either individual practitioners or systemic processes), the Board must be confident that the facility has taken all necessary corrective action to prevent a recurrence.

In terms of volume, the Board has received 294 major incident reports about events that occurred during the first nine months of 2001 (facilities have three months following an incident to submit a report). Table 1 provides summary data on the number of major incident reports received over the past five years.

By their reviews of major incident reports, the PCA Committee and staff are in a unique position to identify quality assurance problems in health care that require broad, state-wide attention. When such problems are identified, advisories, known as PCA Updates, are distributed to all hospitals in the state, alerting facilities about the issue, describing the problem and, sometimes with the aid of advice from experts, offering possible solutions. In 2001, the PCA Committee and staff distributed two such advisories: “Serious Neurologic Complications in Patients Receiving Neuraxial Anesthesia/Analgesia When Taking Medications that Alter Clotting Mechanisms” (August, 2001) and “Unexpected Deaths of

Patients Receiving Patient-Controlled Analgesia” (November, 2001). A listing of all PCA Updates can be found in Table 2.

Table 1. Major Incident Reports: 1998 through 2001

Year	Number of Reports	Change from Prior Year
1998	232	+55%
1999	426	+84%
2000	504	+18%
2001	294*	N/A

Note: Data are based on date of incident and exclude fetal death reports.

**Statistics for 2001 are incomplete due to reporting deadlines. Fourth quarter reports for CY 2001 are due by 4/02.*

As part of its review of major incidents, the PCA Committee and staff work closely with the reporting facility. If the PCA Committee is not satisfied with the facility’s response to an event, it often recommends that the facility take a number of actions. These recommendations have included changes in internal policies or procedures, additional staff training or monitoring, an entire re-review of an incident, cessation of specific surgical or diagnostic procedures, and the hiring of additional staff, such as a hospitalist or an outside QA consultant.

If the PCA Committee remains dissatisfied, it calls for a meeting with the facility’s chair of the board of trustees, the chief executive officer (CEO), the medical director, the director of quality assurance and the chiefs of the major clinical departments. The purpose of the meeting is to educate those present about the Board’s PCA function, convey the Committee’s concerns about the operations of the facility’s PCA program, and recommend changes and improvements. The meetings require a great deal of preparation. Feedback from facility representatives who have met with the Committee indicates that while the experience was

somewhat stressful, in the end, it was educational and helpful. In 2001, the PCA Committee and staff held four such meetings.

Table 2. List of PCA Updates

- Oncology Drug Administration (2/93)
- Intravenous Potassium Chloride (1/97)
- Pediatric Neurosurgical Procedures (1/98)
- Adrenocortical Insufficiency Secondary to Previous Treatment with Adrenal Corticosteroids (10/98)
- Laparoscopic Injuries (5/99)
- Radiology Coverage in Emergency Rooms (6/00)
- Unread Electrocardiograms (8/00)

Released in 2001 – Full copies attached

- Serious Neurologic Complications in Patients Receiving Neuraxial Anesthesia /Analgesia When Taking Medications that Alter Clotting Mechanisms (8/01)
- Unexpected Deaths of Patients Receiving Patient-Controlled Analgesia (11/01)

The PCA Update on neurologic complications distributed in August, 2001 was in response to several major incident reports of patients who were receiving anesthesia or analgesia, administered through spinal or epidural catheters. At the same time, these patients were receiving medications, such as anticoagulants, that altered their clotting mechanisms. In the reported cases, patients exhibited signs and symptoms of hemorrhage (for example, lower extremity numbness or paraplegia) after the catheters had been removed. The Update urged all health care providers, particularly anesthesia personnel, to be vigilant about monitoring a patient's anticoagulation status in the presence of spinal or epidural catheters.

Another trend identified in 2001 was the deaths of patients receiving intravenous analgesia (such as morphine), the administration of which the patients controlled themselves, through an infusion pump. The analgesia was often used to control post-operative pain or to manage chronic or acute pain. Nearly all of the patients involved in the reported major incidents had conditions, such as asthma, sleep apnea, or obesity, which increased their risks for complications. The causes of death were never conclusively determined, although over-sedation coupled with respiratory compromise were often seen as contributing factors. The PCA Update described a number of precautions that hospitals and health care providers should take to lessen the risks for patients using this type of analgesia administration. They included adequate assessment of patients to identify potential risks for respiratory depression, a double-check system for the dose of analgesia and the infusion pump setting, and the immediate availability of oxygen and Narcan (a narcotic reversal agent) for all patients receiving patient-controlled analgesia.

During CY 2001, the PCA Committee and staff embarked on an effort, the goal of which was to evaluate the work of the Unit, including a comprehensive analysis of the major incident reports (over 2,000) received over the years. The PCA Unit, working with the Boston University School of Public Health, applied to the Agency for Healthcare Research and Quality (AHRQ) for a grant to evaluate the major incident reporting system and to expand beyond the current focus on hospitals. Preparing the grant application was time consuming, and although the Unit was ultimately not successful in receiving an award, there is hope for future success in acquiring foundation support.

ATTACHMENTS

PCA UPDATE

Serious Neurologic Complications in Patients Receiving Neuraxial Anesthesia/Analgesia When Taking Medications That Alter Clotting Mechanisms

August, 2001

The Board's Patient Care Assessment (PCA) Committee has recently received reports on several adverse incidents involving serious neurologic complications in patients who had neuraxial (spinal/epidural) anesthesia or analgesia while receiving medications that alter clotting mechanisms. The medications included antiplatelet, fibrinolytic, and thrombolytic agents, and anticoagulants. In all cases, the patients exhibited symptoms of a neuraxial bleed after the spinal or epidural catheters had been removed, although bleeding can also occur following catheter insertion. While the patients' sensory and motor symptoms frequently suggested the development of progressively worsening bleeds or hematomas, in some instances the involved caregivers failed to diagnose and treat these conditions because symptoms were masked by local anesthetics. Of particular concern to the Committee members was the lack of a systemic approach to this problem by most facilities, despite the development of national guidelines.

The Committee recognizes, however, that there are no firm guidelines for all clinical settings in which the potential for neuraxial bleeding exists. Physicians must rely on sound clinical judgment and at times may even accept certain levels of bleeding risk during specific surgeries or emergent conditions. Nonetheless, the Committee urges all anesthesia personnel to be vigilant and to develop institutional guidelines for the optimum reduction and management of this risk. Physicians also should inform patients who have been taking drugs that alter clotting mechanisms about the potential for neuraxial bleeding during or after spinal or epidural anesthesia, with possible long term or permanent neurologic injury.

The Committee believes these adverse outcomes might have been prevented if appropriate perioperative assessment and monitoring of the patients' anticoagulation status had been routinely performed. Frequent monitoring is essential if prevention or timely detection and treatment of this common complication are to occur.

Members of the PCA Committee

Mary Anna Sullivan, M.D., PCA Committee Chair

Arnold S. Relman, M.D., Consultant

Peter N. Madras, M.D., Board Chair

Hart Achenbach, M.D., Consultant

Norman Levinsky, M.D., Consultant

PCA UPDATE

UNEXPECTED DEATHS OF PATIENTS RECEIVING PATIENT-CONTROLLED ANALGESIA

November, 2001

Over the past several years, the Board's Patient Care Assessment (PCA) Committee has reviewed multiple reports of unexpected deaths of patients who were receiving patient-controlled analgesia. In some of the cases, analgesia was being used for post-operative pain management, while others involved patients being treated for management of other causes of chronic or acute pain. Most of the events occurred within the first ten hours of analgesia administration and many occurred during the late evening or night. The majority of the incidents involved women. Nearly all of the patients had medical conditions or physical traits, such as obesity, asthma, sleep apnea, or nasopharyngeal swelling, which potentially increased their risks for respiratory complications. The cause of death was never conclusively determined in any of these cases. However, over-sedation, in some instances coupled with respiratory compromise, was considered to be a causal or contributing factor in some of the deaths.

In two incidents, questions were raised about whether potentially additive effects of intraoperative or supplemental medications, such as opioids, benzodiazepines, sedatives, hypnotics or antihistamines were adequately considered when the patient-controlled analgesia was ordered. Further, because many of the incidents occurred during the late evening or night, PCA Committee members questioned whether enough attention was paid to nighttime changes in patients' metabolic needs and nighttime medications when the analgesia was prescribed.

In none of the incidents described above, did the hospitals conclusively determine that the analgesia pump malfunctioned or that the patient received doses of narcotic in excess of what was ordered. However, this is an issue that should be carefully considered when investigating any incident involving a patient who develops respiratory compromise while receiving this method of analgesia. We assume that all hospitals have procedures for maintaining infusion pumps and that they provide ongoing training and education on the programming and operation of every model of infusion pump used for this purpose.

Corrective actions by the hospitals in response to many of these events included efforts to improve risk assessment of patients prior to initiating patient-controlled analgesia, and more frequent assessment and monitoring of all patients receiving this treatment, particularly those with potential risk for respiratory compromise. Hospitals also reviewed and improved their order forms for patient-controlled analgesia.

We bring these incidents to your attention to remind you of the risks associated with this form of analgesia, which is now widely used in hospitals and considered to be a relatively safe and effective method for pain management. Please review your policies, procedures, and standardized order forms to determine whether they provide for the following:

- adequate assessment by the prescribing physician of any potential risks for respiratory depression or compromise, and consideration of that risk when determining the loading and maintenance dosage for patient-controlled analgesia;
- consideration of intraoperative medications and other medications that the patient received or is receiving prior to calculating the loading or maintenance dosage for patient-controlled analgesia, including any opioids, benzodiazepines, sedatives, hypnotics or antihistamines;
- consideration of the patient's nighttime needs and nighttime medications when adjusting the analgesia, with special emphasis on continuous infusion rates;
- a requirement that the order form for patient-controlled analgesia not be filled by pharmacy unless all sections are completed;
- a system for double-checking the drug being used for analgesia, the pump setting, and the dosage;
- appropriate levels of assessment, monitoring, and documentation of vital signs, oxygen saturations, sedation levels, and degree of pain, particularly immediately following initiation of patient-controlled analgesia and during nighttime hours, including the use of apnea alarms on high risk patients;
- the immediate availability of oxygen for all patients receiving patient-controlled analgesia;
- the immediate availability of Narcan for emergency use in the event of potential over-sedation;
- if an adverse event occurs, procedures for determining whether the pump was functioning properly, and whether the concentration of the drug and rate of administration were as ordered.

Finally, the ability to recognize signs and symptoms of over-sedation and to respond rapidly is crucial to those caring for patients receiving this form of analgesic treatment, as is the ability to distinguish over-dosage from other possible causes of the adverse event, such as pulmonary, neurologic, or cardiovascular complications. We recommend that ongoing education be provided to medical and nursing staff about patient-controlled analgesia, including: associated risks; policies and procedures for administration; and recognition and treatment of signs and symptoms of complications.

Members of the PCA Committee

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