United States General Accounting Office

GAO

Report to the Honorable
William S. Cohen and the Honorable
George J. Mitchell, U.S. Senate

October 1993

MEDICAL MALPRACTICE

Maine's Use of Practice Guidelines to Reduce Costs

GAO/HRD-94-8

GAO

United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-254159

October 25, 1993

The Honorable William S. Cohen
United States Senate

The Honorable George J. Mitchell
United States Senate

Medical malpractice insurance costs added about $7 billion to the nation's health care bill in 1990. Defensive medicine—diagnostic tests, consultations, and treatment procedures performed principally to protect physicians if a malpractice claim is filed—further adds to the total health care bill. According to the latest American Medical Association estimate, defensive medicine cost $15 billion in 1989.

To recover damages in court, an injured patient's attorney must show that his or her client's physician was negligent. That is, the attorney must show that the physician breached a duty to exercise reasonable care in providing treatment and that this breach of duty caused an injury resulting in damages. The scope of the physician's duty to the patient is known as the standard of care. Thus, in a medical malpractice trial, the physician's conduct is evaluated in terms of standards of care.

The customary standard of care is established on a case-by-case basis through the testimony of expert witnesses. Thus, physicians do not know at the outset of patient encounters the exact legal standard of care to which they will be held accountable if a patient subsequently alleges that an injury resulted from the physician's negligence. This uncertainty is compelling physicians to perform the unnecessary diagnostic tests and treatment procedures that are frequently identified as factors leading to increased health care costs.

Several states, including Florida, Maine, Minnesota, and Vermont, have turned to the use of practice guidelines that define the standard of care as one strategy for reducing health care costs while maintaining quality care. Of these, Maine has progressed further than other states in developing and implementing this strategy.

In its recent health care reform plan, the Clinton Administration proposed a medical liability pilot program based on practice guidelines developed by the Agency for Health Care Policy and Research within the U.S. Department of Health and Human Services. Under the pilot program, physicians able to demonstrate that their professional conduct or

treatment complied with appropriate practice guidelines would not be liable for medical malpractice. Maine's experience, which is testing the viability of this strategy and its ability to affect defensive medicine, may provide insights that would be helpful to the Congress as it considers malpractice reform in the context of overall health care reform.

This report responds to your request that we describe the history of Maine's demonstration project, the factors essential to its establishment, and the focus of the guidelines themselves. In a separate report we will provide an assessment of the effect, if any, Maine's project is having on defensive medicine.

Background

As it relates to medical malpractice, defensive medicine has been defined as the alteration of modes of medical practice, induced by the threat of liability, for the principal purposes of forestalling the possibility of lawsuits by patients as well as providing a good legal defense if such lawsuits are instituted.[1] It is difficult to identify and impossible to quantify the effect of the defensive medicine phenomenon because a physician's desire to avoid a medical malpractice lawsuit may be only one factor among many influencing clinical decisions.[2]

Practice guidelines are intended to specify recommendations for treatment regarding diagnoses and procedures.[3] Most guidelines, which number over 1,300 nationwide, are written by physicians for physicians and are intended only as recommendations. Although guidelines can be offered as evidence of acceptable care in court, in most states they must be accompanied by the testimony of an expert witness at a trial and cannot be used as evidence apart from such testimony.

Results in Brief

As part of a larger goal of reducing health care costs and improving the standard of medical care, Maine is testing an innovative medical malpractice reform initiative. In 1990, the Maine legislature established the Medical Liability Demonstration Project. The project set in motion a

[1]Report of the Secretary's Commission on Medical Malpractice, Department of Health, Education, and Welfare (now the Department of Health and Human Services) (Washington, D.C., 1973), p. 38.

[2]"Defensive Medicine: Is Legal Protection the Only Motive?" Modern Healthcare (Sept. 10, 1990), p. 41.

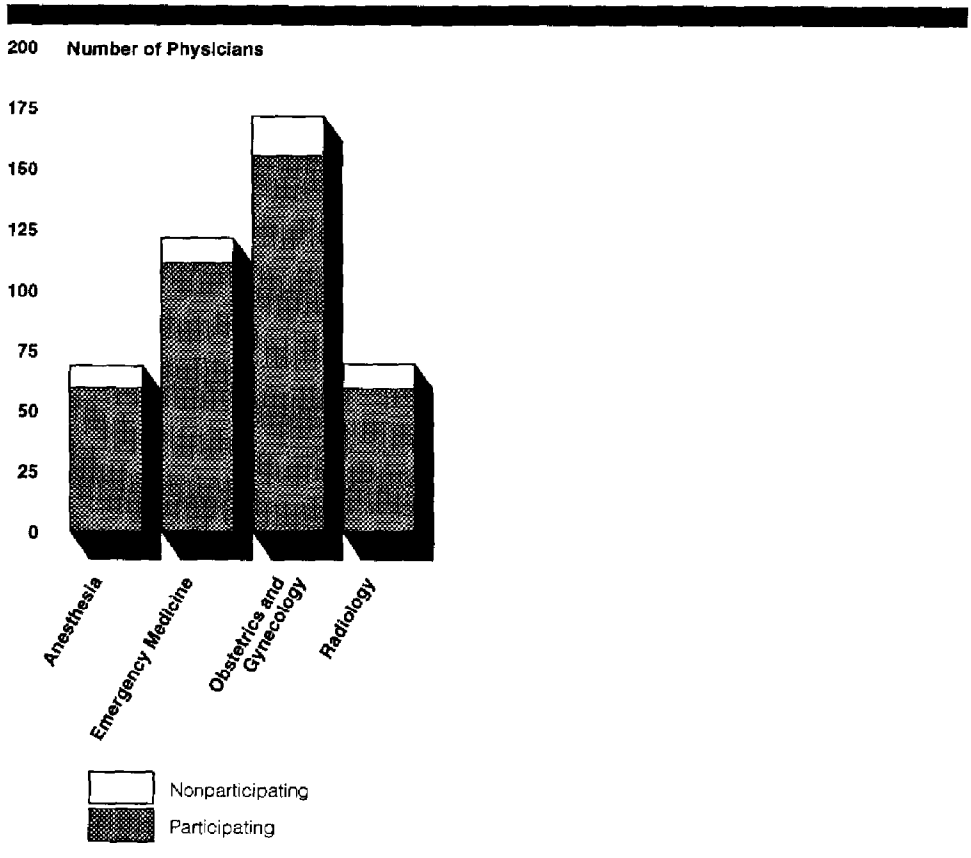
[3]Practice guidelines are also known as practice standards, protocols, algorithms, parameters, indicators, and preferred practice patterns. See Rebecca Rhine Gschwend, "Medical Specialty Societies and the Development of Practice Policies," Quality Review Bulletin (Feb. 1990), p. 58. Risk management protocols establish standards of practice designed to limit liability and increase the defensibility of claims that are pursued.

process that incorporates into state law 20 practice guidelines for four specialties: anesthesiology, emergency medicine, obstetrics and gynecology, and radiology.[4] This reform attempts to resolve malpractice claims by eliminating the need to litigate to establish the standard of care. Maine officials expect that the practice guidelines demonstration project will decrease physicians' motivation to perform medically unnecessary diagnostic tests and treatment procedures and will lead to lower health care costs.

Maine was able to implement practice guidelines into law by (1) gaining broad involvement of those affected by the guidelines, (2) assuring that those developing and choosing the guidelines were accountable to the public, and (3) protecting the physicians who use the guidelines in their practices. Specifically, the project was developed and is overseen by health care providers, payers, and consumers. The project's oversight committee and four specialty advisory committees responsible for developing the guidelines included sufficient numbers of physician representatives to enlist the support of the physician community, while also including sufficient numbers of representatives appointed by elected state officials to assure public accountability. To persuade Maine's physicians to participate in the project once it was developed, the project provides physicians complying with the guidelines a defense in future malpractice lawsuits. With these components, the majority of eligible physicians chose to participate in the project (see fig. 1).

[4]Legislation establishing the project was signed into law on April 24, 1990 (Maine Public Law 1990, Chapter 931), and subsequently amended on June 17, 1991 (Maine Public Law 1991, Chapter 319). The initial legislation provided for the participation of three specialties: anesthesiology, emergency medicine, and obstetrics/gynecology. The 1991 amendment provided for the participation of a fourth specialty, radiology. The legislation is codified at chapter 21 of title 24, Maine Revised Statutes.

Figure 1: Eligible Physicians Participating in the Demonstration Project



Source: Daniel Meyer, Ph.D., and others, The Maine Five Year Medical Liability Demonstration Project: Part II—Physician Participation and Perceptions of the Project (unpublished manuscript).

To maximize savings, the Maine legislature focused on physicians in four specialties because it believed that they were affected by costly malpractice claims that led them to practice defensive medicine. Further, it believed that these physicians would be willing to participate in the project. The specialty advisory committees identified the medical management problems within their specialties that had led to malpractice claims (thus encouraging defensive medicine) and determined the types of guidelines—risk management, clinical-practice requirements, or data-collection requirements—that would address these problems. To obtain physician acceptance and to assure quality, the advisory committees, for the most part, chose national standards that had been

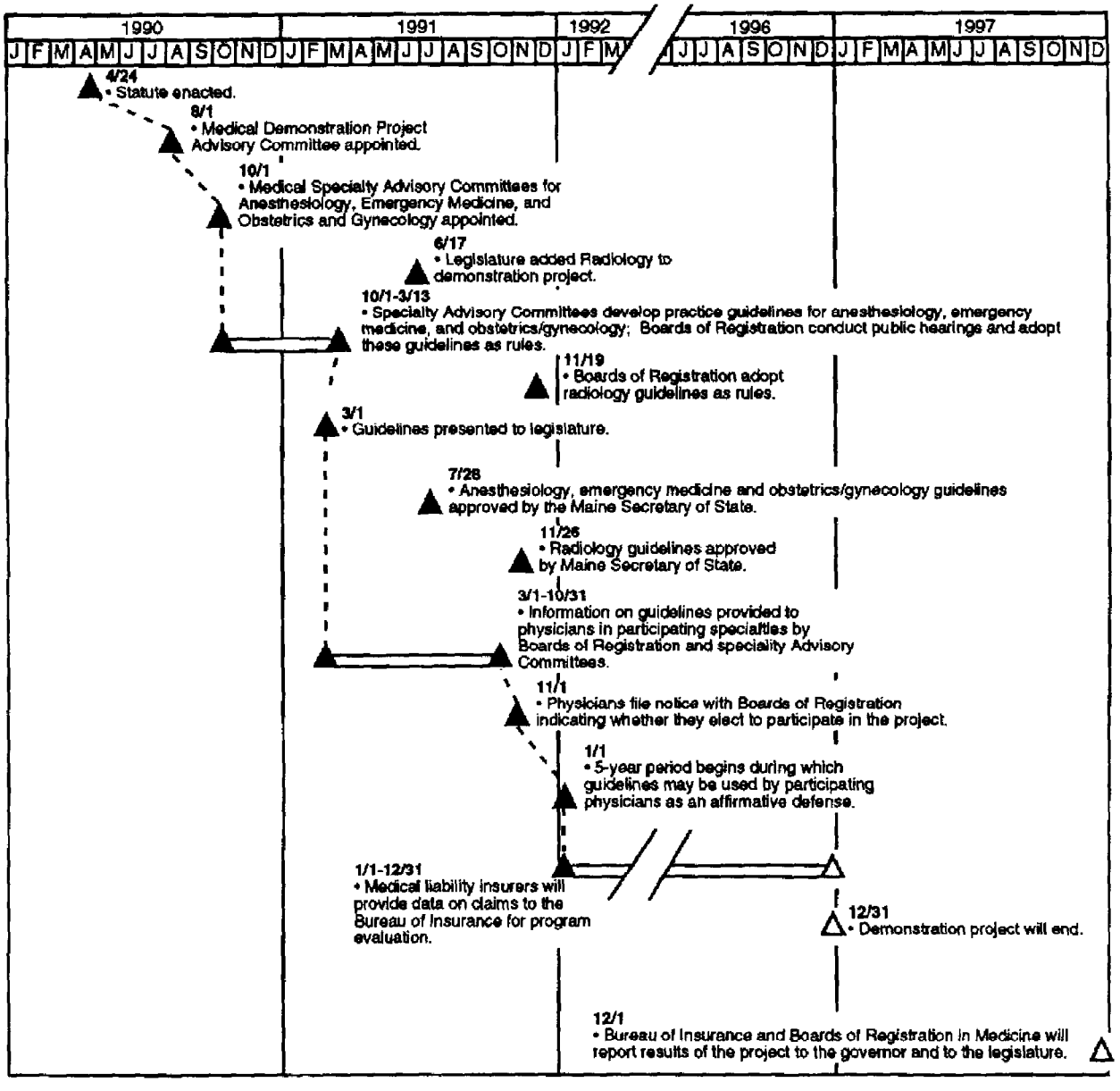
written and disseminated by national specialty societies, such as the American College of Obstetricians and Gynecologists and the American Society of Anesthesiologists. In some instances, however, the advisory committees developed their own standards because national standards did not exist or tailored the national standards to reflect the realities of the Maine health care environment.

GAO's Analysis

Guidelines Attempt to Reduce Costs

A key component in Maine's plan to address the problems of rising health care costs and of limited access to health care for low-income persons was its establishment of the Maine Medical Liability Demonstration Project in April 1990. Figure 2 shows the time line for implementation of the project.

Figure 2: Time Line for Project Implementation



The Maine legislature established committees, made up of physicians and nonphysician representatives, to develop practice guidelines for the four

specialties included in the demonstration project. These specialty advisory committees developed 20 guidelines in anesthesiology, emergency medicine, obstetrics and gynecology, and radiology. A list of the conditions and procedures covered by the guidelines follows.

Conditions and Procedures Covered by Maine's Practice Guidelines

Anesthesiology:

- documentation of anesthesia care,
- anesthesia monitoring standards,
- postanesthesia care, and
- requirements for preoperative testing.

Emergency Medicine:

- cervical-spine X ray and
- patient transfer.

Obstetrics and Gynecology:

- caesarean delivery when labor is not progressing normally,
- assessment of fetal maturity before repeat caesarean delivery or elective induction of labor,
- surgical removal of the uterus,
- inhibition of premature labor,
- extrauterine pregnancy,
- infant in other than head-first position during labor,
- herpes simplex virus infections before and after birth,
- fetal distress during delivery, and
- management of prolonged pregnancy.

Radiology:

- screening mammography,
- ultrasound to assess fetal development,
- outpatient assessment of blood vessel disorders, and
- examination of the lower intestine.

Under the framework established by the legislation, as of January 1, 1992, these practice guidelines were accorded the full force and effect of state law. Thus, the guidelines can be used in a malpractice lawsuit as the standard of medical care without the need for accompanying medical

expert testimony. By incorporating the guidelines into state law, physicians participating in the project know the standard of care to which they will be held accountable if they are sued for malpractice. By establishing legal standards of care, Maine officials hope to reduce the number of unnecessary tests and procedures done for defensive reasons.

Broad Involvement and Physician Protection Necessary to Implement Project

The state legislature involved all groups affected by the project in its development and implementation. For example, the project's oversight committee has membership representing six physician or provider organizations, two legal organizations, a malpractice insurer, a health insurer, the state superintendent of insurance, and three public members. To further assure physician support, the specialty advisory committees that selected the guidelines have two-thirds physician membership and representation from small-, medium-, and large-sized hospitals. Physician control of the advisory committees has assured their acceptance by practicing physicians in Maine.

To assure physician participation, the demonstration project protects physicians complying with the guidelines from future malpractice lawsuits. The demonstration project allows participating physicians to assert the guidelines as a legal defense in a malpractice case. This protection was essential because the project attempts to change physicians' practice patterns.

Despite these efforts, physicians we spoke with who are not participating in the project did not believe the guidelines would protect them from malpractice liability. Hence, they had elected not to participate in the project. This concern about the adequacy of the guidelines as a legal defense against malpractice was also voiced in a letter to its insured members by a leading malpractice liability insurer in the state.

Project Focused on High-Risk Specialties

Because health care cost savings were the impetus for the project, the state legislature focused the project on specialties that have high malpractice claims or awards. Further, the physician specialists involved—anesthesiologists, emergency physicians, obstetricians and gynecologists, and radiologists—were willing to participate in the project. Inclusion of cardiology was considered, but physicians in this specialty decided not to participate. The involved specialties attempted to address the cost of health care within their specialties by identifying procedures that lead to malpractice claims. The respective specialty committees used

malpractice insurers' claims data to identify the medical procedures that lead to malpractice claims, and adopted guidelines that cover these procedures.

The guidelines adopted by the specialty committees are either drawn from guidelines written by national specialty societies or written by the committees themselves. For example, nationally developed guidelines include those pertaining to caesarean delivery for failure to progress and performance of a screening mammography. Committee-developed guidelines include those pertaining to cervical-spine X rays and preoperative testing for anesthesia.

Physicians participating in the project stated that they chose to participate because the guidelines either incorporate national standards or improve the standard of care for their current practice.

Scope and Methodology

To respond to your request, we reviewed the legislation establishing Maine's program and discussed other relevant laws and legislative proposals with officials from Maine and other states. We also interviewed a number of individuals in Maine who represent organizations and interests involved in or affected by the development and implementation of the project. These included state legislators, state medical licensing board officials, health care providers, medical malpractice and health insurers, consumers, and trial lawyers. (See app. IX.) We also conducted telephone interviews with physicians in each of the four specialties included in the demonstration project. These physicians included some who had chosen to participate in the project as well as some who had chosen not to participate. We also looked at the reasons Maine's physicians participated in the project and their views about its likely effect on physicians' clinical behavior.

The results of our work are discussed in detail in appendixes I through III. Appendixes IV through VII provide the details of the practice guidelines that were incorporated into Maine state law for the four specialties participating in the demonstration project. Appendix VIII provides information on other state and federal efforts to develop practice guideline projects. Our work was performed in accordance with generally accepted government auditing standards between January and September 1993.

We discussed a draft of this report with officials involved in the Maine demonstration project. They generally agreed with the information presented. We have incorporated their comments as appropriate. We are sending copies of this report to Maine officials, the Secretary of Health and Human Services, the Director of the Office of Management and Budget, and other interested parties. We also will make copies available to others on request.

Please call me on (202) 512-7104 if you have any questions. Major contributors to this report are listed in appendix X.

Leslie G. Aronovitz
Associate Director,
Health Financing Issues

Contents

Letter		1
Appendix I Background and Legal Basis for Demonstration Project		16
	The Role of Practice Guidelines	17
	The Maine Medical Liability Demonstration Project	19
	Maine Project Gives Practice Guidelines Force and Effect of State Law	20
Appendix II Broad Involvement, Public Accountability, and Physician Protection Key to Implementation and Acceptance		22
	Broad Involvement by Providers, Payers, and Consumers	22
	Committees Responsible for Developing Guidelines Have Public Accountability and Adequate Physician Involvement	22
	Physician Protection Provided	26
	Most Eligible Physicians Participating in the Demonstration Project	27
Appendix III Guidelines Focus on Physician Behavior in High-Risk Specialties		31
	How the Guidelines Were Developed and Implemented	31
	Anesthesia Guidelines Use Risk-Management, Clinical-Practice, and Data-Collection Requirements	32
	Emergency Medicine Guidelines Use Clinical-Practice Requirements and Risk-Management Programs	35
	The Obstetrics and Gynecology Guidelines	37
	The Radiology Guidelines	38
Appendix IV Maine Practice Guidelines for Anesthesiology		42

Appendix V Maine Practice Guidelines for Emergency Medicine		54
Appendix VI Maine Practice Guidelines for Obstetrics and Gynecology		59
Appendix VII Maine Practice Guidelines for Radiology		76
Appendix VIII Other State and Federal Efforts to Develop Practice Guidelines		96
	Florida	96
	Minnesota	96
	Vermont	96
	Agency for Health Care Policy and Research	96
Appendix IX Officials GAO Interviewed		98
Appendix X Major Contributors to This Report		100
Table	Table III.1: Approaches Used in Practice Guidelines	31

Figures

Figure 1: Eligible Physicians Participating in the Demonstration Project 4
Figure 2: Time Line for Project Implementation 6

Background and Legal Basis for Demonstration Project

Physicians' fear of malpractice lawsuits is not without basis. Over the last 2 decades, there has been a significant increase in the number of malpractice claims challenging the way physicians practice medicine. Claims filed per 100 physicians insured by the St. Paul Companies—the nation's largest medical malpractice insurer—increased significantly from 2.6 in 1974 to 13.9 in 1991.[1] Further, malpractice claims are not confined to a small percentage of the physician population. The 1990 American Medical Association survey of nonfederal patient-care physicians reported that 39 of every 100 physicians responding to the survey had had at least one claim filed against them. Among specialties, however, the survey found that 57 percent of obstetricians/gynecologists and 53 percent of surgeons had incurred at least one claim.[2] The potential exists for an even larger number of claims to be filed. Studies conducted in California and New York estimate that only about 1 in 8 to 1 in 10 malpractice errors now result in a claim.[3]

For physicians, "medical malpractice suits—whether actually filed or merely feared—breed anxiety, frustration, discouragement, and resentment."[4] Physicians may respond to the malpractice threat in a number of ways. For example, they may perform additional diagnostic tests, treatment procedures, or both; keep more detailed patient records; increase the time spent with patients; or refuse to see high-risk patients. Although discerning the difference between defensive practices that are wasteful of health care resources and those that represent good clinical care is often difficult, many physicians believe that a large number of diagnostic tests and treatment procedures are motivated by the perceived need to "build a good record" rather than by the belief that they represent good clinical care.[5]

[1]See "Physicians' & Surgeons' Update: The St Paul's 1989 Annual Report to Policyholders" (May 1989); and "Physicians' & Surgeons' Update: The St. Paul's 1992 Annual Report to Policyholders" (1992).

[2]Gonzalez, Martin L., "Medical Professional Liability Claims and Premiums, 1985-1990," Socioeconomic Characteristics of Medical Practice 1992, American Medical Association Center for Health Policy Research (1992), p. 4.

[3]Patricia Danzon, Medical Malpractice: Theory, Evidence, and Public Policy (Cambridge: Harvard University Press, 1985), p. 19; and Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York, the Report of the Harvard Medical Practice Study to the State of New York (Cambridge: Harvard University Press, 1990).

[4]Treating Malpractice, Report of the Twentieth Century Fund Task Force on Medical Malpractice Insurance (New York: Priority Press Publications, 1986), p. 41.

[5]Beyond Malpractice: Compensation for Medical Injuries (Washington, D.C.: Institute of Medicine, 1978), p. 16.

The Role of Practice Guidelines

Practice guidelines are intended to specify recommendations for treatment methods regarding medical diagnoses and procedures. Physicians have generally resisted efforts to set absolute guidelines for appropriate clinical practice—referring to what has been called cookbook medicine. In the past few years, however, physicians have become increasingly willing to participate in the development of guidelines that cannot only improve patient outcomes but also reduce or eliminate avoidable medical injuries and their related malpractice lawsuits.

Most guidelines are written by physicians to aid other physicians in the medical management of their patients and are set forth as recommendations only.[6,7] They are useful in that they can help physicians

"faced with an overwhelming array of often conflicting information, to reduce some of the uncertainty they must cope with and to practice the most clinically effective medicine."[8]

The development of clinically based standards to reduce medical malpractice losses has focused on problems in specialties such as

[6] Generally, clinical practice guidelines are developed in three ways:

• by individual physicians for use in a local context, such as a hospital. These include, for example, the standards developed by the Departments of Anesthesia at Harvard-affiliated hospitals for patient monitoring during anesthesia and the standards developed at the Stanford University School of Medicine for arterial blood gas analysis.

• by commercial enterprises, such as Blue Cross and Blue Shield Association and liability insurance carriers, with physician input. These organizations use the promulgation and enforcement of specific clinical standards as a way to control health care costs and reduce malpractice losses.

• by national medical specialty societies, voluntary health organizations, and government agencies. These include, for example, over 1,300 practice guidelines developed by national medical specialty societies for use by their members, guidelines developed by groups such as the American Cancer Society and the American Heart Association, and guidelines that are developed by the National Institutes of Health and the Agency for Health Care Policy and Research.

See Eleanor D. Kinney, and Marilyn M. Wilder, "Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities," University of California, Davis Law Review, Vol. 22 (1989), p. 427.

[7] Even though groups establishing guidelines generally have viewed them only as recommendations to physicians, some health insurers now use guidelines as a basis for making payments. For example, in the early 1980s, the Blue Cross and Blue Shield Association expressed concern that physicians performed too many preadmission tests on hospital patients. In response, the American College of Physicians developed standards for its members on appropriate tests to provide patients upon admission to the hospital. These standards are used by Blue Cross plans nationwide as the criteria for reimbursing preadmission tests administered to hospital patients. Similarly, in recent years, the Medicare program has based policies and decisions on coverage of medical procedures and technologies on clinical practice guidelines, technology assessments, and other standards developed by medical organizations.

[8] Linda Johnson White, and John R. Ball, "Integrating Practice Guidelines with Financial Incentives," Quality Review Bulletin (Feb. 1990), p. 53.

anesthesia and obstetrics where losses associated with malpractice claims have been high.

The Harvard teaching hospitals were the first to apply practice guidelines directly to the medical malpractice problem. Between 1983 and 1985, these hospitals developed and implemented practice guidelines for anesthesia that were intended to reduce the risk of malpractice lawsuits by reducing the types of errors that produce them.[9] A former vice president of Harvard's Risk Management Foundation stated that a reduction in claims appears to coincide with adoption of the guidelines.[10]

Whether and how practice guidelines can be used to establish the standard of care for a physician in medical malpractice litigation has been unclear.[11] Although guidelines can be offered as evidence of acceptable care in court, in most states they must be accompanied by the testimony of an expert witness, not as evidence apart from such testimony. In the absence of written practice guidelines, the physician may, in some cases, be held to a standard of care that reflects the "habit" of the medical expert testifying rather than an established standard of the profession.[12]

[9]James F. Holzer, "The Advent of Clinical Standards for Professional Liability," Quality Review Bulletin (Feb. 1990), p. 73.

[10]Holzer, "The Advent of Clinical Standards for Professional Liability," p. 73.

[11]Kinney and Wilder, "Medical Standard Setting," p. 438.

[12]Kinney and Wilder, "Medical Standard Setting," p. 427.

The Maine Medical Liability Demonstration Project

The practice guidelines demonstration project was a key component in Maine's plan to address the problems of rising health care costs and expanding access to health care for low-income people by reducing the cost of health insurance.[13] The project was supported by the state's business, labor, and health interests that were affected by rising health care costs. These interests formed a coalition known as the Healthcare Roundtable.[14]

The state's reforms established committees made up of physicians and nonphysician representatives to develop practice guidelines for the four specialties included in the demonstration project. In the winter of 1991, the guidelines for anesthesiology, emergency medicine, and obstetrics and gynecology were approved by Maine's physician licensing organizations and adopted as state law through the state's rulemaking process. Radiology guidelines were added to the demonstration project in June of 1991 and adopted as state law that fall. The guidelines were to be available as a legal defense against malpractice suits beginning January 1, 1992, if at least 50 percent of the physicians in each of the four specialties agreed to participate in the demonstration project by November 1, 1991.

As of September 1993, there were no examples of the guidelines having affected malpractice litigation. Malpractice attorneys told us that the guidelines are most likely to affect malpractice litigation at the pretrial stage. Under Maine law, medical malpractice litigants must submit to a

[13]The legislation that established the malpractice demonstration project responded to a group of concerns in the state focusing on tort reform, practice guidelines, and an insufficient number of physicians delivering babies in rural areas. Many in the state believed that low physician revenues in rural areas and high malpractice insurance costs limited the access of pregnant women to obstetricians and family physicians who deliver babies. A state senator working with the Healthcare Roundtable developed a reform proposal with the following components: caps on compensation for noneconomic damages, such as pain and suffering, anguish, and marital losses; collateral source offsets to reduce injured patients' awards by the amounts that they have already received from other insurance coverage such as health or disability insurance; and a demonstration project to reduce the need for physicians to practice defensive medicine and the number of malpractice claims.

The Maine legislature did not choose to cap awards for noneconomic losses, but it enacted legislation that established the demonstration project and provided for collateral source offsets, with the savings to be used to fund the rural maternal-health initiative. Specifically, the Maine Commissioner of Insurance estimated that collateral source offsets would reduce malpractice insurance premiums by 2 percent and required malpractice insurers to reflect this reduction in their rates. The premium savings were shared as follows: The first $250,000 went to the Rural Medical Access Program to provide malpractice insurance subsidies to physicians providing obstetrics care in medically underserved areas of the state. The next $250,000 was used to reduce insurance costs for all physicians in the state. Any additional savings up to $1 million were split equally between the physicians and the rural access program.

[14]The Healthcare Roundtable consisted of representatives of the Maine Chamber of Commerce and Industry, Blue Cross and Blue Shield of Maine, the Maine Hospital Association, the Maine Medical Association, the Maine Ambulatory Care Coalition (representing rural health centers), and the Maine State Employees Association.

hearing with a pretrial screening panel that issues findings regarding the legal merits of the claim. A unanimous finding by the panel unfavorable to the claimant would be admissible in any subsequent trial regarding that claim. As a result, in cases involving areas of practice covered by the guidelines, attorneys expect that a decision by the panel that the guidelines cover the claim and that the physician followed the guidelines and was, therefore, within the applicable standard of care, will discourage plaintiffs from pursuing their claims to trial.

Maine Project Gives Practice Guidelines Force and Effect of State Law

For participating physicians, the Maine Medical Liability Demonstration Project gives practice guidelines for 20 conditions and procedures in four specialties the force and effect of state law. That means that they can be used in a malpractice lawsuit as evidence to establish the standard of care without the need for accompanying medical expert testimony. With the guidelines incorporated into state law, physicians participating in the project know the standard of care to which they will be held accountable if they are sued for malpractice.

An anesthesia-related malpractice claim, for example, involving a catastrophic injury—such as permanent brain damage or death resulting from lack of oxygen to the brain—might allege that the anesthesiologist had failed to adequately monitor the level of oxygen in the blood. In such a case, how frequently and in what way the anesthesiologist should have monitored the patient, as determined by expert witnesses, would be essential factors in establishing whether the physician was negligent. Maine's anesthesia guidelines, without the use of expert witnesses, establish the appropriate methodologies for anesthesia care before, during, and after surgery, including the assessment of a patient's oxygen levels.

With the guidelines established in law, the uncertainty about the standard of care should be eliminated. For example, when presented with a possible head injury, should a skull X ray be ordered? Physicians know that they may be found negligent if they have failed to order an X ray and any subsequent worsening of the patient's condition could be linked to inadequate diagnosis and lack of appropriate treatment. Yet researchers examining cases involving suspected head injury analyzed 1,500 skull X rays and concluded that the procedure was of limited value when performed on a routine basis for all patients with suspected head trauma.[15] By limiting X rays to cases with at least one of several defined clinical

[15]Beyond Malpractice, p. 17.

symptoms, the researcher reported that 435 X rays—and their resulting costs—could have been avoided. They noted, however, that this approach would have missed one skull fracture that would not have been detected without an X ray. Maine's emergency medicine specialty advisory committee addressed this type of dilemma, relative to cervical-spine X rays in injured patients, by developing guidelines for when a cervical-spine X ray should be ordered.

Broad Involvement, Public Accountability, and Physician Protection Key to Implementation and Acceptance

Implementation and acceptance of Maine's demonstration project hinged on several factors. First, the project was developed and is overseen by health care providers, payers, and consumers. Second, the project's oversight committee and four specialty advisory committees responsible for developing the guidelines included sufficient numbers of physician representatives to enlist the support of the physician community, while also including sufficient numbers of representatives appointed by elected state officials to assure public accountability. Third, physicians complying with the guidelines were protected from future malpractice lawsuits. Using these factors assured most, although not all, physicians that the project was worth their participation.

Broad Involvement by Providers, Payers, and Consumers

The practice guidelines demonstration project grew from concerns about the high cost of health care expressed by the state's business leaders, health care providers, health insurers, labor unions, consumer organizations, and rural health advocates. The idea for the project came from an informal meeting of officials of the Maine Medical Association and the state employees' labor union, in which representatives discussed plans to reduce the cost of health care and improve access to obstetrical care in rural areas of the state.

The two key legislators who sponsored the legislation containing the demonstration project believed that the rural obstetrical care initiative was critical to its enactment. By tying together the practice guidelines project, the obstetrical care initiative, and tort reform, the Maine legislature was able to win support from payers, providers, and consumer groups.

Committees Responsible for Developing Guidelines Have Public Accountability and Adequate Physician Involvement

The membership of the project's oversight committee and four specialty advisory committees responsible for developing the guidelines were prescribed by the legislation. These committees were structured to include sufficient numbers of representatives appointed by elected state officials to assure public accountability, while including sufficient numbers of physician representatives to enlist the support of the physician community. This focus is reflected in the membership of the oversight committee—the Medical Demonstration Project Advisory Committee—which is given below.

- Chair of the Board of Registration in Medicine or a designee;

- Chair of the Board of Osteopathic Examination and Registration or a designee;
- President of the Maine Medical Association or a designee;
- President of the Maine Osteopathic Association or a designee;
- President of the Maine Academy of Family Practice Physicians or a designee;
- President of the Maine State Bar Association or a designee;
- President of the Maine Trial Lawyers Association or a designee;
- Representative for a tertiary-care hospital, to be appointed by the governor;
- Representative of an insurer providing medical malpractice insurance in the state, to be appointed by the governor;
- Representative of a profit or nonprofit health insurer, to be appointed jointly by the president of the senate and the speaker of the house of representatives of the state legislature;
- Superintendent of Insurance or a designee;
- Three public members, one to be appointed by the governor, one to be appointed by the president of the senate, and one to be appointed by the speaker of the house of representatives.

This focus on accountability and physician involvement is also evident in the membership of each of the four specialty advisory committees that had responsibilities for developing the guidelines and recommending changes as needed to remain current with advances in medical knowledge. As shown below, the membership of these committees consists of two-thirds physician specialists and one-third consumer, insurance, business, or labor representatives who are appointed by the governor or legislative leaders.

The Medical Specialty Advisory Committee on Anesthesiology

- One physician who practices in a tertiary hospital, appointed by the Board of Registration in Medicine;
- One physician who practices in a medium-sized hospital, appointed by the Board of Registration in Medicine;
- One physician who practices primarily in a rural area, appointed by the Board of Registration in Medicine;
- One board-certified anesthesiologist, appointed by the governor in consultation with the Maine Chapter of the American Society of Anesthesiologists;
- One public member representing the interests of payers of medical costs, appointed by the president of the senate; and
- One public member representing the interests of consumers, appointed by the speaker of the house of representatives.

The Medical Specialty Advisory Committee on Emergency Medicine

- One physician who practices in a tertiary hospital, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Medical Association;
- One physician, appointed by the Board of Osteopathic Examination and Registration from nominations submitted by the Maine Osteopathic Association;
- One physician who practices primarily in a rural area, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Medical Association;
- One family practice physician, appointed by the Board of Registration in Medicine from nominations submitted by the Maine College of Family Physicians;
- Two physicians, appointed by the governor, at least one of whom is board certified in emergency medicine, appointed in consultation with the Maine Chapter of the American college of Emergency Medicine Physicians;
- One public member representing the interests of payers of medical costs, appointed by the president of the senate;
- One public member representing the interests of consumers, appointed by the speaker of the house of representatives; and
- One public member representing allied health professionals, appointed by the governor.

The Medical Specialty Advisory Committee on Obstetrics and Gynecology

- One physician who practices in a tertiary hospital, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Medical Association;
- One physician who practices in a medium-sized hospital, appointed by the Board of Osteopathic Examination and Registration from nominations submitted by the Maine Osteopathic Association;
- One physician who practices primarily in a rural area, appointed by the Board of Registration in Medicine from nominations submitted by the Maine Medical Association;
- One physician who practices primarily in a rural area, appointed by the Board of Osteopathic Examination and Registration from nominations submitted by the Maine Osteopathic Association;
- One family practice physician appointed by the Board of Registration in Medicine from nominations submitted by the Maine Academy of Family Physicians;
- One board-certified physician, appointed by the governor in consultation with the Maine Chapter of the American College of Obstetricians and Gynecologists;

- One public member representing the interests of payers of medical costs, appointed by the president of the senate;
- One public member representing the interests of consumers, appointed by the speaker of the house of representatives; and
- One public member representing allied health professionals, appointed by the governor.

The Medical Specialty Advisory Committee on Radiology

- One physician who practices in a tertiary hospital, appointed by the Board of Registration in Medicine;
- One physician who practices in a medium-sized hospital, appointed by the Board of Registration in Medicine;
- One physician who practices primarily in a rural area, appointed by the Board of Registration in Medicine;
- One board-certified radiologist, appointed by the governor in consultation with the Maine Radiological Society;
- One public member representing the interests of payers of medical costs, appointed by the president of the senate; and
- One public member representing the interests of consumers, appointed by the speaker of the house of representatives.

The public member on the Obstetrics and Gynecology Advisory Committee stated that her role was to give the patients' view about nonmedical aspects of the guidelines. She believed that her involvement had the greatest impact in areas pertaining to patient education about the treatments they were to receive.

The physicians chairing the respective specialty advisory committees believed that the guidelines had to be written by physicians in order for them to be acceptable to physicians. They also believed that the guidelines had to be easy for physicians to use and easy for them to demonstrate compliance. As a result, the guidelines were targeted to defined problems or treatments. Most are only a few pages in length. The committee chairs stated that if the guidelines were complex, physicians would have had a difficult time determining when the guidelines applied or demonstrating that they had been followed.

Further, the guidelines were written to be suitable for all members of the specialty practicing in the state. The legislature accomplished this by requiring participation on the specialty advisory committees of specialists representing practices in small-, medium-, and large-sized hospitals. The physicians chairing the specialty advisory committees stated that if

specialists could not have used the guidelines in their practices, they would not have supported them in the advisory committees. As a result, the committees avoided guidelines that would have required the use of expensive technology or techniques only needed in tertiary care centers.

Physician Protection Provided

Maine's Healthcare Roundtable had identified defensive medicine as a factor that contributed to increasing health care costs. The Roundtable members believed that because of an unfavorable liability climate, physicians were performing some medically unnecessary tests and procedures that were, in turn, leading to increased health care costs. However, the Roundtable members also believed that physicians could not be expected to change their practice patterns unless they were given some protection from medical negligence lawsuits. The Maine project was premised upon the belief that physicians would change their practice patterns if their fear of malpractice lawsuits could be removed. In some cases, physicians participating in the demonstration project will not order certain tests and procedures identified as unnecessary by the guidelines. Therefore, protecting physicians from any potentially increased risk of lawsuit resulting from this change in practice pattern was critical.

The legislature provided this protection by allowing physicians who participated in the demonstration project to assert compliance with the guidelines as an affirmative defense if they were sued for malpractice. Maine officials believe that the guidelines could have the effect of giving physicians immunity from litigation because there would be no grounds for litigation if a physician could demonstrate compliance with the guidelines.

The law also protects participating physicians who do not use the guidelines because, by statute, only physicians may assert the guidelines as an affirmative defense. Therefore, patients cannot use a physician's noncompliance with the guidelines as evidence that the physician was negligent unless the physician has already admitted the guidelines as evidence.

Some Maine officials expect the restriction on the use of the guidelines will result in a constitutional challenge that ultimately will be decided by the state's supreme court. A representative of the Trial Lawyers Association of Maine stated that the guidelines create a new group of people who are denied compensation when they are injured by using standards that are different than standards used in other parts of the

country. Thus, an injury could be compensable in New York but not compensable in Maine. The legal advisor of the demonstration project's advisory committee stated, however, that he does not believe that there will be a constitutional challenge to the affirmative defense because patients still have an absolute right to a jury trial. The affirmative defense can be raised during the trial and ruled upon by a jury, but any case can still go to trial. He does not believe that there are any issues upon which to base a successful constitutional challenge to the law.

Most Eligible Physicians Participating in the Demonstration Project

The legislation establishing the demonstration project required that at least 50 percent of each specialty had to elect to participate in the demonstration project or physicians could not use the affirmative defense. By January 1, 1992, the first day the guidelines could be legally effective, the majority of eligible physicians in each of the four specialties had chosen to participate. The lowest rate of participation was achieved among radiologists where 59 of 69 (87 percent) of eligible specialists chose to participate, while the highest rate was achieved among emergency physicians where 111 of 121 (92 percent) of eligible specialists chose to participate.

The majority of physicians in each of the four specialties chose to participate despite advice to the contrary and warnings about possible adverse consequences that may result from the project. Officials of Maine Medical Mutual Insurance Company, a leading malpractice insurer in Maine, were concerned that the demonstration project could increase the liability of the physician if patients were eventually allowed to use the guidelines in malpractice trials. To communicate these concerns, Medical Mutual sent a letter to the physicians it insured stating the views of several attorneys the company employed to handle the defense for individual malpractice cases. The views included the following:

"As a defense attorney I applaud each and every effort made by the medical profession and the Legislature to increase the quality of medical care. If the goal of the practice parameters and risk management protocols is to set minimum standards for the proper practice of medicine, that is a good idea. However, if the goal is to 'avoid malpractice claims and increase the defensibility of the malpractice claims that are pursued,' I do not believe that the goal is realistic or capable of achievement."

Another attorney stated:

"The adoption of practice parameters will create check-list litigation (and perhaps check-list medicine). Proof of deviation will create an inference of negligence while proof of compliance will be evidence of due care . . .. The question we want to have answered in a courtroom is, 'Did the doctor practice acceptable medicine under all of the circumstances?' We don't want liability to rest on whether or not the doctor missed an item on a check-list."

Although the defense attorneys expressed these reservations, an official of Medical Mutual stated that despite such reservations, the company did not oppose the project. In fact, the company helped to implement the project by providing malpractice claims data to the specialty advisory committees for use in identifying the procedures and tests to target for guidelines. This official also stated that participation in the project had no effect on physicians' ability to obtain malpractice insurance coverage through Medical Mutual.

Physicians gave a range of reasons for choosing to participate in the demonstration project. A survey of Maine physicians shortly after the project began in 1992 reported that although a major focus of the project was the defensive medicine problem, few physicians based their decision to participate on the specific belief that it would decrease the cost of defensive medicine or the cost of health care.[1]

Physicians responding to the survey gave the following reasons for participating in the demonstration project:

- Guidelines reasonable, no change in practice, good medicine (15 percent),
- Reduce risk of malpractice suits (13 percent),
- Need to try something, interesting experiment (12 percent),
- Will decrease cost of insurance (10 percent),
- Decrease cost of health care or cost of defensive medicine (9 percent),
- Improve outcomes or increase quality of care (7 percent),
- Will set uniform standards (6 percent),
- Will protect doctors from lawyers (6 percent),
- Project has national importance (6 percent), and
- Other (15 percent).

[1]Daniel Meyer, Ph.D., and others, The Maine Five Year Medical Liability Demonstration Project: Part II—Physician Participation and Perceptions of the Project (unpublished manuscript). This survey used open-ended questions to obtain physicians' reasons for their decisions about participating in the project and their views about its likely effect on physicians' clinical behavior.

Physicians participating in the survey who had chosen not to participate in the demonstration project gave various reasons for their decisions. These reasons included:

- missed the deadline for signing up for the project,
- recently retired from practice,
- acted on the advice of personal or malpractice-insurer's attorneys,
- opposed to what they view as the legislation's "cookbook medicine" approach, and
- feared the project would increase the risk of losing if they were sued for malpractice.

In discussions by telephone with two participating physicians from each of the project's four specialties, we found that they generally believed that the guidelines put into law the medical standards they were already using or improved the standard of care by providing a legally sound basis for reducing unnecessary tests and procedures that may carry a risk of injury or lead to further tests.[2] One physician stated that the guidelines improved the standard of care at his hospital because they motivated the hospital's administrators to invest in technology necessary to comply with the guidelines.

The participating physicians we spoke with believed that the guidelines were acceptable because, for the most part, they impose the same medical standards as those of the national specialty societies. They generally believed that the guidelines have reduced their need to practice defensive medicine. They indicated that the guidelines have given them the confidence not to administer procedures that they might have before. For example, one anesthesiologist stated that he has used the guidelines to explain to his patients why he is not ordering certain preoperative tests. He stated that his patients liked not receiving unnecessary tests and liked saving the money associated with these tests. Another anesthesiologist also said that the guidelines gave him the confidence to tell surgeons that certain preoperative tests were not necessary. Without the guidelines, he told us that he would have performed the tests that the surgeons requested.

Some nonparticipating physicians stated that they had been concerned about the legal implications of the project and had decided to take the

[2]At our request, the Maine Board of Registration in Medicine provided the names of three participating and three nonparticipating physicians in each of the four specialties. These physicians do not represent a random sample of physicians practicing in Maine.

advice of Medical Mutual not to participate. Others stated that they wanted to avoid the excessive paperwork that they believed would result from the project. A nonparticipating emergency physician stated that he did not believe the guidelines would result in bad medicine, only that participating in the project would increase his liability. A family practice physician who did not sign up to use the obstetrics and gynecology guidelines said that her decision was based, in part, on the belief that she did not have sufficient time to learn about the guidelines. Therefore, she relied on Medical Mutual's advice not to participate.

Researchers in Maine evaluating physicians' views of the project concluded that the high level of participation in the project suggests that physicians are eager to help find ways to address malpractice issues. They believe that high participation may be due to the project's design that allowed representative groups of Maine physicians to develop the guidelines. The study also reported that informal discussions with physicians in Maine during development and implementation of the project indicate that physicians must feel some level of involvement or representation in the development of guidelines.[3] This was assured, first by the representation of the advisory committees that selected the guidelines, which stipulated physicians make up two-thirds of the committees membership. Second, physicians felt involved because there are so few practicing in the state. With fewer than 125 emergency physicians practicing in Maine, the Emergency Medicine Advisory Committee was able to communicate with all of them to obtain their views of the guidelines.

[3]Meyer, Daniel, and others, The Maine Five Year Medical Liability Demonstration Project, p. 9.

Guidelines Focus on Physician Behavior in High-Risk Specialties

The Maine practice guidelines focus on high-risk specialties[1] in an attempt to change physicians' behaviors by identifying those behaviors that lead to malpractice claims and defensive medicine. As shown in table III.1, each guideline uses at least one of three approaches to change physicians' behaviors: risk-management programs, clinical-practice requirements, or data-collection requirements. Risk-management programs attempt to prevent accidents from occurring. Clinical-practice requirements spell out procedures that must be performed in various clinical situations. Data-collection requirements require physicians to document or comment on a patient's condition or the actions taken by the physician.

Table III.1: Approaches Used in Practice Guidelines

	Risk-management programs	Clinical-practice requirements	Data-collection requirements
Anesthesia	X	X	X
Emergency medicine	X	X	X
Obstetrics and gynecology	X	X	X
Radiology	X		X

How the Guidelines Were Developed and Implemented

The specialty advisory committees used medical literature and malpractice claims data as a starting point to determine which guidelines to implement. Generally, the committees developing the guidelines divided the work of choosing or developing the guidelines among themselves. The committees then proposed the draft parameters and protocols to the Maine Board of Registration in Medicine and the Board of Osteopathic Examination and Registration for rulemaking. The boards initiated the administrative public hearing and comment process, through which the parameters and protocols were eventually adopted as rules, having the force of the law. The guidelines were presented to the legislature in spring 1991 and were approved by Maine's Secretary of State on July 28, 1991.[2] The guidelines were then sent to practicing specialists giving them the option to participate in the demonstration project.

Although Maine's specialty advisory committees generally adopted nationally developed guidelines, the committees were ultimately

[1]High-risk specialties face a higher risk of being involved in malpractice litigation. As a result, such high-risk specialties as obstetrics/gynecology, surgery, and anesthesiology are charged higher malpractice insurance premiums than would be the case for such low-risk specialties as family medicine, pathology, and psychiatry.

[2]Radiology guidelines were subsequently approved by Maine's Secretary of State on November 26, 1991.

responsible for the guidelines they chose to implement. In all cases where national standards were selected, the committees reviewed them to determine if physicians across the state could use the guidelines in their practices. The specialty advisory committees avoided guidelines that they believed were too complex to use as a legal standard in a treatment setting or required expensive technology only available at large tertiary-care hospitals, such as the Maine Medical Center in Portland.

Using national standards also assures the standard of care in Maine will not be lower than the standard in the rest of the country. Furthermore, using national standards helps the advisory committees to keep the Maine standards current with developments in medical knowledge and practice. For example, the Maine obstetrics and gynecology guidelines, incorporated into state law in November 1991, were updated in March 1993 by the Obstetrics and Gynecology Advisory Committee to reflect changes in the national standards made by the national specialty society.

The advisory committees do not have an education or oversight role with respect to how the guidelines are implemented. Individual physicians participating in the demonstration project are responsible for using the guidelines and being able to demonstrate, primarily through the patient's record, that they used the guidelines, in the event of a malpractice claim.

Anesthesia Guidelines Use Risk-Management, Clinical-Practice, and Data-Collection Requirements

Maine's anesthesia guidelines[3] attempt to change physicians' behavior by (1) creating specific risk-management programs, (2) establishing when specific tests must be performed, and (3) requiring that specific diagnosis data be collected. The standards cover the following areas:

- documentation of anesthesia care,
- anesthesia monitoring standards,
- postanesthesia care, and
- requirements for preoperative testing.

To identify major problems warranting guidelines, the Anesthesia Advisory Committee analyzed a national malpractice insurer's data to determine the circumstances under which anesthesia accidents occur. In developing the guidelines for the demonstration project, the committee had several goals.

[3]Chapter 20 of the rules of the Maine Board of Registration in Medicine and of the Maine Board of Osteopathic Examination and Registration.

- First, the guidelines would direct physicians' practice patterns to decrease the probability of major anesthesia accidents occurring.
- Second, the guidelines would provide acceptable anesthesia care, without requiring a series of treatment steps. The committee believed that prescribing the steps from the beginning to the end of an anesthesia procedure would be difficult because there are many variations in acceptable anesthesia treatment and in patient responses to those treatments. The Chair of the Anesthesia Advisory Committee stressed that how a procedure is done is less important than its outcome.
- Third, the guidelines would be sufficiently straightforward so all anesthesiologists could use them. Thus, they had to be short and focused on defined problems or treatments. The committee believed that complex guidelines would be too confusing and difficult for anesthesiologists to use in the clinical setting.
- Finally, the guidelines would not depend upon expensive technology or equipment available only at a tertiary care center.

For the demonstration project, the committee chose to implement guidelines that had been developed by the American Society of Anesthesiologists, except for the guidelines covering preoperative tests. The committee believed that guidelines developed by the national group would be preferable to locally developed guidelines for several reasons. First, the American Society has a larger cross section of experience and knowledge upon which to base the guidelines. Second, ignoring or rejecting guidelines developed by the national association would be difficult for Maine's anesthesiologists. Finally, the American Society's guidelines would have more legal credibility if they were challenged in court.

Anesthesiologists may deviate from the guidelines. The guidelines state that under extenuating circumstances following the guidelines may not be medically appropriate. In these cases, the guidelines require the anesthesiologist to document in the patient's record the circumstances and the care provided.

Anesthesia Documentation Guidelines

The Maine anesthesia guidelines focus on improving record keeping as one method of improving care. Anesthesiologists are required to document or comment on a patient's breathing, the drugs used, the patient's physical position, the management of a patient's fluids, the techniques used by the anesthesiologist, any unusual event occurring during treatment, and the status of the patient at the conclusion of anesthesia.

Preoperative Testing Guidelines

To address defensive medicine, the anesthesia practice guidelines attempt to reduce health care costs by standardizing when Maine anesthesiologists should perform low-cost but frequently performed, preoperative tests. The Maine Anesthesiology Advisory Committee was aware, both from its members' experience and from the growing consensus in anesthesia literature, that an excessive number of preoperative tests were being performed largely for defensive purposes. Further, some anesthesiologists believed that, rather than improving patient care, excessive testing may result in greater harm to patients because each test carries its own risk of injury.

The committee observed that preoperative tests look for chronic diseases the physician already knows about from the patient's history. In addition, the preoperative tests often already had been administered by other physicians, so these test results could be used without performing an additional test. As a result, the committee targeted preoperative tests and developed guidelines that state specifically which preoperative tests must be performed depending on the patient's age, sex, and general health.

For example, according to the guidelines, generally healthy men between the ages of 40 and 50 should have received an electrocardiogram within the past 2 years to test for potential heart problems before receiving general anesthesia; women, however, do not need this test. Both men and women in good health over age 75 need preoperative tests evaluating whether they have anemia, their kidneys are not operating properly, or they suffer from diabetes. In addition, they should receive a chest X ray and an electrocardiogram. With each anemia test costing $9, each kidney test costing $16, each diabetes test costing $11, each electrocardiogram costing $44, and each chest X ray costing $54, not automatically performing these tests on most younger patients can result in significant savings. In addition, not performing urinalyses, electrolyte tests, and more comprehensive blood tests that were ordered by some anesthesiologists or surgeons regularly before the demonstration project also results in savings.

The committee believed that a patient's medical problems rarely change dramatically within the time frames set in the guidelines. The committee members used their judgment and own experience to develop this guideline. As the project progresses, they will monitor the time frames for preoperative testing to see if they need to be adjusted.

Emergency Medicine Guidelines Use Clinical-Practice Requirements and Risk-Management Programs

Maine's emergency medicine guidelines[4] establish clinical-practice requirements for when to administer a cervical-spine X ray and when patients may be transferred between hospitals. These guidelines, unlike those for other specialties, were not selected from guidelines that had been previously developed by a national specialty society. Maine's Emergency Medicine Advisory Committee developed the guidelines based on studies of medical literature, consultation with experts, analysis of medical malpractice liability claims data, and consultations with the national specialty society for emergency medicine.

The cervical-spine X ray guidelines were developed by the Maine Emergency Medicine Advisory Committee. The committee's national specialty society had not developed guidelines for this treatment. The committee had examined the possibility of developing other guidelines in response to a trigger diagnosis (that is, what happens when a diagnosis is missed to prevent a missed diagnosis in the future). However, the committee considered these guidelines to be too complex to be suitable for the initial phase of the demonstration project.

In developing its guidelines, the committee identified as a problem the chasm between administering the guidelines and the clinical realities of practicing emergency medicine. For example, Maine's largest malpractice insurer developed an obstetrics guideline for extrauterine pregnancy and distributed the guideline to the obstetricians and gynecologists it insured. This problem, however, is generally seen by emergency physicians rather than obstetricians, but emergency physicians had not seen the guideline. Although the clinical need to use the guideline was evident to the malpractice insurer, the administrative reality of distributing the information and of educating the physicians who would most likely encounter the clinical situation the guideline addressed had not been properly examined. The Emergency Medicine Committee believes that when guidelines are developed, developing a mechanism for bridging the gap between the clinical demands and the administrative realities of practicing emergency medicine is also important.

Cervical-Spine X Ray Guidelines

The committee, with the help of the state's largest malpractice liability insurer, developed a list of procedures that posed the greatest risk of malpractice claims. Using this information, the committee focused on developing a guideline for a procedure that was done routinely but that

[4]Chapter 22 of the rules of the Maine Board of Registration in Medicine and of the Maine Board of Osteopathic Examination and Registration.

rarely resulted in a useful diagnosis. The committee chose cervical-spine X ray guidelines because they believe medical costs will decline if emergency physicians evaluate the true risk of spinal injury before they order X rays. The committee based this conclusion on recent studies indicating that cervical-spine injuries are easily detectible by emergency physicians in alert acute-trauma patients without other significant painful injuries. Thus, routine cervical-spine X rays are not necessary for these patients.

To reduce the number of unnecessary cervical-spine X rays administered, the guidelines establish criteria to guide emergency physicians in assessing when ordering an X ray is appropriate. According to the guidelines, patients do not need to receive a cervical-spine X ray when (1) they do not complain of cervical-spine pain, (2) they have no localized cervical-spine tenderness, (3) the physician cannot identify any findings of spinal cord or nerve root injury, and (4) the physician can obtain a reliable patient history and physical exam, and these indicators do not imply that an X ray is necessary.

In cases where patients are in pain or cannot provide a reliable medical history, both doctors and patients could be mislead about the true nature of an injury, so the X ray is administered. For example, a person who has both a potential spinal injury and a broken leg might receive a cervical-spine X ray, even if he or she did not describe spinal pain, because the leg wound may mask pain associated with a spinal injury. Thus, a patient must be able to provide a reliable history to be covered by the guidelines and not receive an X ray.

The committee chose cervical-spine X rays despite knowing that to evaluate the guideline's effect on malpractice claims would be difficult. The Co-Chair of the Emergency Medicine Advisory Committee pointed out that no malpractice lawsuits in Maine have alleged an injury resulting from failure to order a cervical-spine X ray because this test is automatically performed on most acute-trauma patients. The committee believed that eliminating excess use of the test will result in reduced health care costs as each test not performed will save about $115.

Patient Transfer Guidelines

The committee developed patient transfer guidelines because they believed that emergency physicians were not sufficiently educated about federal requirements covering patient transfer. The Consolidated Omnibus Budget Reconciliation Act of 1985 required hospitals to treat emergency

patients and all women in active labor, regardless of an individual's ability to pay. The committee was afraid that inappropriate transfer of patients would lead to an increased number of claims if emergency physicians did not follow the federal requirements. Thus, the committee used the guidelines as a tool to educate physicians about these federal requirements. This transfer guideline is the only one in the demonstration project to use a checklist approach. Maine's checklist for transferring patients between hospitals is shown in appendix V.

The Obstetrics and Gynecology Guidelines

Maine's obstetrics and gynecology guidelines[5] are the most extensive of all the guidelines implemented in Maine. The Maine Advisory Committee on Obstetrics and Gynecology developed the guidelines through studies of medical literature, consultation with experts, analysis of national medical malpractice claims data provided by the Physician Insurers Association of America, and recommended standards of the American College of Obstetrics and Gynecology.

The obstetrics/gynecology guidelines cover the following diagnoses:

- caesarean delivery when labor is not progressing normally,
- assessment of fetal maturity before repeat caesarean delivery or elective induction of labor,
- surgical removal of the uterus,
- inhibition of premature labor,
- extrauterine pregnancy,
- infant in other than head-first position during labor,
- herpes simplex virus infections before and after birth,
- fetal distress during delivery, and
- management of prolonged pregnancy.

For the most part, the guidelines selected by the committee are identical to the national standards written by the American College of Obstetricians and Gynecologists. The committee developed its own guidelines for fetal distress, prolonged pregnancy, and for diagnosis of extrauterine pregnancy because the national specialty society had not developed guidelines for these clinical situations.

The guidelines attempt to decrease malpractice claims and to reduce defensive medicine by using all three approaches to change physicians'

[5]Chapter 24 of the rules of the Maine Board of Registration in Medicine and of the Maine Board of Osteopathic Examination and Registration.

behavior—risk management, clinical-practice requirements, and data-collection requirements. For example, the guidelines for caesarean delivery establish risk-management standards that define active labor and the failure to progress. The guidelines also direct physician activities before performing a caesarean delivery and establish who must be notified to assist in the delivery. Finally, they establish what information must be collected for the patient's record.

The committee believed that establishing time frames for the clinical steps that physicians take during the delivery of a baby was a significant accomplishment attributable to the demonstration project. Establishing these time frames in law eliminates a major source of uncertainty for physicians about the legal standard to which they will be held.

The guideline for caesarean sections is also targeted toward the defensive medicine problem. This guideline also may have an impact on health care costs if the number of caesarean sections is reduced because a caesarean section costs from $2,000 to $3,000 more than a vaginal delivery.

The guideline for herpes testing further targets defensive medicine. The committee believed that most pregnant women in Maine were being tested for herpes, although without an evident herpes lesion on the mother at the time of birth, the baby is unlikely to be infected with the virus. The committee believed that this test was wasteful since it does not need to be performed, nor do infected women in an inactive stage of the disease need to have their babies delivered by caesarean in order to prevent infection.

The committee chair stated that the usefulness of the guidelines as an affirmative defense will depend upon physicians' ability to demonstrate compliance with them. While this may require physicians to keep better records, he noted that the committee believed this should also improve the quality of care. As before the project, the patient's record will be critical in reaching a decision on the outcome of a claim.

Since the Maine project began, the committee has adjusted its guidelines to reflect the college's recent changes in the national guidelines. The committee plans to continue to update the guidelines to keep them current with the national standards.

The Radiology Guidelines

Radiology was not included in the original legislation that established the demonstration project. Maine radiologists subsequently asked the Board

of Registration in Medicine for inclusion in the project because they wanted to address the problems they perceived with increasing health care costs and increasing numbers of malpractice claims. Legislation enacted in June 1991 added radiology as a participating specialty in the demonstration project.

The Maine Advisory Committee on Radiology developed guidelines[6] that were based largely on those of the American College of Radiology as well as the committee's review of medical literature, consultation with experts, and analysis of medical malpractice liability claims data. The radiology guidelines primarily use risk-management programs and data-collection requirements. Specifically, Maine's radiology guidelines cover the following areas:

- screening mammography,
- ultrasound to assess fetal development,
- outpatient assessment of blood vessel disorders, and
- examination of the lower intestine.

Although the Maine guidelines were developed from those written by the American College of Radiology, the committee modified them slightly to improve communication between radiologists and referring physicians when a radiological examination indicated a medical condition needing treatment. This improved communication guideline was drawn from the American College's mammography screening guideline, which requires that radiologists report all results classified as high probability to the referring physician in such a manner that the receipt of the result is assured and documented. If a patient self-refers, the guidelines require that high-probability results be communicated to the patient by certified mail and that they indicate the need for further consultation with a physician. The guidelines also require follow-up contact with the patient to determine compliance with follow-up care. This guideline was added to the other radiology guidelines. In addition, the guidelines were changed to reflect where state law already required something not required in the national standards. In Maine, state law requires that state-licensed technologists perform radiology procedures, thus, requiring this in the guidelines was not necessary. The guidelines were also different from the American College's guidelines when the national standards covered both screening and diagnostic procedures. Diagnostic testing should be replaced with screening mammography.

[6]Chapter 26 of the rules of the Maine Board of Registration in Medicine and of the Maine Board of Osteopathic Examination and Registration.

To select the guidelines used in the demonstration project, the committee used malpractice insurer's data to determine where high-cost malpractice cases involving radiology occurred. Prevention of these cases became the committee's focus in developing guidelines. These guidelines are designed to prevent avoidable accidents through risk-management procedures rather than to spell out clinical-practice patterns. The guidelines for a mammography screen, for example, cover the definition of the procedure, its goal, clinical indication for ordering the procedure, frequency of administration, who may perform the procedure, any necessary equipment, the amount of radiation the patient can receive, and the documentation that must be completed for radiology patients.

Mammography Guideline

The mammography guideline was selected to insure proper mammography and data collection. The committee hoped that when radiologists became aware of their own positive statistics for breast biopsies, the number of negative biopsies would decrease. With proper mammography and more awareness of biopsy statistics, the number of suits for missed lesions and the number of biopsies ordered would both hopefully decrease. Not recommending a biopsy will save up to $1,800 in hospital and surgeon fees.

Ultrasound Guideline

The ultrasound guideline was developed to insure complete fetal evaluation. This guideline was intended to improve medical care and to prevent unwarranted malpractice claims, but it is not expected to have an effect on defensive medicine.

Outpatient Assessment of Blood-Vessel Disorders

The guideline covering outpatient examination of blood-vessel disorders, or outpatient angiography, was selected to give physicians the confidence to perform this procedure on an outpatient basis. Doing this procedure on an outpatient basis is relatively new and it saves significant admission and inpatient hospital costs. The committee was also interested in this procedure because a physician in Maine had been in the forefront of the development of guidelines for how and when to perform outpatient angiography.

Examination of the Lower Intestine Guideline

The guideline for examination of the lower intestine (barium enema) was selected because missed colon carcinomas were one of the leading causes of malpractice for radiologists. The colon may be examined with barium

enemas or colonoscopy. Currently, colonoscopy costs from $500 to $600, compared with approximately $200 for a barium enema exam. Colonoscopy is assumed to be 95-percent sensitive and barium enema 90-percent sensitive for detection of colon carcinoma. Colonoscopy carries increased risk and morbidity. Therefore a guideline was developed for barium enemas to assure their maximum sensitivity in detecting colon carcinoma. The committee concluded that if the guideline is followed, the enema would provide the necessary diagnostic data.

Maine Practice Guidelines for Anesthesiology

MAINE PRACTICE GUIDELINES FOR ANESTHESIOLOGY[1]

1. INTRODUCTION:

   A. The Medical Specialty Advisory Committee for Anesthesiology has agreed on a first set of practice parameters. These include: The Anesthesia Record; Standards for Intraoperative Monitoring; Standards for Postoperative Care; and, Preoperative Laboratory Testing for Anesthesia for American Society of Anesthesiologists Class I (ASA I) patients undergoing non-major surgery.

   B. For the most part, these standards are developed from the American Society of Anesthesiologists (ASA) standards and guidelines. However, the adoption of these standards and parameters for use in the Maine Medical Liability Demonstration Project does not imply ASA endorsement or policy, nor have these standards received any form of approval from that body. These standards should be considered unique to the State of Maine.

   C. Practice parameters in Anesthesiology are defined as incorporating standards, guidelines and other patient management strategies that result in high quality of patient care but which also recognize that there is a finite limit of resources available for health care.

   D. These practice parameters, which may be exceeded, apply to all patients who receive anesthesia or monitored anesthesia care. Under extenuating circumstances, it may not be medically appropriate to follow these practice parameters. When this is the case, the circumstances, including the care provided, shall be documented in the record.

2. THE ANESTHESIA RECORD - PRACTICE PARAMETERS FOR DOCUMENTATION OF ANESTHESIA CARE.

   Documentation is a factor in the provision of quality care. The final responsibility for the record rests with the

[1]The guidelines presented in this appendix were reproduced unaltered from Chapter 20 of the rules of the Maine Board of Registration in Medicine and of the Maine Board of Osteopathic Examination and Registration. Effective date: July 28, 1991. (These guidelines do not reflect recent changes recommended by the Anesthesiology Specialty Advisory Committee.)

physician responsible for anesthesia care. Anesthesia is usually viewed as consisting of preanesthesia, perianesthesia, and postanesthesia components. Anesthesia care should be documented to reflect these components and to facilitate review. The anesthetic record should be easily interpreted and use abbreviations that are widely accepted. The record should include documentation of all of the following subsections A through C:

A. Preanesthesia Evaluation

(1) Review of medical record, including:

(a) Pertinent objective diagnostic data (e.g. lab, EKG, chest x-rays.
(b) Old chart review of previous anesthetics when available and pertinent; and,

(2) Patient interview including history of:

(a) Medications
(b) Allergies
(c) Previous anesthetic experiences
(d) Family history of anesthesia problems, and,
(e) Pertinent review of systems;

(3) Physical exam appropriate to anesthesia care and special notation of airway in respect of dentition;

(4) ASA Physical status; and,

(5) Formulation and discussion of an anesthesia plan with the patient and/or responsible adult, including consent to that plan.

B. Perianesthesia

(1) Review immediately prior to initiation of anesthetic procedure:

(a) Record
(b) Patient reevaluation
(c) Check of equipment, drugs, and gas supply

(2) Monitoring of the patient as described in monitoring standards Section 3, following.

(3) Comment on airway management

(4) Amounts of all drugs and agents used, and times given

(5) Patient position and protection

(6) Management of fluids

(a) IV fluids used including blood products
(b) Estimated blood loss
(c) Urine output when appropriate

(7) The technique(s) used

(8) Unusual events during the anesthesia period

(9) The status of the patient at the conclusion of anesthesia

C. Postanesthesia.

(1) Patient evaluation on admission and discharge from the postanesthesia care unit.

(2) A time based record of vital signs and level of consciousness.

(3) All drugs administered and their dosages.

(4) Type and amount of intravenous fluids administered including blood and blood products.

(5) Any unusual events including postanesthesia or post-procedural complications.

(6) Medical interventions.

3. ANESTHESIA[2] STANDARDS FOR BASIC INTRAOPERATIVE MONITORING.

These standards apply to all anesthesia care (although, in emergency circumstances, appropriate life support measures take precedence). These standards may be exceeded at any time based on the judgment of the responsible anesthesiologist. These standards are intended to encourage high quality patient care, but observing them may not guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and

[2]Within these standards, "Anesthesia" is defined as all types of anesthesia care unless otherwise specified by the text.

practice. This set of standards addresses only the issue of basic intraoperative monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, (1) some of these methods of monitoring may be clinically impractical and (2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual[3] monitoring may be unavoidable. Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (*). When this is done, it shall be stated (including the reasons) in a note in the patient's anesthetic record. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

A. STANDARD: Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

OBJECTIVE: Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, (e.g., radiation) to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

B. STANDARD: During all anesthetics, the patient's oxygenation, ventilation, and circulation shall be continually evaluated (i.e., repeated, regularly and frequently...).

(1) OXYGENATION

[3]As used in these protocols, "continual" and "continually" are defined as "repeated, regularly and frequently, in steady, rapid succession," whereas "continuous" means "prolonged, without any interruption at any time."

OBJECTIVE: To ensure adequate oxygen concentration in the inspired gas of the blood.

METHODS:

(a) Anesthesia machines capable of delivering less than 18% oxygen shall not be in use.

(b) Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*

(c) Blood oxygenation: A quantitative method of assessing oxygenation such as pulse oximetry shall be employed.* Adequate illumination and exposure of the patient is necessary to assess color.*

(2) VENTILATION

OBJECTIVE: To ensure adequate ventilation of the patient.

METHODS:

(a) Every patient receiving general anesthesia shall have the adequacy of ventilation continually[4] evaluated. While qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds may be adequate, quantitative monitoring of the C02 content and/or volume of expired gas is encouraged.

(b) When an endotracheal tube is inserted, its correct position in the trachea must be verified by clinical assessment and end-tidal C02 analysis.*

[4]As used in these protocols, "continual" and "continually" are defined as "repeated, regularly and frequently, in steady, rapid succession," whereas "continuous" means "prolonged, without any interruption at any time."

(c) Ongoing evaluation of mechanical ventilation must be assessed by any or all of the following: (i) Clinical assessment; (ii) capnometry; (iii) mechanical tidal volume and rate measurement.

(d) When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.

(e) During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs.

(3) CIRCULATION

OBJECTIVE: To ensure the adequacy of the patient's circulatory function during all anesthetics.

METHODS:

(a) Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*

(b) Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*

(c) Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intraarterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

(4) DISCRETIONARY PHYSIOLOGIC MONITORS

(a) Body Temperature

OBJECTIVE: to aid in the maintenance of appropriate body temperature during all anesthetics.

METHODS: There shall be readily available a means to continuously measure the patient's temperature. When changes in body temperature are intended, anticipated or suspected, the temperature shall be measured.

4. STANDARDS FOR POSTANESTHESIA CARE.

These standards apply to postanesthesia care in all locations. These standards do not apply to Obstetric Epidural Analgesia or Pain Management. These standards may be exceeded based on the judgment of the responsible anesthesiologist. They are intended to encourage high quality patient care, but cannot guarantee any specific patient outcome. Extenuating circumstances may require deviation from the standard, but a note in the patient's record concerning any deviation, shall be made in a timely fashion. These standards are subject to revision from time to time, as warranted by the evolution of technology and practice.

A. STANDARDS: All patients who have received general anesthesia, regional anesthesia, or monitored anesthesia care shall receive appropriate postanesthesia management.

(1) A Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care shall be available to receive patients after surgery and anesthesia. All patients who receive anesthesia shall be admitted to the PACU, except by specific order of the anesthesiologist(s) responsible for the patient's care.

(2) The medical aspects of care in the PACU shall be governed by policies and procedures which have been reviewed and approved by the Department of Anesthesiology.

(3) The design, equipment and staffing of the PACU shall meet requirements of the facility's accrediting and licensing bodies.

(4) The nursing standards of practice shall be consistent with those approved in 1986 by the American Society of Post Anesthesia Nurses (ASPAN).

B. STANDARD: patient transported to the PACU shall be accompanied by a member of the Anesthesia Care Team who is knowledgeable about the patient's condition. The patient shall be continually evaluated (i.e., repeated regularly and frequently) and treated during transport with

monitoring and support appropriate to the patient's condition.

C. STANDARD: Upon arrival in the PACU, the patient shall be reevaluated and a verbal report provided to the responsible PACU nurse by the member of the Anesthesia Care Team who accompanies the patient.

(1) The patient's status on arrival in the PACU shall be documented.

(2) Information concerning the preoperative condition and the surgical/anesthetic course shall be transmitted to the PACU nurse.

(3) The member of the Anesthesia Care Team shall remain in the PACU until the PACU nurse accepts responsibility for the nursing care of the patient.

D. STANDARD: The patient's condition shall be evaluated continually in the PACU.

(1) The patient shall be observed and monitored by methods appropriate to the patient's medical condition. Particular attention should be given to monitoring oxygenation, ventilation and circulation. During recovery a quantitative method of assessing oxygenation, such as pulse oximetry, shall be employed.

(2) An accurate written report of the PACU period shall be maintained.

(3) General medical supervision and coordination of patient care in the PACU should be the responsibility of an anesthesiologist.

(4) There shall be a physician in the facility capable of managing complications and providing cardiopulmonary resuscitation for patients in the PACU.

E. STANDARD: physician is responsible for the discharge of the patient from the Postanesthesia Care Unit.

(1) When discharge criteria are used, they must be approved by the Department of Anesthesiology. They may vary, depending upon whether the patient is discharged to a hospital room, to the ICU, to a short stay unit, or home.

(2) In the absence of the physician responsible for the discharge, the PACU nurse shall determine that the patient meets the discharge criteria. The name of the physician accepting responsibility for discharge shall be noted in the record.

5. PREOPERATIVE LABORATORY TESTING

This parameter applies only to American Society of Anesthesiologists Patient Acuity Classification I (ASA I). The ASA has established patient acuity classifications I - VI. These reflect the medical status of the patient prior to the surgery. As such, they represent a combination of both acute and chronic diseases. They do not reflect the magnitude of the proposed surgery. They are not age dependent.

ASA Classification I is a healthy patient with no underlying systemic diseases.

ASA Classifications II-VI represent patients with increasing severity of medical disease. As these standards for preoperative testing criteria only apply to patients in ASA I classification, these ASA Classifications II-VI are not described.

A. STANDARD: ANESTHESIA PREOPERATIVE TESTING

SURGICAL PROCEDURE: excludes extensive major body cavity, expected significant (e.g., 10%) blood loss or extensive manipulation of physiological variables (i.e., induced hypotension).

TABLE 1: PREOPERATIVE TESTS TO BE PERFORMED ACCORDING TO AGE AND OTHER PATIENT ATTRIBUTES.

Column Headings have the following meanings: Sp/Epi = Spinal/Epidural; MAC = Monitored Anesthesia Care; P. BLK = Peripheral Block (i.e., Axillary, etc.); I.V. Blk = Bier

Attribute	General.	Sp/Epi.	MAC	P. Blk.	IV Blk.	Local
			Age 0-6 months			
Both sexes	Hct.	Hct.	NA	NA	NA	NA
Tested within	1 mos.	1 mos.				
			6 months - 14 years			
Both sexes	NA	NA	NA	NA	NA	NA
			Age 14 - Menopause			
Female	Hct.	Hct.	NA	NA	NA	NA
Tested within	6 mos.	6 mos.				
			Age 15 - 50			
Male	NA	NA	NA	NA	NA	NA
			Age Menopause - 50 years			
Female	NA	NA	NA	NA	NA	NA
			Age 50 - 60 years			
Both	Hct.	Hct.	Hct.	NA	NA	NA
Tested within	6 mos.	6 mos.	6 mos.			
Both sexes	EKG	EKG				

Attribute	General.	Sp/Epi.	MAC	P. Blk.	IV Blk.	Local
Tested within	1 yr.	1 yr.				
Both sexes	BUN/Gluc	BUN/Gluc				
Tested within	6 mos.	6 mos.				
			Age Over 60 years			
Both sexes	Hct.	Hct.	Hct.	Hct.		
Tested within	6 mos.	6 mos.	6 mos.	6 mos.		
Test	CXR	CXR	EKG	NA	NA	NA
Tested within	1 yr.	1 yr.	1 yr.			
Test	NA	NA	Bun/Gluc.	NA	NA	NA
Tested within			6 mos.			

As well as the above testing, for ASA Classification I patients, regardless of sex or age, who are undergoing procedures with potential for significant blood loss (i.e., 10%), the minimum testing is a Hematocrit within two weeks with type and screening of blood products.

B. CRITERIA FOR ANESTHETIC PREOPERATIVE TESTING CRITERIA

(1) Each patient will have an appropriate preoperative history and physical examination prior to the proposed surgery.

(2) These preoperative parameters only apply to the anesthetic management of the patient. The surgical management of the patient may require additional testing, although frequently there will be overlap.

(3) These parameters only apply to elective surgery.

(4) These parameters do NOT apply to those patients who are going to have:

(a) Surgery involving extensive major body cavity procedures;
(b) Surgery with anticipated major blood loss; and/or

(c) Surgery requiring extensive manipulation of physiological variables.

(5) These parameters do NOT apply to those patients who have developed an acute process in addition to or separate from the surgical process necessitating the operation.

(6) Duplicate data is acceptable, provided it meets the following criteria:

(a) The name of the physician (clinic/office) managing the patient's disease;
(b) The location of the practice if not in the immediate vicinity;
(c) At least a verbal report, which may come from the patient if the patient is felt to be a reliable historian, of any indicated tests. (Hard copy is preferred); and
(d) The approximate date of the test.

(7) The anesthetic preoperative evaluation and testing is directed towards developing the appropriate anesthetic care plan. It is not the equivalent of or a substitute for an annual physical examination or other similar screening process.

Maine Practice Guidelines for Emergency Medicine

MAINE PRACTICE GUIDELINES FOR EMERGENCY MEDICINE[1]

1. INTRODUCTION: The Medical Specialty Advisory Committee on Emergency Medicine has developed the following Practice Parameters/Risk Management Protocols for use by participating emergency practitioners in the state of Maine.

In so doing, the definition of Practice Parameters adopted by the American Medical Association has been accepted:

> Practice parameters are strategies of patient management, developed to assist physicians in clinical decision-making. Practice parameters include standards, guidelines, and other patient management strategies. Standards are accepted principles for patient management. Guidelines are recommendations for patient management which identify a particular management strategy or a range of management strategies. Other strategies for patient management include practice policies and practice options.

It is the opinion of the committee that these Practice Parameters, so defined and developed, comply with the requirements for both Practice Parameters and Risk Management Protocols as required by the Medical Liability Demonstration Project. Extenuating circumstances may require deviation from the standard, but a note in the patient's record concerning any deviation, shall be made in a timely fashion.

2. STANDARD: CERVICAL SPINE X-RAYS FOR ACUTE TRAUMA PATIENTS

Recent studies and critical review of earlier literature, reveal that truly asymptomatic Cervical-spine injuries do not occur in alert patients without other significant painful injuries. Therefore, routine Cervical-spine x-rays and immobilization are not indicated for these patients.

A. Criteria for not Obtaining Cervical Spine X-rays.

Significant cervical spine injury is assumed not to be present and Cervical-spine X-rays are not mandatory for trauma patients who meet all of the following criteria:

[1]The guidelines presented in this appendix were reproduced unaltered from Chapter 22 of the rules of the Maine Board of Registration in Medicine and of the Maine Board of Osteopathic Examination and Registration. Effective date: July 28, 1991.

(1) No complaint of cervical spine pain;

(2) No localized cervical spine tenderness by palpation;

(3) No subjective or objective findings of spinal cord or nerve root injury;

(a) Subjective: Weakness or paresthesia
(b) Objective: Motor or sensory deficit; and,

(4) Have a reliable history and physical exam and appropriate response (i.e., appropriate response from patient).

B. Obtaining Cervical-Spine X-Rays

(1) When x-rays of the cervical spine are deemed necessary, adequate lateral films, which demonstrate all seven cervical vertebrae, should be obtained with the patient's neck immobilized. A swimmer's view may be required to see all seven cervical vertebrae.

(2) After clearing the lateral view, AP and odontoid views may be obtained. Immobilization should be continued if clinically indicated.

(3) If plain films are unsatisfactory, or are negative but the clinical suspicion of a c-spine injury remains, additional films and/or CT scan may be indicated.

C. Discharge Instructions: When the emergency medical practitioner determines that a patient may be discharged, written instructions must be documented on the Emergency Department Medical Record and signed by the patient. The instructions should include all of the following, as appropriate:

(1) Specific advice regarding recommended treatment and/or medications relating to the patient's clinical problem;

(2) Information about follow-up, if needed, which includes the name of an appropriate physician and/or clinic and a suggested time period in which the patient should be seen; and,

(3) Instructions to call or return to the Emergency Department if symptoms progress or if the patient encounters difficulty in implementing the suggested follow-up plans.

3. STANDARD: TRANSFER OF PATIENT TO OTHER HOSPITALS.

A. The Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) as amended sets forth federal guidelines and provides civil penalties for noncompliance in the matter of improper transfer of patients between hospitals.

B. The COBRA defines "Emergency Medical Condition" and "Stabilized Condition" as follows:

(1) Emergency Medical Condition: A condition which manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

(a) placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; or,

(b) serious impairment to bodily functions, or

(c) serious dysfunction of any bodily organ or part.

(d) there is inadequate time to effect a safe transfer to another hospital before delivery, or

(e) a threat to the health or safety of the woman or the unborn child if transfer is initiated while a patient is in active labor (i.e., patient is having contractions).

(2) Stabilized Condition: A patient's condition has been stabilized if no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility. A patient in active labor has been stabilized if she has delivered (including the placenta).

C. Figure 1, "CHECK LIST FOR TRANSFER OF PATIENTS TO OTHER HOSPITALS" is the model adopted for use in Maine Hospital Emergency Departments of a form at which should be used to insure compliance with COBRA in effecting inter-hospital transfer of patients. This format may be reproduced locally or modified to incorporate administrative or demographic data required by individual facilities.

Figure 1. CHECK LIST FOR TRANSFER OF PATIENTS TO OTHER HOSPITALS

SENDING HOSPITAL: _____

NAME: _____ DATE: _____

RECEIVING HOSPITAL: _____

RECEIVING PHYSICIAN: _____

RECEIVING HOSPITAL ADMIN REPRESENTATIVE: _____

Y	No	1.	Patient stabilized. (if unstable reason documented on chart.)
Y	NA	2.	Reasons for and the risks/benefits of transfer explained to the patient/family and documented on chart.
Y	No	3.	Patient/guardian signed Transfer Consent forms.
Y	NA		a. Patient unable to sign.
Y	NA		b. No guardian present.
Y	NA	4.	Contact made with the accepting physician, case reviewed, the physician accepts the patient.
Y	NA	5.	Receiving institution administrative representative accepts patient.
Y	NA	6.	Notified the receiving nurse of the patient's condition and transport arrangements.
Y	NA	7.	Arranged appropriate transportation.
Y	NA	8.	The necessary trained personnel will accompany the patient with appropriate equipment, including:
Y	NA		a. medical personnel qualified to handle the existing condition and anticipated problems.
Y	NA		b. appropriate IV access.
Y	NA		c. appropriate airway management.
Y	NA		d. appropriate medications.
Y	NA		e. orders regarding monitoring Vital Signs and Medical Control.
Y	NA	9.	The patient's stability was reassessed immediately prior to transfer. Unstable patients should only be transferred when the hospital lacks the capability to stabilize the patient.

Y NA 10. All appropriate, if available, medical records, including the completed Emergency Department chart, X-ray, Lab, and EKG reports are to accompany the patient or be faxed to the facility.

Y NA 11. Care of the patient should be formally accepted by appropriate medical personnel at the receiving facility.

*WHENEVER NO/NA CIRCLED, DOCUMENT WHY IN THE PATIENT'S RECORD.

PHYSICIAN'S SIGNATURE: _____

Maine Practice Guidelines for Obstetrics and Gynecology

MAINE PRACTICE GUIDELINES FOR
OBSTETRICS AND GYNECOLOGY[1]

INTRODUCTION: Ten practice parameters/risk management protocols have been adopted as of the effective date of these Rules as follows:

1. Procedure: Cesarean Delivery for Failure to Progress
2. Procedure: Assessment of Fetal Maturity prior to repeat Cesarean delivery or elective induction of labor
3. Procedure: Hysterectomy, abdominal (68.4) or vaginal (68.5)
4. Procedure: Hysterectomy, abdominal (68.4) or vaginal (68.5)
5. Treatment: Tocolysis
6. Condition: Presumed Ectopic Pregnancy in a clinically stable patient
7. Condition: Singleton Breech Presentation
8. Condition: Perinatal Herpes Simplex Virus Infections
9. Condition: Intrapartum Fetal Distress
10. Topic: Antepartum Management of Prolonged Pregnancy

Each is set forth individually in the following pages.

Extenuating circumstances may require deviation from the standards. A note in the patient's medical record describing the deviation and the reason therefore must be made in a timely manner.

1. PROCEDURE: Cesarean Delivery for Failure to Progress (74 all; subcode dependent on which type of procedure is used)

[1] The guidelines presented in this appendix were reproduced unaltered from Chapter 24 of the rules of the Maine Board of Registration in Medicine and of the Maine Board of Osteopathic Examination and Registration. Effective date: July 28, 1991. (These guidelines do not reflect the recent changes recommended by the Obstetrics and Gynecology Specialty Advisory Committee.)

A. Indication: Lack of progress (failure to progress) (600.61-failed trial of labor; 662.11-long labor)
Confirmation of Indication:

(1) No change in either dilation of cervix or descent of presenting part after at least 2 hours of active labor.

(2) Active labor indicated by:

(a) Cervix dilated to at least 3 cm in nullipara or 4 cm in multipara;
(b) Contractions at least every 2-3 minutes;
(c) Strength of contractions at least 50 mm Hg internal pressure as measured by intrauterine catheter or inability to indent fundus on palpation at height of contraction.

B. Prior to Cesarean delivery for failure to progress, the following measures should be taken but not necessarily in the order listed:

(1) Rupture membranes.

(2) In absence of active labor, administer oxytocin to augment labor.

(3) Hydrate patient.

(4) Obtain anesthesia consultation and evaluation.

(5) Ensure that qualified personnel[2] are in attendance for resuscitation and care of newborn.

(6) Informed consent.

(7) Fetal Heart Rate prior to surgery, and

(8) Vaginal examination prior to surgery.

(Reference: Quality Assurance in Obstetrics & Gynecology-1989 ed.)

2. PROCEDURE: Assessment of Fetal Maturity prior to repeat Cesarean delivery or elective induction of labor.

[2]To be determined in writing by each institution.

A. Indication: To prevent fetal pulmonary immaturity and to determine the appropriate time of elective C-section or elective induction of labor.

Confirm the indication by the presence of one or more of the following four criteria:

(1) Clinical Criteria needed to confirm a term gestation are:

(a) Fetal heart tones have been demonstrated for at least 18 completed weeks by nonelectronic fetoscope or at least 25 completed weeks by Doppler ultrasound; and
(b) Appropriate uterine size was established by pelvic examination prior to 16 weeks of gestation.

(2) Ultrasound determinations needed to confirm a term gestation:

(a) Gestational age based on the measurement of crown-rump length obtained between 6-12 weeks of gestation; or
(b) Other ultrasound confirmation of gestational age was obtained before 24 weeks of gestation.

(3) If these criteria are not met, amniotic fluid analysis by a recognized test may provide satisfactory evidence of fetal lung maturity; or

(4) The onset of spontaneous labor.

(References: ACOG Tech. Bulletin #110, ACOG Committee Opinion #77 and Harvard Medical Institutional Clinical Standard #11.)

3. PROCEDURE: Hysterectomy, abdominal (68.4) or vaginal (68.5)

A. Indication: Leiomyomata (218.0-218.9)

Confirm the indication by the presence of one or more of the following:

(1) Asymptomatic myomata associated with a uterine size equal to or larger than that after 12 weeks

gestation,[3] determined by physical examination or ultrasound examination.

TABLE 1

UTERINE SIZE AND WEIGHT

Type of Uterus	Size (cm)	Weight (g)
Normal Uterus		
Nulliparous	5	70
Multiparous	6	75-125
Enlarged Uterus (gestational age)		
8 weeks	6	125-150
12 weeks	8	280-320
24 weeks	18	580-620
Term		1,000-1,100

(2) Excessive uterine bleeding evidenced by either a or b:

(a) Bleeding for more than 8 days during more than a single cycle and profuse bleeding (i.e., large clots, gushes, limitations on activity) requiring additional protection;
(b) Anemia due to acute or chronic blood loss.

(3) Chronic pelvic pain for 6 months or longer with a negative effect on patient's quality of life.

(4) Rapid growth in size of uterus/myomata, to a point equal to or larger than that after 12 weeks gestation.

B. Actions Prior to Procedure:

(1) Confirm by cytologic study the absence of cervical pathology. No malignancy found.

(2) Obtain endometrial sample or perform D&C (when abnormal bleeding is present).

[3]Transverse measurement of at least 8 cm or weight of 280 g or more (see Table 1) (included).

(3) Document and attempt to correct anemia if present.

(4) Offer autologous blood donation if appropriate.

(5) Document patient education and informed consent.

C. Contraindication:

(1) Desire to maintain fertility.

(References: Quality Assurance in Obstetrics & Gynecology-1989 ed.)

4. PROCEDURE: Hysterectomy, abdominal (68.4) or vaginal (68.5)

A. Indication: Abnormal uterine bleeding in women of reproductive age (626 all, except 626.0, 626.1, 626.3, 626.7)[4]

Confirmation of indications, all of which must exist:

(1) History of all of the following:

(a) Either or both excessive uterine bleeding and irregular uterine bleeding defined as bleeding for more than 8 days during more than a single cycle and profuse bleeding requiring additional protection; (e.g., large clots, gushes, limitations on activity).
(b) No history of a bleeding diathesis or use of medication that may cause bleeding;
(c) Negative effect on patient's quality of life.

(2) Failure to find, on physical examination, uterine or cervical pathology that would cause abnormal bleeding.

(3) Laboratory data

(a) No finding of endometrial neoplasia;
(b) No malignancy found in cytological studies of cervix;

(4) No finding of endometrial polyps by D&C, hysteroscopy, or hysterogram.

[4]Other diagnoses that should also be evaluated according to these criteria include menorrhagia (626.2, 627.0), hypermenorrhea (626.2).

B. Actions Prior to Procedure:

(1) Determine that attempted hormone treatment (estrogen-progestogen) was not successful or contraindicated or refused;

(2) Hemoglobin or hematocrit documented;

(3) Document and attempt to correct anemia if present;

(4) Offer autologous blood donation if appropriate; and

(5) Document patient education and informed consent.

C. Contraindication:

1. Desire to maintain fertility.

(Reference: Quality Assurance in Obstetrics & Gynecology-1989 ed.)

5. TREATMENT: Tocolysis

A. Indication: Preterm Labor; confirm the indication by (1) and (2), and either (3) or (4):

(1) Gestational age between 20 and 37 weeks confirmed by dates or ultrasound;

(2) Frequent, regular uterine contractions preferably documented by a tocodynomometer;

(3) Documented progressive change in the cervix;

(4) Cervical dilation greater than 2 cm and effacement greater than 80%.

B. Actions Prior to Treatment:

(1) Between 34 and 37 weeks gestation an individual treatment plan is required.

(2) For patient less than 34 weeks:

(a) Document historical risk factors which may include:
(1) Previous preterm labor or delivery;
(2) Pyelonephritis;
(3) Heavy smoking;
(4) Hypertension;

(5) Uterine anomaly;
(6) Age less than 16 or greater than 40 years;
(7) Overdistension of the uterus;

(b) Bedrest;
(c) Adequate hydration;
(d) Documented fetal heart rate and uterine activity monitoring;
(e) Ultrasound to confirm date and rule out anomalies;
(f) Pelvic examine to confirm cervical status;
(g) Laboratory studies including:
(1) CBC;
(2) Urine for culture and sensitivity; and
(3) Group B beta hemolytic strep culture or rapid identification test;
(h) Consider amniocentesis in afebrile patient.

C. Management:

(1) Use of specific drugs should be by individual preference and/or by institutional policies and protocols.

(2) Tocolysis should be instituted if contractions persist for greater than 1 hour or there is documented cervical change.

(3) Appropriate monitoring during tocolysis may include any or all of the following:

(a) Pulmonary status;
(b) Cardiovascular status;
(c) Glucose;
(d) Clotting factors;

(4) Discharge instructions should include:

(a) Instructions regarding early signs of labor;
(b) Early follow-up appointment.

D. Contraindications:

Absolute	Relative
1. Severe hypertension	1. Advanced labor
2. Fetal compromise	2. Cardiac disease
3. Chorioamnionitis	3. Mild hypertension
4. Severe abruption	4. Hyperthyroidism
5. Severe IUGR	5. Diabetes mellitus

6. Lethal fetal anomaly	6. Mild abruption
7. Severe uterine bleeding	7. Mild IUGR
	8. Fetal anomaly
	9. Stable placenta previa

(References: Precis IV; An Update in Obstetrics and Gynecology; Quality Assurance in Obstetrics and Gynecology; The American College of Obstetricians and Gynecologists UNICORN; Guidelines for Obstetrical Care, University of Connecticut Regional Network.)

6. CONDITION: Presumed Ectopic Pregnancy in a clinically stable patient

A. Confirmation of Diagnosis:

(1) Documented history consistent with the diagnosis of ectopic pregnancy, including any of the following:

(a) Pelvic pain;
(b) Abnormal uterine bleeding;
(c) Risk factors such as previous ectopic, PID, tubal surgery, or IUD usage;
(d) Characteristic menstrual history.

(2) Documented physical findings consistent with the diagnosis ectopic pregnancy, including any of the following:

(a) Pelvic tenderness;
(b) Pelvic mass;
(c) Uterine characteristics consistent with pregnancy.

(3) Documented laboratory findings consistent with the diagnosis of ectopic pregnancy, including any of the following:

(a) Positive pregnancy test;
(b) Ultrasound findings consistent with pregnancy test results.

B. Management of a Clinically Stable Patient:

(1) Ultrasound

(a) Assume an intrauterine pregnancy if a fetal sack is visualized in the uterine cavity;
(b) If no fetal sack is visualized then:
    (1) Obtain a baseline quantitative serum bHCG;
    (2) Advise patient of warning signs of ectopic pregnancy;
    (3) Repeat bHCG every 48-72 hours looking for doubling;

        (a) If value doubles every 48 hours, repeat ultrasound until an IUP is confirmed;
        (b) If doubling does not occur, ectopic or nonviable IUP should be suspected and management depends on the clinical and laboratory evaluations:

            (1) Consult and/or referral to a specialist should be considered;
            (2) Recommend serial studies until diagnosis is confirmed;
            (3) Falling bHCG levels can be successfully followed without surgical intervention, provided the patient remains hemodynamically stable and has no other findings that prompt surgical intervention;
            (4) Consider hospital vs outpatient observation.

(2) Document consideration of laparoscopy or laparotomy if intrauterine pregnancy is unlikely based on this evaluation.

(3) Laparoscopy or laparotomy is indicated with any of the following:

    (a) Increasing symptoms;
    (b) Developing mass;
    (c) Suggestive ultrasound;
    (d) High index of suspicion.

(4) Follow-up care

    (a) bHCG should be monitored weekly until serum level is negative (should occur within 8 weeks);
    (b) Low dose prophylaxis, (Microgram), should be considered in an Rh-patient.

(References: Precis IV: An Update in Obstetrics and Gynecology, Gynecology Section, Medical Specialty Advisory Committee, Maine Demonstration Project)

7. CONDITION: Singleton Breech Presentation

A. When the presence of a breech presentation is identified, the patient may be offered the option of external version with the risks being discussed.

B. Cesarean section is currently the most common method for delivery in breech presentation unless delivery is imminent.

C. When a vaginal breech delivery is considered, the physician should inform patient as to which method of delivery is considered best on the basis of the clinical situation and the circumstances of support facilities and personnel.

D. Facilities should include the capability of emergency Cesarean section.

E. The physician must have experience with vaginal breech delivery.

F. Anesthesia personnel should be present for delivery.

G. Presentation should be that of a frank breech. Any other presentation requires further evaluation.

H. The fetal weight should be estimated at less than 4,000 gm.

I. Hyperextension or macrocephaly should be ruled out by clinical examination or appropriate diagnostic imaging.

J. Pelvic size should be adequate and is usually determined by pelvimetry, clinically and/or radiographically.

K. There should be adequate progression of labor in dilation, effacement and descent.

L. Intravenous lines along with facilities for maternal surgery and transfusion should be in place.

M. Fetal heart monitoring is required.

N. Local, pudendal, regional and general anesthesia are all used in breech presentation deliveries.

0. Parity does not effect the route of delivery.

(References: ACOG Technical Bulletin #95 - August, 1986; Precis IV, An Update in Obstetrics and Gynecology: pp 150-151, 1990; Clinical Standards for Obstetrics Services of Harvard Medical Institutions: #19)

8. CONDITION: Perinatal Herpes Simplex Virus Infections

A. Confirmation of Diagnosis:

(1) Characteristic visible lesions;
(2) Immunofluorescent test or culture if either is available.

B. Management:

(1) If there are no visible lesions at the onset of labor, vaginal delivery is acceptable.

(2) Weekly surveillance cultures of pregnant women with a history of HSV infection, but no visible lesions, are not necessary and vaginal delivery is acceptable.

(3) Amniocentesis in an attempt to rule out intrauterine infection is not recommended for mothers with HSV infection at any stage of gestation.

(4) Term patients who have visible lesions and are in labor or who have ruptured membranes should undergo Cesarean delivery.

(5) For patients with active HSV infections and premature rupture of membranes remote from term, there is not enough data to recommend a management protocol that would apply in all clinical situations. The risk of extreme prematurity must be weighed against the risk of neonatal HSV infection. The patient should be encouraged to take an active role in this decision.

(6) Monitoring by fetal scalp electrode is not contraindicated if needed to adequately assess the fetal condition in women with a history of HSV infection but without lesions or symptoms.

(7) Every effort should be made to avoid direct contact with herpetic lesions by the newborn.

(8) Mothers with visible HSV infections should be allowed to breast-feed, providing there are no visible lesions in the regions of the breasts and she has been counseled regarding the possibility of spreading the virus by direct contact.

(Reference: ACOG Technical Bulletin #122 - November 1988)

9. CONDITION: Intrapartum Fetal Distress

A. Introduction:

The goal of Intrapartum Fetal Heart Rate (FHR) Monitoring is to detect signs that warn of potential adverse fetal events in time to permit intervention. Another way to state this is that intrapartum fetal heart rate monitoring tries to identify fetal distress in its early stages. While fetal distress is a widely used term, it is poorly defined in the medical literature. This document defines fetal distress, using a combination of national medical literature and local (State of Maine) definitions.

B. Definitions:

(1) Variable deceleration: Decreases in FHR from the baseline rate that are non-uniform periodic changes that bear little relationship to uterine contractions. Onset may come at any phase of the contraction, and the wave form is usually different from that of the uterine contraction.

(2) Severe variable deceleration FHR of less than 70 beats per minute (b.p.m.) that persists longer than 60 seconds duration.

(3) Persistent severe variable deceleration: Severe variable decelerations that persist for longer than 30 minutes.

(4) Late deceleration: Decrease in FHR from the baseline rate with a lag time of greater than 20 seconds from the peak of the contraction to the nadir of FHR deceleration.

(5) Persistent and nonremediable late deceleration: Late decelerations that do not respond to the usual obstetrical interventions and occur repeatedly over a 10-15 minute time period.

(6) Severe bradycardia: FHR less than 80 b.p.m.

(7) Persistent severe bradycardia: Severe bradycardia that persists for longer than 5 minutes.

C. Confirmation of Diagnosis. For a diagnosis of fetal distress to be made, one or more of the following must be present:

(1) Persistent severe variable deceleration.
(2) Persistent and nonremediable late decelerations.
(3) Persistent severe bradycardia.

D. The following actions should have been performed and documented prior to expediting delivery for fetal distress:

(1) Reposition patient.

(2) Administer oxygen by mask.

(3) Perform vaginal examination to check for prolapsed cord; and

(4) Ensure that qualified personnel are in attendance for resuscitation and care of the newborn.[5]

E. Each of the following actions should be performed and documented prior to starting a Cesarean section for fetal distress:

(1) Perform vaginal exam to rule out imminent vaginal delivery;

(2) Initiate preoperative routines;

(3) Monitor fetal heart tones (by continuous fetal monitoring or by auscultation) immediately prior to preparation of the abdomen; and

(4) Ensure that qualified personnel are in attendance for resuscitation and care of the newborn.[6]

[5]Each institution shall define in writing the term qualified personnel for resuscitation and care of the newborn.

[6]Each institution shall define in writing the term qualified personnel for resuscitation and care of the newborn.

F. When a diagnosis of fetal distress is made, consideration should be given to performing:

(1) Umbilical cord acid-base studies;

(2) Pathologic examination of the placenta.

References:

(1) ACOG Technical Bulletin: Intrapartum Fetal Heart Rate Monitoring. #132 - September 1989.

(2) Quality Assurance in Obstetrics and Gynecology: ACOG Obstetrical Criteria Status, Cesarean Delivery for Fetal Distress. May 1989, p. 23.

(3) Danforth's Obstetrics and Gynecology 6th Edition. Chapter 16 Clinical Evaluation of Fetal Status. Intrapartum Fetal Monitoring, pp. 319-327 c. 1990.

(4) Obstetric, Neonatal, and Gynecologic Care (A Practical Approach for the Indian Health Service) 5th Edition, 1989.

(5) Manual of Obstetrics, Diagnosis and Therapy: 3rd edition, Chapter 24, Fetal Heart Rate Monitoring, pp. 301-314.

(6) Parer and Livingston, What Is Fetal Distress: AM. J. OBSTET. GYNECOL, 1990; 162: 1421-7.

(7) Classification of Fetal Patterns from Dr. Albert D. Haverhamp, M.D.: City and County of Denver, Department of Health and Hospitals: Handout for House Officers, 1979.

(8) Obstetrical Pearls: A Practical Guide For the Efficient Resident, Care of the Laboring Patient, Fetal Monitoring pp. 45-50. c.1989.

10. CONDITION: Antepartum Management of Prolonged Pregnancy

A. Introduction:

The accurate determination of the time of conception is extremely important in reducing the false diagnosis of post-term pregnancy and in precisely ascertaining the point at which a pregnancy becomes high risk. The expected date of confinement (EDC) is most reliably and accurately determined early in pregnancy. Consistency between historical and physical data is important in establishing the reliability of dating.

B. Definitions:

(1) Prolonged Pregnancy is pregnancy that lasts greater than 287 days (41 completed weeks) from the first day of the last menstrual period.

(2) Post-term Pregnancy is a pregnancy that lasts greater than 294 days (42 completed weeks) from the first day of the last menstrual period.

(3) Criteria for confirming gestational age should include 2 of the following in addition to a complete menstrual history.

(a) Fetal heart tones have been documented by 20 weeks gestation by non-electronic fetoscope or by 13 weeks gestation by electronic fetoscope;
(b) Uterine size has been established by pelvic examination, prior to 16 weeks of gestation;
(c) A positive serum or urine human chorionic gonadotropin (hCG) pregnancy test was done and recorded 6 weeks after the last normal menstrual period;
(d) Ultrasound:
(1) Measurement based on the "crown-rump length" obtained between 6 and 12 weeks of gestation, or
(2) Measurement based on the "biparietal diameter" obtained between 14 and 26 weeks of gestation.

(4) Gestational age cannot be accurately determined by using the criteria in (3) above if the patient presents at 22 weeks gestation or later.

C. Action:

(1) At 41 weeks gestation (plus or minus 2 days), the patient should have a nonstress test (NST). If reactive, the practitioner may elect to continue to follow the pregnancy.

(2) Between 41-42 weeks gestation, the patient should have an ultrasound to evaluate adequacy of amniotic fluid. Results of the ultrasound need to be available within 24 hours. If determined to be adequate, the practitioner may elect to continue to follow the pregnancy.

(3) Between 42-43 weeks gestation, the patient should have two (2) nonstress tests (NST) performed. The first should be performed approximately one (1) week after the nonstress test at 41 weeks gestation and the second should be performed three to four (3-4) days after the first. If reactive, the practitioner may elect to continue to follow the pregnancy.

(4) Ultrasound evaluation of the adequacy of amniotic fluid should be completed at weekly intervals after the initial ultrasound completed at 41-42 weeks. Results of the ultrasound need to be available within 24 hours. If determined to be adequate, the practitioner may elect to continue to follow the pregnancy.

(5) If possible, ultrasound exams performed at 41 weeks gestation and beyond should contain a report on the estimated fetal weight.

(6) At 43 weeks gestation, the patient should be delivered.

(7) Contraction stress tests (CST) can be substituted for nonstress tests (NST) in the above actions.

(8) Biophysical profiles can be substituted for ultrasound exams in the above actions.

D. Contraindications to the Proceeding Protocol. Patients with any of the following diagnoses/problems should have individual treatment plans:

1. Gestational Diabetes.
2. Hypertension in Pregnancy.
3. Macrosomic Infant.
4. Intrauterine Growth Retardation.
5. Previous History of Fetal Demise; or,
6. Fetus with uncertain gestational age and/or prenatal care starting at or after 22 weeks gestation.

References:

(1) ACOG Technical Bulletin, Number 130, July 1989, pp. 1-4.

(2) Clinical Standards for the Obstetrical Services of the Harvard Medical Institutions, Dec. 1, 1988.

(3) Guidelines for Perinatal Care, 2nd ed., (Evanston, Illinois: American Academy of Pediatrics/American College of Obstetricians and Gynecologists, 1988). As adapted by the Advisory Committee on Obstetrics and Gynecology Practice Parameters and Protocols.

(4) Eastern Maine Medical Center Family Practice Residency Program Protocol for the Prevention and Management of Postdates Pregnancy, January 1990.

Maine Practice Guidelines for Radiology

MAINE PRACTICE GUIDELINES FOR RADIOLOGY[1]

1. INTRODUCTION: The Medical Specialty Advisory Committee on Radiology has developed the following Practice Parameters/Risk Management Protocols for use by participating radiological practitioners in the State of Maine.

   In so doing, the definition of Practice Parameters of the American Medical Association has been adopted and applies to all the parameters and guidelines set forth here:

   > Practice parameters are strategies of patient management, developed to assist physicians in clinical decision-making. Practice parameters include standards, guidelines, and other patient management strategies. Standards are accepted principles for patient management. Guidelines are recommendations for patient management which identify a particular management strategy or a range of management strategies. Other strategies for patient management include practice policies and practice options.

   It is the opinion of the committee that these practice parameters, so defined and developed, define principles of practice which should generally produce high quality radiological care. The radiologist may exceed an existing standard as determined by the individual patient and available resources. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the radiologist in light of all circumstances presented by the individual situation. Adherence to these standards will not assure successful outcome in every situation. It is prudent to document the rationale for any deviation from these standards in the patient's radiology record.

   Four practice parameters have been adopted as of the effective date of these rules, as follows:

   1. Screening Mammography
   2. Antepartum Ultrasound
   3. Outpatient Angiography

[1]The guidelines presented in this appendix were reproduced unaltered from Chapter 26 of the rules of the Maine Board of Registration in Medicine and of the Maine Board of Osteopathic Examination and Registration. Effective date: November 26, 1991.

4. Performance of Adult Barium Enema Examination.

2. STANDARD: PERFORMANCE OF SCREENING MAMMOGRAPHY

Periodic mammography screening of asymptomatic women has been shown to reduce breast cancer mortality. Screening mammography is one area in which diagnostic radiology services can contribute positively to improve overall patient care. The principles for mammography do not basically differ from those applicable to other radiological examinations. Key points to be considered are the criteria for credentialing professionals, equipment specifications, monitoring and maintenance schedules, standards for image quality, standardized image evaluation procedures, meticulous record keeping and periodic review of data for outcomes of the mammography services when feasible.

A. Definition: "Screening mammography" means an effort to detect unsuspected breast cancer at an early stage in asymptomatic women.

(1) Intent: separate women into groups with low and high probability of breast cancer.

(a) Most screened women can be assured no significant abnormalities exist.
(b) The remainder of the screened women will be informed that abnormality exists which must be investigated further.

(2) Exam: ordinarily limited to craniocaudal and mediolateral oblique views of each breast.

(a) Supplementary views may be needed but should not be done routinely.

(3) If breast physical examination is not available at screening site, women should be informed that physical examination is a complementary and necessary procedure.

B. Goal: Produce the optimum, reproducible quality image at the minimum radiation dose necessary to give adequate image information.

C. Indication: (1) asymptomatic women at least 40 years of age; (2) Women younger than 40 years who present with high risk factors.

D. Frequency: (1) every one to two years between 40 and 49 years of age, with same frequency if screening initiated prior to 40 years; (2) every year after 50 years of age.

E. Qualifications of Personnel

(1) Physician:

(a) Certification or eligibility for certification by the American Board of Radiology or American Osteopathic Board of Radiology, and
(b) Interpret mammograms on a regular basis. Physician should interpret or review minimum of 480 mammograms per year, recognizing that this number may not be achievable in low population areas, and
(c) Continuing Medical Education: initially should have 40 hours of CME credits in mammography, and thereafter 15 hours CME credits every three (3) years.

(2) Radiological Physicist:

(a) Certification by American Board of Radiology in Radiological Physics or American Board of Medical Physics in Diagnostic Radiological Physics recommended.

(3) Radiological Technologist:

(a) State licensure required, and
(b) Perform mammography on a regular basis, and
(c) Be competent in breast positioning and compression, and knowledgeable concerning technical factors, radiation safety, radiation protection, and quality control, and
(d) Should receive continual supervision on image quality from interpreting physician.

F. Equipment Requirements

(1) Designed especially for mammography with a compression device and removable grid.

(2) Precise Specifications

(a) Low energy beam to produce high subject contrast, and

(b) Compression device to improve contrast, minimize radiographic scatter, produce uniform density, and reduce dose and subject motion, and
(c) Film-screen mammography focal spot size 0.3 mm preferable, and
(d) Focal-object distance should be 50 cm or more, and
(e) A dedicated film processor with developer time and temperature setup specifically for the film being used is preferable for film-screen mammography.

G. Radiation Dose: The average glandular dose will be measured at least annually.

(1) For examination of a 4.5 cm thick, compressed breast, consisting of 50% glandular and 50% adipose tissue, the dose will be no more than 0.35 Rad per exposure.

H. Quality Control Program: Documented QC program with procedure manuals and logs.

(1) Technologists' Checks: darkroom cleanliness, processor quality control, screen cleanliness, view boxes and viewing conditions, phantom images, visual check list, repeat analysis, analysis of fixer retention in film, darkroom fog, screen-film, darkroom fog, screen-film contact, compression.

(2) Physicists' Checks: cassette holder assembly evaluation, collimation assessment, focal spot size measurement, Kvp accuracy/reproducibility, beam quality assessment (half value layer measurement), automatic exposure control (AEC) System performance assessment, uniformity of screen, breast entrance exposure and average glandular doses.

(3) Professional Quality Assurance Program

(a) Systems for reviewing outcome data will be established. Included will be:

(i) disposition of positive mammograms,
(ii) correlations of surgical biopsy results with mammogram reports whenever possible.

It is understood that in some practice situations it will not be possible to obtain follow-up information on all positive mammograms.

I. Mammography Report: Definitive diagnosis is usually not rendered, although in some instances a highly suspicious abnormality may be identified which will warrant a recommendation for biopsy.

(1) The report should include:

(a) Description of abnormalities detected, and
(b) Recommendations for subsequent follow-up studies when appropriate, and
(c) Comparison to prior mammograms when practical.

(2) Render report as soon as reasonably possible.

(3) All reports in high probability category should be communicated to the referring physician or his designated representative in such a manner that receipt of the report is assured and documented.

J. Film Retention: Original mammograms shall be retained by a facility or made available to the patient or her designee for a period of at least five (5) years.

K. Self-Referral: Direct access by individuals is permissible without requiring physician referral in advance.
(1) Facilities must have well-developed notification procedures for the patient and her physician, or procedures for referral to a licensed physician who has agreed to accept such patients.

(a) Self-referred (i.e., those women who have no referring physician) patients should be notified of the results of the screening by mail.
(b) Reports in high probability category should be communicated to the patient by certified mail; and,

(i) should indicate need for further consultation with a physician; and,
(ii) follow-up contact with patient or the physician should be made to determine compliance with follow-up care.

L. Free Standing and Mobile Settings

(1) Screening mammography may take place in nontraditional radiology settings where there may not be a physician in attendance.

(2) Mammography offered must follow all of the previously mentioned guidelines with strict adherence to documented protocols.

3. STANDARD: ANTEPARTUM ULTRASOUND

A. Introduction: These guidelines have been developed for use by practitioners performing obstetrical ultrasound studies. In some cases, specialized and/or additional studies may be necessary. While it is not possible to detect all structural congenital anomalies with diagnostic ultrasound, adherence to the following guidelines will maximize the possibility of detecting many fetal abnormalities. A limited examination is acceptable in clinical emergencies but any limited examinations should be documented as such in the medical record.

B. Equipment: The following ultrasound probes are recommended:

(1) Transabdominal scanning: 3 to 5 mHz transducer (probe). For obese patients, 2 to 2.25 mHz transducers may be used;

(2) Transvaginal scanning: 5 mHz or higher transducer.

C. Method: Real time scanning with as low a power setting as possible to obtain the necessary diagnostic information is to be used.

D. Documentation: A record of the examination including a permanent record of the ultrasound images and written report are to be included in the patient's medical record. Any limitation or exclusion of images should be documented in the written report or supplement.

(1) Images to be recorded are outlined in F below as the minimum to be included as part of the record. In cases where an abnormality is suspected, additional images should be recorded if the images more clearly demonstrate the area of suspicion.

(2) Images should be labelled with patient name, date, and site examination. Orientation of the scan may be included if this more clearly demonstrates an abnormal or normal area.

E. Communication

(1) A written report of the findings should be available to the referring physician within a reasonable time period. This period of time is defined under the following principles with the realization that certain findings may require immediate clinical attention.

(a) Any results which mandate immediate intervention or treatment by the responsible physician necessitate direct and immediate verbal communication between the radiologist and the responsible physician.
(b) Findings of a less urgent nature may be communicated by indirect means such as mail, recorded messages, computer printouts, or FAX. In every instance, the time taken to transfer information shall not unreasonably delay treatment of a condition suspected by antepartum obstetrical ultrasound.

(2) Any limitations of the examination should be described with follow-up studies suggested when appropriate.

F. Examination protocols

(1) First trimester (The following parameters should be included as a minimum to be analyzed and recorded as part of a standard antepartum obstetrical ultrasound examination. Any abnormalities should be included on the recorded filmed images and be included in the radiology report.)

(a) Gestational sac analysis (to be used when no fetal pole is visualized)

(i) location of sac within uterus
(ii) measurement of sac for estimate of mean sac diameter
(iii) the presence or absence of a yolk sac

(b) Embryo/fetal pole analysis

(i) crown/rump length measurement to be used when visualized for fetal gestational age until the biparietal diameter can be accurately measured
(ii) biparietal diameter to be used for fetal gestational age in late stages of first trimester when accurate measurement is possible.

(iii) number of embryos present

(c) Fetal viability documentation - The viability of the fetus should be confirmed by real time observation of fetal heart motion. (In general, heart motion can be seen at 7 weeks with transabdominal scanning at 6 weeks with transvaginal scanning.)

(d) Uterine/adnexal analysis includes documenting the following:

(i) uterine wall abnormalities
(ii) cervical abnormalities
(iii) adnexal abnormalities

(2) Second and third trimesters

(a) Fetal viability documentation - Real time observation of fetal cardiac activity and/or fetal motion is necessary for confirmation of viability. Abnormalities of fetal heart rate/rhythm are to be reported.
(b) Fetal presentation/lie - Images and report to document fetal position.
(c) Fetal number - if a multiple gestation is present, the following information should be documented:

(i) amniotic membranes (if present)
(ii) number and location of placenta (-ae)
(iii) fetal size comparison
(iv) fetal gender (if visualized)

(d) Estimate of amniotic fluid volume (increased, decreased, or normal) should be reported.
(e) Analysis of fetal anatomy includes, but should not be limited to, the following:

(i) Abnormalities should be documented on filmed images and reported in the radiology report.
(ii) Analysis of the following regions will detect many structural congenital abnormalities but additional or specialized studies may be necessary. Areas include:
1. cerebral ventricles
2. posterior fossa

3. fetal spine
4. heart
5. stomach
6. renal regions
7. umbilical cord insertion
8. abdominal wall
9. bladder, and
10. limbs.

(f) Analysis of the placenta includes the following:

(i) location and position relative to the internal cervical os
(ii) appearance

(g) Analysis of the umbilical cord includes the following:

(i) establishing the presence of a three vessel cord if stage of development allows (i.e. early second trimester examinations may be limited as small cord size might not allow for visualization)

(h) Uterine/adnexal evaluation includes documenting the following:

(i) uterine wall abnormalities
(ii) cervical abnormalities
(iii) adnexal abnormalities

G. Assessment of gestational age - In general the most accurate age is based on the earliest study. Gestational age determination from subsequent ultrasound examinations should be compared to the initial ultrasound gestational age.

(1) First trimester gestational age is to be determined by:

(a) mean gestational sac diameter (when no fetal pole is visualized)
(b) crown/rump length (when fetal pole is visualized)
(c) biparietal diameter (when accurate measurement is possible in later stages of first trimester)

(2) Second trimester gestational age assessment includes:

(a) age is calculated by head circumference measurement/biparietal diameter and femur length using standard tables.

(3) Third trimester gestational age assessment includes:

(a) age is calculated by measurement of biparietal diameter/head circumference, femur length and abdominal circumference using standard tables.

H. Growth parameters -- For analysis of appropriate fetal growth, the following growth parameters are to be measured and compared to standard tables and, when available, earlier ultrasound examinations.

(1) Second trimester growth parameters including:

(a) biparietal diameter
(b) circumference
(c) femur length

(2) Third trimester growth parameters measured and compared to standard tables including:

(a) estimate of fetal weight
(b) analysis of abdominal circumference (comparison with head circumference and/or standard tables may allow the detection of growth retardation).
(c) biparietal diameter
(d) head circumference
(e) femur length

4. STANDARD: OUTPATIENT ANGIOGRAPHY.

A. Output angiography is now considered safe and feasible for many patients if appropriate precautions are taken. This represents significant cost savings as well as greater convenience for patients and health care providers.

(1) Definition of Outpatient Angiographic Procedures. The following procedures can be considered for outpatient angiographic study:

Abdominal aortography
Peripheral (runoff) arteriography
Thoracic aortography
Renal and mesenteric arteriography
Head and Neck arteriography
Selective extremity arteriography

Pulmonary arteriography
Selective catheter venographic studies (i.e., renal venography, gonadal venography, and testicular vein embolization)
Other angiographic studies may be considered for outpatient procedures if deemed medically appropriate

(2) Patient Selection. Patients considered as candidates for outpatient angiographic procedures should meet the following criteria:

(a) A medical history should be available, including indications for procedure, list of current medication, allergies, and prior relevant surgical procedures.
(b) The patient must have arrangements made for transportation home, preferably with a family member or a neighbor, rather than by taxi or in the company of someone unfamiliar with the patient. Due to medications administered during the procedures, it is necessary that the patient not transport himself/herself home, and
(c) The patient or family member should be able to arrange for the patient's care after the procedure; i.e., due to sedation used during the angiographic procedure, the patient should not be left unattended. If the patient lives alone, it is preferable for a family member or neighbor to attend the patient for at least 8 hours after the time of discharge, and
(d) The patient's mental status should be intact; confused or impaired patients should be strongly considered for an impatient procedure unless careful arrangements can be made for close observation post-procedure.

B. Relative Contra-Indications to Outpatient Angiography

Patients with any of the following are considered at increased risk for outpatient angiography and an impatient procedure may be indicated:

(1) Poorly controlled hypertension (i.e., diastolic pressure greater than 100 mm/Hg) as these patients have a higher incidence of hematoma and bleeding complications at groin puncture sites.

(2) Abnormal renal function because of the potential for further deterioration of renal function after exposure to contrast media.

(3) Abnormal coagulation parameters, electrolyte abnormalities or significant anemias.

(4) Advanced age (greater than 75 years) because of the potential for increased complications. Older patients may be considered appropriate candidates for outpatient angiographic procedures, but only after careful scrutiny of the other criteria. If there are no other significant organ system abnormalities and the patient has a responsible adult available for observed care post-procedure, outpatient angiography may be appropriate.

(5) When observation by a responsible adult cannot be satisfactorily arranged post-discharge from the outpatient procedure.

(6) Travel time greater than one hour from the outpatient angiographic facility; these patients may be studied on an outpatient basis but should be encouraged to arrange an overnight stay close to the facility or nearby hospital to allow for prompt management of delayed complications should they occur.

(7) Diabetics are not necessarily excluded from outpatient procedures; however, caution should be taken to insure that their renal function is normal, that they are satisfactorily hydrated prior to and post-procedure, and that appropriate arrangements for insulin management are made prior to the procedure.

C. Patient Care

The following are offered as minimal guidelines for patient care related to outpatient angiographic procedures. Regardless of the setting, all angiographic procedures should conform to usual and accepted techniques.

(1) Preprocedure Care

(a) The clinical history should be reviewed by the physician to insure that the indications for the study are appropriate. Prior angiographic and other pertinent radiographic studies should be reviewed. In patients undergoing peripheral

vascular evaluation, initial assessment with non-invasive studies with recording of ankle and brachial pressures is recommended.

(b) List of current medications should be available; the patients should be encouraged to bring their medications with them.

(c) Appropriately documented informed consent should be obtained.

(d) Initial assessment should include recording of vital signs, assessment of peripheral pulses and review of laboratory parameters.

(e) Laboratory evaluation may be appropriate as medically indicated and this may include hemoglobin, hematocrit, creatinine, electrolytes and coagulation parameters.

D. Procedure Care

(1) All arteriographic patients who are at high risk should have cardiac monitoring throughout the procedure.

(2) All arteriographic patients should have intravenous access maintained throughout the procedure for administration of medications and fluid resuscitation.

E. Post-procedure Care

(1) Patients with arterial catheterization should be monitored for a minimum of four hours after the procedure. All patients should have post-procedure monitoring of vital signs, assessment of puncture site and distal pulses. Patients undergoing head and neck arteriography also should have monitoring of neurologic function. Monitoring should be increased to six hours in patients with hypertension, or those with a hematoma post-procedure.

(2) Assessment prior to discharge should include evaluation of puncture site, distal pulses and vital signs. Vital signs and pulses should be unchanged from the time of admission; any significant change precludes discharge. The patient should be evaluated by the angiographer or designated nurse/technologist prior to discharge. The patient should be ambulated and the puncture site checked for bleeding and hematoma prior to discharge.

(3) A physician should be available to handle patient problems or questions for 24 hours post-procedure.

(4) Access to impatient care should be available for patients who have unexpected complications or require further procedures at the completion of the angiographic study.

F. Communication

(1) Any results which mandate immediate intervention or treatment by the responsible physician necessitate direct and immediate verbal communication between the radiologist and the responsible physician. This should be documented.

(2) Reporting of less urgent findings may be communicated by indirect means such as mail, recorded messages, computer print outs or FAX. In every instance the time it takes to transfer information shall not unreasonably delay the treatment of a condition specifically diagnosed on the angiogram. The report should be documented in the X-ray record.

G. Indications for Admission

The decision to admit a patient after an outpatient angiographic procedure is at the discretion of the physician. The following should be considered as indications for admission.

(1) Complication resulting from the angiographic procedure including any significant change in pulse in the affected extremity, neurologic changes, persistent bleeding, or persistent nausea and vomiting post-procedure; or

(2) Significant findings on diagnostic angiography warranting further therapy that would necessitate inpatient admission is also a reasonable indication for admission; or

(3) Admission at the time of the study is encouraged if problems are suspected or arise.

H. The Angiographic Facility

(1) The highest possible quality imaging equipment should be available for all outpatient angiography

procedures. This should include high resolution image intensifier, television chain and standard arteriographic filming capabilities to include rapid serial films of at least 14 inches in diameter. Digital subtraction capabilities are highly desirable as they allow decreased contrast volumes and less cardiovascular disturbances during angiography.

(2) There must be adequate facilities for cardiac monitoring and for cardiac resuscitation.

(3) Every angiographic facility should have the appropriately trained personnel to provide proper patient care and operation of the equipment.

I. Quality Improvement

Outpatient procedures should be monitored as part of the overall quality improvement program of the facility. Incidence of complications and unexpected admissions should be recorded and periodically reviewed for the opportunity to improve care. The incidence of delayed admission (i.e., admissions that become necessary after discharge from the outpatient facility) should be less than 2% for problems or complications related to angiography. This data should be collected in a manner which complies with statutory and regulatory peer review procedures in order to protect the confidentiality of the peer review data.

5. STANDARD: PERFORMANCE OF ADULT BARIUM ENEMA EXAMINATIONS.-

A. INTRODUCTION: Examination of the colon by barium enema procedure of proven efficacy. The goal of the radiologic examination is to establish the presence and nature of disease by producing the optimum quality study at the minimum radiation dose necessary. The following standard is for performance of the barium enema in adult patients.

B. INDICATIONS: The indications for barium enema examination include, but are not limited to, suspected neoplasms, diverticular disease and inflammatory bowel disease. However, the barium enema may be helpful in diagnosing almost all disease states intrinsically or extrinsically affecting the colon. History and symptoms serving as indications for the barium enema examination include abdominal pain, diarrhea, constipation, bleeding, anemia, abdominal masses, intestinal obstruction, fever or sepsis, and history of previous neoplasm.

C. PHYSICIAN QUALIFICATIONS: Examinations must be performed by or under the direct supervision of a licensed physician at the site. The physician should have the following qualifications:

(1) The physician shall have spent a minimum of three months in documented formal training in the performance and interpretation of gastrointestinal fluoroscopy in an approved residency training program, and

(2) The physician shall have documented training and understanding of the physics of diagnostic radiology, and the equipment needed to produce the images. This should include conventional plain film radiology, tomography, fluoroscopy, film-screen combinations, conventional and digital image processing, and the processing and development of films. In addition, the physician must be familiar with the principles of radiation protection, the hazards of radiation exposure to both patient and radiographic personnel, and the monitoring requirements.

Certification by the American Board of Radiology or American Osteopathic Board of Radiology is considered proof of adequate physician training.

D. RADIOLOGICAL TECHNOLOGISTS: Full state licensure is required. Qualifications for technologists performing gastrointestinal radiography should be in compliance with existing operating procedures or manuals at the imaging facility and in compliance with the current ACR policy statement that fluoroscopy by a technologist is limited to a positioning or localizing procedure.

E. EQUIPMENT AND QUALITY CONTROL

(1) Examinations should be performed with fluoroscopic and radiographic equipment meeting all applicable federal and state radiation standards.

(2) Each imaging facility should have documented policies and operations for monitoring and evaluating the effective management, safety, and operation of imaging equipment. The quality control program should be designed to minimize patient, personnel and public radiation risks and maximize the quality of the diagnostic information.

(3) At least annually, equipment performance should be monitored and a quantitative dose determinations should be conducted by a qualified medical radiation physicist.

(4) There should be review of the standards for equipment and radiation safety that are currently recognized by such national organizations as the National Council on Radiation Protection (NCRP), the National Electrical Manufacturers Association (NEMA), the American Association of Physicists n Medicine (AAPM), the American College of Medical Physicists (ACMP) or other appropriate federal and state regulatory bodies.

F. COLON PREPARATION: The preparation should consist of any effective combination of dietary restriction, hydration, osmotic laxatives, contact laxatives and cleansing enemas. This should result in a colon which is free of fecal material and excess fluid. In certain clinical situations, preparation may be limited or omitted.

G. EXAMINATION PRELIMINARIES

(1) An appropriate medical history should be available.

(2) The barium enema tip should be inserted by a physician; or a radiological technologist, or a professional nurse trained in enema tip insertion. A retention cuff may be used. It should be inflated carefully.

H. EXAMINATION TECHNIQUE: The following examination descriptions may be modified by the physician to produce examinations of equal or greater quality. The physician should modify any or all parts of the examination as warranted by clinical circumstances and the condition of the patient.

(1) Single-contrast examination: The following is presented as an example of the single-contrast examination.

(a) Barium suspension of approximately 15-20% weight/volume.
(b) Kilovoltage of 100 KVP or greater (depending on the patient's size) during filming.
(c) Manual or mechanical compression of all accessible segments of the colon during fluoroscopy.

(d) Spot films should demonstrate all segments of the colon in profile which are not visualized on overhead films.
(e) overhead films to include frontal and oblique views of the entire filled colon, an angled-beam view of the sigmoid colon, and a lateral view of the rectum.
(f) A post-evacuation film is recommended.
(g) The quality controls specific to this study are:

(i) Each accessible segment of the colon is seen in compression during fluoroscopy, and
(ii) Each segment of the entire colon is seen without overlap, and
(iii) Radiographic technique should ensure radiographic penetration of all segments of the barium filled colon.

(2) Double-contrast Examination. The following is presented as an example of the double-contrast examination:

(a) High density (80% weight/volume or greater) barium suspension commercially prepared specifically for this examination.
(b) Kilovoltage of 90 KVP or greater (depending on the patient's size).
(c) Barium suspension and room air (or carbon dioxide) are introduced under fluoroscopic control to achieve adequate coating and distention of the entire colon. Intravenous or intramuscular glucagon may be administered to facilitate bowel distention and patient comfort.
(d) The colon should be examined fluoroscopically during the course of the examination.
(e) Some combination of films should be taken to demonstrate all of the segments of the colon in double-contrast. A suggested list of possible views would include the following:

(i) Spot films of the rectum, sigmoid colon, flexures and cecum in double-contrast.
(ii) Large format films including prone and supine views of the entire colon, an angled view of the sigmoid colon and a lateral view of the rectum.

(iii) Both lateral decubitus views of the entire colon using a horizontal beam (a wedge filter is recommended.)

(f) The quality controls specific to the double-contrast study are:

(i) Complete barium coating of the entire colon has been achieved, and
(ii) The colon is well distended with gas, and
(iii) Each segment of the colon is seen in double-contrast on at least two films taken in different positions.

I. BARIUM ENEMA QUALITY CONTROLS. The following quality controls should be applied to all barium enema examinations:

(1) When examinations are completed, patients should be held in the fluoroscopic area until films have been checked by the physician.

(2) Poorly exposed or positioned films should be repeated as necessary.

(3) An attempt should be made to resolve questionable radiologic findings before the patient leaves. Repeated fluoroscopy of the patient should be performed as necessary.

(4) Where sufficient follow-up information can be obtained, the following is suggested for a quality control program:

(a) Correlate radiological, endoscopic and pathologic findings where available.

J. QUALITY IMPROVEMENT

(1) Procedures should be systematically monitored and evaluated as part of the overall quality improvement of the facility. Monitoring should include the evaluation of the accuracy of radiologic interpretations as well as the appropriateness of the examination.

(2) Incidence of complications and adverse events should be recorded and periodically reviewed in order to identify opportunities to improve patient care. The

data should be collected in a manner which complies with statutory and regulatory peer review procedures in order to protect the confidentiality of the peer review data.

K. BARIUM ENEMA REPORT: The report should describe the nature, number and location of or extent of lesions in the colon. Any limitations of the radiologic examination should be described and additional studies should be suggested when appropriate.

L. COMMUNICATION WITH REFERRING PHYSICIAN:

(1) Any results which mandate immediate intervention or treatment by the responsible physician necessitate direct and immediate verbal communication between the radiologist and the responsible physician. This should be documented.

(2) Findings of less urgent nature may be communicated by indirect means such as mail, recorded messages, computer printouts or FAX. In every instance the time it takes to transfer information shall not unreasonably delay the treatment of a condition diagnosed on the barium enema exam.

Other State and Federal Efforts to Develop Practice Guidelines

In addition to Maine, three states—Florida, Minnesota, and Vermont—are developing programs that will allow physicians to use practice guidelines in some form as a legal defense in a malpractice case. Further, the Agency for Health Care Policy and Research, which reports to the Secretary of the Department of Health and Human Services, is also developing national practice guidelines. These programs are described briefly below.

Florida

Part of Florida's 1992 health care reform law requires the state Agency for Health Care Administration to develop practice guidelines that physicians can voluntarily use as protection against medical malpractice claims. The agency is committed to adopting 50 guidelines by the end of 1993. The agency plans to adopt standards already developed by national specialty societies or by the federal Agency for Health Care Policy and Research. Specifically, Florida is looking first at areas of high medical utilization and high cost, such as guidelines for using imaging technology, radiation treatment, and rehabilitation, in order to reduce health care costs. The state agency is also looking at ways that it could develop and adopt Florida-specific guidelines. The agency is working with the medical community in Florida to adopt guidelines, partially in order to gain physicians' support for the project.

Minnesota

Part of Minnesota's 1992 health care reform legislation allows the Minnesota Health Care Commissioner to approve and disseminate practice guidelines to use as an absolute defense against malpractice claims. The guidelines may be used in malpractice cases for claims arising on or after August 1, 1993, or 90 days after the Commissioner of Health approves the guidelines, whichever is later. As of June 1993, no guidelines had been approved.

Vermont

Vermont's health care reform legislation of 1992 will allow state-sanctioned practice guidelines to be used as the standard of care in malpractice cases. The Vermont Health Care Authority will designate one or more organizations to make recommendations on practice guidelines. The reform is expected to be implemented in October 1994.

Agency for Health Care Policy and Research

The Agency for Health Care Policy and Research was established by the Omnibus Reconciliation Act of 1989 with a mission to "improve the quality, appropriateness, and effectiveness of health care, and to improve access to health care services." The Office of the Forum for Quality and

Effectiveness in Health Care within the agency was assigned the responsibly of developing and disseminating practice guidelines, quality standards, performance measures, and medical review criteria.

The Agency for Health Care Policy and Research is attempting to address two problems through the development of practice guidelines: high-cost medical procedures that lead to high expenditures for Medicare and procedures that have been demonstrated to be practiced with high variation across the country. As of September 1993, the agency had developed six practice guidelines for use in the medical setting.[1] The agency hopes to adopt 10 more guidelines over the next year.

[1](1) Acute Pain Management: Operative or Medical Procedures and Trauma, (2) Urinary Incontinence in Adults, (3) Pressure Ulcers in Adults: Prediction and Prevention, (4) Sickle Cell Disease, (5) Management of Functional Impairment Due to Cataract in Adults, and (6) Diagnosis and Treatment of Depressed Outpatients in Primary Care Settings.

Officials GAO Interviewed

Brian K. Atchinson
Superintendent, Bureau of
Insurance
Maine Department of
Professional and Financial
Regulation

Pamela P. Bensen, M.D., FACEP
Co-Chair/Secretary
Medical Specialty Advisory
Committee on Emergency Medicine

Theodore Briggs
Executive Director
Medical Mutual Insurance
Company of Maine

Richard C. Chandler, M.D.,
FACEP
Co-Chair, Medical Specialty
Advisory Committee on Emergency
Medicine

Edward David, M.D., J.D.
Chairman
Maine Board of Registration in
Medicine

John S. Dexter, Jr.
President
Maine Chamber of Commerce &
Industry

Richard M.M. Flowerdew, M.B., B.S.
Chair, Medical Specialty
Advisory Committee on
Anesthesiology

N. Paul Gauvreau
Maine State Senator (former)*

*Co-sponsor of the Maine Medical Liability Demonstration Project.

Charles K. Grimes, M.D.
Member, Medical Specialty
Advisory Committee on
Radiology

Barbara Luke, M.D.
Chair, Medical Specialty
Advisory Committee on
Radiology

Barbara A. Leonard, M.P.H.
Assistant Director
Maine Ambulatory Care Coalition

John B. Makin, M.D.
Chair, Medical Specialty
Advisory Committee on
Obstetrics and Gynecology

Daniel L. Meyer, Ph.D.
Director of Research
Maine-Dartmouth Family Practice
Residency

Christopher D. Nyan, Esq.
Oversight Committee of Medical
Liability Demonstration Project

Representative Charlene Rydell*
Maine House of Representatives

Gordon Smith, Esq.
Legal Counsel
Maine Medical Association

Robert Stolt
Maine Trial Lawyers'
Association

*Co-sponsor of the Maine Medical Liability Demonstration Project.

Major Contributors to This Report

Human Resources Division, Washington, D.C.

Sarah F. Jaggar, Director, Health Financing and Policy Issues, (202) 512-7119
Susan D. Kladiva, Assistant Director
William J. Schuyler, Evaluator-in-Charge
Patricia A. Davis, Senior Social Science Analyst

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20884-6015

or visit:

Room 1000
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (301) 258-4066.

PRINTED ON RECYCLED PAPER

United States
General Accounting Office
Washington, D.C. 20548

Official Business
Penalty for Private Use $300

First-Class Mail
Postage & Fees Paid
GAO
Permit No. G100