

accident in 1999. The main funding agency is the central government. Research covers a broad range of subjects from an international comparative policy study and a study on reporting systems to research on intra-hospital safety management systems. The Japanese government's newly developed strategic plan for patient safety confirms the importance attributed to this research.

2. Public concern for medical accidents/errors

a. To what extent are medical accidents/errors getting public concern in your country?

It has been very huge since the serious medical accident happened at the hospital of Yokohama City University.

Japan has recently become the fourth country to develop a nationwide strategy for patient safety, following the US, Australia, and the UK. The Japanese Council for Patient Safety, established by the Ministry of Health, Labour, and Welfare (MHLW) and composed of health and media specialists and patient representatives, issued a widely publicized report on April 17, 2002, "Preventing Medical Accidents."ⁱⁱ The report, outlined in Table 1 below, will guide government policy and influence the entire health care sector.

Like the US and UK, Japan's attention was drawn to the problem of medical safety in large part because of highly publicized incidents of tragic medical error, followed after some delay by government reports and action. In January 1999, a patient mixup at a reputable institution, Yokohama Metropolitan University Hospital, led to heart surgery on a lung patient and lung surgery on a heart patient.ⁱⁱⁱ Several similar accidents followed, duly reported on the front pages. Just as the 1994 Dana Farber accident in Boston and other similar incidents helped trigger medical safety concerns among Americans, and unusually high mortality in infant cardiac surgery at the Royal Infirmary of Bristol roused intense national attention to quality of care in Britain, so the Yokohama incident spurred public concern about safety in the delivery of health care in Japan.

b. Is the number of lawsuit against medical accident increasing?

Yes, it has been increasing. According to the data of the Supreme Court, there were 356 new cases about medical accidents in 1991. And there were 767 cases in 2000. It seems to be the trend of increasing of the lawsuit of medical accident.

c. Is the industry interested in patient safety?

Many industries seem to be interested in preventive errors in health care. However, there has not been any specific action for preventive errors yet.

3. Impact of IOM report

Is a report from the Institute of Medicine in the U.S., "To Err is Human", published in November 2000 known in your country? And if so, did it have influence?

Yes.

To continue the international parallel, the 1999 report "To Err Is Human" could be considered the basis for strategic planning in the US. Strategic planning for patient safety was formulated in 2000 in the UK in a report titled "Organization with Memory." In Australia, the work of the Council for Safety and Quality in Health Care led to a strategic plan called "Safety First," also published in 2000. "Preventing Medical Accidents" is the Japanese analogue to those strategic plans for patient safety.

Many stakeholders have been interested in the IOM report. Ministry of Health, Labor and Welfare (MoHLW) cited this report in its ground design for patient safety policy. Japan Nursing Association refers to the importance of impact of this report.

B. Action by Stakeholders

1. Government action toward medical accidents/errors and patient safety

Is there a governmental policy especially for medical accidents?

Yes. MoHLW is now making a draft plan for patient safety that is called the ground design for Japanese patient safety. And it has funded to make a research about patient safety. And MoHLW started to the pilot study of near miss reporting system.

(See the attachment for more details of government activities for patient safety.)

Prior to the Yokohama Metropolitan University incident, there were no specific government activities for the prevention of medical accidents except the existence of a general policy to improve quality of health care. After the publicity surrounding the Yokohama incident, MHLW formed a committee which found that there is an urgent need for improvement of patient safety in teaching hospitals. In a similar vein, many other stakeholders also commenced activities for patient safety. The National Hospital Group consisting of 229 government hospitals also developed a manual for prevention of medical accidents.

In the year 2000, most government efforts regarding patient safety targeted advanced treatment and central government hospitals, rather than the bulk of private hospitals.^{iv} A government plan for patient safety on advanced treatment hospitals was implemented in April of that year, with four components: (1) guidelines for patient safety, (2) within-hospital reporting systems, (3) establishment of committees for patient safety, and (4) training for employees. Central government hospitals also produced a risk management standards manual in September 2000.

In 2001 MHLW and related research entities underwent a partial organizational shakeup. The Division for Patient Safety Promotion was established within MHLW. The Division of Safety Science was created in the Department of Policy Sciences at the National Institute of Public

Health to provide MHLW with technical assistance. The Japanese Council for Patient Safety, described above, was launched to promote safety measures and to formulate a long-term integrated strategic plan for patient safety. This council consisted of a broad range of specialists, and focused on the promotion of actual patient safety measurement such as reporting of medical errors, educational training for patient safety, reporting and amelioration of problems with drugs and medical devices. Finally, a nationwide campaign for patient safety was inaugurated to disseminate ten principles for patient safety.

A 460 million yen budget (US \$4 million) was allocated for these patient safety actions. Of this amount, 70 million yen (US \$580,000) was allocated to develop a nationwide reporting system for medical accidents, 100 million yen (US \$830,000) for the analysis of these accidents, 16 million yen (US \$130,000) for workshops and seminars, 210 million yen (US \$1.75 million) for patient safety research and development, and finally 63 million yen (US \$525,000) for prevention and control of nosocomial infections.

If there is, please describe the policy including the historical development of the policy.

Actually in Japan the policy development of preventive medical error and patient safety just started in recent years. However, the policy for patient safety in Japan seems to be developed very quickly.

(See the attachment for more details of policy development in Japan.)

2. Action by other stakeholders

Is there a policy by provider association, medical doctor, nurse, or hospital?

Yes. There are several policies by several provider associations. For example, Japan Medical Association started to make actions for patient safety including a policy for it. And Japan Nursing Association makes its own plan of how to deal with patient safety and preventive medical errors.

(See the attachment for more details of policy of key stakeholders.)

Professional organizations, rather than the government, took the lead in introducing concepts of patient safety into Japan. Even prior to the Yokohama Metropolitan University Hospital incident, the Japan Medical Association, under the leadership of its president, Dr. Eitaka Tsuboi, had already initiated the process, broadening the earlier emphasis on the prevention of medical accidents merely as an aspect of the minimization of litigation and compensation risk. Similarly, the Japan Nursing Association started a training course for risk managers; the Japan Hospital Association formed a committee and conducted several seminars; and the Japan Pharmacists' Association developed recommendations for analogous activities.

3. Action by patients, patient groups or representatives

Do patients, patient groups or representatives have a strong influence on governmental or health care professionals' activities for medical error prevention?

There are several patient advocacy groups in Japan. Some member participates in the committee for patient safety of MoHLW. However their influence for patient safety seems to be still small.

4. Third Party Accreditation

With regard to quality, third party organization accredits and evaluates hospital performance in many countries. And in some cases, the organization rates/ benchmarks hospitals or health care institutions. Is there any such an organization in your country?

Yes. Japan Council for Quality Health Care has given an accreditation to health care organization.

C. Information System

1. Reporting system/ information system

Is there any nation wide reporting system for medical accidents, e.g. a reporting system in aviation industry or adverse event reporting system in Australia?

Yes. Near miss reporting system just started last year. But it is the pilot study of near miss reporting system.

If there is,

- a. Is it obligatory or voluntary?
- b. Who collect data?
- c. Who analyze the data?
- d. Is there any legal protection for reported cases against lawsuit?

2. Complains from patients or their family

Is complain data collected and analyzed? If so, how?

No. There is any formal system for collecting complains data.

D. Legislation

a. With regard to a legal system, if someone reports a case and the error is not caused by her/his negligence or system error, we heard that there is indemnification system in some countries. Do you have the same system in your country as well?

No.

b. Is there any no fault compensation scheme for medical errors similar to a no fault compensation scheme for side effects of drug?

No.

E. Concept of Quality and Safety

1. Health care quality and medical error/accident

In the IOM report, "To Err is Human", there is a discussion that we have to take a measure against both health care quality and medical errors because they have the same root cause. Is this concept prevailing in your country?

Some people realize the importance of relationship between quality and medical errors. However most of people involved still focus on reducing errors in fear of financial risk and publicity of mass media.

2. Concept of patient safety

In the same report from IOM, the importance of a concept of patient safety is proposed against risk management to hospitals for litigation. Does a concept of patient safety prevail in your country?

Yes. There seems to be the changing attitude from just preventive medical errors to improve patient safety among stakeholders.

F. Risk Management at Hospital or Clinic level

1. Risk Manager

a. Is there an organization to train a risk manager in your country?

There are mainly four organizations to give a course of the risk manager. Japan Medical Association, Japan Nursing Association, Department of National Hospitals, Ministry of Health, Labor and Welfare, and National Institute of Health Services Management (National Institute of Public Health)

b. Is there any post taking charge of medical error prevention such as risk manager in a hospital?

It is depending on organizations. However, All National University Hospitals set up the place of risk managers. And Almost National Hospitals and Clinics put on risk manager in their organizations.

2. CQI (Continuous Quality Improvement) / Patient Safety

Do you have integrated managing unit in hospital for quality and error?

It is depending on health care organizations. Some private hospital has made a trial to CQI.

3. Fail Safe and Fail Fault System

Is there any pattern of system to improve patient safety in each high risk area such as anesthesia, surgery, ICU, delivery and emergency room in a hospital?

There is not any specific data to identify it.

4. Specific Measure for High Frequency Risk Procedure

Has specific measure been developed to prevent medical errors such as medication error, transfusion error and falls?

Some researches and pilot projects have tried to gather the information about near miss of medical errors. And they analyzed this data. But there does not seem to develop the specific method or measure for it.

5. Risk Analysis Method

What methods are generally employed to analyze risks associated with medical errors at health care institutions?

RCA, FMEA, QFD seems to be prosperous.

6. Education and Training for Employee

- a. Is there any training course for employees in a hospital?
- b. Is there any hospital or clinic which develops educational tools and/or training materials designed to alter behaviors to prevent errors and increase safety?

As far as we know, there is any specific program for preventing medical errors at hospital level.

Table 1. The General Policy for Medical Safety

1) Safety measures in medical institutions

Medical institutions must devise safety measures systematically to assure safety in the provision of health care. This requires standardization of procedures. The government must provide information to improve safety in medical institutions. The following process should be implemented to establish safety control systems in accordance with the specific characteristics of the institutions. Monitoring of results of such processes should be verified and an adequate guidance about the process should be given to the institutions.

(a) Establishment of safety control systems in all hospitals and clinics with beds:

- ① Safety management guidelines
- ② In-house reporting system on adverse events and near misses
- ③ Safety Management Committee
- ④ Education and training of staff for safety management

(b) The following system should be established in special function hospitals and teaching hospitals:

- ① Medical safety managers (full-time in special function hospitals)
- ② Medical Safety Management Unit
- ③ Consultation services

2) Improvement of safety related to drugs and medical devices:

Develop procedures for objective and quantitative evaluation of similarities of appearance of drug brand names and their shape, with investigation of evaluations by third parties and promotional activities regarding the dissemination of drug information.

Develop guidance concerning medical devices by introducing concepts reducing errors based on human behavior, capabilities and related factors.

Develop standardized package inserts for medical devices and dissemination of information relate to operating procedures for medical devices.

3) Education and training concerning medical safety

National licensing examinations of healthcare professions should be revised. Curricula related to medical safety should be clarified, and methods and materials for education and training in medical safety will be developed.

4) Establishment of an environment to promote medical safety

(a) Establishment of systems to settle complaints and consultation

Establishment of consultation services in special functioning hospitals and teaching hospitals.

Guidance on establishment of consultation services in general hospitals and clinics.

Requests to local medical associations to improve consultation capabilities.

Establishment of public consultation systems in each secondary healthcare region, and medical safety consultation centers (tentative name) by third parties at the prefecture level.

(b) Dissemination of useful information on medical safety

Expansion of collection of near miss data nationwide and development of a system to analyze and distribute such data (start investigations on collection, etc. of accident cases, including legal problems).

(c) Promotion of medical safety measures based on scientific evidence, and systematic research required for medical safety.

Table 2.

FY	Category	Researcher	Institute	Title of research	Amount
1998	Special	Haruo Kikuchi	National Cardiovascular Center	Establishment of hospital administration systems	2 million
1999	General	Haruko Kawamura	Kyorin University	Establishment of risk management system in health care	12 million
1999	Special	Takiko Amamiya	Nagano College of Nursing	Night working conditions of nurses	3 million

2000	Special	Hideto Sakai	Tokai University Hospital	Standardization of incident reporting and coding	8 million
2000	Special	Toshihiko Hasegawa	National Institute of Health Services Management	Assessing medical safety administration in a large hospital	8 million
2000	Special	Yoshiko Shimamori	Japan Nursing Association	Medical accidents referring to nursing care	5 million
2000	Special	Michiko Maruyama	Center for Nursing Education and Research	Reviewing the curriculum for medical safety in nursing education	5 million
2000	Special	Akira Kakita	Kitazato University	Establishment of medical safety in specific large scale hospitals	3 million
2001	General	Toshihiko Hasegawa	National Institute of Health Services Management	Risk analysis and fail safe systems in health care	24 million
2001	General	Naruo Uehara	Tohoku University	Quality assurance tools in health provider systems	13 million
2001	General	Hideto Sakai	Tokai University Hospital	Risk management in hospitals	20 million
2001	General	Toshiko Ibe	St Luke's International Hospital	Tasks and functions of risk managers in health care organizations	6.25 million
2001	General	Michio Hashimoto	Yokohama City University	Education and training of safety administration in health care system	11 million
2001	General	Hisashi Oumichi	Japan Council for Quality Health Care	Establishment and implementation of reporting systems for medical adverse events	30 million
2001	General	Takahisa Yamauchi	University in Kitakyushu	Effects of introducing resources and training for preventing medical errors	10 million
2001	General	Mariko Kusumoto	Japan Nursing Association	Manual for incident reporting	4 million
2001	Special	Michio Hashimoto	Yokohama City University	Establishment of effective tools for medical safety with slogans	12 million
2001	Special	Tomonori Hasegawa	Toho University	Preliminary study examining the legal systems for medical safety in foreign countries	15 million
2001	Special	Hideto Sakai	Tokai University Hospital	Investigation of reporting systems for medical safety	5 million

A response to the international comparative survey of medical
Accident prevention and patient safety policy
The USA situation

Respondent: Robert B Leflar

U.S.A

A Survey of Medical Accident Prevention Policy

Questionnaire on international comparison of medical accident prevention policy

Principal Investigator: Toshihiko Hasegawa, M.D., M.P.H., Director, Department of Health Care Policy, National Institute of Health Services Management, Japan

Contact: Junko Yamada, M.A., Research Associate

E-mail: junkoyam@nih.go.jp, Tel: +81-3-3203-4821, Fax: +81-3-3202-6853

Background: Japanese Situation

In January 1999, an unthinkable medical error occurred at one of the prestigious hospitals in Japan. Two patients were mixed up at surgery and a lung was taken out of the wrong patient. Since then several serious medical errors have been reported at prestigious medical centers. The Japanese people's trust in their health care system has been shaken. The government has to respond to the situation. A committee to investigate the root causes of those medical errors was formed in March 1999 and reported the need for integrated activity to prevent medical errors. Other professional associations, such as the Japan Medical Association, Japan Nursing Association, Japan Pharmaceutical Association, Japan Dental Association and Japan Hospital Association have also formed committees to develop preventative measures from their perspective. Particularly, 240 central government hospitals have developed a manual to deal with medical errors in October 1999. 2 million USD is allocated to research on patient safety in the 2001 fiscal year budget. A national committee on patient safety was formed in June 2001 to develop a comprehensive policy.

The main aim of this survey is to investigate medical accident prevention policy in the following countries: the U.S., the U.K., Germany, Sweden, the Netherlands, France, Australia, and New Zealand.

Questions

A. Information on Medical Error

1. Studies and research activities on medical accidents/errors

a. Are there any epidemiological studies in your country concerning medical accidents/errors? Non-epidemiological analytical studies? Please give references if available.

Yes. These are the two leading epidemiological studies:

(a) Harvard Medical Practice Study (based on analysis of New York state hospital discharge records from 1984), described in:

- Hiatt Howard H et al., A Study of Medical Injury and Medical Malpractice, New England J. Med. 321:480-484, 1989
- Brennan Troyen A. et al., Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I, New England J. Med. 324:370-376, 1991
- Leape Lucian et al., The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II, New England J. Med. 324:377-384, 1991
- Russell Localio et al., Relation between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study III, New England J. Med. 325:245-251, 1991.

(b) Colorado-Utah study (based on analysis of hospital discharge records in those two states from 1992):

- Thomas Eric J., Studdert David M., Burstin Helen R., Orav E. John, Zeena Timothy, Williams Elliott J. et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. Med. Care 38(3):261-271, 2000.

b. Is it known whether the number of medical accidents is increasing or decreasing?

No. There are no reliable data on this question. There may be a trend toward a lower number of medical accidents, based on the somewhat lower estimates of preventable error in the 1992 Colorado-Utah data as compared with the 1984 New York data.¹ However, the head of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), believes that at least one type of medical error, wrong-site surgery, is increasing.² The best "ballpark estimate" is that 3-4% of hospitalized patients suffer a non-trivial preventable injury.³

c. How much is allocated in the national health budget for research activities on medical error?

I have been unable to ascertain the total amount at present, since it is spread over many different agencies and entities. I am attempting to obtain an accurate estimate from sources within government and academia.

d. Is the status of medical errors understood well in your country?

Better than ever before, from the volume and quality of studies recently performed.

¹ Gawande Atul A., Thomas Eric J., Zinner Michael J., Brennan Troyen A. The Incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992. *Surgery* 126(1):66-75, 1999, at 71.

² Brown David. Surgical Calamities on Rise, Group Says. *New York Times*, Dec. 6, 2001, at A14 (reporting views of Dr. Dennis O'Leary).

³ Brennan Troyen A. Reporting of Errors: How Much Should the Public Know? *Effective Clinical Practice* 3(6):298-299, 2000.

2. Public concern about medical accidents/errors

a. To what extent are medical accidents/errors arousing public concern in your country?

It has become a matter of high public concern. "The speed and intensity with which this report from the National Academy of Sciences [*To Err Is Human*] captured media, public, political and professional attention surprised everyone."⁴

b. Is the number of lawsuits concerning medical accident increasing? Please provide recent statistics if available.

Since medical malpractice actions are generally matters of state law and consequently are reported, if at all, on a state-by-state basis, good nationwide statistics on court filings are unavailable. We must look to other sources of information to answer this question.

Medical malpractice premiums are one possible barometer of the volume and intensity of malpractice litigation. After six years of relatively stable premium rates, in 2001 malpractice premiums began rising again at a rapid pace. The reasons for the increase are controverted. One report stated, "Insurers put most of the blame . . . on a jump in big awards by juries and large settlements. While the number of malpractice suits has been holding steady, the average jury award rose to \$3.49 million in 1999, up from \$1.95 million in 1993, according to the latest compilation by Jury Verdict Research of Horsham, Pa."⁵ However, a more significant statistic is the average malpractice *payout* (as opposed to jury award); and the average payout has risen only slightly over the past 10 years, from \$39,093 to \$42,607.⁶ An alternative explanation for malpractice premium increases is that insurers kept premiums artificially low while competing for market share and new revenue to invest in the booming stock market until 1999-2000. With the stock market now in a slump, insurers can no longer use stock market gains to subsidize low rates, and have consequently been hiking their premiums.⁷

Closed claims analysis of medical malpractice insurance claims supports the conclusion that the

⁴ Leape, Lucian L. Foreword: Preventing Medical Accidents: Is "Systems Analysis" the Answer? *Am. J. Law & Med.* 27:145-148, 2001.

⁵ Treaster Joseph B. Malpractice Rates Are Rising Sharply; Health Costs Follow. *N.Y. Times*, Sept. 10, 2001.

⁶ New Study Shows Average Medical Malpractice Payouts to Victims Only \$43,000; Virtually Unchanged in 10 Years, Center for Justice & Democracy release, Oct. 16, 2001 (based on National Association of Insurance Commissions data).

⁷ Treaster, *supra*.

number of claims (including both those filed in court and those settled without judicial involvement) has been relatively stable, with a slight rise in claims closed without payment but little change in claims closed with payment, at least for the period 1991-1996. (Because of the lag time between the filing of claims and claim resolution, it is impossible to know from these statistics whether there has been an increase or decrease in claims since 1996.) The table on the next page sets out the latest data.

Number of Medical Malpractice Insurance Claims Closed
1991-2000⁸

	"Occurrence" Policies: Number of Claims Closed		"Claims Made" Policies: Number of Claims Closed	
	With payment	Without payment	With payment	Without payment
1991	8,515	22,049	22,326	53,299
1992	8,299	22,834	22,780	59,903
1993	8,103	23,026	24,718	64,702
1994	8,720	23,583	22,427	69,205
1995	8,664	20,800	22,573	73,380
1996	7,667	17,129	22,855	75,759
1997	5,984	14,896	18,342	64,282
1998	3,962	10,696	13,873	56,398
1999	2,293	6,496	8,126	43,867
2000	557	1,494	2,478	20,786

⁸ *Best's Aggregates and Averages, Property-Casualty, 2001 ed.*, p. 238 (A.M. Best's Co. 2001).

c. Is the industry interested in patient safety?

Yes. Consortia of top corporate executives, such as the “Leapfrog Group,” are at the forefront of medical quality improvement efforts. There are industry-government collaborations, for example in Minnesota and elsewhere, that have shown promising results.⁹ However, it cannot be said that managed care organizations as a whole have responded sufficiently to the problem of patient safety. Many of them appear to be pulling back from direct involvement in medical management to adopt a role more limited to an insurance role, delegating decisions about quality and structure entirely to health care providers. As Havighurst recently observed, “managed care today means little more than subcontracting and capitation.”¹⁰

3. Impact of IOM Report

Please assess the influence in your country of the report from the Institute of Medicine in the U.S., “To Err is Human.”

The influence is very large, in government, health care institutions, and academia. As Dr. Lucian Leape recently observed, “Few publications in recent memory have had the impact of . . . *To Err Is Human*.”¹¹ Likewise, Jacobi and Huberfeld stated: “The Institute of Medicine has returned the problem of medical error to the top of the health-care agenda.”¹² Budgets have increased, top-level commissions have been named, Congress has held hearings, and virtually every hospital has undertaken some kinds of remedial measures.

⁹ White, Elizabeth. Industry, Purchaser-Driven Efforts to Curb Medical Mistakes Grows. BNA Health Care Policy Report 8(23):939-943, 2000.

¹⁰ Havighurst, Clark. Vicarious Liability: Relocating Responsibility for the Quality of Medical Care. Am. J. Law & Med. 26(1):7-29, 2000, at 8.

¹¹ Leape Lucian L. Foreword: Preventing Medical Accidents: Is “Systems Analysis” the Answer? Am. J. Law & Med. 27:145-148, 2001.

¹² Jacobi John V, Huberfeld Nicole. Quality Control, Enterprise Liability, and Disintermediation in Managed Care. Journal of Law, Med. & Ethics 29:305-322, 2001.

B. Action by Stakeholders

1. Government action toward medical accidents/errors and patient safety

Has the government instituted policies especially for medical accidents?

If so, please describe the policies including their historical development.

Although the extent of medical error was generally known to be a serious problem at least since the publication of the Harvard Medical Practice Study, it took the publication of the Institute of Medicine's report, *To Err Is Human*, to spur the various levels of government into serious policy responses.

At the federal level, Congress has debated, but not yet enacted, legislation concerning the duty to report adverse medical occurrences. Federal administrative agencies have been quite active. The Agency for Healthcare Research and Quality (AHRQ) has promoted patient safety through development and dissemination of dozens of standards and guidelines founded on evidence-based medicine.¹³ The Center for Medicare and Medicaid Services (CMMS) has adopted accreditation and financing rules emphasizing the need for hospitals to engage in root cause analyses of adverse events. The Veterans' Administration (VA) has instituted error reduction programs in VA hospitals that have been nationally recognized as outstanding. The Food and Drug Administration is planning, for example, a requirement for bar codes on all prescription drug labels.¹⁴ A top-level commission (the Quality Interagency Coordination Task Force) and a public-private consortium (the National Quality Forum) were formed to address the problem at the highest level.

Likewise, at the state level, many state governments have directed state health departments to improve reporting of adverse incidents, and to oversee hospitals' efforts toward error prevention through direct targeted site visits to hospitals and comprehensive consultation.¹⁵ California, for example, is requiring all hospitals and surgical clinics to put into place plans for reduction of medical errors within three years. These plans must include establishment of a facilitywide

¹³ AHRQ's latest compilation is *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, 2001. A summary is found at <http://www.ahrq.gov/clinic/ptsafety/summary.htm>.

¹⁴ Bar Code Requirement for Drugs Planned As Part of FDA Focus on Patient Safety. BNA Health Care Policy Report 9(47):1815, Dec. 10, 2001.

¹⁵ National Academy for State Health Policy, *State Reporting for Medical Errors and Adverse Events: Results of a 50-State Survey* (Portland ME, April 2000); Ghali William A., Ash Arlene S., Hall Ruth E., Moskowitz Mark A. Statewide Quality Improvement Initiatives and Mortality After Cardiac Surgery. JAMA 277(5):379-382, 1997.

quality system headed by a multi-disciplinary group; development of effective reporting mechanisms; establishment of baseline assessment of systems for preventing medication-related errors; implementation of technology improvements such as computerized physician order entry systems; and literature reviews.¹⁶

¹⁶ California: Hospital Error Prevention Plans Due in January Under State Law. BNA Health Care Policy Report 9(47):1823, Dec. 10, 2001.

2. Action by other stakeholders

What policies have been instituted by provider associations such as medical doctors, nurses, or hospitals?

Each medical specialty, led in the 1980s by anesthesiologists, has developed a focus on patient safety activities. For example, adoption of the pulse oximeter as the standard of care reduced anesthesia-related accidents dramatically.¹⁷ The Anesthesia Patient Safety Foundation brought together representatives from various disciplines – physicians, nurses, and product manufacturers – to apply information-based and human factors strategies to further reduce anesthesia mortality rates, with demonstrable success.¹⁸

Professional societies have been active in promoting clinical practice guidelines and standards. For example, the American College of Cardiology and the American Heart Association Task Force of Practice Guidelines have produced 16 practice guidelines such as those concerning coronary artery bypass graft surgery and management of chronic angina. Specialties have collaborated on some guidelines, for instance the perinatal guidelines developed jointly by the American College of Obstetrics and Gynecology and the American Academy of Pediatrics.¹⁹ The American Society of Health-System Pharmacists is engaged in an initiative to identify and compile a list of safe medication practices at pharmacies.²⁰

However, clinical practice guidelines have proliferated to the point that it is difficult even for specialists to keep up with them all. Many are consensus-based rather than scientifically grounded, many are vague, and some are contradictory.²¹

Another important stakeholder not mentioned in the questionnaire is the insurance industry. Some insurers are intensifying their efforts to encourage insured providers to take effective patient safety measures. For example, starting in 2002, the largest health insurer in New York state will pay hospitals a 4% bonus for meeting two patient safety standards: (1) the use of computerized physician-order-entry systems for prescription drugs, and (2) the staffing of intensive care units

¹⁷ Tinker JH et al. Role of Monitoring Devices in Prevention of Anesthetic Mishaps: A Closed Claims Analysis. *Anesthesiology* 71:541-546, 1989.

¹⁸ Pierce, Ellison C. The 34th Rovenstine Lecture. Forty Years Behind the Mask: Safety Revisited. *Anesthesiology* 87(4):965-975, 1996.

¹⁹ These efforts are summarized in *To Err Is Human*, pp. 144-146.

²⁰ Group Launches Project to Identify Pharmacy-Based Patient safety Practices. *BNA Health Care Policy Report* 9(46):1793, Dec. 3, 2001.

²¹ Mello Michelle M. Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation. *U. Penn. L. Rev.* 149(3):645-710, 2001, at 686-688.

with doctors who are board-certified or board-eligible in critical care medicine.²² Similarly, six health insurers in California are planning to pay bonuses to physician groups that earn high marks on a common set of quality measures, concerning childhood immunizations, breast and cervical cancer screening, appropriate use of inhalers for asthmatics, effective management of blood sugar levels for diabetics, and proper cholesterol levels for coronary artery disease patients, together with a combined patient satisfaction score.²³

²² Empire Blue Cross to Pay Hospitals Bonus for enhancing Patient Safety. BNA Health Care Policy Reports 9(42):1627, Oct. 29, 2001.

²³ Rundle, Rhonda L. California Insurers Plan Bonuses for Doctors. Wall St. J., Jan. 15, 2002, at B12.