3. Action by patients, patient groups or representatives

Do patients, patients' groups or representatives have a strong influence on governmental or health care professionals' activities for medical error prevention? If so, please describe.

Patients' and consumer groups' influence can be assessed in at least two ways. One is through direct participation in the governmental process relating to patient safety. A second is through purchasing decisions in the marketplace.

Patient and consumer organizations active on safety issues include Public Citizen's Health Research Group (Dr. Sidney Wolfe, director) and the American Association of Retired Persons (AARP) at the national level in Washington, and many grass-roots locally based groups in various regions of the country. The Health Research Group has had a particularly strong influence on Food and Drug Administration decisions concerning the safety of medical products. The AARP has considerable clout in Congress, because of the high percentage of elderly people who vote.

The increased availability of medical information has in some ways increased consumers' influence on medical quality through their purchasing decisions. Under the Consumer Assessment of Health Plans Study (CAHPS), for example, individuals can go to the CAHPS website, type in their zip code, find out what Medicare plans are available, and learn what their CAHPS scores are. In a study of Washington state employees with access to this information during their health plan re-enrollment period, employees' most important source of re-enrollment information was found to be the CAHPS report. Employees were more likely to select high-ranked CAHPS health plans, although premium levels were a more important factor in their choices.[24]

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[24] Cleary Paul D. CAHPS: Consumer Assessment of Health Plans Study (presentation at Harvard Conference on Quality of Care in the Age of Consumerism, Nov. 16, 2000.

4. Third Party Accreditation

With regard to quality, a third party organization evaluates hospital performance and accredits hospitals in many countries. And in some cases, the organization rates/ benchmarks hospitals or health care institutions. Is there such an organization in your country? If so, please describe its responsibility and activities briefly. Also, what results (if any) of the evaluation and accreditation process are made publicly available?

The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has recently undertaken a dramatically stronger focus on patient safety issues. JCAHO is the quasi-public entity responsible for accrediting hospitals for participation in the federal Medicare and Medicaid programs. (Revenue from these programs, especially the Medicare insurance program for the elderly, is indispensable for almost all major non-psychiatric hospitals, so JCAHO accreditation is an operational necessity.) JCAHO inspects hospitals every three years, and recently has partially shifted the focus of its inspections from easy-to-ascertain items regarding hospital structure and the process of the provision of health care, to more difficult but more useful criteria such as the measurement of medical outcomes. JCAHO publishes summaries of the results of its inspections on its website so that individual doctors, patients, and news media can access the results, and determine which specific areas in each hospital were out of compliance with JCAHO standards.

JCAHO has recently undertaken a patient safety initiative, effective July 1, 2001. JCAHO inspections now look specifically at whether hospitals conduct "root cause analyses" of adverse events and incidents that could have led to harm; measure and analyze these events; and take remedial measures. JCAHO standards now also require hospitals to inform patients whenever they have been harmed by unanticipated outcomes, and explain why it happened. Since it is a 3-year inspection and accreditation cycle, almost every US hospital will be giving some kind of explanation to patients who suffer harm in the hospital.[25] This is a dramatic change from past practice, bringing practice into accord with the medical ethics code.

The National Committee for Quality Assurance (NCQA), which accredits health plans, engages in somewhat similar activities. Its HEDIS measurement and assessment system is described below.

Both JCAHO and NCQA are engaged in standards development for certification of programs for

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[25] O'Leary Dennis. Joint Commission's New Patient Safety Standards (transcript of statement, July 2, 2001): http://www.jcaho.org/news/nb333_transcripts.html.

disease-specific care.[26]

[26] Three Organizations Developing Standards for Quality of Disease Management Programs. BNA Health Care Policy Report 9(49):1901, Dec. 24, 2001.

C. Information Systems

1. Reporting systems/ Information systems

Is there any nationwide reporting system for medical accidents, analogous to a reporting system in the aviation industry, or the adverse event reporting system in Australia?

At present, there is no nationwide reporting system in place, although Congress is debating whether to implement one. Reporting is currently a matter of state law.

About 21 of the 50 states now have reporting requirements. But "enforcement of such laws is typically underfunded and resisted by providers, resulting in only a small fraction of error reporting in comparison to the projections by the IoM Report."[27] In some states, such as New York, more thorough reporting systems are in place, with data collected by hospitals and forwarded to the State Health Department for analysis.

The federal Center for Medicare and Medicaid Services (CMMS) is pilot testing a mandatory error reporting system for 100 volunteer hospitals in conjunction with peer review organizations, focusing on the states with reporting requirements.[28]

If there is, (a) Is it obligatory or voluntary?

This varies from one state to another.

(b) Who collects and analyzes the data?

Typically, a unit of the state health department collects and analyses the data.

(c) Is there any legal protection for the information reported, so that it cannot be used in lawsuits?

This is a vexed question, the source of considerable controversy. State statutes in almost every state protect peer review proceedings from discovery and prohibit the contents of those

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[27] Noble Alice A, Brennan Troyen A. Managing Care in the New Era of "Systems-Think": The Implications for Managed Care Organizational Liability and Patient Safety. J. Law, Med. & Ethics 29:290-304, 2001, at 291 & n.22.

[28] HCFA Announces New Initiatives to Curb Medical errors, Improve Program Integrity. BNA Health Care Policy Report 8(17):646, 2000.

proceedings from being admitted into evidence in civil trials. Hospital counsel are adept at structuring the operation of systems for collection of sentinel event information, such as that required under JCAHO standards, as part of the duties of peer review committees, to try to take advantage of those peer review protection statutes. Moreover, the attorney-client privilege and the work product doctrine have been advanced by hospital lawyers to shield some limited types of hospital risk management information from the hands of plaintiffs' attorneys.

Still, there is strong precedent holding incident reports of adverse events within a hospital to be discoverable as prepared in the ordinary course of business, outside the protection of the peer review statutes and the attorney-client and work product privileges. The preparation of incident reports, typically by nurses responsible for the affected patients, is not a part of the deliberative process that the peer review statutes are designed to protect. JCAHO-required root causes analyses of sentinel events may likewise be susceptible to treatment as reports prepared in the ordinary course of hospital business, and therefore discoverable, though most state courts facing the issue have not so held. The fear is that if the analyses are discoverable, they will not be done, or not done properly. This has led one leading commentator to observe, "Any effort to prevent injury due to medical care is complicated by the dead weight of a litigation system that induces secrecy and silence. No matter how much we might insist that physicians have an ethical duty to report injuries resulting from medical care or to work on their prevention, fear of malpractice litigation drags us back to the status quo."[29]

Although JCAHO leadership insists that "sentinel events" reported to it are unlikely to become the subject of legal discovery, nevertheless to quell doubt among its hospital constituency, JCAHO has advocated federal legislation making such information confidential.[30]

The quasi-public National Quality Forum (NQF) has recently addressed the conflict between promotion of a culture of safety in hospitals by treating such reports as confidential, and advancing public accountability by open disclosure. The NQF's recommendations are that some mistakes are clear enough, and bad enough, that they should never occur, and when they do, the public has a right to know about them. Reporting of them would be mandatory, and the reports would be public. The NQF came up with a list of 27 of these "never events", organized into six categories: five relating to the provision of care (surgical, drug or device, patient protection, care management, and environmental), and one category that includes criminal events such as sexual or physical assault. Examples of the non-criminal "never events" are surgery on the wrong body

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[29] Brennan Troyen A. The Institute of Medicine Report on Medical Errors: Could It Do Harm? NEJM 324(15):1123-1125 (2000), at 1125.

[30] Bressler Harold. The Sentinel Event Policy: A Response by the Joint Commission. J. Health Law 33(3):519-539, 2000.

part or the wrong patient, or the wrong surgical procedure performed on a patient; operative or immediate postoperative death of a relatively healthy patient; patient death or serious disability associated with a medical device that is contaminated or does not work as intended; patient death or serious disability associated with a medication error or blood mistyping; maternal death or serious disability associated with labor or delivery in a low-risk pregnancy at a hospital or birthing center. If an adverse event is not on the list, and a state wanted to make it subject to mandatory disclosable reports, the state could do so; but otherwise, the presumption is that the adverse event would not be subject to disclosure. The NQF recommendations will go to Congress for consideration later this year.

2. Complaints from patients or their families

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

This varies from one hospital to the next. However, the JCAHO requirement for thorough and credible root cause analyses of adverse events in hospitals, explained elsewhere in this survey response, will give a strong impetus to hospitals to pay close attention to patient complaints.

3. Public availability of medical outcome information

Please describe the extent, if any, to which medical outcome information and other information on medical quality is available to the public. In particular, is such information available on a provider-by-provider basis?

Availability varies by state. Some states, such as New York and Pennsylvania, allow public access to risk-adjusted provider-by-provider outcome results for certain procedures, such as mortality rates for cardiac bypass surgeries.[31] Several states allow access to hospital "report cards" measuring various aspects of hospital and health plan performance.[32] The public also has some access to hospital-by-hospital data based on accreditation results from the Joint Commission for Accreditation of Health Care Organizations (JCAHO), although areas of hospital deficiency are typically made public only after the deficiencies are corrected.[33] In addition, "report cards" on various aspects of managed care plan performance are available from the National Committee for Quality Assessment (NCQA), and from private publications such as *Consumer Reports*.

These trends will be augmented as the nation's health care system invests more heavily in electronic medical records, which will enable the collection and analysis of outcome data, and the performance of risk adjustment tasks, to be far more easily accomplished. Still, at present medical outcome information has had only limited impact on consumer decisionmaking in the

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[31] This initiative was described and analyzed in Japanese as early as 1994. Leflar Robert B. インフォームドコンセントを超えて: 医療情報の公開と治療結果にもとずく医療提供者評価の黎明.北海道法学論集 44:1039-1076, 1994 (H. Sonoo, trans.).

[32] E.g., New York Issues Report on Managed Care Plans. BNA Health Care Policy Report 9(46):1787, Dec. 3, 2001.

[33] To view this information, go to www.jcaho.org and search the site by state for particular hospitals' accreditation results.

health care field.[34]

Medical information in general, of course, has become must more widely available to the public through the Internet. Health care information sites, as a category, are the second most widely accessed by the American public. (Pornography sites are first, but that is outside the scope of this survey.)

[34] Hibbard Judith. Making Quality of Care Information Accessible to the Public. Presentation at the Harvard Conference on Quality of Care in the Age of Consumerism, Nov. 17, 2000.

D. Legislation and Judicial Involvement

1. With regard to the legal system, if someone reports a case and the error is not caused by her/his negligence or system error, in some countries the reporter is protected from legal liability. Do you have the same system in your country as well?

This is the case with regard to reporting of near misses in aviation,[35] but it does not apply to negligence or system error in medicine.

There is, however, a somewhat analogous rule regarding post-accident safety measures taken by a defendant (such as a hospital). Typically, these may not be introduced into evidence in legal proceedings to establish the defendant's failure to take such measures pre-accident.[36]

2. Is there any no fault compensation scheme for medical errors similar to the no fault compensation scheme in some countries for side effects of drugs?

Yes, no-fault compensation systems exist for birth-related neurological injuries in Florida[37] and Virginia.[38] They have met with some success, but at most constitute a partial and limited replacement for the traditional tort system.[39] In addition, a National Vaccine Injury

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[35] National Aeronautics & Space Administration, Aviation Safety Reporting System, at http://asrs.arc.nasa.gov/; Bovbjerg Randall R., Miller Robert H., Shapiro David W. Paths to Reducing Medical Injury: Professional Liability and Discipline vs. Patient Safety and the Need for a Third Way. J. Law Med. & Ethics 29:369-380, 2001.

[36] Federal Rule of Evidence 407, and analogous state-law rules.

[37] Fla. Stat. Chs. 766.301-.316.

[38] Va. Code Ann. §§ 38.2-5000 to –5021.

[39] Sloan Frank A., Whetten-Goldstein Kathryn, Entman Stephen S., Kulas Elizabeth D., Stout Emily M. The Road from Medical Injury to Claims Resolution: How No-Fault and Tort Differ. Law & Contemp. Problems 60:35-70, 1997; Bovbjerg Randall R., Sloan Frank A., Rankin Peter J. Administrative Performance of "No-Fault" Compensation for Medical Injury. Law & Contemporary Problems 60(2):71-115, Spring 1997; Studdert David M., Fritz Lori A., Brennan Troyen. The Jury Is Still In: Florida's Birth-Related Neurological Injury Compensation Plan After a Decade. J. Health Politics, Policy & Law 25(3):499-526, 2000.

Compensation Program exists to compensate those injured by e.g. swine flu vaccines.[40]

The Institute of Medicine's report, *To Err Is Human*, emphasized the importance of system re-design rather than individual blame. Consequently, some commentators have offered proposals for no-fault systems on a broader scale, perhaps combined with enterprise liability at some level (see below).[41] As yet, these proposals have not met with any legislative acceptance.

With the rise of managed care, considerable academic attention is now being given to the idea of enterprise liability for adverse results of medical care.[42] Tort suits recognizing direct liability for negligence by managed care organizations may represent a step along this road.[43] However, to be implemented on a systematic, nationwide basis, enterprise liability proposals would require federal legislation, and no such legislation is likely at least during the Bush Administration.

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[40] Ridgway Derry. No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury compensation Program. J. Health Policy, Politics & Law 24:59, 1999.

[41] Studdert David M., Brennan Troyen A. Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States. Am. J. Law & Med. 27:225-252, 2001.

[42] Jacobi John V., Huberfield Nicole. Quality Control, Enterprise Liability, and Disintermediation in Managed Care. J. Law, Med. & Ethics 29:305-322, 2001; Havighurst Clark C. Vicarious Liability: Relocating Responsibility for the Quality of Medical Care. Am. J. L. & Med. 26:7-29, 2000; American Law Institute. *Reporters' Study: Enterprise Responsibility for Personal Injury,* vol. 2, *Approaches to Legal and Institutional* Change 114-115, 1991; Weiler Paul C. *Medical Malpractice on Trial* 134-139 (Cambridge: Harvard U. Press 1991).

[43] E.g., Jones v. Chicago HMO, 730 N.E.2d 1119 (Ill. 2000).

E. Concept of Quality and Safety

1. Health care quality and medical error/accidents

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

Yes. A purpose underlying the publication of "To Err is Human" was to focus public attention on the need to improve health care quality, by putting a spotlight on the most dramatic aspect of that problem: the widespread toll from medical error. As Dr. Leape puts it, safety is a "subset of quality."[44]

2. "Risk management" and patient safety

The practice of "risk management" in some settings has come to signify the protection of hospitals against the risk of litigation by patients. The IoM report stressed, by contrast, the importance of patient safety as the proper goal of risk management. How would you assess the actual practice of "risk management" as it exists in your country, as between these two models?

The profession of risk management may be said to be in a state of transition. Traditional risk managers have had as their primary concern the protection of the hospital against litigation, with patient safety and accident prevention activities viewed as a subset of that function. But recently, the greater attention at the hospital management level to issues of patient safety has created a tendency for risk managers to be conscripted to the pursuit of accident analysis and prevention to a greater degree than before.

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

F. Risk Management at Hospital or Clinic Level

1. Risk Managers

a. Are there organizations to train risk managers in your country?

Yes.

b. Do hospitals in your country have a specific post for a person charged with the responsibility of medical error prevention?

Yes, typically major hospitals will have one or more staff whose primary job is patient safety and error prevention.

2. CQI (Continuous Quality Improvement) / Patient Safety

Do you have integrated managing units in hospitals for continuous feedback loops to improve quality and prevent error? If so, please describe.

Yes, many hospitals have been active in setting up such feedback loops as part of their CQI initiatives. For examples, see the references in this section of the questionnaire.

3. Fail Proof and Fail Safe Fault Systems

Is there any package of systems to improve patient safety in each high risk area in a hospital, such as anesthesia, surgery, ICU, delivery and emergency room? If so, please describe.

Yes. Systems have been developed in each of the areas mentioned in this question. Infection rates have substantially decreased after putting into effect standardized improvements in surgeons' inpatient practices.[45] In addition, computerized reminder systems have been proven effective in increasing the rate of delivery of preventive care measures, such as pneumococcal and influenza vaccination and prophylactic heparin and aspirin at discharge.[46]

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[45] James BC. Quality Improvement in the Hospital: Managing Clinical Processes. Internist 34(3):11-13, 17, 1993.

[46] Dexter Paul R., Perkins Susan, Overhage J. Marc, Maharry Kati, Kohler Richard B., McDonald Clement J. A Computerized Reminder System to Increase the Use of Preventive Care for Hospitalized

Patients. New England J. Med. 345(13):965-970, 2001.

4. Specific Measures for High Frequency Risk Procedures

Have specific measures been developed and widely instituted to prevent common accidents such as medication errors, transfusion errors and falls? If so, please describe.

The most well-verified success story has been computerized prescription order entry,[47] which can be effectively linked to computerized medical records. For example, the Veterans Health Administration system, by bar coding administered drugs and medical standards embedded within its system, is able to advise caregivers at the point of clinical decisionmaking whether drugs are indicated based on lab results and other patient data.[48] Also, ward-based clinical pharmacists participating in rounds are effective in preventing adverse drug events.[49]

Bar coding to prevent transfusion errors, and hospital bed rail policies to prevent falls, are in general use. Mortality from community-acquired pneumonia has significantly decreased due to implementation of standard treatment guidelines.[50]

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[47] Bates David W., Leape Lucian L., Cullen David J., Laird Nan, Petersen Laura A., Teich Jonathan M. et al. Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors. JAMA 280(15):1311-16, 1998; Raschke Robert A., Gollihare Bea, Wunderlich Thomas A., Guidry James R., Leibowitz Alan I., Peirce John C. et al. A Computer Alert System to Prevent Injury from Adverse Drug Events. JAMA 280(15):1317-1320, 1998.

[48] Weeks WB, Bagian JP. Developing a Culture of safety in the Veterans Health Administration. Effective Clin. Practice 3:270-276, 2000; Andrews RD, Beauchamp C. A Clinical Database Management System for Improved Integration of the Veterans Affairs Hospital Information System. J. Med. Systems 13(6):309-320, 1989.

[49] Kaushal R et al. Medication Errors and Adverse Drug Events in Pediatric Patients. JAMA 285:2114-20, 2001; Leape LL. Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit. JAMA 282:267-270, 1999.

[50] Dean NC. Decreased Mortality After Implementation of a Treatment Guideline for Community-Acquired Pneumonia. Am. J. Med. 110:451-457, 2001.

5. Risk Analysis Methods

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

As part of the accreditation process, JCAHO requires hospitals to engage in thorough and credible "root cause analyses" of adverse events, as noted above. These efforts must employ validated quality performance measures. Aside from JCAHO requirements, a great many hospitals are attempting to incorporate principles of total quality management (TQM) and continuous quality improvement (CQI) in routine operations. Their success in doing so is variable, in part because of resistance or inertia among physicians.

The prevailing system of quality performance measures for health care plans is HEDIS, the Health Plan Employer Data and Information Set. This is a standardized set of measures to compare the performance of both private and public managed care plans. Updated annually, HEDIS contains performance measures relating to cancer, heart disease, smoking, asthma, and diabetes. Recent versions of HEDIS also include a survey of consumers regarding the health plan's performance on non-medical matters. Use of HEDIS is a requirement for accreditation of health plans by the National Committee for Quality Assurance.[51]

HEDIS has been controversial. Of 52 performance indicators, only 16 assess quality of care, and most of these focus on process rather than outcome. Moreover, HEDIS contains no risk adjustment mechanisms.

6. Education and Training for Employees

a. What special training courses oriented toward patient safety, if any, are offered or required for specific groups of hospital employees?

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?

These activities are too widespread and numerous to list in detail.

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[51] This summary is taken from Kinney Eleanor D. The Brave New World of Medical Standards of Care. J. Law Med. & Ethics 29:323-334, 2001, at 328-9.

7. Peer Review

Please briefly describe the peer review systems prevailing in your country, or provide descriptive references.

Medical licensure and discipline is chiefly controlled by state law. Licensure in the US is typically described as a system of professional self-regulation, even though the boards act as state agencies, because they are dominated by members of the licensed profession.[52] These boards have been criticized by consumer groups for the small number of doctors who are subjected to significant disciplinary measures. The disciplinary sanctions are collected and available to the public, naming those practitioners who are disciplined.[53]

More important as a practical matter is peer review conducted at the hospital level. Within hospitals, questionable practices may lead a physician to have his or her hospital admitting or clinical privileges limited, suspended or revoked. The peer review function is performed by the hospital's medical staff, or special committees of the medical staff.

Additionally, the Medicare Utilization and Quality Control Peer Review Organization Program is the federal government's primary tool for assuring that services provided to Medicare beneficiaries are medically necessary, of acceptable quality, and provided in an appropriate setting. These professional peer review organizations participate in national quality improvement projects, concerning clinical areas such as acute myocardial infarction, heart failure, pneumonia, stroke, diabetes, and breast cancer. They take on both the role of sponsor of local quality improvement projects in these areas, and the role of quality enforcer for the Medicare program, investigating complaints by patients and sanctioning physicians failing to meet program standards.[54]

Under the Health Care Quality Improvement Act, significant peer review actions against a physician, as well as malpractice judgments and settlements, must be reported to the National Practitioner Data Bank. Hospitals are required to query this data base when they credential or

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[52] Furrow Barry R., Greaney Thomas L., Johnson Sandra H., Jost Timothy S., Schwartz Robert L. *Health Law: Cases, Materials and Problems* (4th ed., West Publishing Co. 2001), at 92.

[53] Public Citizen Health Research Group. *Questionable Doctors Disciplined by State and Federal Governments* (2000 ed.). The information is published on a state-by-state or regional basis.

[54] Furrow Barry R. et al., *Health Law* (2d ed., West hornbook series 2000), at 91-94.

re-credential physicians. However, hospitals are reported to often protect their physicians by not sanctioning them or by using nonreportable sanctions.[55]

[55] Baldwin LM, Hart LG, Oshel RE, Fordyce MA, Cohen R, Rosenblatt RA. Hospital Peer Review and the National Practitioner Data Bank: Clinical Privileges Action Reports. JAMA 282:349-355, 1999.

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

Respondent: Sarah Atkinson, Dorcas Atkinson, Emma Gent

England A Survey of Medical Accident Prevention Policy

Questionnaire on international comparison of medical accident prevention policy

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Background: Japanese Situation

In January 1999, unthinkable medical error occurred at one of the prestigious hospitals. Patient was mixed up at surgery and lung was taken out from the wrong patient. Since then several serious medical errors have been reported at prestigious medical center. Trust on Japanese health care system by Japanese people has been shaken. The government has to respond to the situation. A committee to investigate the root cause of those medical errors has formed in March 1999 and reported the need for integrated activity to prevent medical errors. Other professional associations, such as Japan Medical Association, Japan Nursing Association, Japan Pharmaceutical Association, Japan Dental Association and Japan Hospital Association have also formed a committee 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 the research on patient safety in 2001 fiscal year budget. 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.

A. Situation on Medical Error

1. Studies and research activities on medial accidents/errors

a. Is there any study on facts and occurrences of medical accidents/errors?

Yes. (A list of recent studies can be found at the end of this document.) The following table summarizes some of the key findings from the Department of Health (DOH).

Source	*Event*	*Estimated annual*

		number
Complaints data	Written complaints about aspects of clinical treatment in hospitals	27,949*
	Written complaints about all aspects of treatment in primary care	38,857*
NHS Litigation Authority claims data	Clinical negligence claims settled by the Authority above local excess levels	810#
Regional Serious Untoward Incident Reporting Systems	Serious Untoward Incidents	2,500+
Medicines Control Agency	Reported Adverse Drug Reactions	18,196* (9,819 serious)
Medical Devices Agency	Adverse incidents involving medical devices	6,610
Confidential Inquiry – Suicides and homicides	Suicides by people in contact with mental health services in the 12 months prior to the event	1150*
	Homicides by people in contact with mental health services in the 12 months prior to the event	40*
Confidential Enquiry – Maternal deaths	Deaths of women during pregnancy or within one year of giving birth	125#
Confidential Enquiry – Peri-operative deaths	Deaths within 30 days of surgery	20,000
Confidential Enquiry – Stillbirths and deaths in infancy	Stillbirths and infant deaths	7,800#